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What's New in the 2014 WikiLeaks TPP Intellectual Property Text?

The TPP's New Plant-Related Intellectual Property Provisions¹

The newly-released Trans-Pacific Partnership (TPP) intellectual property (IP) chapter would help seed conglomerates like Monsanto prevent farmers from saving and using seeds that contain patented plant materials, even when such use is for their own personal consumption. The TPP language would also prevent breeders from using plants seeds that contain patented plant materials to research and develop new varieties. Most plant variety protection (PVP) systems allow farmers to save and reuse seeds (for noncommercial purposes) and permit breeders to use protected plant varieties to research and develop new varieties. In contrast, patents on plant-related inventions, as outlined in the TPP, may have few exceptions. This new text constitutes a huge step in the wrong direction, changing the plant IP regimes of many of the negotiating countries to the detriment of their populations.

Article QQ.E.1.3.

Consistent with paragraph 1, each Party confirms that it makes available patents for plant-related inventions.⁵⁵

FN55 For greater certainty, no Party shall be required to make patents available for plant varieties that are protectable in that Party under the International Convention for the Protection of New Varieties of Plants [1991](UPOV Convention)

Under the most recent TPP language, parties will be required to make patents available for plant-related inventions that are not protectable under the 1991 International Convention for the Protection of New Varieties of Plants (UPOV). Article QQ.A.8. of the TPP already requires the negotiating parties to accede to the 1991 version of UPOV. Article QQ.E.1.3 adds another layer of enforceability to the 1991 UPOV.

If the most recent version of the TPP is implemented, the negotiating parties will be forced to make available patents on plant-related inventions, such as plant genes, methods of genetically engineering plants, and even methods of conventional breeding (in addition to existing

¹ Dr. Burcu Kilic (bkilic@citizen.org) & Hannah Brennan (hbrennan@citizen.org), Public Citizen's Global Access to Medicines Program, October 2014.

commitments to provide PVP protection for plant varieties under the 1991 UPOV). Although the new TPP text does not make patents on plants *per se* available, **this language will functionally subject many plants to patent protection**. Additionally, due to the complex nature of plant-related inventions, plant varieties, which are traditionally covered by PVP, may still be subject to patents.

Traditional Breeding Methods vs. Genetic Engineering

With the advent of genetic engineering, plant breeders have developed new breeding processes and complex plant traits. Today, new plants can either be created in the traditional way, through conventional breeding techniques, or through genetic engineering. Genetic engineering and conventional plant breeding differ both in the processes they entail and the products they generate.

“As a general rule, conventional breeding develops new plant varieties by the process of selection, and seeks to achieve expression of genetic material that is already present within a species.”² Conventional breeding employs processes that occur in nature, such as sexual and asexual reproduction, with the resulting plant product emphasizing certain characteristics. However, the characteristics displayed are not technically “new” for the species; “the characteristics have been present for millennia within the genetic potential of the species.”³

Genetic engineering, in contrast, enables scientists to insert carefully-selected genetic material into the genome⁴ of a particular organism.⁵ This process does not occur in nature, and it allows researchers to more precisely control the expression of certain genes. Furthermore, the genetic material inserted into a particular plant’s genome does not have to be present in the original species.⁶ For example, researchers once introduced an antifreeze gene from Arctic flounder into tobacco and tomato plants.⁷ Genetic engineering also allows scientists to create *new* genetic material, the expression of which leads to new plant characteristics.

Plant Variety Protection v. Plant-Related Inventions

Plant variety protection was developed specifically to protect the products of traditional plant breeding. PVP systems vary widely from country to country. However, UPOV has attempted to create an international standard for Plant Variety Protection. Currently, 72 nations are UPOV signatories: 52 have ascended to the 1991 version of the UPOV, 19 to the 1978 version of the UPOV, and 1 to a 1972 version. Under the UPOV, a new plant that has a suitable denomination

² Michael K. Hansen, GENETIC ENGINEERING IS NOT AN EXTENSION OF CONVENTIONAL PLANT BREEDING, CONSUMER POLICY INSTITUTE/CONSUMERS UNION 1 (2000).

³ *Id.*

⁴ A genome is the genetic material of an organism.

⁵ Peggy G. Lemaux, *Genetically Engineered Plants and Foods: A Scientist’s Analysis of the Issues (Part I)*, 59 Ann. R. Plant. Bio. 771, 773 (2008); Hansen, *supra* note 2, at 1.

⁶ Hansen, *supra* note 2, at 1-2.

⁷ R. Hightower, et al., *Expression of Antifreeze Proteins in Transgenic Plants*, 17 PLANT MOL. BIOL. 1013 (1991). These products were never commercialized.

can be protected as a plant variety if it is: 1) new (not known in the market), 2) distinct from existing or commonly known varieties, 3) homogenous or uniform, and 4) stable.

PVP grants breeders some degree of exclusive rights over the vegetative and reproductive materials of plant varieties they have invented or discovered. Because the objective of PVP is protection of the propagating materials of plant varieties, plant breeders' rights do not cover "technical processes for the production of those varieties."⁸ In other words, **breeders cannot obtain exclusive rights over particular breeding methods**, such as methodologies used to genetically engineer or conventionally breed new plants, through PVP systems.

However, these methodologies and breeding processes **can be protected under patent systems** that make patents on plant-related inventions available. Plant genera and species that are not protectable under PVP systems may be eligible for patent protection.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires members of the World Trade Organization (WTO) to make patents available for "any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."⁹ However, WTO members can exclude processes from patentability plants and animals and/or essentially biological processes for the production of plants or animals other than non-biological and microbiological.¹⁰ Even though TRIPS does not require members to provide patents on plant-related inventions, member may choose to provide such patents. If members choose to provide patents on plants or plant related-inventions, then they **must** comply with the TRIPS requirements on patentability.

A plant patent can be described as a patent on the plant as a whole, whereas a patent on a plant-related invention would be a patent on a particular aspect or feature of a plant, such as the process used to create that plant or genes inserted into that plant's genome. For example, if a manufacturer creates a new gene that enables plants to become resistant to a certain type of pesticide and then implants that gene into a particular plant's genome, the manufacturer may be able to obtain patent protection on both the pesticide-resistant gene and the plant genome into which it was inserted. The patent on the plant would prevent any person, other than the patent holder, from making, using, offering for sale, selling, or importing the pesticide-resistant plant.¹¹ The patent on the gene would prevent any person, other than the patent holder, from making, using, offering for sale, selling, or importing any organism containing that gene.¹² Thus, the patent on the gene—the plant-related invention—actually has a broader

⁸ Claudio Chiarolla, *Commodifying Agricultural Biodiversity and Development-Related Issues*, 9 J. WORLD INTELL. PROP. 25, 28 (2006).

⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 1197, 1869 U.N.T.S. 299.

¹⁰ *Id.*

¹¹ Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 28, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 1197, 1869 U.N.T.S. 299.

¹² *Id.*

reach than the plant patent, in practice. Because the gene patent provides the patent holder with an exclusive right to the gene, any plant genome into which the gene is inserted effectively becomes patent protected.

Even though plants are *per se* excluded from patentability in some jurisdictions, if that same jurisdiction makes patents on plant-related inventions available, plants that contain plant-related inventions within them, such as genetically-engineered & conventionally-breed plants, will still be *functionally* protectable by patents. Every plant resulting from a patented process or containing a patent-protected, inventive element can be subject to patent protection. If a known plant were modified in some way, for instance if a fish gene were introduced into the plant's genome, it would become a novel transgenic plant that may fall under the scope of patent protection in jurisdictions that grant patents on plant-related inventions.¹³

The scope of the exclusive rights granted to patent holders is much greater than the scope of rights granted to breeders under PVP systems due to the exceptions and limitations to breeders' rights present in most PVP systems. For example, the UPOV provides two important exceptions and limitations to breeders' exclusive rights: the breeders' exemption¹⁴ and the farmers' privilege.¹⁵ The breeders' exemption precludes member states from granting breeders the right to authorize or refrain from authorizing other breeders' use of their protected variety to create new varieties or to market those new varieties.¹⁶ In other words, breeders **may not** wield their rights to prevent other breeders from **creating new varieties** or marketing those new varieties. The farmers' privilege enables farmers to use the seeds (and other propagating materials) of protected plant varieties for noncommercial purposes **without the breeders' prior authorization**. However, the 1991 UPOV, unlike the 1978 UPOV, prohibits farmers from selling or exchanging seeds with other farmers for propagating purposes.¹⁷

Patent systems do not allow for similar exceptions and limitations—there are neither exemptions for the research and development¹⁸ of new plant varieties nor privileges for

¹³ Philip Webber, *Does CRISPR-Cas Open New Possibilities for Patents or Present a Moral Maze?*, 32 NATURE BIOTECH. 331, 332 (2014).

¹⁴ International Convention for the Protection of New Varieties of Plants art. 15(1)(ii), Mar. 19, 1991; International Convention for the Protection of New Varieties of Plants art. 5(3), Oct. 23, 1978.

¹⁵ LAURENCE R. HELFER, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTELLECTUAL PROPERTY RIGHTS IN PLANT VARIETIES INTERNATIONAL LEGAL REGIMES AND POLICY OPTIONS FOR NATIONAL GOVERNMENTS 25, (2004), available at <http://www.fao.org/3/a-y5714e.pdf>.

¹⁶ International Convention for the Protection of New Varieties of Plants art. 15(1)(ii), Mar. 19, 1991; International Convention for the Protection of New Varieties of Plants art. 5(3), Oct. 23, 1978.

¹⁷ HELFER, *supra* note 17, at 29 (citing J. WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 141 (2000)).

¹⁸ A limited exemption for research, or the breeding and developing of new plant varieties, through use of patented biological material might be deemed consistent with the three-step test of Article 30 of TRIPS. However, a comprehensive breeding exemption might conflict with basic premises of patent law. The divergent interests of countries should be considered, and special solutions might be needed for different countries. The vagaries of Article 30 provide good reason for adopting flexible solutions in patent law. See, Prifti Viola, *The Breeding Exemption in Patent Law: Analysis of Compliance With Article 30 of the TRIPS Agreement*, 16 J. WORLD INTEL. PROP. 218 (2013).

farmers that wish to save and exchange seeds for noncommercial purposes. Therefore, plant varieties that include patented traits or are produced via patented technologies will **not be available for further research and development** unless a license has been obtained. Moreover, farmers may not save, exchange, or use the seeds of plants that contain patented traits or were produced via patented technologies.

For more on patents and the differences between patents and plant variety protection, see: *The Differences between Plant Variety Protection and Patent Protection on Plants*, PUBLIC CITIZEN, available at <http://www.citizen.org/documents/differences-between-plant-variety-protection-and-patents-on-plants.pdf>.

Plant-Related Inventions in Europe

In Europe, plants varieties are excluded from patentability.¹⁹ However, plant varieties can be protected by the European Community PVP system provided that they fulfill the criteria of distinctness, uniformity, stability, and novelty set forth in the UPOV Convention.

Some plant-related inventions such as new conventional breeding technologies, new genetics technologies, and isolated genes with specific traits cannot be protected by PVP. Instead, biotechnology patents are used to protect these kinds of inventions. EU Directive 98/44/EC on the legal protection of biotechnological inventions (Biotech Directive) came into force in July 1998.²⁰ The Directive confirmed that plants or animals might be patentable if the technical teaching of the invention (e.g. a genetic modification) is not limited to a particular plant variety.²¹

In 2010, in the landmark broccoli and tomato cases, the Enlarged Board of Appeals of the European Patent Office found that a process for the production of plants comprising the steps of crossing and selection is excluded from patentability even if it contains an additional step of a technical nature, such as the use of molecular genetic markers.²² This case highlighted the importance of more detailed and precise parameters for the patentability of plant-related inventions, such as the definition of essential biological processes, restrictions in the patentability of native traits, and the technological steps required.

Patent law, in general, does not allow for a research and development exception,²³ similar to the UPOV's breeders' exemption, whereby breeders may freely use a patent process or product to develop new plant varieties. Cognizant of the issues this creates in the field of plant

¹⁹ Convention on the Grant of European Patents art. 53(b), Oct. 5, 1973, [13 I.L.M. 276](#) [hereinafter EPC].

²⁰ Council Directive 98/44/EC, 1998 O.J. (L 213) 13 (EC) [hereinafter Directive 98/44], available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:213:0013:0021:EN:PDF>.

²¹ *Id.* at Preamble ¶ 29 (“Whereas this Directive is without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions which concern plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety.”)

²² Tomato I (G 1/08) & Broccoli I (G 2/07).

²³ See *supra* note 18.

breeding, France and Germany²⁴ have introduced an exemption for breeding purposes in their national patent laws.

Furthermore, Article 12 of the Biotech Directive provides for compulsory licensing of PVPs and patents where the existence of one patent or breeders' right hinders the acquisition/exploitation of other rights.²⁵

Even though European patent systems do not allow farmers to reproduce patented seeds for commercial purposes, the Biotech Directive explicitly introduces a farmers' privilege that allows a farmer "to use the product of his harvest for propagation or multiplication by him on his own farm."²⁶ This privilege is specifically designed to safeguard traditional farming practices, such as the utilization of saved seeds from previous harvests.

Conclusion

Patent systems should aim to achieve a balance between access and innovation. To this end, nations should be permitted to maintain certain restrictions on patentable subject matter, to ensure the quality of the patents and their claims, to provide exceptions for the research and development of new plant varieties, and to grant farmers' privileges (allowing farmers to engage in seed saving for personal consumption). These measures should be incorporated into national patent laws in order to maintain biodiversity, protect the livelihood of farmers, and ensure food security.

²⁴ Patentgesetz [PatG] [German Patent Act], Dec. 16, 1980 BGBl. 1 AT 1, § 11(2a) ("The effects of a patent shall not extend to: . . . the use of biological material for breeding, discovery and developing of a new plant variety type.").

²⁵ Directive 98/44/ at art. 12.

²⁶ *Id.* at art. 11(1).