BUSINESS LAW INTERNATIONAL

Business Law International

Vol 20 No 2 pp 91–190 ISSN 1467 632X **May 2019**

Published by the Legal Practice Division of the International Bar Association

VOL 20 NO 2 MAY 2019

Plant variety rights versus plant patents: legal developments and frictions in a regional perspective

*General editors**

Jan Holthuis and Marc van der Velden

Contributing editors[†]

Africa: Sara Moyo, Louis van Wyk, Dave Cochrane, Chyreene Truluck, Arnold Z Chikazhe and Jabulani Kwaramba

China: Li Jiao and Jan Holthuis

European Union: Jan Holthuis and Marc van der Velden

India: Nusrat Hassan

South America: Alvaro Carrau, Patricio Albornoz, Elysangela Rabelo and Marcela Ejnisman

United States: Richard S Cahoon, Michael R Ward, Michael L Goldman, Otis Littlefield, Claire Bendix, Yuhe Liu and Katie Hyma

Introduction

New gene-editing technologies can help to overcome challenges in sustainable food supply. These biotechnologies enable agricultural professionals to meet an ever-growing demand for food. However, understanding of their impact is incomplete, the data required for risk assessment is only partially available and there are ethical and societal concerns. Legal systems vary between prohibition, case-to-case product risk analysis and systems based on a precautionary principle.

In addition, the impact of recent mega-mergers in the agrochemical market prompts warnings of market dominance.[1] The mergers of Dupont-Dow in the US, ChemChina-Syngenta in China and Bayer-Monsanto in Europe look set to dominate the global agricultural, chemical, seed and genetically modified (GM) food markets.

This article reflects on regional regulatory developments in light of the friction between plant variety rights versus plant patents.

Conventional plant breeding rights versus genetic engineering plant traits

Conventional breeding versus genetic engineering

Plants can be created in two different ways: through conventional breeding or genetic engineering. Conventional or 'traditional' plant breeding and

---

* Jan Holthuis is Chair of the IBA Agricultural Law Committee and partner of Buren NV in Amsterdam, the Netherlands.
Marc van der Velden is attorney at law at Buren NV in Amsterdam, the Netherlands.
The editors would like to thank Plantum, the Netherlands, for their contribution to this article.

† Sara Moyo, Arnold Z Chikazhe and Jabulani Kwaramba, Honey & Blanckenberg, Harare, Zimbabwe; Louis Van Wyk, Dave Cochrane and Chyreene Truluck, Spoor & Fisher, Pretoria, South Africa.
Li Jiao is counsel at Buren NV in Amsterdam, The Netherlands.
Nusrat Hassan is Vice Chair of the IBA Agricultural Law Committee and co-managing partner of Link Legal India Law Services in Mumbai, India.
Alvaro Carrau, Bado, Kuster, Zerbino & Rachetti, Montevideo, Uruguay; Patricio Albornoz, M&M Bomchil, Buenos Aires, Argentina; Elysangela Rabelo and Marcela Ejnisman, TozziniFreire Advogados, Sao Paulo, Brazil;
Richard S Cahoon is President, BioProperty Strategy Group Inc and Adjunct Professor, International Programs, Cornell University; Michael R Ward & Otis Littlefield are Partners and Claire Bendix & Yuhe Liu are Patent Agents at Morrison & Foerster LLP in San Francisco, United States.

1 Meg Weddle, 'Global food trade: new merger prompts warnings of market dominance', International Bar Association, 18 April 2018, available at www.ibanet.org/Article/NewDetail.aspx?ArticleUid=14FFC159-B621-4A1E-AD5D-C8341C4D76E2 accessed 27 March 2019.

genetic engineering are different in the processes that are used and the products they generate.

In conventional plant breeding, breeders develop new plant varieties by selection and crossing, seeking to achieve an expression of genetic material that is already present within a species. Conventional breeding uses processes that occur in nature, such as sexual and asexual reproduction, with the resulting plant emphasising certain characteristics. Conventional breeding increasingly makes use of biotechnological methods (excluding genetic modification).

Genetic engineering uses biotechnology to modify genetic material and create a species with a trait that does not occur naturally. Traditional genetic engineering does not occur in nature, although spontaneous mutations do happen naturally. Genetic engineering allows researchers to more precisely control the expression of certain genes and to create genetic material, the expression of which leads to new plant characteristics. A distinction is made between transgenic technology, which involves the insertion of foreign DNA into an organism's genome, and techniques such as mutagenic technology, by which mutation is induced without the introduction of foreign DNA.

Mutagenic technologies such as clustered, regularly interspaced short palindromic repeats (CRISPR)/CRISPR-associated genes and proteins (Cas) are being used at an accelerated rate to alter DNA in a living organism's genome (similar to transgenic biotechnology) and to develop new plant varieties and products. There is intense legal debate over whether the use of CRISPR/Cas and similar technologies should be covered by specific containment measures (such as pre-market entry risk assessment and genetically modified organism (GMO) labelling). The Court of Justice of the European Union (CJEU) recently decided that technologies such as CRISPR/Cas are subject to restrictive conditions set out in the EC 2001 directive[2] which imposes high hurdles for developing GM crops for food. The CJEU found that only mutagenesis techniques that have 'conventionally been used in a number of applications and have a long safety record are exempt from those obligations'. Reference was made to mutations caused by chemicals or radiation, which were considered conventional and to have a long safety record.

CRISPR/Cas9

Genome-editing is broadly a set of technologies that allows scientists to modify an organism's DNA in a targeted manner. They allow genetic material to be

2 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms.

deleted, inserted, substituted or modified at specific and directed locations in the genome. A number of such technologies have been developed and often use site-specific engineered endonucleases, including zinc finger nucleases (ZFNs), mega-nucleases, transcription activator-like effector-based nucleases (TALENs), CRISPR and CRISPR-associated protein 9 (CRISPR/Cas9).

One of the most recent developments, CRISPR/Cas9 has generated excitement in the scientific community and beyond. It has advantages over previous genome-editing technologies, including being less expensive, faster and easier to implement. Cas9 is a ribonucleic acid (RNA)-guided DNA endonuclease enzyme associated with CRISPR. Although previously studied, the full CRISPR/Cas9 system as a powerful molecular biology tool was published in 2012.[3] CRISPR/Cas9 enables technicians to easily alter DNA sequences and modify gene function. It can be used to add or delete single or multiple nucleotides from a DNA sequence or to turn gene sequences on or off.

The CRISPR/Cas9 discovery itself was not patentable, but technology inventions that use CRISPR/Cas9 can be patented. In May 2012, the University of California, Berkeley filed an application with the United States Patent and Trademark Office (USPTO) that was directed to editing of prokaryote genomes. Another research group at the Broad Institute of Harvard University and the Massachusetts Institute of Technology filed an application with the USPTO for CRISPR/Cas9 directed to editing of eukaryote genomes in December 2012, and used an accelerated prosecution option. A fierce and unprecedented battle between the research institutes has followed, the details of which fall outside the scope of this article. Patents on CRISPR/Cas9 are presently granted in the Australia, China, Europe, Japan, the US and other jurisdictions, and in each the division of patent rights between the institutes (and other entities) is different.

CRISPR/Cas9 has created many possibilities for creating genetic forms of microbes, animals and plants.[4] It can also be used to increase the speed of transfer of naturally occurring traits into desired plant varieties. Clearly, CRISPR/Cas9 has the potential for enormous changes, which could lead to an explosion of plant intellectual property (IP) filings. CRISPR-based biotechnology is widely considered to be a game changer

---

3 M Jinek, K Chilynksi, I Fonfara, M Hauer, J Doudna and E Charpentier, 'A programmable dual-RNA-guided DNA endonuclease in adaptive bacterial immunity', *Science* (17 August 2012), 337 (6069), pp 816–821.

4 E Boglioli and M Richard, *Rewriting the Book of Life: A New Era in Precision Gene Editing*, Boston Consulting Group Working Paper, September 2015, available at http://media-publications.bcg.com/BCG-New-Era-Precision-Gene-Editing-09Sept15.pdf accessed 27 March 2019.

in gene-editing and investors have poured millions into companies that use the technology to develop medicines and crops.

Intellectual property protection in plant breeding

The protection of plant varieties is a mandatory obligation for members of the World Trade Organization (WTO) which are obliged to implement the provisions of the Agreement on Trade-related Aspects of Intellectual Property Rights ('TRIPS Agreement').[5] Article 27.3(b) requires members to protect plant varieties by patents, by an effective *sui generis* system or by any combination thereof.

Since the commencement of the TRIPS Agreement in 1995, countries have generally adopted the Acts of the International Convention for the Protection of New Varieties of Plants ('UPOV Convention')[6] by way of compliance.[7] The majority of the parties have ratified or acceded to the 1991 UPOV Convention Act, while a smaller number of parties are bound by the 1978 Act, and only one is bound by the 1961 UPOV Convention and the 1972 Act.

Breeders' rights

To qualify for protection under the UPOV Convention, the plant variety must be new, which means that it has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of exploitation beyond the grace periods. The plant variety must fulfil three other criteria: it must be distinct (clearly distinguishable from any other variety whose existence is common knowledge); uniform (the relevant plant characteristics should be consistent from plant to plant); and stable (the relevant plant characteristics should be genetically fixed and remain the same from generation to generation).[8]

According to the 1991 UPOV Convention Act, the plant breeder's right is a right to control the performing of certain acts by others. The UPOV Convention specifies the following acts that require the breeder's authorisation in relation to propagating material of the variety and, under certain conditions, to the harvested material:

---

5 Agreement on Trade-related Aspects of Intellectual Property, Annex 1C to the Agreement Establishing the World Trade Organization, available at www.wto.org/english/docs_e/legal_e/27-trips.pdf accessed 27 March 2019.

6 International Union for the Protection of New Varieties of Plants, available at www.upov.int/upovlex/en/acts.html accessed 27 March 2019.

7 M Blakeney, 'Patents and Plant Breeding: Implications for Food Security', *Amsterdam Law Forum* (2011) 3(3), p 73.

8 International Convention for the Protection of New Varieties of Plants (1991), Arts 6–9.

- production or reproduction (multiplication);
- conditioning for the purpose of propagation;
- offering for sale, selling or other marketing;
- exporting;
- importing;
- and stocking for any of the above purposes.

Breeders may decide to exploit the variety or grant licences to others on an agreed basis. In addition to the protected variety itself, the scope of the breeder's right also applies to: varieties that are not clearly distinguishable from the protected variety; varieties whose production requires the repeated use of the protected variety; and essentially derived varieties.[9]

The minimum duration of plant variety rights under legislation based on the 1991 UPOV Convention Act is 20 years (or 25 years for trees and vines) counted from the date of grant.

Breeders' exemption and farmers' privilege

Under the breeder's exemption in the UPOV Convention, the authorisation of the breeder to use protected varieties for breeding is not required. Thus, authorisation of the breeder to use a protected variety for breeding 'other' varieties is not required. In addition, acts done with the 'other' varieties (eg, marketing) do not require the authorisation of the breeder of the protected variety, except for the circumstances specified in the 1991 UPOV Convention Act.

According to the International Association of Plant Breeders for the Protection of Plant Varieties and the International Seed Federation, among others, the breeder's exemption is essential for the progress of plant breeding.

Article 15(2) of the UPOV Convention provides an optional exception, which permits UPOV members to exclude, for example, farm-saved seed from the breeder's right, subject to certain conditions. This exception covers three aspects: the farmer's holding – where it can take place; the product of the harvest – the material involved; and the reasonable limits and safeguarding of the legitimate interests of the breeder.[10]

9 *Ibid*, Art 14.

10 See Art 15 (exceptions to the breeder's right), para 1(i) and (ii) provides that: 'The breeder's right shall not extend to (i) acts done privately and for non-commercial purposes, (ii) acts done for experimental purposes and' and Art 15, para 2 (Optional exception) 'Notwithstanding Article 14, each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate rights of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety covered by Article 14 (5)(a)(i) and (ii).'

Article 15(1)(i) of the UPOV Convention provides for a compulsory exception for 'acts done privately and for non-commercial purposes'. The Explanatory Note (UPOV, 2009b) indicates that acts that are private and for non-commercial purposes are covered by the exception. Non-private acts, even where for non-commercial purposes, may be outside the exception.

The scope of the farmer's privilege varies widely. Some nations restrict permission to farmers to plant seeds saved from previous purchases to be used only for replanting, while others extend permission to sell limited quantities for reproduction purposes

As of 11 January 2019, the UPOV has 75 members covering the territories of 94 states.

Members of UPOV Convention 1972/1978/1991 (The boundaries shown on this map do not imply the expression of any opinion whatsoever on the part of UPOV concerning the legal status of any country or territory)

ITPGRFA farmers' rights and UPOV

The objectives of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) are the conservation and sustainable use of plant genetic resources for food and agriculture, and the fair and equitable sharing of the benefits arising from the use of PGRFA for food security and sustainable agriculture.

Article 9 recognises the contribution of indigenous communities and farmers to the conservation and development of plant genetic resources for food and agriculture. It requires State Parties to the ITPGRFA, in accordance with their needs and priorities and subject to national legislation, to protect farmers' rights, including through the protection of traditional knowledge, benefit-sharing and the participation by farmers in decision-making on PGRFA.

In relation to farmers' rights, the ITPGRFA requires that nothing in Article 9 should be interpreted as a limitation to the right of farmers to save, use, exchange and sell farm-saved seed and propagating material, subject to national law. In the countries with dual membership (UPOV and ITPGRFA) the provisions in Article 9 of the ITPGRFA are to be read with national legislation implementing Article 15(2) of the UPOV Convention for farm-saved seed of relevant protected varieties, subject to certain conditions.

The UPOV Convention provides that the permission for a farmer to use, for propagating purposes, the product of the harvest of the protected variety obtained in the farmer's holding applies only to that farmer on that holding. The UPOV farm-saved seed provisions under Article 15(2) do not allow farmers to freely exchange and sell seeds of protected varieties. It is therefore 'important to interpret and implement the two Treaties in a mutually supportive way in the context of each Contracting Party'.[11] Dialogue between the memberships to the two instruments is taking place with a view to exploring the interrelations and sharing views and implementation experiences.[12]

The practical granting of breeders' rights and realisation of farmers' rights happens within a country's jurisdiction. Member States to the ITPGRFA are obliged to ensure the conformity of national laws, regulations and procedures with the ITPGRFA. To become a UPOV member the advice of the UPOV Council on the conformity of a future member's law with the UPOV Convention is required. This procedure leads to a high degree of harmony in those laws, thus facilitating cooperation between UPOV members in the implementation of the UPOV system.[13]

---

11 See key message from the closing remarks summarising the experiences of the contracting parties to the UPOV Convention and the ITPGRFA presented at the Symposium on Possible Interrelations between the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the International Convention for the Protection of New Varieties of Plants (UPOV Convention), held in Geneva, 26 October 2016, available at www.upov.int/edocs/mdocs/upov/en/upov_itpgrfa_sym_ge_16/upov_itpgrfa_sym_ge_16_2_proceedings.pdf accessed 27 March 2019.

12 Food and Agriculture Organization of the United Nations, 'Symposium on possible interrelations between the International Treaty and the UPOV Convention', available at www.fao.org/plant-treaty/meetings/meetings-detail/en/c/445033 accessed 27 March 2019.

13 See document UPOV/EXN/EXC/1 paragraph 1: 'The purpose of these Explanatory Notes is to provide guidance on the 'Exceptions to the Breeder's Right' under the 1991 Act of the International Convention for the Protection of New Varieties of Plants (UPOV Convention). The only binding obligations on members of the Union are those contained in the text of the UPOV Convention itself, and these Explanatory Notes must not be interpreted in a way that is inconsistent with the relevant Act for the member of the Union concerned.' See UPOV Lex, available at www.upov.int/upovlex/en accessed 27 March 2019.

Most countries bound by the UPOV Convention are developing. Members have introduced the UPOV plant variation protection (PVP) system to provide farmers a choice of improved varieties.

The PVP system and UPOV membership were found to be associated with:

- increased breeding activities;
- greater availability of improved varieties;
- increased number of new varieties;
- diversification of types of breeders (eg, private breeders or researchers);
- increased foreign new varieties;
- encouraging the development of industry competitiveness on foreign markets; and
- improved access to foreign plant varieties and enhanced domestic breeding programmes.

Some developing countries, in which the practice of freely saving, using, exchanging and selling of seeds is more widespread, have raised reservations about the restrictions on farmers' rights in the PVP system.[14] [15]

As of 25 January 2019, 75 states and the European Union are bound by the UPOV Convention (all acts) and the ITPGRFA. Notable non-ITPGRFA members are China, Mexico, Russia and South Africa.

Patent rights on plant material

The development of biotechnologies associated with genetic engineering has permitted the introduction of a range of desirable traits into plants, such as insect and virus resistance and herbicide tolerance. These technologies, with the introduction of beneficial plant traits, have become the subject of IP protection in the form of patents.

Transgenic constructs can be quite straightforwardly identified as inventions. Various techniques for plant transformation have been patented since the 1980s. At present, more than 90 per cent of plant patents concern GM inventions.[16]

---

14 For instance, section 31 of the Malaysia Protection of New Varieties Act 2004; section 43(d) of the Philippines Plant Variety Protection Act. Both countries are members of the ITPGRFA and not members of the UPOV Convention.

15 Deutsche Gesellschaft für Internationale Zusammenarbeid (GIZ) GmbH, *The UPOV Convention, Farmers' Rights and Human Rights* (June 2016): 'it is difficult to see how an UPOV 91-based PVP system could be considered to advance the realization of the Farmers' Rights as they are enshrined in ITPGRFA, especially for small-scale farmers. Rather, it results in restricting these rights in several ways.'

16 CCM Van de Wiel, LAP Lotz, HCM De Bakker and MJM Smulders, 'Intellectual Property Rights and Native Traits in Plant Breeding', *WUR*, 2016, 10, available at http://library.wur.nl/WebQuery/wurpubs/fulltext/382232 accessed 27 March 2019.

There are several differences between PVP and patent protection, including subject matter and eligibility requirements. Possibly the most critical relates to the scope of the protection. The exclusive rights granted to a breeder under a TRIPS-compliant patent system are much greater than that of a typical PVP system, owing to the exceptions and limitations present in most PVP systems, such as the farmer's privilege and the breeder's exemption (although the EU includes a farmers' privilege in its patent law and a limited breeder's exemption, discussed below).

The TRIPS Agreement came into effect on 1 January 1995. Its provisions on plant varieties do not refer to any pre-existing IP agreements, such as the 1978 and 1991 UPOV Conventions. This differs from other conventions on IP (patent, copyright and trademarks) whose standards of protection the TRIPS Agreement expressly requires WTO members to comply with in pre-existing agreements. WTO members are required neither to become members of UPOV nor to enact national laws to comply with obligations under the UPOV Convention.

Therefore, because TRIPS-compliant patent systems do not allow for similar exceptions and limitations with respect to plant variety rights, the scope of exclusive rights conferred by patent protection is more absolute than that provided by PVP systems. Patents and breeders' rights are separate IP rights with different conditions of protection, scope and exceptions. Breeders can use breeders' rights, patents or other forms of IP, or a combination if such systems are available in the territory concerned.

With recent technological developments, the rising number of gene-related patents and rapid progress in the field of genetic engineering, for example, patents and breeders' rights are more interlinked.

United States

In the US, plant variety rights and patent rights are separate bodies of IP law that operate independently. They have, however, a multifaceted relationship in their treatment of plant inventions created through breeding methods. It is important to understand this relationship as it affects the creation of plants through traditional breeding and biotechnology.

In the legal sphere, two areas of utility patent law are of interest in the context of plant invention through breeding. Both are the subject of significant legal debate in the US. The first is the general issue of biological inventions as patentable subject matter. The second is the question of the acceptable scope of claims regarding such biological subject matter. Both clearly implicate patents on plants and plant-related subject matter, and represent evolving areas of law.

This section provides an overview of the complex and ever-changing field of plant IP protection in the US, taking a close look at utility patents on plant traits and plants as patentable subject matter, especially given the advent of CRISPR/Cas9.

US system of plant IP protection

There are three types of statutory IP in the US relevant to plants: utility patents, plant patents and PVP certificates. The enabling legislation for each is:

- utility patents: US Patent Acts of 1790, 1793, 1836, 1952; Leahy-Smith America Invents Act (AIA) of 2011; 35 USC sections 101, 102, 103 and 112;
- plant patents: US Plant Patent Act of 1930; 35 USC section 161;
- PVP certificates: Plant Variety Protection Act of 1970 (PVPA), 7 USC sections 2321–2582.

A utility patent is issued by the USPTO and can cover any plant or plant part as long as the invention satisfies the basic criteria of patentability under US law (ie, the invention is unique, useful, non-obvious and not a product or law of nature). A utility patent can also protect plant traits embodied in a group of plants. There are no limitations on the number of claims of a utility patent, and such claims can issue on a range of plant-related subjects, including plant genetics, plant products and processes or methodologies associated with plants.

A utility patent allows the holder to prevent others from making, using, selling, offering for sale and importing or exporting the patented invention in the US. There are no exemptions to these prohibitions relevant to commercial agriculture. A utility patent has a 20-year term from the filing date of the application. A deposit of plant material may be necessary to obtain a utility patent on a plant. Once claims in the application have been granted, the biological deposit becomes publicly available.

Since the *Ex parte Hibberd* ruling,[17] thousands of utility patents have been issued on many plants – there is no limitation on the type of plant patented. One important implication is that patent holders can prevent others using the patented variety for breeding.

A plant patent is issued by the USPTO and can be issued on a new and distinct plant variety that is asexually propagated. Plant varieties acceptable for plant patents include any cultigen, mutant or hybrid, made by breeding,

17 227 USPQ 443, 447 (Bd Pat App & Int 1985). GE Bugos and DJ Kevles, *Plants as Intellectual Property: American Practice, Law, And Policy in World Context* (California Institute of Technology, Pasadena 1991), available at https://authors.library.caltech.edu/39568/1/HumsWP-0144.pdf accessed 27 March 2019.

genetic engineering or discovered in a cultivated state (eg, orchard or field). Tuber-propagated plants and plants found in uncultivated states (ie, wild or undomesticated) are excluded from plant patent protection. If a plant variety has been asexually reproduced, it can be protected with a plant patent, even if it is capable of sexual reproduction. Asexual propagation can take many forms, including cuttings, bulbs and tissue culture.

To be patentable under a plant patent, a plant variety must be sufficiently botanically described. The standard for a 'sufficient' description varies by plant species and case. Descriptors can include growth habit, characteristics of plant structures (ie, foliage, flowers or fruit) and resistance to disease. These descriptors establish the uniqueness of the plant compared to similar plant varieties, and are generally quantitative, use international standards or refer to botanical reference standards. Photographs or drawings illustrating the plant's distinctive characteristics are required. The names of the parental varieties are often included in the description if the variety was bred. Unlike utility patents and PVP, plant patents do not require a deposit of the claimed plant at an official repository.

Like a utility patent, a plant patent has a 20-year term from the filing date. It grants the holder the right to prevent others from asexually reproducing, selling, offering for sale, importing, exporting or using the patented plant for any purpose in the US. Unlike a utility patent, a plant patent has only one claim, which is limited to the plant described in the application.

PVP certificates are issued by the Plant Variety Protection Office (PVPO) of the US Department of Agriculture under the Plant Variety Protection Act (PVPA), 7 USC sections 2321–2582. The PVPA is the US's legislative compliance under its obligations as a signatory to the UPOV Convention. A PVP certificate may be issued on a plant variety that can be sexually propagated, or is tuberous, and if it satisfies the criteria of being new, distinct, uniform and stable. The PVP certificate covers only one plant variety, not a group of plants that share a common trait, and in this sense is more similar to a plant patent than a utility patent. A PVP application requires a deposit of viable seed of the plant in a public repository. The genetic pedigree of the variety must be disclosed. The certificate grants the holder the right to prohibit others from selling, offering for sale, reproducing, importing, exporting or using the plant in commercial production. The protection provided is primarily against unauthorised commercial use of the variety. The PVP certificate lasts 20 years (25 years for vines and trees) from the date of issue.

An important feature of PVP is the exemption for research and breeding, which allows varieties protected by PVP to be used for research purposes and in breeding new varieties. These acts, as well as private or non-commercial uses, are not considered infringements of PVPA (7 USC sections 2541–2545).

The PVP owner must also allow limited seed saving by farmers. PVP is less restrictive than utility or plant patent protection, allowing certain uses of the protected variety in research and agricultural contexts.

A unique feature of PVP is the protection of essentially derived varieties (EDVs). EDVs retain the essential characteristics of the protected variety but are distinguishable from the protected variety. An example of an EDV would be the sport of an apple tree[18]. Sports are particularly important for many tree crops, as they are often a source of valuable new varieties. The protection for EDVs means that PVP is potentially broader than plant patent protection, which is limited to the specific variety described in the patent.

Although trade secrets often play a role in the strategy of IP protection of plant varieties, they are outside the scope of this article. The reader is referred to other works for a discussion of trade secret use and plant IP protection.[19] [20] [21] [22]

Strategy considerations for plant IP protection in the US

Each of the aforementioned forms of plant IP protection is unique in scope of coverage, the extent of rights granted and the requirements for the plant protected. Depending on the plant species and the method of reproduction, it is possible to obtain more than one form of IP on the same plant invention. Multiple factors, therefore, should be taken into consideration to determine the best approach.

One option is to protect a plant variety with a utility patent and a plant patent, which grant the same rights and have the same lifespan. The key difference lies in the scope of the claims. The plant patent covers only the entire plant of the new variety as described in the application. The utility patent allows coverage beyond a single plant variety and, therefore, appears

18 Note that until December 2018, apple trees could not be protected under US PVP law because they are asexually reproduced.

19 Mark D Janis, 'Intellectual Property Issues in Plant Breeding and Plant Biotechnology' in *Biotechnology, Gene Flow, and Intellectual Property Rights: An Agricultural Summit* (2002), available at www.repository.law.indiana.edu/facpub/2560 accessed 27 March 2019.

20 T Dhar and J Foltz, 'The Impact of Intellectual Property Rights in the Plant/Seed Industry' in J Kesan (ed), *Seeds of Change* (Oxon UK: CABI Press 2005).

21 JD Dunn and PF Seilor, 'Trade Secrets and Non-Traditional Categories of Intellectual Property as Collateral', Second International Symposium on Secured Transactions: Security Interests in Intellectual Property Rights, UNCITRAL, Vienna, January 2007, available at www.uncitral.org/pdf/english/colloquia/2secint/Seiler.pdf accessed 27 March 2019.

22 2001 Plant Science Industry: Guide to Intellectual Property Crop Life International, available at https://croplife-r9qnrxt3qxgjra4.netdna-ssl.com/wp-content/uploads/pdf_files/Industry-Guide-to-Intellectual-Property-English.pdf accessed 27 March 2019.

to be the better option, though cost may influence this choice. Prosecuting a plant patent is typically less complicated and less costly than a utility patent.

Similar decisions are faced when choosing between a utility patent and PVP. A utility patent may cover all uses of the plant variety and a PVP will not. The former would be the preferred approach if the breeder is concerned that a competitor will use a variety in breeding. On the other hand, PVP allows exemptions for research, private use, breeding and seed-saving. PVP also covers EDVs, which can be valuable for a breeder. Although rarely invoked, the PVPA provides for compulsory licensing in certain national interests, unlike utility or plant patents. Surprisingly, PVP often costs more than a utility patent. Given the differences between patent and PVP, the first choice is generally patents, but many will seek patents and PVP for maximum protection.

Determining factors for choosing IP protection type include crop type, economic value, required level of control, litigation issues, licences, exemptions and the necessity of a deposit. It is not always necessary to decide between IP protection types because for some plants, the combination of IP types provides optimal protection. For applicants with an international presence, the interplay of US and international plant IP protection types and laws will be a consideration.

Developments in plant IP law

In the legal sphere, two areas of utility patent law are potential game changers. First, questions have been raised about the scope of acceptable patentable subject matter for biological inventions.[23] [24] [25] These questions clearly implicate patents on plants and plant-related subject matter. Second, utility patent claims directed to plant traits have been issued in the US, but questions remain (see China, Europe and India sections). In addition, the types of plant IP protection continue to change. For example, the recently

23 H Wimberly, 'The Changing Landscape of Patent Subject Matter Eligibility and its Impact on Biotechnological Innovation', *Houston Law Review* , 2017, 54:4, Comment 3/13/2017.

24 J Gordon, 'The Impact of Myriad and Mayo: Will Advancements in the Biological Sciences Be Spurred or Disincentivized? (Or Was Biotech Patenting Not Complicated Enough?)', *Cold Spring Harbor Perspectives in Medicine*, 2015, May 5(5), available at www.ncbi.nlm.nih.gov/pmc/articles/PMC4448587 accessed 27 March 2019.

25 EH Tallmadge, 'Patenting Natural Products After Myriad', *Harvard Journal of Law & Technology*, 2017), Vol 30 No 2, p 569, available at https://jolt.law.harvard.edu/assets/articlePDFs/v30/30HarvJLTech569.pdf accessed 27 March 2019.

signed Farm Bill will expand the PVPA to include asexually reproduced plants, such as apple trees.[26]

On the technological front, CRISPR/Cas9 has significant potential for disruption in agriculture and plant IP given its power, ease of use and relatively low cost.

Utility patents on plant traits

Claims in a utility patent can issue on a range of plant-related matters. Unlike the single claim in a plant patent, the multiple claims of a utility patent allow specific aspects of the plant variety to be claimed. The use of utility patents to claim particular plant traits is of interest to applicants and practitioners because it can be a powerful and effective means of protection.

Claims covering traits in utility patents vary in format and can include characteristics, genetic components or gene names. They can also include deposit information as support. For example, several deposits can be included to provide separate sources or examples of the trait. Although seed deposits can be used to support claims directed to plant traits, the claims need not be tied to a seed deposit.

An advantage of obtaining a utility patent on plant traits is that the coverage can be broad. Multiple varieties with the same trait can be covered in a single application, providing that those varieties do not have IP from another source. Further, the patent can also cover plant varieties with that same trait that are independently developed later.

A disadvantage is that this type of patent is challenging to obtain. Questions remain about how much support is needed for claims on plant traits. For example, multiple plant varieties with the trait are needed, but it is not clear how many are sufficient to demonstrate possession of the trait or whether all varieties should be deposited. Similarly, pedigree information to demonstrate the independence of plant varieties or genetic characterisation to demonstrate that the trait is the same across all varieties may be required.

Another disadvantage is the uncertainty about the scope of these claims. It is also unclear how much coverage claims directed to plant traits would provide in the case of a legal challenge. To our knowledge, a legal challenge of this type of utility patent has not occurred in the US and so there is no legal precedent. Despite these open questions and the potential risks associated with pursuing these types of patents, utility patents directed to plant traits in the US continue to increase.

26 T Bliss and S Small, 'Farm Bill Brings IP Options for Breeders of New Plants', Law 360, 2019, available at www.law360.com/articles/1115621/farm-bill-brings-ip-options-for-breeders-of-new-plants accessed 27 March 2019.

Effect of new technology: CRISPR/Cas9

The availability of IP protection for organisms generated using genome-editing technologies is usually dependent upon the nature of the modification. For example, if the technology is used to insert a transgene into an organism, the patentability, or lack thereof, of the modified organism will essentially be the same as that of organisms containing the transgene introduced by prior methodologies. Put another way, if the transgenic organism produced by *Agrobacterium* mediated transgene insertion was patentable in a jurisdiction, the transgenic organism produced by genome-editing should also be patentable.

Clever claim drafting may allow one to obtain utility patents on modified varieties created through such accelerated breeding, even in jurisdictions where utility patents are not allowed for naturally produced varieties. While a modified variety and a naturally produced variety will be very similar, they are likely to be distinguishable. The distinguishing characteristic would be the genetic markers that are closely linked to the allele of interest from the donor variety that is not found in the recipient variety.

A variety produced by natural breeding is likely to have those markers from the donor plant and the allele of interest. In contrast, the modified variety produced by genome-editing should only have the specific allele from the donor variety. A claim directed to a modified plant that has the donor allele but lacks the closely linked genetic markers could be argued to be a claim to a genetically modified plant in jurisdictions that allow the patenting of a genetically modified plant, but not of plants produced through natural breeding.

Summary and conclusion

It is currently possible to protect a plant variety by one or more of three types of IP in the US: utility patent, plant patent and PVP certificate. A utility patent is often the primary choice for plant IP protection. For valuable seed-reproduced plant varieties, breeders often seek PVP and patent coverage. As aforementioned, this calculus may change now that efforts to expand the PVPA to include asexually reproduced plants have been successful.

The utility patent is an especially appealing form of plant IP protection owing to the USPTO's willingness to grant such patents on individual varieties and broader plant traits. Utility patents on plant traits give the IP strategist the opportunity to maximise the patent coverage on a particular plant variety or group of plant varieties. This potentially broad coverage has many economic advantages which can offset the difficulty and cost of obtaining a utility patent.

Perhaps the most interesting biotechnological change of recent years is the development and implementation of the CRISPR/Cas9 system as a genome-editing tool.

In the US, any of the plant IP protection forms could be used for plants developed using CRISPR/Cas9. CRISPR/Cas9 has the potential to create thousands of useful plant traits, all of which could be patentable in the US. In this scenario, there could be an explosion of plant IP filings over the next few decades. As plant IP protection possibilities continue to change, protection strategies will develop accordingly.

South America

Uruguay

Since 1994, Uruguay has adhered to the UPOV, which gives legal protection for plant varieties to plant breeders. There are two main laws, 16.811 and 18.467. The National Seeds Institute keeps the register of cultivar ownership, which recognises and guarantees rights to the breeder of new plant varieties by means of the grant and registration of a title of ownership, in accordance with the Convention for the Protection of New Varieties of Plants.

Uruguay's legal system for the protection of the plant varieties is based on the UPOV Convention. In these regards, Laws 16.811 and 18.467 grant the exclusive right for the use of the varieties to the person that has registered the plant variety.

The country's Patent Law 17.164, states that plants are not patentable but allows micro-organisms and the biological procedures for the production of plants and animals to be patented, with the exception of non-biological or microbiological procedures.

Under Uruguay's regulations it is not possible to patent genetically modified plants, any plant created using CRISPR/Cas9 or the CRISPR/Cas9 procedure.

Argentina

Argentina adheres to the UPOV Convention (1978 Act) and plant varieties are protected only by the UPOV breeder's right and not by patents. Plants or groups of plants that are not protected by Act 20247 (the 'Seeds Act') are not protectable by the breeder's right or the Patent Act.

Section 20 of the Seeds Act grants protection to:

'phylogenetic creations or cultivars which are distinguishable from others that are known at the filing date of the property application, and whose

individuals possess sufficiently homogeneous and stable hereditary characteristics through successive generations'.

The requirements of novelty, differentiability, homogeneity and stability are defined in section 26 of Regulatory Decree 2183/91.

The Patent Act does not contain any provision expressly referring to plants. Nevertheless, the following norms are applicable to them:

- Article 6, paragraph (g) excludes from patentability 'all kinds of living matter and pre-existing substances in nature'. The grammatical ambiguity of this phrase obscures its literal meaning; and
- for its part, Article 7 excludes from patentability:

  'the totality of biological and genetic material existing in nature or its replication in the biological processes implicit in animal, plant and human reproduction, including genetic processes related to the material capable of conduct their own duplication under normal and free conditions as occurs in nature'.

Article 6 of the Regulatory Decree states that 'plants, animals (with the exception of microorganisms) and essentially biological procedures for their reproduction shall not be considered patentable subject matter' and therefore excludes plants and animals in general from patentability. It does not differentiate between whether a transformation by humans has occurred – as would be the case for transgenic plants and animals – or whether the plants and animals are pre-existing in nature, the exclusion of which is clear from the legal text. Although the validity of this provision is questioned by part of the doctrine, in practice, it is considered valid and is applied by the National Institute of Industrial Property (INPI), the state agency responsible for patents. In addition, there is no regulation for the protection of creations of plants that are not varieties.

The INPI Patent Guidelines establish that:

'no claims of plants or animals will be allowed even when they are produced through a biotechnological process. The exclusions to the patentability contemplated in art. 6 RLP, applies to plants and animals regardless of the way they are produced. For example, plants and animals which contain genes introduced through recombinant DNA technology and those obtained through micro propagation, cloning or any other biotechnological technique or other reproductive method, even if human intervention is significant.'

This section applies to CRISPR/Cas9, as it is a gene-editing tool. Therefore, we understand that as long as the interpretation of IP regulation remains the same, this technology will not change the IP landscape in Argentina.

Brazil

Under Law No 10,711/2003, which regulates the Brazilian National System of Seeds and Seedlings, conventional plant breeding may use a seed or a seedling. To manufacture, trade, import and export seed or seedlings: (1) individuals and legal entities must be on the Brazilian National Seeds and Seedling Register (Registro Nacional de Sementes e Mudas or RENASEM); and (2) the plant variety must be registered at the Brazilian National Plant Variety Register. Under the Biosecurity Law (11,105/2005), a genetically engineered plant is a GMO. All activities involving GMOs and their derivatives, including scientific research, technological development and industrial production, are restricted to legal entities and must be approved by the National Technical Commission for Biosecurity.

The protection of plant varieties developed using conventional plant breeding is regulated by the Plant Variety Protection Law (9.456/1997), which states that the protection of IP rights related to the plant variety is effected through the granting of a plant variety protection certificate, considered the only means of protecting plant varieties.

As a type of GMO, genetically engineered plant traits are protected under IP law (9.279/1996), which provides that the whole or part of plants that exhibit, due to direct human intervention, a characteristic that cannot be attained under natural conditions are patentable, as long as the GMO complies with three requirements: novelty, inventive activity and industrial application.

European Union

IP rights on plant varieties

A European patent on plant varieties is excluded by Article 53(b) of the European Patent Convention (EPC). It is possible to obtain a plant variety right in the EU under the UPOV Convention by applying to the Community Plant Variety Office (CPVO). The CPVO is an EU agency based in Angers, France, which manages the EU system of plant variety rights covering the Member States. To obtain plant variety protection in the EU, the variety should meet the requirements of novelty and be distinct, uniform and stable.

> 'Plant variety' is defined in Article 5, sub 2 of EU Regulation 2100/94 as: 'any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety are fully met, can be (a) defined by the expression of the characteristics that results from a given genotype or combination of

> genotypes, (b) distinguished from other plant grouping by expression of at least one of the said characteristics, and (c) considered as a unit with regard to its suitability for being propagated unchanged.'

In G 1/98 the Enlarged Board of Appeal of the European Patent Office ('Enlarged Board') concluded that if specific plant varieties were not claimed individually, the claim was not excluded from patentability. As plant variety rights are only granted for specific plant varieties, technical teachings that are implemented in an indefinite number of plant varieties are not excluded from patent protection.

Plant varieties containing genes introduced into the ancestral plant by recombinant gene technology are still excluded from patentability. According to the Enlarged Board, the exception to patentability applies to plant varieties no matter how they are produced and, therefore, includes genetically modified varieties.

European Patent Office's position on patents on plant traits

The rules at the European Patent Office (EPO) on patentability of plants and animals have been in flux in the past few decades. Central to the changing rules is the interpretation of Directive 98/44/EC[27] (the 'Directive'), issued on 6 July 1998, which provides legal guidance on the protection of biotechnological inventions in the EU. Article 4 provides that plant and animal varieties and essentially biological processes for the production of plants or animals are not patentable. Article 2 defines essentially biological processes as processes consisting 'entirely of natural phenomena, such as crossing or selection'. The Directive does not specifically address the patentability of products made by essentially biological processes, which is left open to interpretation.

One interpretation of the Directive is that it forbids patenting of the essentially biological processes but not the products thereof. Under this view, even though plant varieties are deemed to be not patentable, plant traits that are not tied to a specific variety should be. This interpretation was adopted by the Enlarged Board when they upheld the plant patents in their decisions rendered in G2/12 ('Tomato II') and G2/13 ('Broccoli II'). The Enlarged Board based its decisions on Rule 27 of the EPC, which provides that plants or animals are patentable if the 'technical feasibility of the invention is not confined to a particular plant or animal variety'

27 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

(Rule 27(b)) or a product obtained by means of a technical process other than a plant or animal variety (Rule 27(c)).

The situation took a turn when the European Parliament asked the European Commission (the 'Commission') to look into the issue of the patentability of plants and animals after the Tomato II and Broccoli II decisions. The Commission disagreed with the Enlarged Board on its interpretation of the Directive. In a notice[28] issued on 8 November 2016, the Commission stated that: 'Patent protection is not appropriate for such [essential biological] procedures and their products.'

On 20 February 2017 the Council of the EU adopted conclusions confirming the Commission's notice that products created through essential biological processes should be excluded from patentability. The conclusions urge Member States, as members of the EPO, to advocate that the practice of the EPO be aligned with the content of the conclusions.

Even though it is not bound by the notice, the EPO decided to change its rules to align with the interpretation of the Commission. On 29 June 2017, the EPO amended Rules 27 and 28 of the EPC 'to exclude from patentability plants and animals exclusively obtained by an essentially biological breeding process'. Most notably, Rule 28(2) of the EPC now reads: 'under Article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process.'

The new rules went into effect on 1 July 2017, and have since been applied to all pending and newly filed European applications by the EPO. A direct impact of the rule change is that claims (including trait claims) directed to plants produced by conventional breeding techniques, such as natural crossing or selection based on genetic markers[29] and traits, will no longer be allowed by the EPO. Unexpectedly, on 5 December 2018 the EPO Technical Board of Appeal decided that plants produced by means of essentially biological processes should be patentable, which contradicts the amendments to the rules.

The EPO Technical Board of Appeal made its decision during an oral hearing in which it decided that the amended Rules 27 and 28 are in conflict with Article 53(b) of the EPC. This would render the amendments to Rules 27 and 28 from 2017 meaningless because based on this decision plants produced by means of essentially biological processes are patentable and can no longer be refused on the basis of Rule 28(2).

---

28 Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions.

29 A gene marker is a gene or DNA sequence with a known location on a chromosome that can be used to identify individuals or species and their characteristics (specific traits). It can be described as a variation that can be observed.

As a result of this decision, uncertainty about the patentability of plants in the EU is again affecting the agricultural market sector.

Limited breeder's exemption

Free use of patented plant material for further breeding is only possible when an explicit exemption is included in the national patent law of a Member State. France, Germany and Switzerland have a limited exemption for plant breeding, which was recently followed by the EU in its 'unitary patent' – which will make it possible to get patent protection in all EU Member States – and by the Netherlands in its patent law.[30]

With the introduction of the limited exemption for plant breeding, breeders are allowed to use patented biological material for breeding and developing plant varieties. For commercialisation of the newly bred variety, however, a licence of the patent holder is required when the proprietary trait is still present in plant material. There are ongoing discussions with respect to a broader breeder's exemption, in which commercialisation would also be allowed.[31]

CRISPR/Cas9 and ruling on mutagenesis

On 25 July 2018 the CJEU was requested to answer the preliminary question on whether organisms obtained by new mutagenesis techniques (including using CRISPR/Cas9) would constitute genetically modified organisms within the meaning of Article 2 of Directive 2001/18/EC and be subjected to obligations for the release and placing on the market of genetically modified organisms (precautionary, impact assessment and traceability measures) or whether the exemption would only apply to organisms obtained by conventional random mutagenesis methods by ionising radiation or exposure to chemical agents existing before those measures were adopted.

The CJEU ruled that only organisms obtained by means of techniques or methods of mutagenesis that have conventionally been used in a number of applications and have a long safety record are excluded from the scope of that directive, and are exempt from the obligations for release and placing on the market.

New mutagenic biotechnology techniques, such as CRISPR/Cas9, would therefore not be excluded. In its statements of 25 July and 20 September 2018 the European Seed Association stated that the CJEU ruling presented unacceptable socio-economic risks for European plant breeding, and that

30 (33 365 (R1987) 'Wijziging van artikel 53b van de Rijksoctrooiwet 1995 in verband met de invoering van een beperkte veredelingsvrijstelling').

31 CCM Van de Wiel, LAP Lotz, HCM De Bakker and MJM Smulders (2016), n 10 above, p 9.

farmers, processors, traders and consumers would be put at a competitive disadvantage to regions with more enabling regulations.[32]

Industry initiatives

Recognising the challenge of patent rights with respect to the principle of open innovation, key players in the vegetable seed industry have set up the International Licensing Platform for vegetable plant breeding (ILPV). Major vegetable seed companies, including global industry leaders, have become members. ILPV members represent more than 50 per cent of the global vegetable seed market.

The main objective of the ILPV is to guarantee worldwide access to patents that cover biological material.[33] On 6 April 2018, ILPV members unanimously approved amendments to the ILP rules which clarify that patents covering traits made using new breeding technologies such as genome editing are accessible for licensing through the ILPV, as long as these traits are not regulated as genetically modified. The aim was to ensure the long-term sustainability of the ILPV as a mechanism to guarantee access to biological material for plant breeding.[34]

The platform provides a so-called FRAND (fair, reasonable and non-discriminatory) licensing system based on a 'free access but not for free' principle.[35] Under the terms and conditions of this platform, ILPV members must make all of their patents accessible to other members, who license the breeding and commercialisation of new varieties. The licensee has to pay a royalty for the commercialisation of the new variety, if still covered by the patent, in countries where a patent right exists.[36]

If negotiations between parties do not result in a licence agreement within three months, parties can submit their case to a panel of independent experts who will decide according to the principles of 'baseball arbitration'. If no agreement is reached, the decision is referred to the panel of independent experts who will decide the most reasonable proposal, which will become binding. This arbitration system encourages the parties to propose reasonable terms and conditions.

Owing to the principles of baseball arbitration – and the possible far-reaching consequences – ILPV members have so far refrained from having to use the panel.

32 See www.euroseeds.eu/system/files/publications/files/esa_18.0638.pdf accessed 27 March 2019.

33 See www.ilp-vegetable.org accessed 27 March 2019.

34 See www.ilp-vegetable.org/news/berichten/amendments-to-the-ilp-rules.html accessed 27 March 2019.

35 D Matthews and H Zech (eds), *Research Handbook on Intellectual Property and the Life Sciences* (Edward Elgar Publishers, Inc 2017), p 156.

36 *Ibid.*

China

Article 25 of Patent Law of the People's Republic of China (the 'Patent Law') provides a list of subjects excluded from patent protection, which includes 'scientific discoveries' and 'animal and plant varieties'. Plant varieties are not patentable in China because a 'plant is a living thing'.[37]

There is no clear definition of a 'plant variety' under the legal regime in relation to patent application and protection in China. Nevertheless, the Guidelines for Patent Examination (the 'Guidelines'), the latest version of which was effective as of 1 April 2017, enacted by the Chinese patent office, the State Intellectual Property Office (currently the National Intellectual Property Administration (CNIPA), provide interpretations of the term 'plant variety' and guidance for the implementation of Article 25 of the Patent Law.

First, the Guidelines define the term 'plant' mentioned in the Patent Law as follows:

> 'life form which maintains its life by synthesizing carbohydrate and protein from the inorganics, such as water, carbon dioxide, and inorganic salt, through photosynthesis, and usually is immovable.'

They also clarify that the plant may be a taxon of any rank of animal and plant, such as kingdom, phylum, classis, order, family, genus or species.

Moreover, they elaborate on the patentability of a micro-organism, gene or a DNA fragment, a single plant and its reproductive material, and a transgenic plant.

Microorganism

A microorganism is not classified as a plant by the Guidelines, and thus it is patentable. The Guidelines clarify that a microorganism can be patented only when it is isolated into pure culture and has a particular industrial use.

Gene or DNA fragment

A gene or a DNA fragment is regarded as a chemical substance and includes those isolated from a microorganism, plant, animal or human body, as well as those obtained by other means.

Gene or DNA fragments found in nature are merely a discovery, which falls under 'scientific discoveries' as stipulated in Article 25 of the Patent Law, and cannot be patented. However, a gene or a DNA fragment and the process to obtain it can be patentable if it is isolated or extracted for the first

37 Quote from the Guidelines for Patent Examination.

time from nature, its base sequence is unknown in the prior art and can be definitely characterised, and it can be exploited industrially.

'Plant' versus 'plant variety'

It is worth noting that the Guidelines confuse the concept of 'plant variety' with 'plant' as defined here. They provide that 'plant' and 'plant variety' are equivalent.

Single plant and its reproductive material

According to the Guidelines, a single plant and its reproductive material that exist by synthesising carbohydrate and protein from the inorganics, such as water, carbon dioxide and inorganic salt, through photosynthesis, belong to the plant variety category and cannot be patented. However, if a cell, a tissue and an organ of a plant do not possess the aforementioned characteristics, they cannot be regarded as plant varieties and, therefore, do not belong to the subjects excluded in Article 25 of the Patent Law.

Transgenic plant

The Guidelines provide that transgenic plants are those obtained by biotechnological methods, such as DNA recombination technology or genetic engineering. The plant still belongs to the plant variety category. No patent right shall be granted to them.

It may be concluded from the Guidelines that any plant-related inventions, inasmuch as the claims extended to the 'plant' set forth therein, cannot be eligible for patent protection in China.

Based on the amplified interpretation of the term 'plant variety' provided by the Guidelines, the CNIPA is prone to exclude all the claims in relation to a 'plant', even in some cases the cells, tissues, gene or DNA fragment, which may be patentable, according to the Guidelines. Under present practice, the CNIPA holds that plant cells belong to the category of reproductive materials falling into the category of plant variety and are thus patentable.

Processes used in producing plant varieties

Lastly, according to Article 25(2) of the Patent Law, a patent right may be granted for processes used in producing animal and plant varieties. The production processes herein refer to non-biological processes and do not include those for the production of animals or plants through essentially

biological processes. Whether a process is an essentially biological process depends on the degree of human technical involvement. If human technical involvement is the controlling or decisive factor for achieving the result or effect of that process, the process is not essentially biological.

Plant variety rights

Although plant varieties are not patentable, plant variety protection is possible in China.

The origin of China's new plant variety rights is the UPOV Convention. China became a party to the 1978 UPOV Act in 1999, but not to the revised 1991 Act. As a result, it only extends new plant variety protection to certain plant species. Other differences include the protection term and the scope of protection.

The Chinese New Plant Variety Regulations were promulgated in 1997 and their interpretation was last amended in 2014. To qualify for new plant variety registration under the regulations, the application must prove that the plant variety is:

- included in the list of nominated plant varieties (last updated in May 2016);
- novel;
- distinctive from other plant varieties;
- uniform (all plants in the plant variety have the aforementioned characteristic after propagation, the relevant characteristics of the variety remain consistent except for foreseen aberrance); and
- stable (the plants in the variety can be reproduced consistently from generation to generation, or after a cycle generation in case of hybrid varieties).

A breeder's right to apply for plant variety right (PVR) protection and the PVR itself are transferable. Agricultural PVRs are protected for 15 years and fruit tree PVRs are protected for 20 years. A PVR holder enjoys exclusive rights within the duration of the PVR protection. Without the consent of the PVR holder, a party cannot:

- produce or sell, for commercial purpose, the propagation materials of the protected varieties; or
- repeatedly use the propagation material of the protected varieties to produce propagating materials of other varieties for commercial purpose.

Under the following circumstances, the licence of the PVR holder is not required and no licence fee needs to be paid: (1) using a protected variety for breeding or other scientific research activities; and (2) a farmer's personal use of the propagation materials of a protected variety.

CRISPR/Cas9

The government encourages experimental research and application of CRISPR/Cas9 in agricultural areas carried out in accordance with the law and regulations. Although there are many experimental projects on breeding gene-edited plants supported by the government, the legal status of plant variety of CRISPR/Cas9-edited plants remains unclear.

Under Chinese law, there is no legislation specifically regulating genome-editing technologies. Although there is no official clarification published, according to consultation with the government, the view was held that CRISPA/Cas9-edited plants should fall within the category of genetically modified organisms provided by the Regulations on Administration of Agricultural Genetically Modified Organisms Safety (the last version was revised in October of 2017) (the 'GMO Regulations'). As defined under the GMO Regulations, agricultural genetically modified organisms are animals, plants, microorganisms and their products whose genomic structures have been modified by genetic engineering technologies for the use in agricultural production or processing.

Based on this, gene-editing methods, such as CRISPR/Cas9, which is a more precise method of genetic engineering, shall be regulated by the GMO Regulation. However, many Chinese academics believe that the supervision of CRISPR/Cas9-edited plants should not be regulated by the GMO Regulations if foreign DNA has not been inserted into the organism of the plant. According to their research, gene-edited plants are safer than GMO crops.

Since CRISPR/Cas9-edited plant varieties will be deemed GMO varieties by the Chinese regulators, the application of PVRs for CRISPR/Cas9-edited plant varieties shall follow the rules applicable to GMO varieties. According to the rules, in the event that a variety for which an application for variety right is filed is a GMO variety, the applicant must supply a copy of the safety examination and approval certificate of the agricultural genetically modified organism or the safety certificate for the agricultural genetically modified organism (for productive use) which are issued at the stage of test production.

When it comes to patent protection for CRISPR/Cas9-edited plants, only specific new methods using CRISPR/Cas9 in plant DNAs can be patented in China.

India

India has always been a primarily agricultural economy and has enacted various laws protecting the rights of farmers, such as the Protection of Plant Varieties and Farmers' Rights Act 2001 (the 'PVR Act'). Indian law does not permit plant patents.

India passed the PVR Act after the ratification of the TRIPS Agreement to give effect to paragraph 3(b) of its Article 27, which requires members to provide for the protection of plant varieties by patents or an effective *sui generis* system or any combination. Although India is not a signatory to the UPOV Convention or its revisions, it incorporated elements from the 1978 and 1991 versions in the PVR Act.[38]

One of its core objectives was to recognise farmers' contribution in conserving, improving and making available plant genetic resources for the development of new plant varieties. Farmers have, inter alia, been provided the right to:

- register a new variety and claim other protection as a breeder of a variety under the PVR Act;
- claim benefit sharing, post the registration of the new variety; and
- save, use, sow, re-sow, exchange, share or sell farm produce, including protected varieties, in the same manner as they had the right to before the enforcement of the PVR Act.

Even though the PVR Act includes farmers in the definition of a 'breeder', farmers in India face various practical challenges in taking advantage of such rights on account of, inter alia, the criteria of distinctiveness, uniformity and stability, conforming to which is a requirement to register any variety under the PVR Act. It is pertinent to note that even though farmers' varieties have the highest number of applications, they have registered the lowest rate of conversion in the number of certificates granted.[39]

India has ratified the Convention on Biological Diversity 1992, which provides the framework for the conservation and use of biological resources, and the ITPGRFA, which emphasises conservation, sustainable use and benefit sharing.[40]

---

38 Nusrat Hassan, 'Agricultural Law in India: Overview', *Global Agricultural Law, A Global Guide from Practical Law*, available at https://uk.practicallaw.thomsonreuters.com/1-604-1046?transitionType=Default&contextData=(sc.Default)&firstPage=true&comp=pluk&bhcp=1 accessed 27 March 2019.

39 Rajshree Chandra, 'Farmers' Rights in India: "Globally Sui Generis"', *South Asia Chronicle,* 6/2016, s 119–144, available at https://edoc.hu-berlin.de/bitstream/handle/18452/9170/7a.pdf?sequence=1 accessed 27 March 2019.

40 Philippe Cullet and Radhika Kolluru, 'Plant Variety Protection and Farmers' Rights – Towards a Broader Understanding', 24 *Delhi Law Review* 41, available at www.ielrc.org/content/a0304.pdf accessed 27 March 2019.

The Biological Diversity Act 2002 (the 'Biodiversity Act') addresses India's assertion of sovereign rights over natural resources and puts stringent limits on access to biological resources or related knowledge for foreigners. Indian citizens and legal persons are required to give prior intimation of their intention to obtain biological resources to state biodiversity boards. The Biodiversity Act is more stringent in terms of IP rights, which require all inventors to obtain the consent of the National Biodiversity Authority (NBA) before applying for the rights. The Biodiversity Act also requires any company incorporated in India with any non-Indian participant in its share capital or management to obtain the consent of the NBA for, inter alia, obtaining any biological resources in India. The NBA may also impose a condition for granting permission and may require the applicant to share the benefit of the rights with others or create any other system of benefit sharing, including sharing with the farmer contributor.

Plant variety rights versus patent protection

India does not have a specific law protecting 'plant varieties by patents'. The two laws, the PVR Act and the Patent Act, operate in different fields. The former provides protection to the new plant variety created by a breeder or farmer, whether by using technology or simply by other processes. The latter provides protection to an invention including any technology developed for industrial use. The scope of rights, such as the right of exclusivity to use the variety or invention after registration, granted under the two laws is similar because they were both enacted to give effect to the TRIPS Agreement.

The patent legislation also influences plant variety protection in India. The Patents (Amendment) Act, 2002 (the 'Patents Act') was amended to allow compliance with the TRIPS Agreement. It brought uniformity in the duration of rights to 20 years. It stated that plants in whole or any part, including seeds, varieties and species are not patentable, and excluded microorganisms. It also addressed the concerns of biopiracy by imposing a disclosure of source and geographical origin of biological material in the patented invention.

The patenting of genetic engineering technology used in the creation of GM crops is still unexplored territory in India since only bacillus thuringiensis ('Bt') cotton is permitted[41] to be manufactured in India. The Genetic Engineering Approval Committee (GEAC) in October 2009 recommended

41 A list of commercially approved crops in India is available at www.geacindia.gov.in/approved-products.aspx accessed 27 March 2019.

that Bt Brinjal was safe for environmental release.[42] Soon thereafter, Jairam Ramesh, then the Environment Minister, imposed a moratorium on the release of Bt Brinjal.[43] It is expected that with the growth and acceptance of GM crops there will be significant development in patent rights in genetic engineering technology used in the production of GM crops.

In a recent decision of the division bench of Delhi High Court sitting in appeal in *Nuziveedu Seeds Ltd v Monsanto Technology LLC,*[44] the Court analysed the rights under the PVR Act and Patents Act. Monsanto had licensed its patent IN214436 relating to Bt cotton technology to different Indian companies, including Nuziveedu. The patent allowed the Indian companies to produce seeds that are resistant to bollworm attacks. Owing to disputes, Monsanto terminated its contract and initiated action against Nuziveedu and others for an injunction against infringement of its patent and trademark. Nuziveedu filed a counterclaim for revocation of Monsanto's patent on the grounds that it was invalid because it fell under the lists of inventions that cannot be patented under Section 3(j) of the Patents Act, which inter alia states that plants and animals, in whole or any part thereof, are not inventions and therefore not patentable.

The High Court concluded that Monsanto's invention would fall under the aforementioned provision and was not patentable. It gave Monsanto three months to register under the PVR Act. Monsanto preferred an appeal in the Supreme Court.

The Supreme Court[45] set aside the order of the division bench and remanded the case to the single judge of the Delhi High Court, thus restoring Monsanto's claim on Bt cotton until the final decision of the single judge. The Supreme Court has left open all questions of facts and law and held that since the issues involved are complex, summary adjudication by the division bench was not desirable or permissible in the law. The decision of the judge is much awaited on this complex issue of the patentability of plant varieties and other gene-engineering technologies and their products. This judgment could become a landmark moment for the biotechnology sector and its ability to protect plant-related inventions in India.

---

42 97th Meeting of the Genetic Engineering Approval Committee held on 14 October 2009, available at www.moef.gov.in/sites/default/files/geac/decision-oct-97.pdf accessed 27 March 2019.

43 'India divided over plans for GM aubergine', BBC News, 9 February 2010, available at http://news.bbc.co.uk/2/hi/south_asia/8503825.stm accessed 27 March 2019.

44 *Nuziveedu Seeds Ltd v Monsanto Technology LLC*, available at http://lobis.nic.in/ddir/dhc/SRB/judgement/12-04-2018/SRB11042018FAOOSCOMM862017.pdf accessed 27 March 2019.

45 *Monsanto Technology LLC v Nuziveedu Seeds Ltd.(Supreme Court)*, available at www.sci.gov.in/supremecourt/2018/16059/16059_2018_Judgement_08-Jan-2019.pdf accessed 27 March 2019.

Regulation and CRISPR/Cas9

The law in India governing GMOs is the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells 1989 (the 'Rules'), incorporated under the Environment (Protection) Act 1986.[46] The Rules are primarily implemented by the Ministry of Environment and Forests and the Department of Biotechnology under the Ministry of Science and Technology through six committees, the most important of which is the GEAC.

The general view is that the Rules are wide in their scope and would cover developments related to the use of CRISPR/Cas9 and other gene-editing technologies. However, the lack of a specific regime or an official stance for the regulation of gene-editing technologies, which require different treatment from gene-modifying technology, is seen as a hurdle for development in this area. The Food Safety and Standards Authority of India, another regulatory body empowered to regulate the production and import of GM foods, has so far only issued draft rules on the regulation of GM foods. The Rules, therefore, continue to solely govern GMO in India and, by extension, gene-editing technology.[47]

Conclusion

Scientists made strides in early 2018 when using CRISPR/Cas9 for the first time in India to edit the genome of banana to improve nutritional quality and increase pathogen resistance.[48] Although there has been significant growth in India's biotechnology sector, the regulatory regime has not kept up and is plagued with various problems, such as overlapping functions of bodies, lack of coordination and failure to update to meet the requirements of recent developments.[49] Due to this, there remains a vacuum in the approval processes and innovation protection for genetically engineered foods, which

46 Vibha Ahuja, 'Regulation of emerging gene technologies in India', *BMC Proceedings*, 2018; 12(Suppl 8): 14, available at www.ncbi.nlm.nih.gov/pmc/articles/PMC6069684/ accessed 27 March 2019.

47 DTE Staff, 'India is consuming banned GM food owing to lack of regulations', *Down To Earth*, 19 September 2018, available at www.downtoearth.org.in/news/food/india-is-consuming-banned-gm-food-owing-to-lack-of-regulations-59931 accessed 27 March 2019.

48 Yogesh Sharma, 'Indian scientists have used latest gene-editing techniques to modify the banana genome, for the first time', *Biotech Times*, 24 January 2018, available at https://biotechtimes.org/2018/01/24/indian-scientists-use-crispr-edit-banana-genome accessed 27 March 2019.

49 Ananth Padmanabhan, R Shashank Reddy and Shruti Sharma, *Modern Biotechnology and India's Governance Imperatives* (2017), available at https://carnegieendowment.org/files/CP_311_Padmanabhan_FNL4WEB.pdf accessed 27 March 2019.

is seen as a major impediment to the sector's growth. Several scientific advancements have been made and adopting CRISPR/Cas9 by fostering the correct regulatory environment and a conducive ecosystem would result in higher crop productivity in terms of yield and nutrition, and prove essential in feeding the growing population in times of climate uncertainty.

Africa

Eritrea is the only African country that is not a member or observer of the WTO. Algeria, Equatorial Guinea, Ethiopia, Libya, Somalia, South Sudan and Sudan have observer status while the rest of the African nations are members.[50]

Kenya, Morocco, South Africa, Tanzania and Tunisia are members of the UPOV in their own right, and Egypt, Ghana, Mauritius and Zimbabwe have initiated the procedure for acceding to the UPOV Convention.[51]

Two regional African organisations deal with the protection of intellectual property rights: the African Intellectual Property Organisation (Organisation Africaine de la Propriété Intellectuelle or OAPI) and the African Regional Intellectual Property Organisation (ARIPO).

The OAPI covers the territory of its 17 Member States: Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea-Bissau, Mali, Mauritania, Niger, Senegal and Togo. OAPI Member States do not have their own IP laws and systems and it is not possible to designate countries of interest.

There are 19 ARIPO Member States: Botswana, The Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Namibia, Rwanda, São Tomé and Príncipe, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania (mainland), Uganda, Zambia and Zimbabwe. Angola, Algeria, Burundi, Egypt, Eritrea, Ethiopia, Libya, Mauritius, Nigeria, Seychelles, South Africa and Tunisia have observer status. Most ARIPO Member States have their own IP laws but cooperate for the purpose of IP rights applications under the ARIPO. In an application for IP rights, specific Member States that have acceded to the protocol must be designated.

The OAPI is a member of the UPOV and operates a plant breeder's rights (PBR) system, and the ARIPO has initiated the procedure for acceding to the UPOV Convention.

The World Intellectual Property Organization (WIPO) administers, inter alia, the WIPO, WTO, and Patent Cooperation Treaty conventions and provides for administrative cooperation among the IP unions established

50 World Trade Organization, see www.wto.org accessed 27 March 2019.

51 International Union for the Protection of New Varieties of Plants, see www.upov.int accessed 27 March 2019.

by its treaties.[52] All UN-recognised African states except South Sudan are members of WIPO.

On a regional level, the preamble of the ARIPO Protocol for the Protection of New Varieties of Plants recognises 'the need to have an effective sui generis system of intellectual property protection of new varieties of plants that meets the requirements of Article 27.3 (b)' of the TRIPS Agreement.[53] Article 4(1) of the Protocol provides protection to breeders' rights on the basis of one application in all designated contracting states, provided that the designated contracting state has not refused the grant. By the end of 2017, only The Gambia, Ghana, Mozambique, São Tomé and Príncipe and Tanzania had signed the Protocol, which will only enter into force 12 months after four states have deposited their instruments of ratification or accession.[54]

The ITPGRFA promotes equitable sharing of the benefits arising from plant genetic material between breeders, scientists, farmers and the wider community. It recognises sovereign rights over plant genetic resources for food and agriculture. Article 6(2)(c) promotes plant breeding efforts, which, with the participation of farmers, particularly in developing countries, strengthens capacity to develop varieties particularly adapted to social, economic and ecological conditions, including in marginal areas. All African countries with the exception of Botswana, Cabo Verde, Comoros, Equatorial Guinea, Gambia, Mozambique, Nigeria, Somalia, South Africa and South Sudan are contracting parties to the ITPGRFA.[55]

Domestic law protection

As with all other IP rights, once registered, plant breeders' rights are property. Thus, even where there is no provision for specific protection of breeders' rights, the scope of general property rights protection under the constitutions of many African nations is broad enough to provide various levels of protection against the government and, in some cases, against private parties. This can be exemplified by the constitutions of Botswana (Chapter 8), Kenya (section 40), Namibia (Article 16), Nigeria (section 44), South Africa (section 25) and Zimbabwe (section 71(1)(d)). While Zimbabwe's Constitution protects property of 'any description and any right or interest in property', the Kenyan Constitution goes further by expressly mandating the state to 'support, promote and protect the intellectual property rights'.

52 World Intellectual Property Organization, see www.wipo.int accessed 27 March 2019.

53 Preamble to the Arusha Protocol for the Protection of New Varieties of Plants.

54 *ARIPO Annual Report 2017*, see www.aripo.org/publications/annual-reports/item/265-aripo-annual-report-2017, accessed 1 April 2019.

55 Food and Agriculture Organization (FAO), see www.fao.org accessed 27 March 2019.

South Africa

In South Africa, new plant varieties can be protected under the South African Plant Breeders' Right Act No 15 of 1976. South Africa is a signatory to the UPOV Convention as revised in 1978. Although South Africa has not yet acceded to the 1991 revision of the UPOV Convention, its Plant Breeders' Right Act already complies in many respects.[56]

Provided that the variety is on the list of prescribed kinds of plants and complies with the novelty and distinct, uniform and stable requirements of the Plant Breeders' Right Act, it is possible to obtain protection in South Africa, whether the variety has been developed by normal cross-breeding techniques or by genetic engineering. An application for a plant breeder's right is lodged with the Department of Agriculture. Within a year of filing the application, the applicant must submit or make plant material available to the Department for evaluation. Although it is usually the phenotypic characteristics of the plant that are examined, the Department has also relied on the use of DNA-based marker-assisted variety identification for evaluation purposes. The term of protection for a plant breeder's right is 20 years and 25 years in the case of vines and trees, calculated from the date of grant.

Under section 25(4)(b) of the South African Patents Act No 57 of 1978 (the 'Patents Act'), a patent shall not be granted for any variety of animal, plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process. There is no case law in South Africa interpreting the meaning of this provision. The wording of section 25(4) of the Patents Act is similar to Article 53(b) of the European Patent Convention and it is likely that the courts in South Africa will follow a similar approach to those in Europe. Specifically, it is likely that South African courts will allow claims directed to transgenic plants and biotechnological methods of obtaining transgenic plants. However, claims directed to plants produced by classical breeding techniques, or methods of obtaining plants that do not include biotechnological steps, should be avoided as these are likely to be found unallowable.

The South African Patent Office merely examines application formalities but does not conduct substantive examination. In the absence of voluntary amendment, a patent application will be accepted and granted with the original specification. It is a ground for revocation of a South African patent if 'the declaration [in Form P3] contains a false statement which is material and which the patentee knew or ought reasonably to have known to be false at the time that the declaration was made'. In this regard Form P3 states 'to the best of my/our knowledge and belief, if a patent is granted on the

56 Dean and Dyer, *Introduction to Intellectual Property Law* (Oxford University Press 2014), p 284.

application, there will be no lawful ground for the revocation of the patent'. It is thus imperative that any invalidities in the specification or claims of which the applicant is aware are cured by way of amendment before grant. The term of a patent in South Africa is 20 years from the date of filing. It is not possible to extend the term of a patent in South Africa.

Other African jurisdictions

Some constitutional states, such as Zimbabwe, also have constitutional measures that indirectly protect IP through measures such as mandating the government to domesticate international instruments (section 34), mandating the courts to interpret fundamental rights by taking into account international law and all treaties and conventions the nation is a party to (section 46(1)(c)) and preferring legislative interpretation that is consistent with international conventions, treaties or agreements binding the nation (section 327).

In line with the TRIPS Agreement and obligations under various treaties, most African nations have laws that protect plant breeders' rights and provide for the procedure for the registration of the same. Section 30 of South Africa's Plant Breeders' Rights Act binds the state to plant breeders' rights in the same way as private parties. Part V of Zimbabwe's Plant Breeders Rights Act (Chapter 18:16) criminalises various acts with respect to plant breeders' rights and provides for penalties that include fines and imprisonment. In Kenya, plant breeders' rights are defined and protected by Part V of the Seed and Plant Varieties Act.

Countries such as Botswana and Namibia have not yet enacted specific legislation that protects plant breeders' rights**.** The Nigerian National Agricultural Seeds Act does not expressly provide for plant breeders' rights but provides protection by allowing the registration of seed varieties and seed breeders, and prohibiting the production, processing and marketing of seeds for commercial purposes without registration (see sections 7(1)(a), 21(c) and 22(1)).

For Botswana, the lack of legislation is partly because the nation did not affect the seed privatisation process that most African nations underwent in the late 1980s as part of structural adjustment programmes instituted by the World Bank. As well as the lack of express plant breeders' rights and the absence of an adequate institutional and policy framework to support private-sector participation in the seed sector, private participation has been stifled by the dominance of the government in the seed market, which it

heavily subsidises.[57] International players nevertheless participate in the seed market in Botswana through contractual agreements with the government which protect their rights.[58] Generally, there is a progressive trend in Africa for the concomitant protection of plant breeders' rights and attainment of national food security.

CRISPR/Cas9

There is growing interest by African researchers to explore the repurposing of CRISPR/Cas9 to create genetically modified crop varieties. Most of the research is aimed at eradicating hunger and poverty by, inter alia, enhancing drought tolerance, resistance to viruses and improving crop yield.[59] This is exemplified by Uganda where research is underway to edit genomes in the cassava plant by cutting out strands of DNA that retard growth and enhancing strands that cause the plant to grow normally.[60]

In spite of the growing interest, gene-editing technology has not been amicably received by governments and local communities. Civic organisations such as the African Centre for Bio-diversity have openly rejected gene-editing techniques on the alleged grounds that the risks associated with them have not been ascertained.[61]

There is thus an urgent need for stringent regulatory laws, national policies and guidelines for scientific and ethical research and adequate safeguards and structures to protect the dignity and rights of local communities.[62] Legislation in African states mostly focuses on regulating the agricultural use of GMOs in line with the 2003 Cartagena Protocol on Biosafety, which recommends stringent regulation on the basis that the long-term effects

57 P Malope, *Prospects and challenges of seed sector privatisation* (Department of Agricultural Economics, Education and Extension Botswana College of Agriculture, Gaborone, Botswana, June 2011).

58 'Botswana gets a new hybrid seeds', *Sunday Standard*, 3 June 2018.

59 E Rodriguez, 'Ethical issues in genome editing using CRISPR/Cas9 system', *Journal of Clinical Research and Bioethics*, 2016, 7:266, available at https://doi.org/10.4172/2155-9627.1000266 accessed 27 March 2019.

60 Lominda Afedraru, 'Africa could become a world agricultural leader in CRISPR and other new breeding techniques (NBTs)', Genetic Literacy Project, 22 February 2018, available at www.geneticliteracyproject.org/2018/02/22/africa-world-agricultural-leader-crispr-new-breeding-techniques-nbts accessed 11 December 2018.

61 'Biosafety risks of genome editing techniques in plant breeding', African Centre for Biodiversity, February 2017.

62 Cletus Tandoh Andoh, 'Genome Editing Technologies: Ethical and Regulation Challenges for Africa', *International Journal of Health Economics and Policy*, 2017; 2(2), pp 30–46.

of the introduction of foreign DNA into genomes are unknown.[63] South Africa enacted the Genetically Modified Organisms Act No 15 of 1997 and Uganda passed the Genetic Engineering Regulatory Bill 2018 to regulate the development and application of biotechnology. In Egypt the Biosafety Law Bill regulating genetically modified crops and food products was completed in 2011 but is yet to be passed by parliament.[64]

Patenting genome-editing in Africa

With respect to registration of rights, as of 11 February 2019 there were only two patents related to genetic modification filed with the ARIPO. The first application, titled *Methods for treating HIV infection* and filed by the University of the Witwatersrand, Johannesburg, concerns non-agricultural use of the technology. The other application, filed by the University of California and titled *Methods for autocatalytic genome editing and neutralizing autocatalytic genome editing and compositions thereof,* is undergoing substantive examination. It is for the use of CRISPR/Cas9 to target suppression of crop pests, among others.[65]

It is evident that there is a lacuna in the regulation of gene-editing tools in African domestic and regional policy. By inference, the stance that will possibly be adopted at this point will be much like the legislation in South Africa and in the near future Ghana and possibly Egypt, which have placed stringent restrictions on the development of GMOs.

Farmers' rights

The contentions surrounding farmers' rights in Africa are mainly the protection of traditional knowledge relevant to plant genetic resources for food and agriculture and the right to save, use, exchange and sell farm-saved seed. The majority of the regional IP regimes and national legislations, however, do not yet recognise and protect the rights to sell exchange and use PGRFA. Most seed laws do not regulate farm-saved crop seed varieties or permit the saving and selling of farm-saved seeds as commercial varieties.

Section 25 of the South African Plant Breeders' Rights Act allows farmers to save seeds from protected varieties for their own use. It has been noticed, however, that many farmers, in particular smallholder farmers, are unaware

63 Pillay S, Thaldar DW. CRISPR: Challenges to South African biotechnology law *S Afr J Bioethics Law,* 2018;11(2):89-92. DOI:10.7196/SAJBL.2018.v11i2.653, available at www.ajol.info/index.php/sajbl/issue/view/17844, accessed 3 April 2019.

64 'Biosafety Law protecting citizens from chaos caused by genetically modified food products', available at www.loc.gov accessed 27 March 2019.

65 African Regional Intellectual Property Organisation, see www.aripo.org accessed 27 March 2019.

of their rights.[66] There is also minimal awareness of the implications of these rights.

Swaziland developed access and benefit sharing (ABS) policy guidelines with provisions that allow communities to lawfully use genetic resources on land to which the community has rights, as well as knowledge and innovation related to the use of genetic resources on their land.[67] The guidelines also prohibit the selling, assignment and transfer of community genetic resources and intellectual and cultural knowledge and innovations without prior informed consent and effective participation of the communities or cultural clans concerned. In Zambia, the government established a National Genetic Resources Centre in a bid to engage farmers and identify farmers' indigenous plant varieties and place them on the national register. To date, a number of varieties of plants, such as maize, groundnuts, cowpeas and sorghum, have been registered.[68]

Other African states recognise these rights differently. Zambia has ABS guidelines that require prior informed consent and equitable sharing of benefits from the use of genetic resources.[69] There have also been increased efforts to improve seed accessibility for farmers by harmonising seed regulations across sub-regional organisations, such as the Southern African Development Community seed harmonisation regulations. Only the formal seed sector, however, is supported through policy and regulatory frameworks such as plant breeders' rights. Countries that have enacted legislation to this effect are Egypt, Ethiopia, Kenya, Malawi, Morocco, Nigeria, South Africa, Tanzania, Uganda, Zambia and Zimbabwe. There is still no clarity or policy guidelines in respect of farmers' plant genetic resources and their rights.[70]

The framing of national policy and legislation for the realisation of farmers' rights has been further undermined by the adoption of the 1991

---

66 Netnou-Nkoana NC, Jaftha JB, Dibiloane MA, Eloff J. Understanding of the farmers' privilege concept by smallholder farmers in South Africa. South African Journal of Science (3) 2015, p.47. http://dx.doi.org/10.17159/sajs.2015/2013-0344

67 Swaziland Submission, FAO and ITPGRFA, 'Views, Experiences and Best Practices as an example of possible options for the national implementation of Article 9 of the International Treaty Submitted by Contracting Parties and Relevant Organizations', 20 July 2018, available at www.fao.org/fileadmin/user_upload/faoweb/plant-treaty/submissions/FRs_SWZ.pdf accessed 27 March 2019.

68 Zambia Submission, FAO and ITPGRFA, 'Views, Experiences and Best Practices as an example of possible options for the national implementation of Article 9 of the International Treaty Submitted by Contracting Parties and Relevant Organizations', 30 June 2018, available at www.fao.org/fileadmin/user_upload/faoweb/plant-treaty/submissions/FRs_Zambia.pdf accessed 27 March 2019.

69 *Ibid.*

70 FAO and ITPGRFA, 'Stakeholders' Consultation on Farmers' Rights – African Position Paper', June 2016, available at www.fao.org/3/a-bq550e.pdf accessed 27 March 2019.

UPOV Convention, which does not recognise the challenges to implementing Article 9 of the ITPGRFA in Africa. The challenges include weak and contradictory policy and legislation, lack of financial support to develop support structures, lack of common strategies among stakeholders and lack of awareness on what constitutes farmers' rights.[71]

Developments

Owing to differences in the resources and capacities of African states to develop national policies on GMOs and to assess the biosafety of such products and ingredients, the Common Market for Eastern and Southern Africa (COMESA) drafted regional policies and guidelines on biosafety in 2010.

The guidelines, titled *Draft Policy Statements and Guidelines for Commercial Planting of GMOs, Trade in GMOs and Emergency Food Aid with GMO Content*, were prepared by the Regional Approach to Biotechnology and Biosafety in Eastern and Southern Africa (RABESA) initiative and were presented to the 19 Member States in an attempt to harmonise the region's stance on GMO imports.

Summary and conclusion

Pursuant to becoming parties to international treaties and conventions such as the UPOV Convention, the ITPGRFA, the WTO, which includes the TRIPS Agreement, and the WIPO Convention, many African states have enacted IP legislation that protects plant breeders' rights in relation to new plant varieties. This is particularly salient in Africa where it is pivotal to develop and protect new varieties that adapt to social, economic and ecological conditions. The legislation in countries such as South Africa and Zimbabwe outlines the requirements to obtain protection of plant breeders' rights.

Many African states still have a lacuna in legislation specific to the protection of IP rights in respect of recent technological advancements, such as CRISPR/Cas9 and genome-editing. This gap may continue into the foreseeable future.

In light of the CJEU ruling to regard new plant varieties as GMOs and subject them to the same strict requirements, Africa, as the biggest exporter of agricultural food, may be dealt a heavy blow. In 2017, Africa exported €16bn worth of agricultural food products to the EU, making it the bloc's largest trading partner. As a result African countries that export agricultural food products to the EU will not be able to adopt gene-editing tools.

71 *Ibid.*

Some African nations have begun research on this technology. It remains to be seen whether new policy and legislation will be enacted so as to recognise the use of this technology and offer protection of IP rights accordingly.

Observations

Recent developments around the world serve as evidence that the ongoing debate on the scientific, ethical and social concerns of new gene-editing technologies combined with economic realities have resulted in different codification in various legal systems.

In the EU, a recent decision by the EPO paved the way for patents to be granted on plants obtained by essentially biological processes. As this decision is diametrically opposed to the position taken by the EU Member States and the European Commission, the European agricultural market sector is back into uncertainty when it comes to the patentability of plants in the EU.

At the same time, the 25 July 2018 ruling by the CJEU, which subjects plants obtained using new gene-editing technologies (eg, CRISPR/Cas9) to the EU's regular GMO legislation, is widely regarded as a missed opportunity to advance research and innovation within the EU. These techniques may help breeders and farmers to do more with fewer inputs: less water, less fertilizer and less pesticide. Unless EU regulators act swiftly to change course, innovative seed-breeding companies may move their facilities outside the EU. This possibility is expected to increase the pressure on EU regulators and politicians to act to prevent this from happening.

In the US, the recently enacted Farm Bill includes a major amendment to the PVPA, leading to an extension of PVP to include asexually reproduced plant varieties. As a result, PVPs will be able to protect essentially derived varieties of asexually reproduced plants, such as tree crops (eg, apple trees). This means that varieties essentially derived from PVP protected varieties will fall under the scope of the PVP. The commercialisation of such essentially derived varieties will only be possible with authorisation of the title holder of the initial variety. This update to PVPs could change plant IP protection strategies in the US.

Fast-growing economies such as China invest enormously in new plant technologies, and China intends to be the world leader in plant gene-editing technology and supports many projects to gene-edit plants. For example, seed and chemical giant Syngenta AG, run by state-owned China National Chemical Corp, is building a Beijing hub for developing cutting-edge technologies like CRISPR/Cas9.

Although many significant results have been achieved in the agricultural field, the regulations have not kept up and there continues to be a vacuum

in the approval processes and innovation protection possibilities for genome-edited foods. The slow development of regulatory processes and legal protections allows for uncontrolled research and illegal commercialisation of gene-edited crops. Currently, gene-edited plants may be governed by GMO Regulations, which will impede the development of the biotechnology sector. While the legislation in terms of risk assessment and commercialisation remains unclear, there is a degree of flexibility available to promote gene-editing technology in the fast-growing market of new foods.

Overall, the right of farmers to use, exchange and sell farm-saved seeds remains a challenge, especially in developing countries. The majority of countries bound by the UPOV Convention are developing. UPOV members have introduced the UPOV PVP system to provide farmers with a choice of improved varieties for the benefit of society. Developing a plant variety in scientific breeding systems generally takes 10 to 15 years and requires substantial investment and sophisticated research centres, so providing IP protection for these improved varieties is important for economies. However, some consider the UPOV system to be too strict as farmers' rights in national laws remain problematic in terms of effective implementation and compliance. This might again have the effect that high-tech seeds will not be introduced to these countries owing to the lack of IP protection and other commercial constraints. On the other hand, scientific plant breeding methods are not generally available to small-scale farmers, and the seed of improved varieties that substantially increase agriculture yields per hectare are often considered too expensive, so providing protection for small-scale farmers is important for agriculture. One option to address these issues might be to allow developing countries to implement a more flexible national legal regime that better supports smallholder farming, to protect traditional practices and to implement ITPGRFA-based farmers' rights.

A system of open innovation – that is, the free use of commercialised plant material for research and development – forms the basis of plant variety rights. However, it is important to balance this system with a market-based environment for the creation of plant varieties. National patent laws need to support research and development as well as market-driven plant variety creation. Ideally, these principles would also be present in applicable international patent treaties such as the TRIPS Agreement.

In the context of population growth, food security and climate change, the objectives of the UPOV Convention and the ITPGRFA play an important role in meeting those challenges. Therefore, it is important to continue exploring synergies between the UPOV Convention and the ITPGRFA and to interpret and implement the two treaties in a mutually supportive way in the context of each contracting party. Regional differences in plant-technology research

capabilities, financial resources and effective enforcement of IP protection and food safety regulations are likely to be a disruptive force for years to come. Questions about how smallholder farming in developing economies will adapt or survive in this dynamic legal environment remain open.