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Review

Open Intellectual Property Models for Plant Innovations in the Context of New Breeding Technologies

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Special Issue

The Role of Policies in Plant Breeding—Rights and Obligations

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Open Intellectual Property Models for Plant Innovations in the Context of New Breeding Technologies

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Abstract: Plant related innovations are critical to enable of food security and mitigate climate change. New breeding technologies (NBTs) based on emerging genome editing technologies like CRISPR/Cas will facilitate "breeding-by-editing" and enable complex breeding targets—like climate resilience or water use efficiency—in shorter time and at lower costs. However, NBTs will also lead to an unprecedented patent complexity. This paper discusses implications and potential solutions for open innovation models.

Keywords: new breeding technology; CRISPR/Cas; patent thickets; open innovation

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1. Introduction

Agriculture is a critical enabler of food security and global wellbeing but in its current form also a major contributor to climate change [1–3]. The negative effect will likely increase due to population growth and dietary changes. [4] However, to classify agriculture as a "necessary evil" would be simplistic, as allowing agriculture to remain a major carbon emitter is not sustainable as climate change will eventually destroy agriculture. More than 90% of the Earth's soils could be degraded by 2050 if we continue on the current path [5]. On the other hand, agriculture also has the potential to be a carbon sink, i.e., a solution for climate change rather than a cause.

One enabler of this change is to maximize agricultural innovation and its use. A substantial improvement of crop production with a reduction of inputs and use of natural resources use cannot be expected from the current GM technology which focuses primarily on herbicide tolerance and insect resistance and is not adapted to manage complex traits such as yield and resource efficiency. While there is reason for skepticism in view of the past promises related to GM crops, new breeding technologies (NBTs) are more than a "GMO 2.0". By facilitating "breeding-by-editing" they enable complex breeding targets—like climate resilience or water use efficiency—in shorter time and at lower costs. NBTs can also "democratize" plant biotechnology and re-invigorate competition in a field where recently only a handful multinational companies were able to act.

Intellectual property (IP) can play an important role as an incentive to create innovation but could also be an obstacle to maximize innovation use. This paper discusses the impact of NBTs on the IP landscape, shows that NBTs will likely increase patent complexity, and analyses whether current solutions could evolve the patent system into an open innovation framework.

2. Plant Related Innovations: Towards Complex Traits

The 2018 OECD report on "Concentration in Seed Markets" emphasizes that "global agriculture faces the triple challenge of raising productivity while ensuring sustainability and improving resilience. To achieve these goals, innovation in the form of high-performing varieties is essential" [6]. Studies which suggest that future yield gain will almost exclusively be contributed by improved genetics [7] might be overly simplistic [8]. However, to manage complex traits will be a critical contributor to increased performance, climate resilience, and resource use efficiency. Breeders face an increasing complexity of challenges

from mitigating biotic and abiotic stresses [9], over resource use efficiency to improved quality. In contrast to pharmaceuticals, where one drug targets one disease, breeders need to "stack" all traits into a single variety. Thus, the essence of breeding—including conventional breeding by crossing and selection—is "stacking". These "stacks" (i.e., combination of favorable traits) need to be established in a short time to meet the rapidly evolving market need, especially the rapidly changing climate conditions in many regions. Currently this is not the case because of the lengthy process of conventional breeding driven by trial and errors takes seven to 12 years depending on the crop and significant financial investment. A substantial acceleration of breeding in required to meet the challenges to agriculture.

The strong market pull for higher level stacks is based on multiple drivers:

(i) Resistance against established insect resistance (IR) and herbicide tolerance (HT) traits are developing rapidly, especially for GM traits. This needs to be mitigated by stacks providing double or even triple mode-of-actions. For GM events the trend towards stacking is quite advanced [10,11]. The US Department of Agriculture estimated that 89% of cotton acres and 80% of corn acres were planted with stacked seeds in 2019 [12]. In maize it is meanwhile common to stack six events with up to ten traits. For example the stack commercialized under the brand "SmartStax™ Pro x Enlist™" comprises the events MON87427, MON89034, TC1507, MON87411, 59122, and DAS40278. It offers resistance against three herbicides (glyphosate, 2,4-D, and glufosinate), three different mode-of-action traits against lepidopteran pests (above the ground), and four different mode-of-action traits against coleopteran pests (below the ground) [13].

(ii) Another driver is the increasing regulatory, environmental, and public scrutiny against chemical pesticides. The natural resistance genes of plants could be attractive alternatives, if the currently cumbersome process of introgression could be facilitated. The trend towards stacks of patented traits (both native traits and mutants) can be seen in the PINTO database of the European Seed Association (ESA) [14]: While the number of total varieties has not changed substantially over years, the number of stacks i.e., varieties which are comprising two or more traits and are in consequence covered by two and more patents increased substantially [15]. The trend towards higher stacks of patented traits is paralleled by a trend of higher stacks of patents which cover the specific varieties: While a 2019 analysis showed only 3 out of about 700 varieties with stacked, proprietary traits, by the end of 2021 this number was already at 108 out of 881 varieties in total (see Table 1). In several crops the percentage of stacks of patent traits has reached double-digits. Sunflower is leading due to a high use of herbicide tolerance. But also the use of stacks for disease resistance in lettuce and Brassica is rapidly increasing. Here also stacks of traits covered by patent owned by different parties are utilized.

Table 1. EU varieties covered by patents. The traits include both "native" traits and mutants obtained by conventional mutagenesis.

No of Patents	Sunflower	Pepper	Brassicas	Melon	Tomato	Lettuce	Cucumber	Maize	Other	Total
1	38	69	54	49	104	178	28	122	131	773
2	5	5	9	4	6	24	8	21	9	91
3			1			1				2
4	15									15
Total	58	74	64	53	110	203	36	143	140	881
% Stack	34.5	6.8	15.6	7.5	5.5	12.3	22.2	14.7	6.4	12.3
Stack with mixed patent ownership			1			19				

The trend towards "patent stacking" may have three root causes: The first one is the advanced technical capability to establish and describe breeding traits in a clear, concise, and complete way required for patentability [16]. The second factor is a shorter variety development cycle due to technical progress. Breeding has always been stacking. However, if the variety cycle is more than 20 years, patents on the stacked traits would never overlap. With a shorter variety cycle, stacking of patent traits will be the norm. The third cause is a psychological: While outside the area of GM traits, patents are often rather a cost factor than "business critical" [17], an "armament race" of patenting is compelling parties to patent "their" traits to create bargaining chips [18].

The third pull are climate-change-related breeding challenges like yield, water use efficiency, or drought resistance which can only be met by complex traits which are based on contributions of 10 and more alleles [19–21]

The more complex the characteristic, the less statistically likely the chance to establish it by conventional breeding in a reasonable time [22]. While variety development cycles in conventional breeding shortened over the last decades [23] and artificial intelligence combined with big data, sensors and hyperspectral imaging will likely further increase efficiency and support decision making, conventional breeding is approaching a biological barrier and will likely remain a time and resource intensive process.

The market pull meets a technology push: NBTs enable "multiplexing" [24–26] i.e., evolving multiple plant genes in parallel in a targeted way. NBTs—especially CRIP-SPR/Cas [27–32]—have the potential not only to enable targeted knock-outs but to facilitate "breeding-by-editing" [33] to establish complex traits with multiple allelic changes in a precise and efficient way which could not be achieved by conventional breeding. The use of NBTs will substantially reduce development times and costs: The development of a maize variety by conventional breeding takes 8–10 years and costs 8–10 million USD.The costs can be brought down by at least 80% at the development time to 3–4 years.

While a broad use of genome editing in healthcare is at least a decade away, NBT-derived varieties are already approved for market launch and in some countries likely already on the market [34]. A high adoption rate of NBTs is very likely provided that they are not locked down by non-science-based concerns and regulations. The question, however, is whether the current IP regime is able to cope with the volume, speed, and complexity of the resulting change. If in the near future, stacking of traits is paralleled by stacking of patent rights together with an increasing complexity to obtain access to germplasm and traits, the capacity to perform breeding which relies on the ability to stack will be negatively affected.

3. Plant-Related Patents: Towards a Gordian Knot?

Intellectual property rights (IPRs) and how they are deployed are important to enable food security [35–39]. However, the argument that more IPR encourages more investment and innovation is overly simplistic in general but especially in the context of food and agriculture [40]. On one hand, IPRs alone will not support agricultural innovation and food security unless embedded in a supportive socio-political and economic environment [41–46]. On the other hand, IPRs may not only have positive effects on innovation: Heller and Eisenberg [47,48] introduced the concept of "the tragedy of the anti-commons" where they warn that complex patent situations might impede innovation by creating a "patent thicket" i.e., "a dense web of overlapping intellectual property rights that a company must hack its way through to actually commercialize new technology" [49]. The negative impact of patent thickets is debated for several technology areas [50–52].

The international practice for plant related patents is highly heterogeneous. The TRIPS Agreements provides a unique flexibility to members when it comes to plant related innovations [53]. Or in other words: Members do not have to provide patent protection for plants and breeding processes as long they provide for protection by plant breeders rights (PBR), i.e., a sui generis system. However, members can use also any combination of patents and PBR if the wish so. Countries have made intensive use of the flexibility

and there are almost no two countries which have established a similar solution [54–56]. Countries like the United States of America, Australia, Republic of South Korea, Japan, and Canada have practically no restriction to the patent eligibility of plant-related inventions. However, the use of patents to protect plant varieties is quite different: While in the US the number of allowed variety patents is high, in the other countries the number of filed and permitted variety patents is rather low. The European Patent Convention and the Countries of the European Union bound by the EU Biotech Directive 98/44/EC, only exclude (specific) plant varieties and essentially biological processes for the production of plants or animals from patentability, but allow for patents on plants "*if the technical feasibility of the invention is not confined to a particular plant or animal . . . variety* [57]." This interpretation—also enshrined in the decision of the EPO Enlarged Board of Appeal in G 1/98 [58]—has been limited by decision G 3/19, which found that plants which do not include a man-made change in their genome are excluded from patentability under the exception for "essentially biological processes" if the related application was filed after 1 July 2017 [59–61]. The majority of the WTO member states excludes plants and plant varieties from patentability and does not allow any claim on plants, seeds, or propagating material. However, usually in these countries claims can be obtained on modified (i.e., non-natural or man-made) DNA sequences, which provide protection for plants comprising these sequences. Whether a claim (e.g., on a DNA sequence) can cover a plant when plants are explicitly excluded from patentability is debated. However, decisions suggest that such claims on modified DNA sequences are valid and enforceable against a use of plants comprising said sequences [62–65].

Other intellectual property rights such as trade secrets and contracts including bag-tag agreements add to the complexity, especially in common law countries where such agreements can overrule statutory exemptions such as the breeders' or farm-saved-seed exemption.

Concerns about a potential negative impact of patents on breeding and seed innovations have been raised already in the early 1990-ies i.e., prior to the rise of GM crops. Hermitte proposed a system of compulsory licensing of dependence to limit a negative effect of low-quality patents, a proposal which—in part—got included into the Biotech Directive 98/44 [66]. Trommetter in his 2008 review sees already the potential for patent thickets resulting from plant related patents especially for gene intervening in several functions and a function depending on the interaction of several genes [67]. However, so far freedom-to-operate related issues for plant related inventions have been predominantly limited to genetically modified (GM) crops. In consequence the issues remained limited to the few GM crops and countries which are growing them. In the context of GM crops, Golden Rice [68] is cited as example for a patent thicket with more than 70 patent families [69–73]. Nevertheless, Golden Rice is less a proof for patent thickets in plant biotechnology than an example of how a naïve use of proprietary technology can lead to barriers in deploying a promising innovation [74]. As thickets are prevalent in "complex" rather than "discrete" industries [75], biotechnology has—so far—been seen as a field without significant thickets [76]. Only rarely the early patents on plant biotechnology triggered a debate. Most issues were resolved among a small group of multinational companies by cross-license agreements [77]. In Europe, the concern about FTO in plant breeding increased with the raise of patent on "native traits": The need for breeders to monitor their "freedom-to-breed" and the resulting limitations on germplasm use led to a heated debate which after more than a decade resulted in the decision G3/19. However, so far the patent landscape for native traits hardly qualified as a "patent thicket" but rather as a "minefield" where FTO is constrained by the difficulty to identify the relevant patents and to negotiate licenses in an efficient way.

Plants obtained by new breeding technologies like CRISPR/Cas will comprise modified DNA sequences and should be—in principle—patentable in all legislations. The protection may be conferred with by claims on plants or claims on the modified DNA sequence. Therefore, the below analysis on the impact of patents on plants related innovations should apply to most legislations. In fact, the patentability of plants obtained by

new breeding technologies will expand "patents on plants" to many crops and legislations where it so far has not been an issue. As a consequence patent thickets resulting from NBT-related patents and patent minefields from complex trait stacking are emerging (see detailed discussion below; Figures 1 and 2, Tables 2 and 3). Both are affecting plant varieties and create a challenge for the use of plant genetics which is unlike any other industry:

- A plant variety may comprise a stack of multiple patented traits, some owned by the holder of the varieties, others in-licensed usually without a right to sublicense. To breed with such variety and to commercialize the resulting new variety will require highly complex license negotiations with all owners of such trait patents.
- The traits in a plant variety may have been established by using several method patents. As in some countries the scope of the patents covers the trait, to breed with such variety and to commercialize the resulting new variety will require highly complex license negotiations with all owners of such method patents.

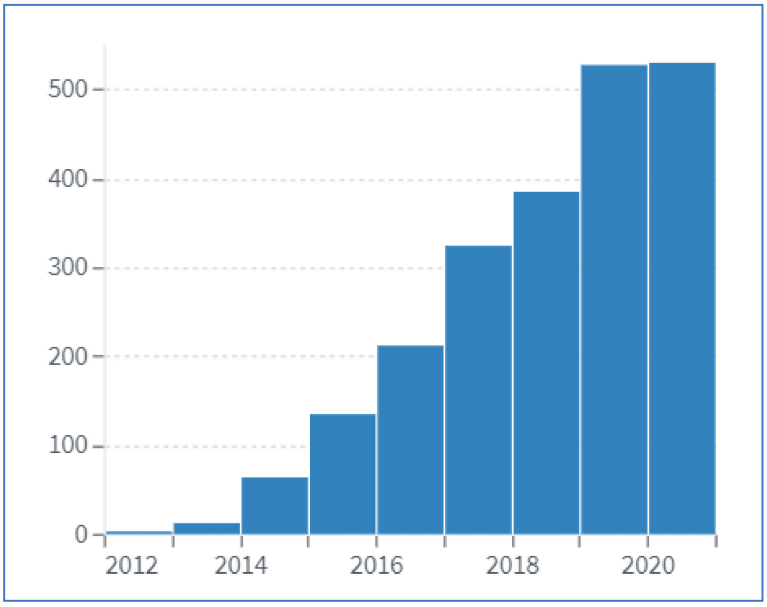

Figure 1. Number of PCT patent applications publications per year related to CRSIPR-Cas technologies relevant for plants.

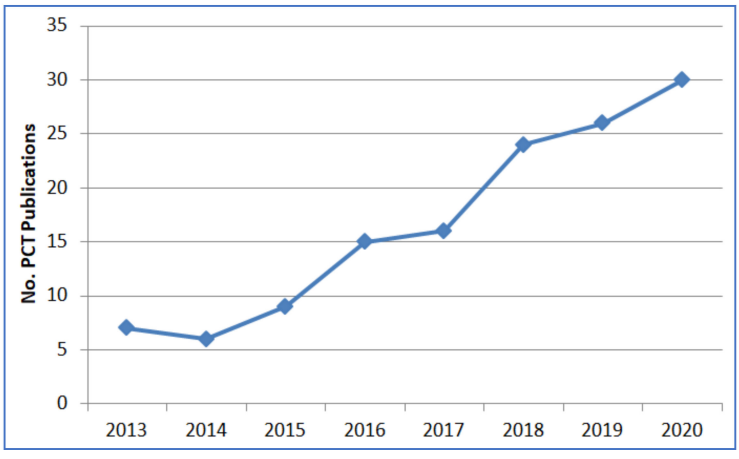

Figure 2. PCT applications on NBT derived plants traits.

Whether the current solutions can deal with these challenges is discussed below (Section 5). NBTs and NBT-derived varieties are not affected by the exemption for "essentially biological processes" and resulting products under Rule 28(2) EPC. Thus, NBT-derived traits and plants—in general—can be protected by patents [78]. While we are at the beginning of the NBT era, the patent landscape is already highly complex and, especially in the case of CRISPR/Cas, recognized as a thicket due to numerous overlapping patents. Concerns regarding inhibitory effects of overly broad patents have been expressed [79–82]. However, what has been discussed so far is likely only the proverbial tip of the iceberg i.e., the direct and visible impact on users of the CRISPR-Cas technology as such. What has not been discussed is the indirect and far less visible impact on breeders which do not use NBTs but merely the product made with NBTs. Here, the complexity and risk of infringement is determined by two factors: (1) Technology method patents which extend to NBT-derived products and (2) product patents on the NBT-derived plants and/or the modified sequences. Like for an iceberg it is well possible that 9/10 of the NBT-related FTO issues are in the first category and "under water" which makes them intrinsically more dangerous: Breeders will be affected by the deterrence-effect of a minefield with an unknown number of mines ("hidden risks") and will likely stay within their own genepool. Farmers may be requested to pay farm-seed-royalties to parties they did not have on their radar-screen. Food processors, retailers, and society may be affected by higher prices due to royalty stacking.

3.1. The Patent Landscape for CRISPR-CAS Technologies

NBT-derived plants may be covered indirectly by process patents. It is well possible that a double-digit number of patented processes is involved in the making of a NBT-derived plant covering the use of a specific Cas-enzyme, methods of enhanced sequence replacement or base-editing, germplasm-independent delivery, or enhanced regeneration.

The protection of a patented process for a plant usually encompasses products directly obtained by the process [83]. In countries where the extension is limited to direct products, an impact on the final seed can likely be excluded as the commercialized seed is usually not the direct product but the result of several generations of propagation [84]. However, creative claim drafting may overcome this limitation [85]. In other countries the scope of protection extends beyond direct products to later generations and other down-stream products as long as the effect of the method is still preserved [86]. In the EU, Article 8(2) of the Biotech Directive 98/44 extends the scope to biological material obtained through propagation as long as it possesses the "specific characteristics as a result of the invention" [57]. For NBTs the question arises, whether a general method of enablement extends to all products made with such processes as long they still comprise the edited sequence i.e., to products comprising any characteristic made the technology (discussed under 5.2.3 "Expand Legal Certainty and Freedom-to-Breed").

While NBTs comprise additional technologies other than CRISPR-Cas, the patent landscape for CRISPR-Cas alone has become highly complex in a period of a few years. A recent study identified 7427 patent families related CRISPR filed by 1850 institutes and companies. Out of these, 1232 related specifically to plant modification [87]. Design arounds and/or improvements to the initial Cas9 discovery make about 4500 patent families. Cpf1—an alternative to Cas9—already gathers 899 patent families in the current landscape [87].

An own independent search identified 2228 PCT patent families with claims to the use of CRISPR-Cas technology in plants and a publication date until 31 December 2020 (see Figure 1) [88]. Out of these, 1669 PCT application are classified with the IPC classes A01H or C12N i.e., the two most relevant classes for plant related inventions.

This is more than the plant-specific applications found in the cited study which can be expected as several technologies have general applicability for plant and mammalian applications. The landscape does by far not include all patented technologies which may be used for making a NBT-derived trait or plant. Additional relevant patents may relate to (i) delivery of the editing machinery (ii) efficient generation of plants after editing and (iii) technologies to enhance HDR-mediated repair (SDN2/3). These technologies can be used in combination with CRISPR-Cas but also with other genome-editing technologies such as zinc fingers nucleases (ZFN) or TALENs and at least double the relevant patents.

The number of patent families is only one element of the complexity. The overlap between the various families is another one. Irrespective of granting the Nobel Price to Doudna and Charpentier for the discovery of Cas9, at least six parties are fighting for their "piece of the cake" when it comes to the Cas9 foundational patents [89]. Most intense is the ongoing interference between The University of California/Berkeley and The Broad Institute [90,91]. Recently, two additional interferences have been added between Toolgen and The Broad Inst. and Toolgen and The University of California/Berkeley, respectively. In both proceedings Toolgen is indicated the Senior Party i.e., the party which the patent office sees entitled to the earliest priority date [92–94]. Additional interference with Sigma-Aldrich can be expected. Also in Europe almost every patent for Cas9 and Cpf1 is opposed by several parties, usually through "strawman opponents" [95]. Almost all patents have challenges when it comes to substantive issues (e.g., enablement of the priority applications) or formalities (e.g., assignment of inventorship). It is already foreseeable that the final landscape will differ from country to country with a strong regional bias [96]. Depending on the specific use of the Cas9 enzyme four or more licenses may be necessary for a simple edit in a plant.

The costs spend by the parties in defending their rights or invalidating the rights of others is substantial: The reimbursement for IP costs to the Broad Institute alone meanwhile add up to $81.6 million USD [97]. The total burn is likely in the range of $400–500 M [98]. In view that most of the foundational patents are owned by public institutes this seems a terrible "waste" of money. Even more substantial is the chilling effect of the legal uncertainty which likely causes a significant under-utilization of the Cas9 technology especially in small and medium enterprises which do not benefit from the general non-assert policy for academic users.

Normally such a situation would call for a patent pool. Despite some initial attempts [99,100] a holistic patent pool is not (yet) foreseeable [101]. For use in plants, collective licenses under the estates of Vilnius University, The University of California/Berkeley and The Broad Institute (i.e., a mini patent pool) are available, however, under onerous conditions (see under Section 4.1).

3.2. The Patent Landscape for NBT-Derived Products

NBT-derived traits, related sequences and plants, can be protected by patents if the genetic change—or the combination of changes—does not pre-exist in nature. However, it is difficult to identify patents on NBT-derived plant traits. It seems that applicants try to camouflage how certain traits are obtained. Often various approaches for random and targeted mutagenesis are described. The lack of transparency may have various reasons: A lack of FTO is a likely explanation, but also concerns that a disclosure may cause regulatory issues or "black listing" by consumer organizations or other NGOs is possible.

Nevertheless, one can estimate the number of NBT-derived plant traits by combining regulatory, science literature and patent information. A recent review shows more than 40 projects for NBT-based traits in many crops and in many regions of the world [102]. In the US alone, 156 approvals have been granted recently under the A.I.R. ("Am I regulated") process [103] for a commercial launch of genome edited plants (see Tables 2 and 3). Some products are already cultivated under closed loop conditions. The approved products represent only a small fraction of what is in the pipeline of companies. In other countries—

especially Argentina and China—a more extensive use of NBT-derived varieties is possible as no announcements are made.

Table 2. "Am I Regulated" A.I.R approvals related to NBT-derived plant traits per plant species. [103].

Target	A.I.R Approvals (4 January 2021)
Grasses	20
Soy	19
Canola	13
Potato	11
Corn	11
Tree	9
Tobacco	7
Tomato	7
Sugarcane	6
Flowers	6
Pennycress	6
Rice	6
Other Plants	35
Total (Plant)	156
Non-plant	13
Total	169

Table 3. Am I Regulated" A.I.R approvals related to NBT-derived plant traits per applicant [103].

Applicant	A.I.R Approvals (4 January 2021)
Cibus	14
University Georgia	11
University Florida	10
Ceres	8
Corteva	8
Simplot	8
Living Carbon	8
Calyxt	5
Celectis	4
Illinois State Univ.	4
Scotts	4
Yield10	4
Inari	3
Benson Hill	3
Others	62

For most approved products at least one product-related patent can be identified. However, it is unclear by how many process related patents the products might be covered as the specific process of making is only rarely fully described in the patent applications. A search for patents on specific plant characteristics which are most likely developed with CRISPR-Cas resulted in 138 applications since 2013 (Figure 2).

An extension to all NBTs (including for example zinc finger nucleases, TALENs etc.) resulted in about 800 PCT applications on plant traits. The number seems low likely because most companies are still in the capability building phase and in a waiting pattern due to the FTO or regulatory uncertainties. In addition, a number of technical issues still need to be resolved to make CRISPR-Cas a scalable tool, especially targeted editing (vs. a targeted cut) and germplasm independent delivery. Once these issues have been solved—which can be expected within the next 3–5 years—an exponential increase will result as the list of potential targets is long.

As discussed above, NBT-derived plants will in most cases comprise man-made sequences, which do occur in nature, and will therefore likely be patentable in virtually all legislations. In consequence, this author believes that NBTs will not only cause an increase of plant-related patents and expand patent activities to many crops and regions, but also lead to an increase in patented plant varieties. With the exception of the US which allows for patents on specific plant varieties with a very low threshold [104], in most other countries the patent coverage for non-GM plants is very low. Today, in Europe out of the currently 881 registered varieties [13,14] less than 1.5% are covered by patents [105,106]. This quota will change in the EU but also in many other countries. By 2030—depending on the country—5% to 30% of the varieties in major crops may comprise genome edited traits and will be covered by patents. This author estimates that by 2040, the number can be expected to be larger than 80% in the Americas and close to 50% in Europe. Eventually, Europe (and other countries) may face a situation as the US today, where virtually all elite germplasm is covered by patents.

3.3. The Impact of Shorter Innovation Cycles on Complexity and Freedom to Operate

Plant innovations have a unique character in that their complexity and extent of integration continuously increases. In contrast to other innovation areas, new plant innovations are not replacing the former but are building on and further improving them forming ever more complex "stacks". This has consequences for patent rights as the patent rights for the individual innovations may also start to "stack". As long as the innovation lifecycle is equal or longer than the normal patent lifecycle of 20 years stacking can be avoided (Figure 3—upper panel).

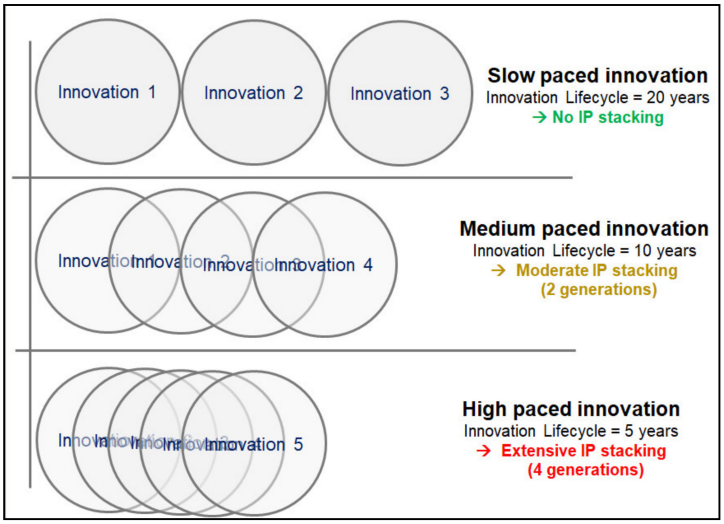

Figure 3. Stacking of patent rights on improvements depending on the innovation lifecycle.

The extent of patent stacking is accelerated if the innovation lifecycle shortens: Multiple generations of improvement start to overlap. For an area with innovation lifecycle of 10 years, at maximum two generations of innovations will overlap (see Figure 3—middle panel). If the innovation lifecycle is 5 years—as can be expected for the field of NBTs—already 4 generations will overlap (see Figure 3—lower panel).

The situation becomes even more complex if the initial innovation triggers more than one subsequent innovation (see Figure 4).

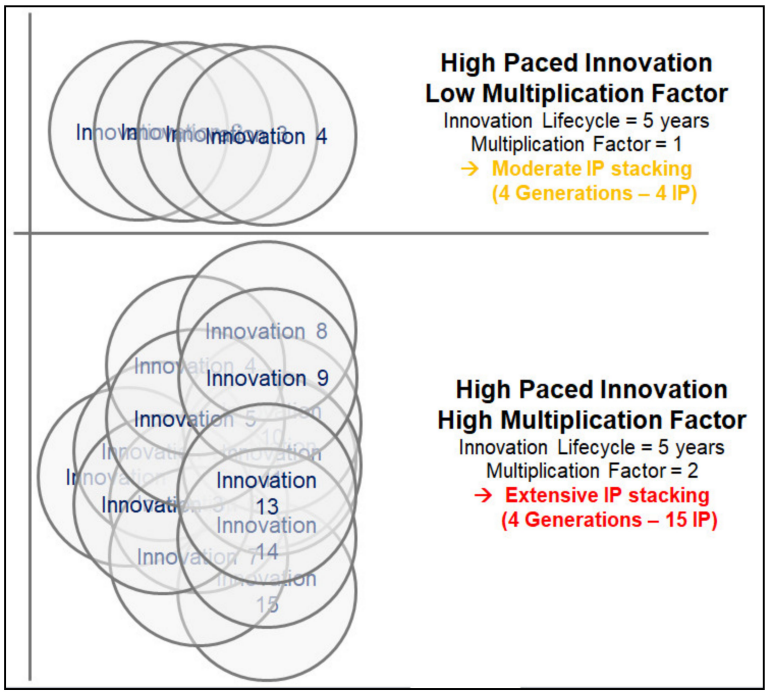

Figure 4. Stacking of patent rights in a high pace innovation fields.

If one innovation triggers only one subsequent improvement (multiplication factor = 1) the number of "stacked" patents in a situation with an innovation cycle of 5 years can reach a number of four during the lifecycle of the first patent. Obtaining four licenses would already be difficult, if the four patents are owned by four different players. However, if each innovation triggers two subsequent innovations (multiplication factor = 2) the number of patents in a situation with an innovation cycle of 5 years will reach a number of 15 during the lifecycle of the first patent. Obtaining 15 licenses is practically impossible, unless they are all held by a single entity. However, such monopoly would be undesirable.

Unless the access to each invention and FTO under all related patents can be facilitated there is a substantial risk that new innovations are blocked or will only happen within the innovation and germplasm pool of the specific breeder. Any exchange of germplasm will come to an end. Most countries have only a very narrow or no patent law research exemption which would cover breeding activities. Even in the EU countries which provide a patent law breeders' exemption the stifling effect would be substantial: As segregation of multiple patented traits is practically impossible, the resulting plant will in most cases comprises one or more patented traits which will require a license prior to commercialization [107,108].

The complexity will also have consequences for farmers. In most countries farmers do not enjoy a farmers privilege under patents. Here, their current farming practice would be substantially constrained. Even in the EU, which has an exemption for farm-saved-seed in patent laws, the complexity is not without impact. So far farmers have only to interact with the owner of one plant breeders right (PBR) on the variety when it comes to information and royalties. In the future, farmers will have to interact with the holder of one PBR and with multiple patent holders in parallel as the law does not comprise any guidance how to deal with multiple rights [109].

3.4. Scenarios for the Future

The risk of change and the need for mitigation not only depends on the potential impact described above but also on the likelihood of change i.e., the likelihood that NBTs will become a widely used, disruptive technology. This likelihood depends primarily on two factors (i) resolving the remaining technical challenges and (ii) the regulatory framework. Eventually two primary scenarios can result:

1. Scenario 1 "Democratization": Breeding by editing becomes a standard and is used on many crops in many countries. In 10 years >50% of all varieties comprise at least one genome-edited characteristic. In 20 years essentially all commercial varieties will comprise characteristics obtained by genome editing, many will comprise 5 or more of such characteristics.
2. Scenario 2 "The world as we know it": Genome editing remains complex and regulated and in consequence limited to a few major crops (i.e., corn, soy) and "controlled by a few multinational companies.

Based on the recent positive signals regarding a positive regulatory environment from France [110], Japan [111], and the UK [112], the trend currently clearly goes towards scenario 1. As impact and consequences are high, risk mitigation becomes critical. It will require solutions for the problem of patent thickets [113]. In consequence, the requirement for openness becomes a necessary and unavoidable consequence of technology success.

Scenario 2 is however still possible: An unfavorable regulatory framework which classifies NBT-derived varieties as GMO with high regulatory and stewardship costs could be one driver. An unfavorable "IP framework" which limits the use of NBTs to a few multinational companies could be the other. In addition, it is also possible that emerging or unresolved NBT-related IP issues delay or prevent a more favorable NBT regulatory framework.

4. Managing Patent Thickets

It is often alleged that complex IP situations ("patent thickets") slow innovation by increasing transaction costs and market entry delays [49,114–117]. However, patent tickets are not necessarily a hurdle for innovation [118]. A 2011 report for the European Commission observes:

> *"while 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."*

The authors of the 2011 report found that the methodology to map thickets is still "*in its infancy*" and "*the welfare effects of thickets might actually be ambiguous*" [76]. It is also still largely uninvestigated whether different types of users have better or poorer access to the solutions in a "thicket", i.e., whether a thicket impacts the structure of an industry sector. However, the CRISPR-Cas IP landscape is meanwhile recognized as a patent thicket [79–82]. The chilling effect of the legal uncertainty cannot be denied especially for small and medium enterprises which usually lack the capability to assess and manage patent-related risks. This chilling effect is already present today while the impact of method claims on products has not even been considered in the present discussions.

Strategies to avoid a "tragedy of the anti-commons" [48] comprise cross-licenses, patent pools, compulsory licenses or a broad breeder's exception. Mossoff—based on the "sewing machine war" and the resulting first "patent pool"—concludes, that "*patent thickets have long existed*" and "*that patent owners have the incentives to resolve the problem of patent thickets—exercising their property and contract rights within the framework of these preexisting private-ordering regimes*" [119]. Whether this view that "patent thickets resolve themselves" applies to all industries and technologies is discussed below (Section 5). There is growing recognition in the seed industry, politics, and academics that for plant innovations an emphasis on "exclusivity" is not desirable. Several initiatives attempt to evolve the use of

plant related patents from exclusivity to inclusivity and openness [120,121]. The European Seed Association's database PINTO [13,14] improves patent transparency. When it comes to facilitating access, the solutions explored so far for plant related innovations can be grouped in four models:

1. "Patent pools" [122] deal with complex innovations by creating a "one stop shop" which enables collective licensing for a reasonable price [123,124]. They "clear" patent thickets with pro-competitive effects [125]. Patent pools of a larger size: (i) have in general a simple royalty sharing mechanism based on quantity (i.e., number of patents) rather than quality i.e., value of the innovation [126] (ii) do not allow to license only a sub-selection of the technologies (ii) consist of a rather small and homogenous group of patentees. Patent pools are not always seen positively, especially when it comes to their effect on stifling innovation as they may reduce the incentive innovate [127]. Patent pools also require careful anti-trust consideration and usually regulatory clearance [128]. For plant innovations, no holistic patent pool has been developed yet, although there have been attempts to establish a patent pool for CRISPR-Cas9 [99,100]. The joint initiative of Corteva and The Broad Institute (see under Section 4.1) intents to create a mini-pool although some usually required elements might be missing and others potentially not compatible with the antitrust scrutiny on patent pools [129].
2. "Patent clearing houses" facilitate access to collections of patented technologies. They usually work with standard agreements and terms and have no mechanism to deal with stacking. Clearing houses are therefore less an approach to manage patent tickets than to pragmatically establish FRAND terms [130]. The international Licensing Platform—Vegetables (ILP) (see under Section 4.2.2) is an example for a successful clearing house.
3. "Open Source Models" [131] have been primarily developed for software related innovations where copyright is established automatically without the need for any registration. There have been attempts to establish open source models for plant related innovations by obligations not to patent (see under Section 4.4).
4. "Licensing Pledges" are declarations to grant licenses. License pledges can be made in various forms, sometimes even official declarations at the patent offices [132]. Several seed companies have made "licensing pledges" through e-licensing and other instruments (see under Section 4.3).

Selected models and their impact are subsequently discussed in more detail [133].

4.1. Patent Pools

Corteva and the Broad Institute under the headlines of "democratic CRISPR Licensing" and "open innovation" [134] announced to "join forces to enable democratic CRISPR licensing in agriculture" "to jointly provide non-exclusive licenses to CRISPR- Cas9 intellectual property under their respective control for use in commercial agricultural research and product development. Such foundational intellectual property (IP) for CRISPR-Cas9 technology will be freely available to universities and nonprofit organizations for academic research" [135]. Corteva alleges that it "*intends to enable others wanting to develop agricultural products using CRISPR through access to intellectual property, technology capabilities, infrastructure and scientific expertise*" [136].

The license seems to include several patent families and patents and patent applications from several parties including The Broad Inst., MIT, Harvard University, Rockefeller University, Editas Medicine, Inc., Iowa State University, Tokyo University, New York University, NY Genome Center, Vilnius University, University of California, University of Vienna, CARIBOU Biosciences, and Pioneer Hi-Bred International, Inc. In principle such collective licensing qualifies or—at least—could be seen as a patent pool. However, the honorable statement to "enable others" and openness seems to be only partially realized to date. While licenses to the CRISPR-Cas technology are freely available to universities and nonprofit organizations for academic research [135], licenses for a commercial use or to commercial entities are only available under non-disclosed terms which are likely quite

onerous. If the terms and conditions of the collective license are similar to the publically available redacted version of a license agreement issued by The Broad Institute [137–139] it would not meet several requirements for patent pools listed in paragraph 261 of the TT-Guidelines [125] including (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) the pooled technologies are licensed out to all potential licensees on FRAND terms; (d) the licensees are free to challenge the validity of the pooled technologies. However, the Broad CRSPR-Cas license agreement does not only include in Article 10.2.4. a right to terminate the license in case of a patent challenge [137], but also requests royalties for products which are not covered by a valid patent claim i.e., "*enabled products*" [140], which are merely "*made, identified, discovered, developed, optimized, characterized, selected, derived from or determined to have utility*" by using the licensed technology but are—by definition of the license agreement—outside the scope of the patent.

The "reach-through" seems to address that in most countries the ultimate plant resulting from a general genome editing process is outside the scope of any claim covering a general enabling technology [141]. It may also be intended to cover the "workaround" that a trait is discovered using CRISPR-Cas, but then established in the target plant using conventional technics of mutagenesis. However, it is questionable whether such "reach-through" royalty meets the requirement of FRAND as any third party could use such products without paying a royalty to the patentees. While such clauses may be enforceable in a bilateral license agreement under US law under certain circumstance, they may not withstand antitrust review in other legislations [142].

4.2. Patent Clearinghouses

Patent clearinghouses do not enable collective licenses but rather facilitate licenses to individual technologies under simplified procedures and often standardized terms.

4.2.1. The BiOS Initiative

Cambia, a non-profit organization founded in 1992 to promote open science in plant biotechnology [143], initiated the Biological Open Source (BiOS) initiative in 2005 [144–148]. While named "Open Source" BiOS was essentially a patent clearing house, maybe only a licensing pledge, as the estate of licensed patents did not grow beyond the initial patents contributed by Cambia. In consequence, the current spelled-out name "Biological Innovation for Open Society" seems more appropriate to describe the intent: To change the use of biotech patents from a right to exclude to a right to invite and collaborate.

Cambia's BiOS included TransBacter [149] as an alternative to the patented Agrobacterium tumefaciens system and GUSPlus, a marker system [150]. BiOS Materials are transferred under Material Transfer Agreements (MTAs) [151]. Instead of royalties, the BiOS license [152] requires licensee to comply with three conditions which create a "protected commons":

- To license to all BiOS licensees any patent on a non-severable improvements to the BiOS technologies.
- Not to assert against other BiOS licensees any patents which dominates the BiOS technologies.
- Share with the public all information about the biosafety of the BiOS technologies.

While described to be cost-free, Annex D of the BiOS license requires commercial licensees to pay an annual subscription fee which with US $150,000 for entities with more than 500 employees is substantial [152]. The BiOS license is described to have over 300 licensees worldwide [147]. However, to this author's knowledge, no major seed and biotech company has joint the commons and users are almost exclusively in the academic field.

While the established BiOS license agreements are likely still in force, the initiative currently seems to be "retired". The reasons why the BiOS initiative—despite its honorable objective—did not gain momentum may be "intrinsic" (i.e., self-made) and "extrinsic" (caused by others):

- BiOS had an "interesting" core of technology but the related patent applications were rather weak to establish an incentive to take a license [153]. In consequence, the value proposition was limited to save some time and efforts by accessing the materials. In view of the relatively high subscription fee, the requirement to make own IP available, and the fact the most commercial players had already a license to the Agrobacterium technology, the costs and benefits were not in proportion.
- BiOS was not able to grow into a "one-stop-shop" by attracting additional technology patents. The BiOS license did not compel BiOS licensees to make own enabling technology patents—other than non-severable improvements to the core BiOS patents—available to the commons. Whether such a requirement would have been accepted or rather scarred away licensees can be debated. Most likely the core patents of the BiOS platform were not sufficiently attractive to support such "pull-in".
- Aggressive third parties filed selection inventions which blocked a meaningful use of the BiOS patent estate and/or created a penumbra of legal uncertainty which deterred parties to take a license [154]. In contrast to Cambia the third party was able to obtain granted patents. The impact was significant as because it was the only differentiation technology in the BiOS portfolio.

The example provides a number of interesting lessons learned:

- Learning 1: Any licensing platform needs a sufficiently attractive core of technologies protected by valid and sufficiently broad patents to attract licensees and additional technologies.
- Learning 2: A licensing platform needs to include a mandatory "give 'n take" provisions. Parties who want to take licenses have to make similar technologies available to other platform members. Such "pull-in" needs to be support by a sufficiently attractive core.
- Learning 3: Selection inventions can always occur. A constraining effect on the FTO of a clearing house can never be completely mitigated. However, the likelihood of such effect can be reduced by attracting the majority of the related industry sector to the platform. Platform members are discouraged to file blocking patents as the blocking effect is lost by the mandatory "pull-in" effect. A singular non-member player could theoretically block individual assets of the platform but would face opposition by the strong platform community.

Nevertheless, the BiOS initiative was fruitful as it inspired the ILP (see Section 4.2.2).

4.2.2. International Licensing Platform—Vegetables (ILP)

The International Licensing Platform—Vegetables (ILP) is a widely accepted "patent clearinghouse" in plant breeding [6]. It was founded in 2014 with support from the Dutch government and currently represents more than 60% of the global vegetable seed market [155]. Every party can join the ILP irrespective of whether it owns patents or not. Based on the principle "*free access but not access for free*" the ILP enables access to patented traits under fair and independently determined financial conditions [156–158]. While a use for research and breeding is free, a licensee has to pay a royalty for the commercialization, if and where the sale of the seeds is still covered by the patent. In addition, the ILP provides access to "variety patents" which in the US protect specific plant varieties [159]. The ILP has been described in detail elsewhere [160]. Therefore, only a summary is provided herein:

- *Defined scope*: The ILP provides access to two classes of patents relevant for vegetable breeders "traits patents" [161] and "variety patents". It enables the use of legally available vegetable material covered by a patent for further breeding. The ILP does not enable use of proprietary technologies nor does it mandates material transfer [162]. The ILP is limited to traits which are not regulated as GMOs [163]. When it comes

to NBTs and the current "patch-work" of regulatory classification, the ILP enables licenses to NBT-derived traits in and for countries where those traits are not considered GMOs. Such limitation is necessary as GMO liability requires a qualification from licensees which would undermine the ILP principle that access is available for everybody.

- *"All-in"* and *"pull-in"*: The ILP became the "*one-stop-shop*" for vegetable trait patents by creating an "all in" obligation: If a party wants to take a license through the ILP it has to become a member and will be obligated to make all its own vegetable-related patents available to other ILP members. This "conditional openness" enable a strong pull-in effect: The ILP enables access to more than 260 trait patent families and numerous variety patents [164]. This represents more than 60% of the relevant patent families in this field.
- Contractual Breeders Exemption: ILP members grant each other a mutual, royalty-free non-assert under US variety patents to use a legally available variety for the breeding and commercialization of new varieties. Two conditions apply: The new variety has to be sufficiently distinct from the protected variety, and a notification needs to be send to the patentee.
- Trait Licenses under FRAND Terms: ILP licensees have to pay a royalty for the commercialization of a variety if and where it is still covered by the patent. The ILP members agree to enter into bilateral negotiations for a license. Only if these fail after three months, the ILP's baseball arbitration mechanism kicks in as a "safety net [165–167]. The baseball arbitration is based on a standard license agreement ("SLA") where only the percentage royalty on net sales is subject to arbitration. No other element is negotiable [168]. The parties have to submit a binding, written proposal for a fair royalty with supporting evidence and reasoning. If the dispute is not resolves, the Expert Committee will render a binding decision. However, they can only pick the one submission they believe is "more fair". No detailed reasoning needs to be provided. Based on the "game theory" [169] this creates a strong incentive for the parties to be reasonable, which eliminates inflated claims [170]. The established royalty is final and binding [171]. Changes are only possible if the value of the trait changes substantially [172]. The resulting valuation is likely as close to the true value of the technology as possible, or as noted by Lemley and Shapiro: "*The Nash equilibrium of the game should be for each party to generate a proposed salary equal to the true value of the player" and "so long as the arbitration procedure itself is unbiased, bargaining in the shadow of binding arbitration will tend to lead to reasonable rates* [173]." The same should apply in a licensing situation with respect to the submission of a royalty proposal which should equal the true value of the patented trait. Judge Arnold referenced baseball arbitration as one easy solution to establish FRAND terms as "*the procedure forces both parties to pitch their offers close to what is objectively FRAND*" [174–177].

The ILP's incentive to reach an agreement bilaterally is strong: After six years of ILP the baseball arbitration was not used even once. However, according to this authors understanding, several license agreement and portfolio swaps have been established.

- Most Favoured Nation clause: The ILP provides for a Most Favoured Nation ("MFN") clause which requires to grant licenses under the best financial terms granted to any other Member under the SLA. Once an MFN percentage is set any licensee may request to an SLA with the same percentage.
- The Expert Committee: The independence of the Expert Committee is key for the success of the ILP [178]. The seven experts collectively bring expertise in IP, economics, the vegetable seed market, plant science, and accounting. They are proposed of the ILP Board and need to be confirmed by a majority of at least 2/3 of the ILP Members [179].
- Other elements: Every interested party can join the ILP even if it does not own patents. ILP members can continue to in- or out-license patents to third parties outside the ILP. They can freely choose which ILP patents they want to in-license. No "bundling"

occurs. In addition, there are several elements safeguard the pro-competitive effect of the ILP, e.g., members can always challenge the validity of a patent.

By enabling access to traits at low transaction costs, the ILP provides "free access but not for free." The use of fair and non-discriminatory licensing conditions in addition to transparent and pragmatic procedures were key for its broad acceptance in a stakeholder group with diverse interests.

While the ILP helped to establish a basis for cooperation and trust within the global vegetable breeding community, it is not perfect. Critical voices point out that the ILP is only a clearinghouse at first sight as it is "set up as a multiparty agreement between the participating companies, and strongly characterized by a membership principle, possibly creating a club atmosphere [180]." In addition, the ILP provides no solution for regulated technologies or how to establish FRAND conditions for stacked characteristics (discussed below under Section 5.1). Further, so far the ILP remains limited to vegetables. While there is an European-led initiative to establish an ILP for row crops, it might be challenging to bring such idea to life. Especially US-based multinational seed companies seem to favor an exclusive plant IP system and may be opposed to the idea of an ILP. As they often have the majority of germplasm ownership in key crops like maize, soy, cotton, canola and other crops an ILP without their participation will likely lack the critical mass.

4.3. E-Licensing and Licensing Pledges

In 2013 Syngenta launched its e-licensing platform Traitability™ [181] with the objective "*to become the iTunes of plant patents with as much transparency as possible*" [182]. A key feature is a cost-free access for breeding and development of new varieties. Royalties are only due for commercialization of newly-developed variety which contains the patented trait. All terms and conditions including the royalty rates are transparent. The Syngenta initiative is seen as "*an impressive effort to establish a fully fletched standardized licensing clearinghouse in the sense that it organizes access to patented subject matter on in advance defined standard terms"* [121]. Subsequently, other players like Monsanto [183], Enza [184], and Corteva [185]—adapted e-licensing or open-licensing platforms but didn't disclose the term and conditions for their licenses which makes it questionable whether such system can qualify as "open". Van Overwalle observes "*Unfortunately, details on the royalty terms are lacking, so it cannot be verified whether Enza is indeed a standardized licensing clearinghouse, offering access at predefined financial terms*". [121].

4.4. Open Source Models

Open Source [186] and creative commons [187] models have been first established in for software related innovations. Based on the concern that germplasm ownership becomes increasingly concentrated and controlled by few companies [131], the Open Source Seed Initiative (OSSI) was established in 2014 by US plant breeders, farmers, and other stakeholders with a "pledge to preserve unencumbered exchange of germplasm for breeding and research purposes" with rights to save and replant harvested seed from OSSI varieties [188–193]. The pledge [194]—though legally hardly enforceable—is intended to create a moral obligation. The OSSI initiative in Germany goes a step further in using a bag-tag contract with the seed bag which by opening the bag obliges the user to comply with the conditions of the contract [195].

Louwaars sees the OSSI critical [196]. He not only questions the sustainability of the OSSI business model and whether it could sustain investments in plant breeding he also sees the OSSI in conflict with national sovereign rights on genetic resources and the openness enabled by the breeder's exemption. Eventually the OSSI may create an anti-common effect.

Indeed, the term "open source" is misleading: Open source models in software—especially the obligation to grant-back derivatives and improvements—are functional not because are "IP-free" but they are based on enforceable copyright. Copyright in contrast to patents or PBRs does not require formal registration but is established with the act

of creation. Such model works for software and other copyrightable subject matter but cannot be directly transferred to technology or plants. Thus, OSSI creates less an open-source environment but rather an unprotected commons. It does not create shareware, but freeware. Such approaches are usually seen as problematic—even in the open source literature—as they encourage to (mis)appropriate "derivatives" [189].

The OSSI's negative position to IP ignores that it is not IP per se which is the problem, but how IP is used. It can be used to exclude or to invite. The situation can be compared with a lock to the door of your house: Even if there is a lock you can decide to have an inviting, open-house attitude. Without a lock you have no opportunity to keep even a burglar outside. Thus, the key question is not whether to have IP or not, but how to create incentives for and/or shape the IPR system towards openness.

4.5. Discussion of Current Solutions

4.5.1. A Word on Anti-Trust

The antitrust aspects of patent pools and clearinghouses like the ILP have been discussed by Kock and ten Have [160]. Assessing collective licensing structures under antitrust laws is challenging, especially in a global context. The mere fact that a group of the companies in a given industry establishes a licensing framework is inherently sensitive from an antitrust perspective. Also, the IP-antitrust interface is a topic for antitrust enforcers [197]. In the EU, patent pools and clearinghouses fall outside the scope of the Technology Transfer Block Exemption Regulation ("TTBER") [198] and companies are required to conduct an in-depth "self-assessment" whether their arrangement is reconcilable with the EU antitrust rules. For patent pools the associated guidelines ("TT-Guidelines") [125] contain a "soft law safe harbor" [199]. Pools that satisfy certain conditions [142] generally fall outside the scope of the cartel prohibition. However, clearing houses like the ILP do not qualify as pools as they do not offer license packages ([125], at para.244), but facilitate individual license agreements. In addition, while patents for a pool have to be selected in view of their essentiality [200], this is not the case for the 250 traits in the ILP. They are important for certain market segments but—likely—not "essential" in a strict legal sense [201].

Thus, as found by the Commission in the 3G3P case "*the legal doctrine on patent pools was not directly applicable*" [202]. While in principle possible, the EU Commission has so far refused to grant guidance for specific collective licensing arrangements. Thus, the only limited relief can be found in a Commission statement that even for licensing structures not qualifying as pools: "most of the rules governing patent pools under competition law could be used as guidance" [202]. The reluctance of the EU Commission to support pro-competitive solutions is certainly not helpful and indeed—as noted by Lerner and Tirole—"at least in part, the reluctance to form pools may be due to the ambiguities surrounding the manner in which proposed pools will be evaluated" [203]. Although there has not been any official direct "blessing" of the ILP as a pro-competitive instrument there are a number of supportive statements from relevant stakeholders including the EU Commission [204] and the OECD, which describes the ILP as *"a promising development"* because *"this innovative approach allows access to traits at modest transaction costs, yet maintains incentives for innovation through the licensing fee. The ILP therefore provides "free access but not for free* [6]*."*

While the key antitrust concerns expressed in the TT-Guidelines—i.e., price fixing and technology foreclosure—are not obvious in the absence of package licensing, they may become more relevant with the increasing importance of stacking. Here, also the issue of essentiality will become relevant and the question may be raised if the concept of essentiality should have the same central role as in patent pools associated with standards. Alternatively, the broader definition of essentiality in the context of gene related patents as proposed by Henry and Stieglitz could be considered [205].

4.5.2. Current Solutions: Fit for Future?

Thus, patent thickets which have been the primary incentive for establishing patent pools will become a reality for plant related innovation. The question arises "*how do we move ahead*"? What actions will be required from stakeholders, breeders and legislators, to ensure that breeding is not coming to a grinding hold, once, in 10 years >50% of all varieties comprise at least one genome-edited characteristic and in 20 years essentially all commercial varieties will comprise 5 or more of such characteristics.

While today the solution of the PINTO Database to create patent transparency and the ILP to enable access to patent traits are pragmatic approaches at least for vegetables, it is questionable whether these solutions can be evolved to meet the challenges of the future i.e., specifically (i) the increasing patent complexity of stacked traits and effects of method patents and (ii) the extension of patent activities to many crops and countries. All approaches have their shortcomings (see Table 4).

Table 4. Strengths and weaknesses of solutions for access and transparency for plant patents.

	Advantages	Disadvantages
Patent Pools (No example yet)	Resolves complexity ("patent thickets) by providing a "one-stop-shop" to large patent portfolios	High antitrust hurdles: All patents needs to be essential. Usually associated with standards. Number game: Royalty allocations does not consider individual innovation value [206]. Take it all or leave it: No flexibility to pick and choose.
Clearing houses (Example: ILP)	Establish FRAND terms for individual innovations. Broad acceptance. Low costs in running.	High setup costs and efforts. No solution for stacking. No solution for "external" method patents
Licensing Pledges (Example: Traitability™)	Easy to establish, no negotiation, limited anti-trust assessment.	Voluntary, not holistic. Lack of governance. Often not transparent. No solution for stacking.
Open Source (Example: OSSI)	Simple, low transactional costs.	Economically not sustainable. Risk of anti-common effect and misappropriation.
Transparency Pledges (Example: PINTO)	Simple, low transactional costs.	Voluntary w/o sanctions. Not holistic (only EU patents, EU varieties, ESA Members).

A classical patent pool is not foreseeable and likely also unnecessary for the plant sector with the exception of specific technology area like CRISPR-Cas9. Breeders need an option to "pick-and-chose" the necessary licenses based on the traits in their new variety. These licenses may be to several trait patents and several method patents which extent to the trait (see under Section 3). It is unlikely that all these patent owners would join a pool or licensing platform, already because many of the method patent owners are academic institutes i.e., "non-practicing entities" which only provide licenses but do not need any.

5. Moving Forward

As will be shown below, it is unlikely that only industry solutions or only legislative actions can be successful. It is possible that not even a creative combination of legislative action and stakeholder solutions can solve the challenge of future patent thickets and a major holistic redesign of the IPR system for plant related innovations is likely necessary (see Section 5.2.2). However, some measures could at least provide solutions for a transition period.

5.1. Evolving the ILP

The ILP is a well-functioning mechanism for the current situation but may require evolution in view of the emerging challenges:

(i) The ILP is limited to vegetables and there are no parallel solutions for field crops or the ornamental and horticultural sector. The solution to expand the current ILP to all crops is not advisable when assessed in details [207]. Solution: Set-up parallel ILPs for field crops and ornamentals/horticulture based on the existing ILP model with separate expert committees [208].

(ii) The ILP has no mechanism to deal with stacked traits. The current baseball arbitration is intrinsically limited to a two-party dispute and must fail for multi-party situations. The questions (i) how to avoid that royalty stacking becomes punitive and (ii) how to allocate a royalty to different patentees is currently not answered. Solution: Royalty stacking could rapidly reduce the earnings of a breeder to zero. However, a general "cap" to total royalties (e.g., 30–50% of net income) would create an unhealthy incentive for stacking as any additional trait would not cost more. In consequence, the first "step" in the solution needs to be a benchmarking with the industry practice and/or a clear technical need (e.g., resistance management). The burden of proof needs to be with the party who applies for a cap. The second "step" is setting the total royalty for a solution. Here, a variation of the standard baseball arbitration named "night baseball" arbitration [209] can be helpful: The set-up is the same, and the pitches are the same. The difference is that the arbitrator renders his or her call before the parties show their numbers. The party with the proposal closest to that of the arbitrator prevails. While this system increases the workload for the arbitrator, it enables pitches by multiple parties. The third "step" is the allocation of the total royalty to the different patentees. In cases where an individual royalty has already been established for each technology this should be straight forward: Each royalty is reduced by multiplication with the quotient of the capped royalty by the aggregated royalty. For example, if a license package includes seven technologies which each has been licensed for a 10% royalty on net sales (*i.e.*, an aggregated royalty of 70%) and the royalty cap has been set at 35% on net sales then each individual royalty is reduced to 5%. If an individual technology has not yet been valuated, then such technology first needs to be valued in separate "normal" baseball arbitration. *Challenges*: A lower %-royalty does not necessary mean a lower income for the innovator if the added value of the trait combination can be full realized. However, if the royalty-rate is a percent of net sales licensees may choose to rather gain market share with cheaper prices than maximising value. This would erode the trait value and potentially negatively impact the incentive to innovate. Such erosion could be avoided by employing an added-value based trait fee *i.e.*, a defined value for the trait package and each of its components. However, as trait value could become a substantial part of the total product value and sales price this could be problematic from a competition law perspective as it could have a "price fixing" effect. Even if the risk of value erosion is accepted for simplicity, other dynamic elements of a stack solution need to be considered: Patents are not equally filed and granted in all countries. They expire at different times and can be refused. So a highly dynamic, country-by-country royalty setting and allocation scenario is likely, which would require sophisticated IT-solutions to manage [210].

(iii) The ILP has no mechanism how to deal with reach-through royalties for method claims as they may related to most NBT-derived traits. Two scenarios are foreseeable: (i) The products are covered by a valid claim as it could be in the US, Canada, Australia, and some other countries which extent methods claims broadly to resulting products, or (ii) the products are merely "enabled products" outside the scope of the patent but the licensee is contractually obliged to pay reach-through royalties. Scenario 1 "Covered by a Valid Claim": Here, no solution is foreseeable within or through the ILP. While ILP members have no duty to ensure full freedom-to-operate under third party patents, they need to use reasonable efforts to inform other members if

a certain material is made by NBTs and whether its FTO might be constrained in some countries. It would be the duty of the licensee to obtain additional licenses from the NBT-patentee directly or—if contractually permitted—through a sublicense from the other ILP member. The terms and conditions of such license would not be governed by the ILP but considered a bilateral agreement. Scenario 2 "Enabled Products": If the product is outside the scope of the patent a reach-through royalty obligation can unlikely bind another ILP member. The ILP does not enable licenses to any specific product of a member but it grants a license under a certain patent to use legally available material covered by said patent for further breeding. The material could be material of the licensor, but also material made by the licensee or by third parties. In consequence, the ILP is *de facto* rather a passive non-assert under a patent right than an active license to a certain product of the licensor. This should effectively deny any contractual reach-through beyond the direct contract partner [211]. If an ILP Member would consider raising such contractual argument to deny a license or to ask for addition royalties, such act would be considered a breach of the ILP obligations if the NBT license was entered after the member becoming an ILP member then.

Can these "evolutions"—especially the expansion to field crops and the management of dynamic royalty caps and value allocation—be realistically implemented? The assumption of Mossoff "*that patent owners have the incentives to resolve the problem of patent thickets—exercising their property and contract rights within the framework of these preexisting private-ordering regimes*" [119] needs to be questioned for plant related innovations as both the innovation, innovator, and user landscape is complex, more than in any other industry:

- Users and Patentees: The list of parties establishing and using plant related inventions is complex. It has horizontal and vertical dimensions [212]. There are universities, breeders, biotechnology companies, crop protection companies, grain traders, food producers and retailers, growers etc. Users will have all different sizes and both an international or local footprint. Most importantly not all users are innovators and patent owners, not all innovators and patent owners are users. Already today, several ILP members are small breeding companies with no own patent estate. Further, not every patent owner is also a patent user (i.e., a practicing entity). Especially academic institutes, who own a substantial part of today's NBT-related patent assets, are on the best way to become "patent trolls" in exploiting patent positions far beyond the patent's actual scope hardball tactics. Even major EU universities, which hold several patents on plant traits and NBTs, have not yet joint the ILP. From a public policy perspective this is a paradox, but maybe not surprising as universities as non-commercial entities would unlikely enjoy benefits from obtaining licenses under the ILP but rather limited their flexibility to leverage their IP.
- Crops: The landscape includes food, feed, industrial and ornamental crops, commercial and as well as subsistence crops. The value chain and value capture differ substantially for each of those.
- Countries and cultures: Plant breeding is a global activity, whereas seed sale and use are very local activities. As discussed briefly above, today's IPR systems for plant related innovations differ substantially from country-to-country with a strong cultural element which spans from an aversion against patents on seeds—like in India—over a reluctance for "patents on nature"—like in the EU—to a rather agnostic view like in the USA. However, breeders need to be able to move and use their plant genetics usually in a global context.
- Lack of standards and essential facilities: While the smart phone industry has the "benefit" of a strong encouragement resulting from the telecommunication standards which forces all owners of standard essential patents to enable access, such effect is lacking and also not foreseeable in the seed sector. Cases which attempt to expand the essential facility doctrine beyond standards will likely remain rare and narrowly defined exceptions. While likely everybody would agree that seed and breeding are "essential" for food security and wellbeing, it would require a fundamental legislative

change to define the seed of each and every variety and all related patents as an "essential facility".

- Self-propagating nature of seed products: Seed is a high-tech product in an exceptionally easy-to-copy form [213]. This enables significantly more potential "producers" than in any other technology area. It also requires mechanism of royalty capture and IP enforcements which consider the divers user landscape and country-by-country differences.

The complexity has a consequence: While an evolution of the current solutions will be necessary it is unlikely sufficient. Any seed industry initiative needs to be embedded in or "encouraged" by legislative changes.

5.2. Legislative Adjustments

Most countries have—so far—accepted the co-existence of patents and PBRs and the fact the PBR exemptions for breeding and farm-saved-seed are essentially abolished by patents covering the variety. Especially in the US this comes at the price that the exchange of germplasm and biodiversity is substantially reduced and breeders work predominantly in their own germplasm pool [214]. However, so far US breeders benefit from the more liberal access to germplasm in most other legislations. If with the raise of new breeding technologies "patents on plants" expand to all crops and all legislations, the US model becomes global it likely also becomes unsustainable. As Bellivier observes: "The variety of corn 'Inra 258′ created from two American lines, a Spanish line and a French line, could probably have been developed only after years of negotiations with the countries of origin if the system of the CDB had been applied [67,215]."

So far only few countries have established plant-specific adjustment in their patent laws. Especially the EU and Switzerland have taken specific measures to harmonize patent and plant breeders rights. The Biotech Directive 98/44 states that between patents and PBRs "*harmonisation is necessary to clarify the said uncertainty*" and attempts a harmonization both on the level of protection and the level of rights including farm-saved seed and compulsory cross-license [216].

The most likely option for the legislator is to "do nothing" or to use pragmatic fixes *e.g.*, a "dynamic interpretation" of the law as in G3/19. However, there are limits. While the allowance of rights can be somewhat flexible, to "meddle" with already granted rights is problematic [217]. Certain challenges and uncertainties like—for example—the scope of method claims can and need to be mitigated by clarifications within the current legislative framework. Others can hardly be mitigated without changes. The following options are possible in principle:

(i) Abandon patents for plant related inventions.
(ii) Merge patents and PBRs into a new holistic system for open innovation.
(iii) Further smooth the interface between patents and PBR.

5.2.1. Option 1: Abandoning Patents

On a first glance, abandoning patents for plant related innovations looks like a suitable solution. NBTs could trigger a paradigm change with new varieties being developed faster, at a lower cost and brought to the market years before a patent is granted [218]. As the development time but also the product lifecycle shortens, patents will play a smaller role and are not business critical as for GM technologies. The "copyright effect" of PBR in combination with trade secrets could be a sufficient alternative. However, it may not protect the lead time of the original breeder unless it is combined with a moratorium to the breeders exemption as proposed by Smith [214]. However, such moratorium will unnecessary delay breeding progress and an "access and benefit sharing"-based solution might be preferable.

While excluding plants from patentability and the effects of patents is permitted under Article 27(3)(b) of the TRIPS agreement, abandoning patents or restricting patent rights for fields where they are provided is problematic and potentially in conflict with constitutional laws as they would affect established property rights [219]. On the other hand, there is precedent for changes to patent law which retroactively limited already existing rights: Examples are the breeders exemption or the farm-saved-seed exemption in patent laws. They came into effect also for already existing patents.

Abandoning patents would also create an incentive to rely on trade secrets. Trade secrets in combination with the copyright-effect of PBR could provide an efficient protection strategy especially for complex traits which are difficult to reverse engineer [220] and even more difficult to transfer by conventional crossing. However, an incentive for trade secrets would undermine knowledge dissemination and is not be desirable from a public policy perspective [221,222].

Abandoning patents could also trigger a "tragedy of the commons" effect, i.e., a stimulus to underinvest in own innovation and merely exploit third party innovation thereby depleting or spoiling the shared resource through a collective action [223–225]. Smith concluded that without robust IPR there would be no investment in and no sustainable use of plant related inventions [226]. However, this effect needs to be balanced with the "tragedy of the anti-commons" effect, which is more likely in a breeding landscape where NBTs play a critical role. At least as long the copyright-effect of PBR is still in place and new varieties cannot be bluntly copied by mere propagation, there is still a strong incentive for innovation, especially if they become cheaper and more frequent. The first-to-market incentive may already provide a sufficient incentive assuming that NBTs are affordable and widely available including an appropriate research capability in the public sector which is accessible for small and medium size breeding companies. Not investing into innovation and improved varieties will render a breeder non-competitive in an even shorter period of time than today.

An "abandoning" of the current IP systems could also happen "de facto" by the users if the system stops to provide sufficient benefits. Especially if the patents system remains as slow as it currently is, this is not an unlikely scenario. However, abandoning patents is likely only legally feasible as long there is no retroactive effect on existing patents or already filed patent applications. This also means that the impact of patents will not go away for another 20 years.

5.2.2. Option 2: Redesign IP system

In contrast to the below discussed Option 3, this option considers replacing the current patent and PBR system by a new holistic system. As the excluding plants as patentable subject matter can only provide an incomplete solution due to the indirect protection through claims on DNA or processes, this will likely require a specific exception from the patent rights for plants, their making and use.

Proposals to radically redesign the IP systems for critical innovations like healthcare and agriculture are not new. Stieglitz suggested a "price system" which "entails giving a prize to whoever comes up with an innovation" [227]. Van Overwalle propose the introduction of an "inclusive patent": *"The inclusive patent is perceived as a one-sided right geared to include rather than to exclude others, and encompasses as an attribute the right to enforce sharing behaviour and take non-sharing users to court. The inclusive patent is further conceived as a registration patent obtainable at low cost. The inclusive patent regime may be developed as a semi-codified regime where the inclusive patent entitlement is provided by law and the open source copyleft type license is built on top by private parties, or as a fully-codified regime where the legislature imposes universal and sustainable access and use ex ante* [121]*."*

Rapela suggests a "Plant Germplasm Integrated System" as a comprehensive and inclusive proposal for the protection of plant varieties, biotechnological developments, genetic resources, and biosafety [228]. In addition to aspects of the patent and the PBR system is also integrates the elements of the Convention on Biological Diversity (CBD), the International Treaty for Plant Genetic Resources (ITPGRFA) and the biosafety and regulatory law for genetically modified plants. The Integrated IP System shall be valid with the same scope in all member states and should be the sole system for plant protection.

Also Zech and Metzger argue for a unified protection regime which should replace the current PBR and patent system. DNA should not be patentable if and to the extent a claim extends to plants [229]. The unified system provides for a Type I protection for plant varieties and a Type II protection for innovative new, man-made traits. The enhanced "Type II" protection is only available if the responsible gene sequence has been disclosed. Applicants should either apply for Type I or Type II rights but not for cumulate rights.

While a redesigned, holistic IPR system has a strong appeal and should be compliant with the requirements of the TRIPS agreement [230] the current proposals leave many questions and details open and more substantive work is necessary before such system can be considered. Even if there would be a group of interested UPOV parties to bring such "UPOV 2030" to life it will take substantial time and effort and require a lengthy transition period of more than 20 years before the new system will have effectively replaced the existing systems. Thus, transition solutions will anyway be required.

5.2.3. Option 3: Smooth the Interface between Patents and PBR

With respect to smoothing the interface between patents and PBR, the EU and Switzerland can be seen as trailblazer. Their patent laws (i) enable farm-saved-seed (FSS) for patented varieties under the terms and conditions of the PBR system (ii) provide for a limited breeders exemption, and (iii) establish a compulsory cross-license provision if a PBR rights cannot be exploited without a license under the patent. In addition, the EU excluded from patentability plants exclusively made by conventional breeding [231] and limited the scope of protection for biotech patents by excluding from the protection processed products like meal.

There are national initiatives to further smoothen the interface: France established a comprehensive breeder's exemption in patent law by excluding from the scope of protection varieties which have been obtained exclusively by essentially biological processes and independent from the material of the patentee. A recent initiative in Switzerland [232] attempts to: (i) improve patent transparency (ii) clarity the prerequisites for the compulsory licenses and cross-licenses (iii) create an exemption from the patent right for varieties independently obtained from the patentee's material by biological processes [233], and (iv) implement Rule 28(2) EPC on a Swiss national level [234].

All these measures could provide a blueprint how to further harmonize patents and PBRs. They could have a double function: Provide a solution as such, and create an incentive for stakeholder solutions. Clear criteria for a compulsory cross-licensing would create an incentive to expand concepts like the ILP. A legal obligation to create patent transparency would create an incentive to expand concepts like PINTO. Legislative incentives and stakeholder solutions could act synergistically and provide a robust solution framework. Together they could achieve what none of them can individually (see Table 5).

Table 5. Benefits and disadvantages of legislative and stakeholder solutions.

	Advantages	Disadvantages
Legislative Solutions	• Mandatory • Enforceability	• Country-specific • Often "one-size-fits-all" • Slow to establish and to adjust • Costly, lengthy proceedings • Conflict-driven
Stakeholder Solutions	• Tailor-made to a specific field • Potential to be global • Cost efficient, fast proceedings • Solution driven	• Voluntary • Complex to establish and adjust [235] • Antitrust concerns

In the following some potential measures are described in more details.

Expand Legal Certainty and Freedom-to-Breed

The effects of a patent could be limited to ensure that products obtained independent from the material of the patentee by essentially biological processes are not covered by the patent. France provides such solution in their national patent law [236]. While the wording can be improved [237], such provision in national patent laws could achieve what G3/19 will unlikely achieve: Legal certainty for conventional breeders as it would be applicable to all patent irrespective of their filing date [238].

Important is also a clarification of the scope of claims on general method of enabling. While for a claim to make a specific characteristic (e.g., disease X based on mutation Y) a third party can identify the related patent, no such opportunity exists for general enabling technologies. It is virtually impossible to tell from the product which general enabling technologies have been used in the making of the product. In some countries such broad interpretation is currently possible. In the EU, while there is no explicit court decision on that matter, one judge seems to hold a broad interpretation possible [239]. However, the "obiter dictum" does not seem to be based on a thorough legal analysis and would likely conflict with the legislator's intent. Although the legislative history on the related provision is scarce, there is evidence that the legislator only intended an extension if the specific characteristic is a characteristic „according to the invention" ("erfindungsgemäße Eigenschaft") [240] i.e., a characteristic that "has originally been disclosed and the reason for the grant of the patent" [241]. Any other interpretation would create an unacceptable legal uncertainty as neither breeders nor farmers would have any way to identify which general enabling technology patent may affect a seed product. Here, a clear guidance—or another notice—from the European Commission would be desirable. Further, the German transposition law in the context of transposition of Article 8(2) emphasizes that this provision does not extend to plant varieties and animal races i.e., "the exclusion of patents for plant varieties and animal breeds cannot be circumvented" [240].

Compulsory Cross-Licensing

The argument more IPR encourages more innovation is overly simplistic especially in the context of agriculture [40]. Outside the field of GM crops, plant related patents are likely rather a cost factor then an enabler of value. The patenting, transactional, licensing, lobbying and other related costs are likely higher than the patent-related revenues. Often seed companies file patents merely to create bargaining in a business "armament race". Most breeders would agree that their world would be a better place without patent. However, abandoning patents—or rather the protection for new characteristics—may endorse piggyback approach and discourage investment into trait development activities and pre-breeding, which seems to make patents a "necessary evil".

The International Licensing Platform is a widely accepted patent clearinghouse for plant related trait patent. However, critics complain that the participation in the platform is voluntary and limited to vegetables. The acceptance would likely benefit from clarifications to the compulsory license and cross-license provisions in patent laws.

Bjørnstad suggested that breeders should be allowed to use patented plant material, but are required to declare the patents used when they register a new variety. A fair royalty fee could be established by a system such as the ILP Vegetables example. This approach could also be used for patented processes and methods [242].

In the EU, today, the entry barrier for compulsory cross-licenses under Article 12 of the Biotech Directive 98/44 is high due to the legal uncertainty resulting from vague terms like "*significant technical progress of considerable economic interest*" which is a prerequisite for a license [86]. Also Henry and Stieglitz proposed a compulsory license system as a public measure [204]. A clearer criteria would strengthen the bargaining position of potential licensees. With respect to the required "*significant technical progress of considerable economic interest*" Switzerland improved legal certainty by linking it to the seed market authorization [243]. However, there is room for further clarification. To be listed in the catalogue, which is a prerequisite for varieties to be marketed in the EU, varieties must have 'satisfactory value for cultivation and use' (VCU) [244]. If an agricultural plant variety demonstrates a VCU, the requirement of a "technical progress" could be deemed automatically satisfied [245]. Thus, a variety would be automatically entitled to a license if it fulfills the requirement for seed marketing [60]. Such interpretation seems reasonable and could be implemented without a change of the Biotech Directive 98/44, e.g., by a further Commission Notice or Guidance. However, VCU is only applicable to some agricultural varieties, especially to cereals and potatoes, but not to vegetables, fruits and grasses that are not intended for the production of fodder plants. For those other varieties the 'satisfactory value' test could only be applied in analogy. Such solution would lower the hurdle for compulsory licenses significantly. The only outstanding issue for a judge would be determining the fair compensation. A patentee can likely avoid a compulsory license by making a binding licensing offer under the framework of a licensing platform like the ILP. Here, the reasonable compensation is determined by an expert committee, which likely will lead to a more educated determination.

For follow-on breeders it should be possible to raise their willingness to conclude a compulsory license with FRAND terms as a defense in enforcement proceedings [246]. Like this, patent holders could not block the marketing of innovative plants using their protected traits but only ask for FRAND license fees. Moreover, the chilling effects of possible patent lawsuits for follow-on innovators would be reduced.

Mandatory Transparency

Patent transparency i.e., a clear understanding which plant material is affected by which patent is of fundamental importance for breeders to make educated choices. The PINTO database [13,14] of the European Seed Association (ESA) discloses the patent status of many varieties approved for marketing in the EU and is recognized as an important step towards transparency. However, it is criticized: (i) for being a voluntary instrument, (ii) only binding members of the European Seed Association (ESA) and (iii) for only referencing EP Patents in relation to variety on the EU catalogue [247].

A breeder can ask the owner of a variety for its patent status and usually the rules of forfeiture [248] should be sufficient to ensure that the breeder cannot be found liable if the breeder in good faith uses a variety assuming it does not comprise a patented trait [249]. However, currently the burden of proof would be with the breeder and there could be circumstance where an act in bad faith is difficult to prove. Especially if the patentee does not respond to the inquiry at all, he may try to argue later that he never received such letter or that such letter was received by a person not well informed.

This "deficiency" can be overcome by implementing in national patent laws a duty to disclose the patent status of a commercially available variety [250]. Such duty can be fulfilled either on request by any interested party, by declaring the patent status in the context of obtaining seed market authorization, or in a publicly accessible database like by PINTO. The "duty to disclose" can be given teeth by linking it to the enforceability of the patent: If a patentee does not make the disclosure even on a written request of an interested party he should not be entitled to enforce the patent against a use in good faith by said party [251]. As such "forfeiture of rights" would already be the consequence under the existing laws of most EPC countries it would be nothing more than a clarification which provides breeders a clear process how to obtain legal certainty. It would also support initiatives like PINTO by encouraging a broader participation and maybe expansion to other territories.

5.3. Conclusions

The patent thicket for plants will become increasingly dense as a consequence of NBTs and the trend to more complex stacks of patented traits. Unless the IPR systems for plant related innovations can be evolved towards openness, breeding utilizing a wide range of plant diversity—as we currently know it—may come to a hold within the next two decades thereby reducing the ability for plant breeders to provide new varieties to farmers and consumers, and mitigate climate change. While a complete redesign of the IPR system might be desirable, a continuous alignment of the patent and PBR system in combination with further evolving seed industry solutions is necessary. Laws can be interpreted without major amendments to encourage collaborative licensing initiatives. Licensing initiatives like the ILP can be evolved to deal with stacking and complexity, provided that all members agree. While the evolution of the current systems by synergistic interaction between legislative changes and evolving industry solutions may provide a robust transition for the next decade, it unlikely provides a long-term solution. A system failure can only be prevented by a fundamental redesign of the IP system for plant innovations into one holistic system which combines elements of patents, plant breeder rights, and the Convention for Biological Diversity into an open innovation framework. Such system could consider also the shorter innovation cycles in providing a shorter protection term and could evolve the current IPR system from exclusivity to inclusivity i.e., a liability regime which enables "access and benefit sharing". To be continued . . .

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75. "Complex" industries are sectors where patents have a sunstantial strategic bargaining value, while in "discrete" industries patents have rather a stand-alone innovation value, see Cohen, W.M.; Nelson, R.R.; Walsh, J. *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*; National Bureau of Economic Research Working Paper; National Bureau of Economic Research: Cambridge, MA, USA, 2000; p. 7552.
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77. Companies developed biotech products under licenses or cross-licenses. The complexity of the IP and the competition landscapes were limited so that license deals have been possible with reasonable efforts. Meanwhile the majority of the early enabling technology patents expired and there is a basic tool kit of off-patent technologies. In addition, plant biotech patents have been relevant for few MNCs which were developing their own GM traits, but not for breeders at large. Plants with GM traits can usually be easily identified and are limited to a few crops, so that breeders are able to avoid issues.
78. At least novelty is provided as long the induced change—Or the combination of changes—Does not pre-existing in nature.
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83. The extension to products is provided – for example - by Article 28 (1)(b) second alternative The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Article 25 lit. c Agreement on a Unified Patent Court (UPCA), Article 64 (2) European Patent Convention.
84. In Monsanto Technology LLC v Cargill International SA (Case No: HC06C00585; decision of Oct. 10, 2007) HJ Pumfrey for the UK High Court of Justice denied extension of the scope of process claims to down-stream progenies. He decided that "the phrase "directly obtained by means of the process" means "the immediate product of the process', (No. 35) and found that "all the RR soybean plants in Argentina . . . can be described as the ultimate product of the original transformation of the parent plant. But I cannot see that it can be properly described as the direct product of that transformation, a phrase I would reserve for the original transformed plant. This aspect of the claim must fail." (No.37 of the ruling).Available online: https://www.casemine.com/judgement/uk/5a8ff75f60d03e7f57eabda1 (accessed on 10 June 2021).
85. Applicants could—For example—Add the feature of "optionally further propagating said plant" to a method claim to avoid that final plants fall outside the literal scope of the claim (see. EN.48).
86. In the US process claims likely extent in general to down-stream products under 35 USC 271(g). Other countries (e.g., Australia and Canada) may also extent process claims to downstream products under the so-called "Saccharine Doctrine"
87. Available online: https://www.ipstudies.ch/2020/10/2020-crispr-patent-landscape-where-do-we-stand/ (accessed on 5 January 2021).
88. Search in "The Lens" (available at lens.org, accessed 5 January 2021) with the following search profile: claims:(CPF1* OR CPF-1* OR CMS-1* OR CMS1* OR CAS1* OR CAS2* OR CAS3* OR CAS4* OR CAS5* OR CAS6* OR CAS7* OR CAS8* OR CAS9* CAS12* OR CAS-1* OR CAS-2* OR CAS-3* OR CAS-4* OR CAS-5* OR CAS-6* OR CAS-7* OR CAS-8* OR CAS-9* OR CAS-12* OR CAS-phi OR CRISPR*) AND claims:(PLANT* OR SEED* OR CROP* OR FRUIT* OR MAIZE OR CORN* OR SOYA OR SOYBEAN* OR WHEAT OR RICE OR TOMATO* OR VEGETA* OR CEREAL* OR FLOWER* OR ROOT* OR NITROGEN OR STATURE OR "WATER USE" OR DROUGHT OR BIOMASS OR YIELD OR ABIOTIC*)AND classification_ipcr:(A01H* OR C12N*)
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92. Interference 106126 (BROAD-Toolgen). Available online: https://acts.uspto.gov/ifiling/PublicView.jsp?identifier=106126 (accessed on 9 June 2021).
93. No. 106127 (UCB-Toolgen). Available online: https://acts.uspto.gov/ifiling/PublicView.jsp?identifier=106127 (accessed on 9 June 2021).
94. Noonan, K.E. Separate Interferences Declared between Toolgen and Broad and CVC over CRISPR Priority Question. Patent Docs. 2021. Available online: https://www.patentdocs.org/2021/01/separate-interferences-declared-between-toolgen-and-broad-and-cvc-over-crispr-priority-question.html (accessed on 23 January 2021).
95. In a strawman opposition the party in interest remains undisclosed as the opposition is filed in the name of patent attorney of law firm or a company specifically set-up for such kind of oppositions (e.g., „Strawman Ltd.").

96. Martin-Laffon, J.; Kuntz, M.; Ricroch, A.E. Worldwide CRISPR patent landscape shows strong geographical biases. *Nat. Biotechnol.* **2019**, *37*, 613–620. Available online: https://hal.archives-ouvertes.fr/hal-02148307/document (accessed on 6 January 2021). [CrossRef]
97. The Reimbursement for Aggregated Patent Expenses by the Pharmaceutical Start-Up Editas Medicine, Inc. to the Broad Inst. Were $14.0m, $14.2m, $18.7m, $23.6m, $9.4m, and $1.7m for the years 2019–2014 (i.e., Accumulated $81.6m USD). 10-K Reports of Editas Medicine. 10-K Report 2019, available online: https://ir.editasmedicine.com/static-files/fcdbc9e0-a378-4020-846a-8013ff5fbe75; and 10-K Report 2018 available at https://ir.editasmedicine.com/static-files/bd9916b8-4cca-41c9-ba27-d362c131fda0 (accessed on 16 January 2021).
98. It can be expected that the costs for UC Berkeley are similar to those of The Broad Inst., followed by somewhat lower costs for Toolgen, Sigma et al.
99. MPEGLA suggested a CRISP patent pool in 2019. The initiative has not yet gotten any visible traction. Available online: https://www.mpegla.com/crispr/initiative/. See also related article https://www.mpegla.com/wp-content/uploads/IAM-article-July-5-2019.pdf (accessed on 16 January 2021).
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101. According to Broad Inst. "the best thing, for the entire field, is for the parties to reach a resolution. This is why, for seven years, we have made many attempts to engage University of California-Berkeley, directly and through their exclusive licensee and through patent pools. These efforts began before UCB licensed its IP exclusively and entirely to commercial entities, and we will continue to pursue a path towards resolution." Broad Communications, Updated 27 September 2020.Available online: https://www.broadinstitute.org/crispr/journalists-statement-and-background-crispr-patent-process (accessed on 23 January 2021).
102. Ku, H.K.; Ha, S.H. Improving Nutritional and Functional Quality by Genome Editing of Crops: Status and Perspectives. *Front. Plant Sci.* **2020**, *11*. Available online: https://www.frontiersin.org/articles/10.3389/fpls.2020.577313/pdf (accessed on 6 January 2021). [CrossRef]
103. Under the previous regulations, APHIS offered an inquiry process for sevelopers to setermine if their NBT-derived organism met the definition of a regulated article. This process was discontinued on 17 June 2020, and replaced with the SECURE rule's confirmation process beginning on 17 August 2020. Available online: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated (accessed on 21 December 2020).
104. In the US, depending on the variety, already more than 80% of varieties are patent protected
105. The catalogues list about 28.800 vegetable species. Plant Variety Catalogues, Databases & Information Systems. Catalogue for Vegetable Species. Available online: https://ec.europa.eu/food/plant/plant_propagation_material/plant_variety_catalogues_databases_en; Catalogue for Vegetable Species
106. The catalogues list about 28.760 agricultural species. Plant Variety Catalogues, Databases & Information Systems. Catalogue for Agricultural Species. Available online: https://ec.europa.eu/food/sites/food/files/plant/docs/plant-variety-catalogues_agricultural-plant-species.pdf (accessed on 1 January 2021).
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108. Prifti, V. *The Breeder's Exception to Patent Rights*; Analysis of compliance with article 30 of the TRIPS Agreement; Springer International, International Law & Economics series; Springer: Cham, Switzerland, 2015.
109. One may assume that the variety owner would collect all royalties and splits them among the different IP owners, but such mechanism is not foreseen in the law. Unless established by contract the variety owner would not be entitled to collect royalties for patents of third parties
110. Reuters Business News (18 January 2021) France Backs Non-GMO Regulation for Crop Gene-Editing in EU. Available online: https://www.reuters.com/article/us-france-agriculture-gmo/france-backs-non-gmo-regulation-for-crop-gene-editing-in-eu-idUSKBN29N1T9 (accessed on 30 January 2021).
111. Seed World. ISF Statement on the Notification of Genome Edited High-GABA Tomato In Japan. 2021. Available online: https://seedworld.com/isf-statement-on-the-notification-of-genome-edited-high-gaba-tomato-in-japan (accessed on 30 January 2021).
112. Defra Consultation. Available online: https://consult.defra.gov.uk/agri-food-chain-directorate/the-regulation-of-genetic-technologies/ (accessed on 9 June 2021).
113. Scenario 2 would not require such solution, but it would also be a clear signal of market failure and under-utilization of innovation which hopefully can be avoided in view of the challenges of climate change
114. Hall, B.H.; Helmers, C.; von Graevenitz, G. *Technology Entry in the Presence of Patent Thickets*; NBER Working Paper 21455; National Bureau of Economic Research: Cambridge, MA, USA, 2017; p. 51.
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118. Despite complex patent thickets smartphones still exist. Would we have better smartphones if the patent system was more "open"? Defining a "but-for" situation is intrinsically difficult and the conclusion that weaker patents enable more innovation is difficult to verify with hard data
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125. Communication from the Commission. Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements (2014/C 89/03) "TT-Guidelines", para. 245. "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." And at para. 245: "There 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." Available online: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014XC0328(01)&from=EN (accessed on 9 June 2021).
126. Typical methods for royalty sharing include (i) Patent Points: The sharing is based on patent use. Revenues are shared based on a point system following patents ownership or (ii) Equal Sharing: Royalties are allocated among the patent owners in equal parts or (iii) Mixed methods. Combination of of (i) and (ii), (iv) Enforcement Premium. Additional revenues can be allocated to owners that make patents available for enforcement.
127. Vermeulen, F. Patent Pools: Do They Kill Innovation? Forbes 2013. Available online: forbes.com/sites/freekvermeulen/2013/01/22/patent-pools-do-they-kill-innovation/?sh=1cb0b74558f4 (accessed on 7 May 2021).
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129. While the joint license agreement of Corteva and the Broad institute is not public, it is likely that it is similar to the publically accessible terms of the Broad license to Editas (EN.102). Problematic are the missing limitation to essential patents, the lack of equal treatment of licensees, the lack of transparency of conditions, the extension of royalties to products not covered by the patents, penalties for patent challenges etc.
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134. Available online: http://openinnovation.corteva.com/ (accessed on 30 January 2021).
135. The Broad Inst. Press Release: DuPont Pioneer and Broad Institute Join Forces to Enable Democratic CRISPR Licensing in Agriculture, 18 October 2017. Available online: https://www.broadinstitute.org/news/dupont-pioneer-and-broad-institute-join-forces-enable-democratic-crispr-licensing-agriculture (accessed on 30 January 2021).
136. Available online: https://crispr.corteva.com/our-promise-crispr-cas-corteva-agriscience/ (accessed on 30 January 2021).
137. Amended and Restated Cas9-I License Agreement by and between President and Fellows of Harvard College, the Broad Institute, Inc. and Editas Medicine, Inc., 29 October 2014 Amended and Restated as of 16 December 2016. Available online: https://www.sec.gov/Archives/edgar/data/1650664/000155837017000174/edit-20161117ex992b17c22.htm (accessed on 9 June 2021).
138. Cas9-II License Agreement by and between the Broad Institute, Inc. and Editas Medicine, Inc. 16 December 2016. Available online: https://www.sec.gov/Archives/edgar/data/1650664/000155837017000174/edit-20161117ex993f74f02.htm (accessed on 9 June 2021).
139. CPF1 License Agreement by and between the Broad Institute, Inc. and Editas Medicine, Inc. 16 December 2016. Available online: https://www.sec.gov/Archives/edgar/data/1650664/000155837017000174/edit-20161117ex9916e543d.htm (accessed on 9 June 2021).

140. Enabled Product" means any product, other than a Licensed Product, which is or incorporates, or which is made, identified, discovered, developed, optimized, characterized, selected, derived from or determined to have utility, in whole or in part, by the use or modification of, (a) any Patent Rights or any technology or invention covered thereby, (b) any Licensed Product or any Institution Technology Transfer Materials, (c) any progeny, modification or derivative of a Licensed Product, or (d) any living or nonliving cell, organism, microorganism (including viruses), plant, plant tissue or plant seed made or modified through use of a Licensed Product or technology covered by the Patent Rights, or any progeny, clone, modification or derivative of such living or nonliving cell, organism, microorganism (including viruses), plant, plant tissue or plant seed.
141. The final plant will not comprise any of the Cas-machinery. Further, in most countries the scope of a method claim is limited to "direct products" i.e., the plant cell directly edited and does not extend to the ultimate plant
142. It also remain to be seen, whether indeed the licenses are granted to all commercial entities even their commercial interest is solely outside the US where such license terms will be difficult to enforce
143. Cambia Webpage available online: http://www.cambia.org/ (accessed on 30 January 2021).
144. See details for BiOS License under https://cambia.org/bios-landing/ (accessed on 30 January 2021).
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147. https://en.wikipedia.org/wiki/Biological_Innovation_for_Open_Society (accessed on 16 January 2021).
148. https://cambia.org/bios-landing/the-cambia-bios-initiative/ (accessed on 16 January 2021).
149. TransBacter uses Rhizobium, Sinorhizobium and Mesorhizobium bacteria. See under Broothaerts, W.; Mitchell, H.J.; Weir, B.; Kaines, S.; Smith, L.M.; Yang, W.; Mayer, J.E.; Roa-Rodriguez, C.; Jefferson, R.A. Gene transfer to plants by diverse species of bacteria. *Nature* **2005**, *433*, 629–633. [CrossRef]
150. Cambia. An Inventory of BiOS-Licensed Patents. Available online: https://cambia.org/bios-landing/bios-licensed-patents-inventory/(accessed on 30 January 2021).
151. Available online: https://cambia.org/bios-landing/bios-compatible-materials-transfer-agreements-mta-listing/ (accessed on 16 January 2021).
152. The CAMBIA "Biological Open Source" (BiOS) License for Plant Enabling Technologies Version 1.5. Available online: https://cambia.org/wp-content/uploads/2017/10/BiOS-License-and-Tech-Support-Agreement-version-1_5.pdf (accessed on 16 January 2021).
153. TransBacter related patent applications published as US 2005/0289672, US 2005/0289667, WO 2006/004914, and EP 1781082. None of the applications was granted a patent. All were rejected or abandoned.
154. See Monsanto's patents and patent applications "USE OF NON-AGROBACTERIUM BACTERIAL SPECIES FOR PLANT TRANSFORMATION" WO 2007/137075, US 7888552, US 9365859, US 10006035, US 10724042, EP 2361986, EP 2371964, EP 3196311 A1.
155. Detailed information about the statutes, members, and current patent estate can be derived from the ILP web-page: http://www.ILP-vegetable.org (accessed on 16 January 2021).
156. Kock, M. Plant breeding innovations: Free access but not access for free—A new approach to facilitate FRAND licenses for plant related patents. *Bio Sci. Law Rev.* **2015**, *14*, 123–129.
157. Van der Kooij, P.; Suelmann, M. Het International Licensing Platform: Een mijlpaal. *Ber. Ind. Eigend. BIE* **2014**, *12*, 260. Available online: https://www.ipeg.com/the-international-licensing-platform-vegetable-a-milestone/ (accessed on 9 June 2021).
158. Bruins, M. A Full Count for Vegetables. European Seed 2015, 2/1. Available online: https://european-seed.com/2015/04/a-full-count-for-vegetables/ (accessed on 16 January 2021).
159. For variety patents the ILP establishes a cost-free mutual non-assert for breeding of new varieties. This comes as close as possible to a full breeders exemption under PVP
160. Kock, M.; ten Have, F. The International Licensing Platform—Vegetables': A prototype of a patent clearing house in the life science industry. *J. Intellect. Prop. Law Pract.* **2016**, *11/7*, 496–515. Available online: https://www.ilp-vegetable.org/uploads/Bestanden/News/Article%20ILP%20Journal%20of%20Intellectual%20Property%20Law%20&%20Practice%202016.pdf (accessed on 16 January 2021). [CrossRef]
161. Trait patents cover to plant characteristics such as disease resistance, or nutritional value. The ILP is limited to unregulated traits, i.e., traits not considered genetically modified.
162. Members are nor precluded to grant such rights under a bilateral license agreement.
163. The reason results in the fact that handling GM technologies requires specific capabilities which are not compatible with the ILP's requirement to be open for all interest parties. Especially smaller breeders will not have the capability to handle GM technologies nor the capacity to cover for the related risks and liabilities
164. ILP Patent Register. Available online: https://www.ilp-vegetable.org/uploads/Bestanden/Patent%20Register/ILP%20Patent%20Register%20-%20total%2005102020%20changes%20marked%20in%20yellow.pdf (accessed on 16 January 2021).
165. Baseball arbitration was developed as alternative to free agency for professional baseball players. Players and teams would submit their proposed salary based on evidence like e.g., player performance or comparative salaries. The panel can only accept the proposal they deem most realistic. The award is final and issued without explanation

166. Samples, L.B. Resolving Construction Disputes through Baseball Arbitration. 2019. Available online: https://www.americanbar.org/groups/construction_industry/publications/under_construction/2019/spring/resolving-dispute-baseball/ (accessed on 18 January 2021).
167. Debevoise International Arbitration Clause Handbook ("Handbook"). Debevoise & Plimpton LLP. P. 74. Available online: https://www.debevoise.com/-/media/files/insights/publications/2020/06/debevoise-international-arbitration.pdf (accessed on 18 January 2021).
168. Usually parties will prefer a bilateral licensing arrangement with MTA and cross-licensing deals elements, rather than a Standard License Agreement. Therefore the ILP "only" provides a safety net in case no bilateral agreement can be found. Bilateral agreement cannot be subject of a baseball arbitration
169. Habbuand, A.; Buonaguro, P.V. A Game Theoretic Model for Determining When Baseball Arbitration Creates the Proper Incentives for Litigants. 2011. Available online: http://ssrn.com/abstract=1889768 or http://dx.doi.org/10.2139/ssrn.1889768 (accessed on 9 June 2021).
170. The experts cannot propose an average of the two proposals. Thus, if one proposal is unreasonable, automatically the other is adapted. In addition, the "losing" party has to pay the costs for the arbitration proceedings (30.000€)
171. There is only an opportunity for a formality review of the proceedings, i.e., 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.
172. This can—For example—Happen if there is emerging resistance for a disease resistance trait
173. See Lemley, M.A.; Shapiro, C. Simple Approach to Setting Reasonable Royalties for Standard-Essential Patents, Stanford Public Law Working Paper No. 2243026. 2013. Available online: http://ssrn.com/abstract=2243026 (accessed on 21 February 2021).
174. Ruubel, S. Tech Patent Claims Should Go to Arbitration as "Practical" Step, London Judge Says. In Mlex Maket Insight. *Mlex.* 2015. Available online: https://mlexmarketinsight.com/. (accessed on 2 December 2015). (subscription required).
175. Contreras, J.L.; Newman, D.L. Developing a Framework for Arbitrating Standards-Essential Patent Disputes. Journal of Dispute Resolution 23; American University, WCL Research Paper 2014-20. Available online: http://ssrn.com/abstract=2335732 (accessed on 9 June 2021).
176. The proposal to use baseball arbitration in the standard setting context is also criticized. See Larouche, P.; Padilla, J.; Taffet, R. Settling FRAND Disputes: Is Mandatory Arbitration a Reasonable and Non-Discriminatory Alternative?" HOOVER IP^2 Working Paper Series No. 13003; Tilburg Law School Research Paper No. 023/2013. Available online: http://ssrn.com/abstract=2346892 (accessed on 9 June 2021). [CrossRef]
177. Sidak, J.G. Mandating Final-Offer Arbitration of FRAND Royalties for Standard-Essential Patents. 2014. Available online: https://www.criterioneconomics.com/lemley-shapiro-baseball-arbitration-frand-royalties-seps.html (accessed on 21 January 2021).
178. An expert cannot in the five year before their appointment have been (i) a board member, secretary or expert; or (ii) a shareholder, an employee—Or had a special interest in or other relationship—With a vegetable breeding company.
179. The current Expert Committee was confirmed by all Members which demonstrates the high standing of the experts in the field
180. Van Overwalle, G. Patent pools and clearinghouses in the life sciences: Back to the future. In *Research Handbook on IP and the Life Sciences*; Matthews, D., Zech, H., Eds.; Edward Elgar: Cheltenham, UK, 2016; p. 23. Available online: https://core.ac.uk/reader/34657460 (accessed on 2 June 2021).
181. Available online: https://www.traitability.com/ (accessed on 21 January 2021).
182. Gould, C. 2013. Available online: https://www.forbes.com/sites/stevenkotler/2013/04/03/open-sourcing-food-security/#71d2e83e3d56 (accessed on 9 June 2021).
183. Available online: https://www.seminis-us.com/e-licensing/ (accessed on 21 January 2021).
184. The e-licensing web-page of Enza is not any more accessible. It seems that the initiative as been stopped. A review is still available under https://www.groentennieuws.nl/article/89814/e-licensing-platform-enza-zaden-live/ (accessed on 6 December 2020).
185. Corteva declared to make germplasm, laboratory, and field testing technologies, and expertise available through collaborations with third parties via an "open-innovation" website at https://openinnovation.corteva.com/ (accessed on 9 June 2021).
186. Available online: https://opensource.org/ (accessed on 2 January 2021).
187. Available online: https://creativecommons.org/ (accessed on 21 January 2021).
188. Luby, J.J.; Bedford, D.S. Cultivars as consumer brands: Trends in protecting and commercializing apple cultivars via intellectual property rights. *Crop Sci.* **2015**, *55*, 2504–2510. [CrossRef]
189. Luby, C.H.; Goldman, I.L. Freeing crop genetics through the open source seed initiative. *PLoS Biol.* **2016**, *14*, e1002441. [CrossRef]
190. Luby, C.H.; Goldman, I.L. Improving freedom to operate in carrot breeding through the development of eight open source composite populations of carrot (*Daucus carota* L. var. *sativus*). *Sustainability* **2016**, *8*, 479. [CrossRef]
191. Luby, C.H.; Kloppenburg, J.; Michaels, T.E.; Goldman, I.L. Enhancing freedom to operate for plant breeders and farmers through open source plant breeding. *Crop Sci.* **2015**, *55*, 2481–2488. [CrossRef]
192. Doyle, K. *Open-Source Plant Breeding: New Freedom for Farmers*; American Society of Agronomy: Madison, WI, USA, 2015; Available online: https://www.agronomy.org/story/open-source-plant-breeding-new-freedom-farmers (accessed on 21 January 2021).
193. Laursen, L. Plant breeders test drive first open-source seed bank. *Nat. Biotechol.* **2017**, *35*, 700. [CrossRef]
194. "You Have the Freedom to Use These OSSI Pledged Seeds in Any Way You Choose. In Return You Pledge Not to Restrict Others' Use of These Seeds or Their Derivatives by Patents or Other Means, and Include This Pledge with Any Transfer of These Seeds or Their Derivatives". Available online: https://osseeds.org/about/ (accessed on 9 June 2021).

195. Kotschi, J.; Horneburg, B. The Open Source Seed License: A novel approach to safeguarding access to plant germplasm. *PLoS Biol.* **2018**, *16*. [CrossRef]
196. Louwaars, N. Open Source Seed, a Revolution in Breeding or Yet Another Attack on the Breeder's Exemption? *Front. Plant Sci.* **2019**, *10*, 1127. [CrossRef]
197. See e.g., the recent speech by EU Commissioner M. Vestager "Intellectual Property and Competition". 2015. Available online: https://ec.europa.eu/commission/2014-2019/vestager/announcements/intellectual-property-and-competition_en (accessed on 21 January 2021).
198. European Union. *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*; European Union: Brussels, Belgium, 2014; Official Journal L 93, 17–23.
199. *Soft law* in this context indicates that the safe harbour is part of the TT-Guidelines rather than the TTBER. Thus, the Commission has more leeway to decide in an individual case whether enforcement is warranted, *even* if the safe harbor conditions are met.
200. This requies according to the TT-Guidelines (at para. 252), that there are no viable substitutes "both from a commercial and technical point of view"
201. To qualify every patent that would cover a variety as "essential" would be circular and render the test meaningless
202. The *3G3P* case related to the third generation ("3G") mobile equipment. Choumelova, D. Competition Analysis of Patent Licensing Arrangements—The Particular Case of 3G3P'. *Compet. Policy Newsl.* **2003**, *1*, 41.
203. Lerner, J.; Tirole, J. Efficient Patent Pools. *Am. Econ. Rev.* **2004**, *94*, 691–711. [CrossRef]
204. European Commission. DG Competition, CASE M.8084—Bayer/Monsanto, Merger Procedure Reg. (EC) 139/2004, Paragraphs 257–261. Available online: https://ec.europa.eu/competition/mergers/cases/decisions/m8084_13335_3.pdf (accessed on 21 January 2021).
205. Henry, C.; Stiglitz, J.E. Intellectual Property, Dissemination of Innovation and Sustainable Development. *Glob. Policy* **2010**, *1*, 337–351. [CrossRef]
206. The necessarily simple royalty allocation mechanism of patent pools favors large companies with many "Patent Points" and disfavor smaller or young companies with small patent portfolios, even if they contribute breakthrough innovations. Patent pools may create an unhealthy incentive to file many patents to increase "Patent Points" and thereby the royalty share which could further contribute to the ticket.
207. The pull-in effect may be too strong. In addition, already the practical difficulty to find candidates for the expert committee would be tremendous. Currently experts must have no affiliation with a vegetable seed company for the last five years and most are coming for field crop companies. An "all-crop" ILP would require the expert to have no affiliation with any seed company which would be in conflict with the requirement of expertise
208. As long as the established ILP model is used the efforts might be moderate. All ILP related documents and agreements are available from the ILP web page
209. Bresee, W.F. It Might Be a Big-League Move to Consider Baseball Arbitration in Construction Contract Disputes. 2018. Available online: https://www.leechtishman.com/insights/blog/it-might-be-a-big-league-move-to-consider-baseball-arbitration-in-construction-contract-disputes/ (accessed on 21 January 2021).
210. The uniform license fee of patent pools can likely not be employed, already because the applicable patents do not qualify as standard essential patents.
211. In Quanta the US Supreme Court reaffirmed the patent exhaustion doctrine Quanta Computer, Inc. v. LG Electronics, Inc., 553 U.S. 617 (2008).
212. Horizontal competitors are offering substitute products or services. Vertical competitors act along a channel or a value chain and compete on how much they get to wrest from the total relative to each other
213. While making the first seed can be costly and laborious, the subsequent propagation is usually cheap and easy
214. Smith criticizes the "low bar of the non-obviousness test for grants of utility patents to varieties per se" and find that "maize breeders have generally failed to take advantage of UP [utility patents] to broaden the repertoire of useful germplasm even as diversity within heterotic pools has declined and the loss of genetic variance will accelerate as improved selection methods are implemented." He "sees no valid public policy rationale to maintain eligibility of plant varieties per se for UP (utility patent) protection unless plant breeders take on board the potential protection provided by UP (utility patent) and undertake the risks and challenges associated with the introduction of new exotic genetic diversity." Smith, J.C.S. The Future of Essentially Derived Variety (EDV) Status: Predominantly More Explanations or Essential Change. *Preprints* **2021**, 2021050398. Available online: https://www.preprints.org/manuscript/202105.0398/v1 (accessed on 28 May 2021). [CrossRef]
215. Bellivier, F.; Noiville, C. *Contrats et Vivant. Le Droit de la Circulation des Ressources Biologiques, Col. Traité des Contrats*; LGDJ: Paris, France, 2006; 321p.
216. Dir 98/44/EC EN.33. Recital (9) Whereas in certain cases, such as the exclusion from patentability of plant and animal varieties and of essentially biological processes for the production of plants and animals, certain concepts in national laws based upon international patent and plant variety conventions have created uncertainty regarding the protection of biotechnological and certain microbiological inventions; whereas harmonisation is necessary to clarify the said uncertainty.
217. It could be sees as interfering with the constitutional right to property and the principle of legitimate expectation

218. Biotechnology related patents of require at least 5–7 years to grant. For controversial cases, such as native traits in Europe, most patents are already pending in examination for more than 10 years.
219. Professor Kirchberg in the context of the pepper case submitted an opinion in which he expresses several concerns with a the exclusion of plants with native traits from patentability. Specifically he sees an issue with Article 14 of the German Constitution (Grundgesetz) which protects property including intellectual property including technical inventions. This right starts prior to grant: Even if no exclusive right has been established, the application can be of license agreements and provides for provisional rights. Kirchberg notes, that such limitation is especially problematic if it would be implemented with retroactive effect as it would violate the principle of protection of a legitimate expectation ("Vertrauensschutzprinzip"). Opinion.Available online: https://register.epo.org/application?documentId=E2B11MCS3486DSU&number=EP12756468&lng=en&npl=true (accessed on 20 December 2020).
220. While the options for reverse engineering by sequencing are increasing quickly, they may only be an option for NBT-derived varieties if the initial variety is known and accessible. Only then will it be possible to narrow the possible causative changes. Otherwise it is still „complex" to identify causative changes in the genome. Usually this still requires to establish genotype-phenotype associations by field testing which for complex traits (QTLs) could be highly laborious
221. Hayes, D.J.; Lence, S.H.; Goggi, S. Impact of intellectual property rights in the seed sector on crop yield growth and social welfare: A case study approach. *AgBioForum* **2009**, *12*, 155–171.
222. Smith, S.; Lence, S.; Hayes, D.; Alston, J.; Corona, E. Elements of intellectual property protection in plant breeding and biotechnology: Interactions and outcomes. *Crop Sci.* **2016**, *56*, 1401–1411. [CrossRef]
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224. Hardin, G. The tragedy of the commons. *Science* **1968**, *162*, 1243–1248.
225. See also: https://en.wikipedia.org/wiki/Tragedy_of_the_commons (accessed on 30 December 2020).
226. Smith, S. The Foundations, Continuing Evolution, and Outcomes from the Application of Intellectual Property Protection in Plant Breeding and Agriculture. In *Plant Breeding Reviews*; Goldman, I., Ed.; John Wiley & Sons Inc.: Hoboken, NJ, USA, 2020; Volume 43, ISBN 9781119616733.
227. Stiglitz, J.E. Economic foundations of intellectual property rights. *Duke Law J.* **2008**, *57*, 1693–1724. Available online: https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1362&context=dlj (accessed on 30 December 2020).
228. Rapela, M.A. *Fostering Innovation for Agriculture 4.0*; Springer Nature: Cham, Switzerland, 2019; p. 71ff. [CrossRef]
229. Metzger, A.; Zech, H. Comprehensive Approach to Plant Variety Rights and Patents in the Field of Innovative Plant. In *Honour of Hanns Ullrich (Tbc)*; Springer: Cham, Switzerland, 2021; Available online: https://ssrn.com/abstract=3675534 (accessed on 30 December 2020).
230. The implementation of a holistic system requires to exempt plants from any protection by patents whether directly (e.g., through claims on plants), indirectly (e.g., through claims on DNA) or by a deferred protection (e.g., as a product of a protected method claim). Such exemption is covered by Article 27(3)(b) TRIPS, which allows Members to exclude plants from patentability. However, it needs to be implemented rather as a limitation to the patent rights than by rules on patentability. Such limitation should ensure that "the effects of the patent shall not extent to a plant, any of its parts, and the making or use of the before mentioned". Similar exemptions exist in the Swiss patent law which prescribes—For example—That "The effects of the patent do not extend to . . . "biological material that is obtained in the field of agriculture due to chance or is technically unavoidable (Art. 9f) or "individual preparation of medicinal products in pharmacies" (Art. 9h). https://www.fedlex.admin.ch/eli/cc/1955/871_893_899/en (accessed on 10 June 2021).
231. Based on a strong push from the EU Parliament and the Commission, the EPO's Administrative Council implemented Rule 28(2) EPC which excludes plants obtained by essentially biological processes (i.e., plants obtained by conventional breeding) from patentability. The EPO's Enlarged Board of Appeal in decision G3/19 ("Pepper") confirmed the validity of this Rule thereby reverting its earlier decision in G2/07 ("Broccoli I")
232. Motion 20.3674 "Geistige Eigentumsrechte. Anpassung im Bereich Pflanzenzucht" by Maya Graf. Available online: https://www.parlament.ch/de/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20203674 (accessed on 9 June 2021).
233. A compulsory license or cross license differs from an exemption as the compulsory license requires a reasonable compensation for the use while an exemption ensures that the respective plant is not covered by the patent rights.
234. The Federal Council has rejected the motion declaring is as unnecessary.
235. The ILP took more than 2 years to establish. It requires an unanimous consent of all members for all material changes to the ILP. With a growing membership this could become more difficult to achieve.
236. Article L613-2-3, Art. 10 para 3: The protection conferred by a patent relating to a biological material possessing, by virtue of the invention, specific characteristics does not extend to biological matters possessing said specific characteristics obtained independently of the patented biological material and by essentially biological processes, nor biological materials obtained from them, by reproduction or multiplication. (Unofficial translation by the author).

237. In view of the deviating definition for „essentially biological processes“ is should be considered to avoid this term and to rather use the alternative „crossing of entire genomes” suggest by Switzerland. With respect to the criteria of independent breeding it needs to be considered that a 3rd party can also reproduce the teaching of patent without using the material of the patentee. Therefore independence should also be from a use of the teaching of a patent. A possible wording could be: The protection conferred by a patent relating to a biological material possessing, by virtue of the invention, specific characteristics does not extend to biological matters possessing said specific characteristics obtained independently of the patented biological material and the teaching of the patent by an essentially biological process, nor biological materials obtained from them, by reproduction or multiplication.
238. While not a limitation to patentability, it would achieve the legislative intent of the EU Commission while avoiding ambiguity and a substantial limitation of the rights the patentee. Kock, M.A.; Zech, H. Pflanzenbezogene Erfindungen in der EU—Aktueller Stand. *GRUR* **2017**, *119*, 1004–1013.
239. See Judge Arnold in Medimmune Ltd vs. Novartis Pharmaceuticals UK Ltd. (2011) EWHC 1669 (Pat), Case No: HC09C04770, HIGH COURT OF JUSTICE, No. 571 “571. In my judgment it is clear that, to the extent that claim 8 of 511 and claim 1 of 777 do enable the production of biological materials, namely phage and phagemids, those materials do possess specific characteristics as a result of the invention. Thus they contain nucleic acid encoding the binding molecules displayed at their surface and so on”. The patents EP 0 774 511 (“511”) and 2 055 777 (“777”) relate to method of producing phage display antibodies for any particular target epitope or antigen.
240. Deutscher Bundestag Drucksache 15/1709, 15. Wahlperiode 15 October 2003, Gesetzentwurf der Bundesregierung Entwurf eines Gesetzes zur Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen. Available online: http://dip21.bundestag.de/dip21/btd/15/017/1501709.pdf (accessed on 9 June 2021).
241. Schulte KG Köln. Die bestimmten Eigenschaften müssen ursprünglich offenbart und der Grund für die Patenterteiilung gewesen sein. In *Patntgesetz Mit Europäischem Patentübereinkommen*; Carl Heymanns Verlag: Cologne, Germany, 2017.
242. Bjørnstad, Å. Do Not Privatize the Giant”s Shoulders’: Rethinking Patents in Plant Breeding. *Trends Biotechnol.* **2016**, *34/8*, 609–617. [CrossRef] [PubMed]
243. Swiss Patent Law—Art. 36a-1. If a plant variety right cannot be claimed or used without infringement of an earlier patent, the breeder or the owner of the plant variety rights is entitled to a non-exclusive license with the scope necessary for the claiming and utilization of the plant variety rights provided that the plant variety demonstrates a significant technical progress of considerable economic interest with respect to the patented invention. For varieties relating to agriculture and food the criteria of the seed regulation of 7 December 1980 shall to be taken as a point of reference. (Non-official translation by the author. Emphasis added). The use of the term “point of reference” creates an unnecessary ambiguity, which could be resolved by making the requirements for seed market authorization the decisive criteria for a license.
244. Council Directive 2002/53/EC on the Common Catalogue of Varieties of Agricultural Plant Species. OJ L193/1, Art 4. 2002. Available online: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:32002L0053 (accessed on 9 June 2021).
245. VCU requires “a clear improvement either for cultivation in general or for the specific uses which can be made of the crops or the products derived therefrom” which can be deemed the plant specific equivalent of a “significant technical progress of considerable economic interest”. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL On the production and making available on the market of plant reproductive material (plant reproductive material law)/* COM/2013/0262 final—2013/0137 (COD) * final—2013/0137 (COD); Article 58.
246. Case C-170/13 Huawei Technologies v ZTE (ECJ 16 July 2015) EU:C:2015:477. Available online: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A62013CJ0170 (accessed on 10 June 2021).
247. In consequence, it only comprises a fraction of the varieties of varieties which breeders would be interested in, including breeders in the EU. A breeder in the EU might be interested to use a variety which is marketed in a non-EU country (e.g., US or Brazil) but today would be in no position to understand whether this Variety comprises a trait which in the EU is protected by a patent.
248. These patents would not be necessarily considered “submarines” as they are usually published. What is however not transparent is whether a certain variety is covered by a patent or not as the related traits is not always promoted and not always phenotypically expressed. Under the principle of forfeiture a patentee can lose the right to enforce a patent if the alleged infringer could trust that he would not infringe any patent and has made investments in that trust (circumstance factor). Usually such circumstances lay in a time factor i.e., a delay to take action over several years. However, a mere lack of action is usually not sufficient to establish forfeiture. It is necessary that the later assertion on the patent right would violate the principle of good faith. A contradictory behavior of the patentee and a clear opportunity to initiate a case can substantially shorten the time factor. A contradictory behavior and a violation of good faith would certainly be given if a patentee on a written inquiry by a breeder does not clarify whether one of his varieties comprises a patented trait and then years later initiates a patent infringement case when the breeder brings his new variety to the market. Busse Patentgesetz §139 Rd, 190.

249. The same should apply if the patentee has deliberately denied the information or provided misleading information.
250. Linking effective enforceability to the public listing of the patents protecting a commercial product is also one of the principles behind the Orange Book FDA listing in the US, which triggers the Hatch-Waxman ANDA litigation procedure. Hence this is a tried and tested way to "manage" the interests of patentee sand third parties in high stakes litigation on valuable products.
251. Possible language: A patent cannot be asserted against anyone who has produced a new plant variety in good faith by using biological material of a plant variety approved for seed marketing. A breeder is considered to be in good faith if he has asked the owner of the said plant variety, who is also the patent owner or a company associated with it, and within 30 days of receipt of this request: a) does not receive a response confirming the patent protection of this biological material; and b) could not find any patents in the plant variety register or in a database recognized and recognized by breeders regarding the plant variety used.