AN EVALUATION OF LEGAL PROTECTION OF NEW PLANT AND ANIMAL VARIETIES UNDER INTELLECTUAL PROPERTY LAW

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> *…..invention may lie in the idea, and it may lie in the way in which it is carried out, and it may lie in the combination of the two; but if there is invention in the ideas plus the way of carrying it out, then it is good subject-matter for Letters Patent.*[1]

ABSTRACT

The article evaluated the legal protection of new plant and animal varieties under intellectual property law. This issue has become a subject of increasing concerns to the international community. Hence, international and regional agreements have been entered into as well as national legislation enacted to address this sensitive subject of biological interventions. It was discovered in the study that though scientific propagation of plant and animal varieties is of ancient times, yet patent laws in some countries, including Nigeria, expressly prohibits the patentability of any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a microbiological process or the products of such a process. The article concludes that though indisputably, ethical and moral questions will inevitably arise in the exploitation of biological interventions, nonetheless, the more fundamental question is how they should be addressed. This is because splicing morality provision into patent laws will result in an unstable fusion.

KEYWORDS: Animal Variety, Breeder's Right, Intellectual Property Right, Patentability, Plant Variety, TRIPS Agreement.

1. INTRODUCTION

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[1] *Hickson's Patent Syndicate v. Patents & Machine Improvements* (1909) 26 R.P.C. 339 at p.348, per Fletcher Moulton L.J.

The scientific propagation or creation of new plant varieties evokes ethical and ecological discussions even within the province of intellectual property law. This biotechnological debate falls within the same controversial arena like the profound issues of genetically engineered animal tissue.[2] Until recent times, such intellectual manipulations which have increasingly stirred controversy would have sounded like science fiction, but some researchers and even non-scientists believe that they are possible.[3] Back in the Bible days, the Book of Genesis records how one of the patriarchs, Jacob, through the inspiration of God, began creating animal varieties using 'rods of green poplar, and of the hazel and chesnut tree; and pilled white strakes in them and made the white appear which was in the rods [a]nd …set the rods which he had pilled before the flocks in the gutters in the watering troughs when the flocks came to drink, that they should conceive…[a]nd the flocks conceived before the rods, and brought forth cattle ringstraked, speckled, and spotted.[4]

It is notable that the development of plant varieties emerged over centuries through the sharing of seeds and the exchange of information among famers. This practice has continued even in modern times among the developed and developing countries. Nonetheless, with the evolution of commercial plant varieties by seed companies, there has emerged a novel pattern of production and dissemination, centered on intellectual property rights. Due to the responsibility required by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), World Trade Organization (WTO) member countries have now seen the vital need of providing some elements of intellectual property protection on plant varieties.[5]

The granting of intellectual property rights, such as exclusive right to the holder, implies that other individuals were barred from using the protected subject matter during the pendency or duration of the protection.

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[2] W. R. Cornish, *Intellectual Property: Patents, Copyright, Trademarks and Allied Rights* (4th ed., Sweet & Maxwell, 1999), p. 785.

[3] Sometime ago there was a report of 'Dolly, the Sheep' which was reputed to be the first world's cloned mammal. It was reported that the technique adopted to clone animals could be applied to prevent people suffering from the mitochondria disease. See *The Guardian*, Thursday, 23 September 1999, p. 25. See also 'Stem Cells: Has Science Gone Too Far?' *Awake!* (Watchtower Bible and Tract Society, 22 November 2002), p.8. See also, H. D. Griffin, 'Dolly: The Science Behind the World's Most Famous Sheep' (Roslin Institute, Edinburg). Available at< www.ri.bbsrc.ac.uk> .Accessed on 22 march 2017.

[4] See *The Holy Bible*, The Book of Genesis, Chapter 30:37-39; Chapter 31:10, King James Version.

[5] Calos M. Correa and Sangeeta Shashikant and Francois Meienberg, *Plant Variety Protection in Developing Countries: A Tool for Designing a Sui Generis Plant Protection System: An Alternative to UPOV 1991*(Association for Plant Breeding for the Benefits of Society [APBREBES], 2015), p.1.

Initially, such rights were intended for mechanical inventions and literary works, but with time, the scope was expanded to cover other fields like living matter. Thus, individual commercial breeder conceived the idea of creating intellectual property rights in the area of plants or animals at the close of the nineteenth century, leading ultimately to the implementation of specific *sui generis* regime in the United States of America and some European countries regarding plant varieties.

The enjoyment of the exclusive right regarding plant variety or breeding was defended on the ground that it would provide encouragement towards the growth of better plant varieties. It was assumed that the creation of new plant varieties had the capacity of increasing and diversifying the pool of seeds or propagating materials and thus, making them available to farmers. However, the adoption of plant varieties under the plant variety protection (PVP) introduced a radical modification to the model of producing and dispersion of plant varieties on the basis of sharing and exchange of seeds among farmers.[6]

Unfortunately, patent laws both in the United Kingdom and in other European Patent Convention countries expressly exempts from patentability:

> *…any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a microbiological process or the product of such a process.*[7]

The position is similar in Nigeria where legislative shield is denied for the protection of plant and animal varieties or essentially biological processes for the production of plants or animals other than microbiological processes and their products. [8] The focus of this article is to examine the various Conventions and legislation that have been enacted to protect new plants and animal varieties and how effective they have been.

2. THE EMERGENCE OF LEGISLATIVE PROTECTION

Intellectual property protection for living organisms, plants, animals and biological processes is not a new or recent occurrence. Proprietary protections specifically for plant and animal varieties have evolved in the United States over the last 60 years and in other countries of Europe. The issue has also become a subject of increasing concerns to the global community. Thus, international agreements and national laws have been

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[6] *Ibid.*

[7] Patents Act 1977, section 1(3)(b) ; European Patent Convention, Article 53(b).

[8] Patents and Designs Act Cap. P2, Laws of the Federation of Nigeria, 2004, section 1(4).

made to encourage patentability of these biological interventions or varieties. This section of the article examines some of these frameworks.

2.1. Patentability of Plant Variety in the United States of America

The idea of providing a legislative shield for the legal protection of new plant varieties through intellectual property rights materialised in the United States of America (USA) at the inception of the nineteenth century. Basically, in the USA, there are three types of patents available, namely, utility patent,[9] design patents,[10] and plant patents.[11] Of the three mentioned procedures of granting patents, only utility and plant patents are relevant for this discussion.

The United States of America was obviously the first country in the world to provide a statutory shield for the protection of plant varieties. This was through the enactment of the United States of America's 1930 Plant Patent Act (PPA) that authorised the granting of patents' rights for asexually reproduced plants varieties, which obviously was distinct from the 'utility patents.'[12] According to the provision of the PPA, a plant variety protected under the legislation afforded the inventor an exclusive right to bar others from asexually reproducing the protected plant and from using, offering for sale or selling the protected plant so reproduced, or any of its part all over the United States of America or from importing the patented plant, or any parts thereof in the country.[13]

A little excursion back to the time when the PPA was introduced reveals that several features of the plant breeding were considered as making plants inappropriate for utility patent protection. One of such possible reasons was that plants were considered as not being patentable since the US Patent Office precedent banned patents from being granted for 'products of

[9] A utility patent may be granted to any person who invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvements thereof, subject also to satisfying the novelty, non-obviousness, utility and written description conditions. See 35 USC 101.

[10] Design patents are granted in respect of any novel, original and ornamental design for an article of manufacture. See 35 USC 171.

[11] A plant patent may be granted to any applicant who invents or discovers and asexually reproduces any distinct and new variety of plant, inclusive of cultivated sports, mutants, hybrids, and newly found seedlings, apart from a tuber propagated plant or a plant found in an uncultivated state. See 35 USC 161.

[12] Carlos M. Correa, *Patent Protection for Plants: Legal Option for Developing Countries* (South Centre, Research Paper 55, 2014), p.6. In the USA, the first utility patent in respect of a plant was granted in *re Hibberd* in 1985 in relation to a variety of corn altered to contain a higher level of tryptophan.

[13] See 35 USC 163.

nature.'[14] Secondly, there were reservations raised regarding the capability of inventors of new plants varieties to satisfy the written explanation obligation required under the utility patent law.[15] Arguably, this later requirement was regarded as constituting a grave hindrance to the patenting of plants for a number of reasons such as, difficulty in describing in writing intricate living organisms such as plants; challenges in differentiating new plant varieties from existing varieties, mostly where the distinction relates to slight differences in colour, fragrance or task; and difficulty and impracticability of providing comprehensive description of the new variety and the nature in which it was reproduced in order to assist third parties in reproducing the variety after the expiration of the patent period.[16]

As a means of addressing the difficulties connected with conformity with the utility patent regime, the PPA ushered in a number of conditions targeted at ameliorating these challenges. Thus, to surmount the 'products of nature' complaint, the PPA stated that only cultivated plants could qualify for protection. The written specification requirement was also relaxed. In this regard, the PPA regime enjoined that no plant patent would be declared illegal on grounds of non-compliance with the written specification requirement so far as the description of the plant 'is as complete as is reasonably possible.'[17]

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[14] In *Ex-Parte Latimer*, Dec. Comm. Pat. 123 (1889), it was held by the US Commissioner of Patents that in order for the material found in nature to be qualified for patent, it was incumbent on the applicant to establish that the material has been modified from its natural condition by providing it with some novel features or functions which it does not have in its natural condition. This 'product of nature' doctrine was later affirmed by the US Supreme Court in the case of *Funk Brothers Seed v. Kalo Inoculant Co.* 333 USC 127 (1948). See also *American Fruit Growers v. Brogdex Co.* 283 US 1, 8 U.S.P.Q. (BNA) 131 (1931). See also Allen Bloom, 'Designer Genes and Patent Law: A Good Fit,' 26 *N. Y. L. Sch. L. Rev*. 1041 (1981); Iver P. Cooper, 'The Patent System and the "New Biology," 8 *Rutgers Computer & Tech. L.J.P*., 1, 18(1980). See also Geertrui Van Overwalle, 'Patent Protection for Plants: A Comparison of American and European Approaches,' (1999) (39)(2) *IDEA: The Journal of Law and Technology*, p. 149.

[15] Under the utility law, it was a necessary condition that in order to secure a legitimate utility patent, an inventor must file a description containing a written account of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to assist any person skilled in the art to which it relates, or with which it is most obviously associated, to make and use the same, as well as setting out the best mode contemplated by the inventor of carrying out his invention. See 35 USC 112.

[16] See 'Plant Patent Law and Practice: Australia, North America and Europe,' Discussion Paper, ARC Discovery Project DP0987639 'Promoting Plant Innovations in Australia: Maximising the Benefits of Intellectual Property for Australian Agriculture,' (Australian for intellectual Centre Property in Agriculture, 2011), p.8.

[17] See 35 USC 162.

However, there were some unsuccessful attempts aimed at amending the PPA with the objective of *inter alia*, including within the range of its patentable subject matter sexually reproduced varieties. The failed attempts culminated in the enactment of a complementary law, the Plant Variety Protection Act 1970 (PVPA),[18] which introduced a 'UPOV-like' protection for sexually-reproduced varieties of plants,[19] but excluded from the plant variety protection 'the seeds, plants, or transplants of okra, celery, peppers, tomatoes, carrots, and cucumbers.'[20] Although the success of enacting the PVPA has been attributed to the politics of plants patenting,[21] but some writers have contended on the contrary that the judiciary, instead of the legislature, was the motivating force behind the expansion of the frontiers of patent protection for plants varieties in the USA.[22]

It is perhaps necessary to discuss some of the court decisions that reshaped the scope of patentability and consequently opened the floodgates for the legal protection of sexually reproducing plants. In *Diamond v. Chakrabarty*,[23] the United States' Supreme Court held that a genetically altered bacterium that was capable of degrading crude oil qualified as patentable subject matter for the purpose of a utility patent. The court pointed out that the mere fact that the subject matter claimed was living was not a bar to patentability. It was the court's opinion that the vital difference is not between living or non-living things, but between products of nature, irrespective of whether it is living or not, and is of human-made inventions. Although the court made a hasty generalization that 'anything under the sun made by man' was patentable, yet it admitted some exemptions to such a sweeping statement. In this respect, the court admitted that only products of

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[18] 7 USC 2321-2582.

[19] See, Mark D. Janis and Jay Kesan, *U.S. Plant Variety Protection: Sound and Fury...?* (2002) 39 *Houston Law Review*, pp.727-778. *Articles by Maurer Faculty.* Paper 430. Available at <http://www.repository.law.indiana.edu/facpub/430. Accessed on 14 March 2017.

[20] See PVPA 1970, section 42. See also Mark D. Janis and Stephen Smith, 'Technological Change and the Design of Plant Variety Protection Regimes, (2013) 82(3) *Chicago-Kent Law Review*, p. 15.

[21] *Ibid*, where the authors expressed the views, *inter alia*, that plant protection under the PVPA 'owes its existence as much (or more) to expediency in the politics of plants patenting as to a clear-eyed normative vision of the appropriate range of protection for types of plant innovation,' and that 'the PVPA emerged not because it was necessarily compelling on its own merits, or because it was an inevitable complement to existing patent protection, but because it appeared to be the politically least objectionable alternative when no consensus could be found for including plants explicitly in utility patent statute,' at pp. 737, 743-744.

[22] 'Plant Patent Law and Practice: Australia, North America and Europe,' *op. cit*., p.9.

[23] 447 US 303 (1980); 65 Law Ed. (2d) 144 (1980).

human ingenuity are patentable, whereas natural laws, human beings and physical occurrences cannot be patented.

Again, in *Ex-Parte Hibberd*,[24] the Board of Patent Appeals and Interferences (BPAI) held that both sexually and asexually reproduced plants are eligible for utility patent protection regardless of whether or not they otherwise qualify for protection under the PPA and the PVPA. As a result of this decision, the US Patent and Trademark Office (USPTO) commenced the granting of utility patents for plants.

However, in *JEM Ag Supply v. Pioneer Hi-Bred International Inc*,[25] the unsettled debate surrounding the patentability of plant variety resurfaced. In the case, Pioneer Hi-Bred International Inc instituted patent violation proceedings against JEM Ag Supply regarding some of its specific patents in respect of hybrid and inbred corn seeds and plants. In its reaction, JEM Ag Supply challenged the legality of the said patent, thereby reopening the old wound of whether plants were patentable subject matter under the utility patent law. The US Supreme Court, by a majority, held that plants were covered by the utility patent statute.[26]

It would therefore, not be out of place to assert that coupled with judicial pronouncements, utility patent statute and the enactment of the PPA and its complementary PVPA, the argument on statutory protection for plants under the general patent Act have now been settled in the United States.[27]

2.1.1. Some Differences in the various categories of plant variety protection in the USA

The significant dissimilarities between the numerous types of plant variety protection in the United States of America can be briefly stated as follows:

(i) The PPA restricts protection to asexual reproduction. Such limitations are neither contained in the PVPA or Utility Patent laws;

(ii) A utility patent allows the applicant to claim multiple parts of the plant, including plant genes coding for non-plant proteins. However, under the PPA, protection is restricted to reproduction of the entire plant, as well as selling and using parts of the plant so reproduced. Additionally, unlike utility patents, plant patents are not available regarding methods of producing plants;

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[24] 227 USPQ 443 (1985).

[25] 534 US 124 (2001).

[26] At the time of this decision, over 1800 utility patent had been granted for seed and plant-related patents. See 'Plant Patent Law and Practice: Australia, North America and Europe,' *op. cit*., p.11.

[27]Geertrui Van Overwalle, 'Patent Protection for Plants: A Comparison of American and European Approaches,' (1999) (39)(2) *The Journal of Law and Technology*, pp. 144,163.

(iii) A utility patent may be employed to claim multiple varieties. Such is not the case for either the PPA or the PVPA;

(iv) The latitude of protection under the PPA and the PVPA is narrowed down to individual plants. On the other hand, depending on the language and type of claim, the scope of protection available under utility patents may extend to other plant varieties; and

(v) The range of protection under the PVPA is subject to a number of exceptions, including farm-saved seed, experimental use, and the breeder's exemption. In contrast, the only exemption to the scope of protection granted by a utility or plant patent is experimental use, which the courts have given a narrow interpretation.[28]

2.2. Plants and Animal Varieties Patent in Europe

In Europe, worries regarding the weakening of the patent system created a robust struggle in relation to the applicability of patents to plants.[29] A special regime for the protection of plant varieties was initiated in the Netherlands in 1942 and followed by Germany in 1953.[30] However, in most countries within the European Economic Community,[31] patentable subject matter is regulated by the European Patent Convention (EPC).

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[28] O. Mills, *Biotechnological Inventions: Moral Constraints and Patent Law*, (Aldershot: Ashgate Publishing Ltd., 2005) at p. 120.

[29] See, Dhār, Biswajit, *Sui Generis Systems for Plant Variety Protection. Options under TRIPS*, p. 4. Available at <http://www.qiap.ca/documents/SGcol1.pdf, >. Accessed on 14 March 2017.

[30]Geertrui Van Overwalle, 'Patent Protection for Plants: A Comparison of American and European Approaches,' (1999) (39)(2) *IDEA-The Journal of Law and Technology*, 143-194 at p. 161. The German law of 1953 provided a significant pattern by exempting breeding activity from liability. See, Mark D. Janis and Jay Kesan, *U.S. Plant Variety Protection: Sound and Fury...?* (2002) 39 *Houston Law Review*, pp.727-778; (2002). *Articles by Maurer Faculty.* Paper 430. Available at <http://www.repository.law.indiana.edu/facpub/430. Accessed on 14 March 2017.

[31]The European Economic Community (EEC) was first established in 1957 when the Treaty of Rome was signed by the six founding members, namely: France, West Germany, Luxembourg, Belgium, Italy and the Netherlands. It was initially anticipated to be an economic union, but with policy initiatives such as the Maastricht Treaty, it gradually progressed into a political, economic and monetary union. Members of the EEC include Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom. As of 2014, the ECC became known as the European Union (EU). But in 2016, the United Kingdom voted to exit the EU, in what is now commonly known as 'Brexit.' See 'Brexit: All you need to know

Article 52 of the EPC provides for patentable inventions. It states that European patents shall be granted for any inventions, in all areas of technology on the condition that they are new,[32] involve an inventive step[33] and are capable of industrial application.[34] However, discoveries, scientific theories, mathematical methods, aesthetic creations; schemes, rules and methods for performing mental acts, playing games or doing business and programmes for computer or presentations of information are excluded from the definition of inventions.[35] Like the position in the United States, there is no general exclusion of living organisms from the range of patentable subject matter under the EPC.[36] But the situation regarding the patentability of plants and animals varieties in Europe is significantly more complex than in the United States, for some reasons.

First, the EPC specifically forbids the granting of patents regarding plant or animal varieties.[37] This prohibition echoes the fact that at the time the EPC was negotiated and entered into force, the UPOV Convention contained a prohibition on dual protection of plant varieties both by patent law and plant variety rights (PVR).[38] Unfortunately, although the exclusion on dual protection has since been removed from the 1991 revised version of the UPOV Convention, the prohibition is still reserved under the EPC. Secondly, the EPC disallows the granting of patents in respect of 'essentially biological processes for the production of plants or animals.[39] It also stipulates that patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to "*ordre public*" or morality.[40] Thirdly, methods for treatment of the human or animal body by

about the UK leaving the EU,' *BBC News*. Available at <http://www.bbc.com/news/uk-politics-32810887>. Accessed on 20 March 2017.

[32] European Patent Convention, Article 54.

[33] *Ibid*, Article 56.

[34] *Ibid*, Article 57.

[35] *Ibid*, Article 52(2)(a)-(d).

[36] *Ciba-Geigy/Propagating Material* T49/83 [1979-85] EPOR C758, at p. 759.

[37] EPC, Article 53(b).

[38] In order to ensure that plant breeders were prevented from securing patent protection and plant variety protection for the same plant variety, it was decided that the two Conventions should be mutually exclusive. Thus, an applicant could be granted a plant variety right or patent protection, but not both. See B. Sherman and L. Bently, *Intellectual Property Law* (2nd ed., Oxford: Oxford University Press, 2004), at p. 426. See also 'Plant Patent Law and Practice: Australia, North America and Europe,' *op. cit*., p.12.

[39] EPC, Article 53(b). This does not include microbiological processes or the products thereof.

[40] EPC, Article 53(a).

surgery or therapy and diagnostic methods practised on the human or animal body are also excluded from patentability.[41]

Though the debate on the latitude of the exemption of plant varieties from protection is now reasonably settled, there are concerns regarding the purview of the prohibitions in relation to the phrase, 'essentially biological processes' as well as inventions the publication or exploitation of which would be contrary to public order or morality. In *Ciba-Geigy/Propagating Material*,[42] the EPO held that the exclusion 'prohibits only the patenting of plants or their propagating material in the genetically fixed form of the plant variety.' On the other hand, plant innovations 'which cannot be given the protection afforded to varieties are still patentable if the general requirements (of novelty, inventive step, and industrial application] are met).'

This interpretation was also followed in *Lubrizol/Hybrid Plants*,[43] in which claims to hybrid seed and plants were held to be patentable on the ground that at least one of the parent plants is heterozygous with respect to a specific trait and hence will never breed true, with the result that the subsequent generations of plants, consider as a whole population, were not stable and therefore could not be considered as a 'variety.' The EPO also held that the inquiry of whether or not a process is 'essentially biological' had to be determined on the 'basis of the essence of the invention' taking into consideration the 'totality of human intervention and its impact on the result achieved.' Thus, human intervention was not, in itself, sufficient to bring the process outside the exclusion.

Similarly, in *Novartis/Transgenic Plant*,[44] the Enlarged Board of Appeal of the EPO provided further clarification of the ambit of the prohibition. In particular, the Board held that the exclusion only applies to claims specifically directed to a particular plant variety. This means that claims to plants will be allowed even if they encompass a plant variety, so long as they do not individually claim specific plant varieties.[45]

Moreover, in December 2010, decisions made by the Enlarged Board of Appeal of the European Patent Office stated that essentially biological processes, making use of gene markers for selection, were not patentable subject matter, though it failed to pronounce on products obtained from these

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[41] EPC, Article 53(c). However, this exclusion provision shall not apply to products in particular substances or compositions, for use in any of these methods.

[42] T49/83 (1979-85) EPOR C758; (1984) O. J. EPO 112.

[43] T320/87 (1990) EPOR 173; (1990) O. J. EPO 59.

[44] G01/98 [2000] EPOR 303.

[45] *Novartis/Transgenic Plant* G01/98 [2000] EPOR 303, at p. 322. The decision thus overrules the earlier decision of the Technical Board of Appeal of the EPO in *Plant Genetic Systems/Glutamine Synthetase Inhibitors (Opposition by Greenpeace)* T356/93 [1995] EPOR 357, in which the Board held that claims that encompassed or included within their scope a plant variety could not be patented.

processes.[46] But in its subsequent March 2015 decisions in *Tomato 11*[47] and *Broccoli 11*[48] which addressed the issues of patentability of plants and plant parts created by orthodox breeding processes, it was the Board's view that products emanated from using essentially biological methods might be patentable although the procedure used to obtain the product (i.e. selecting and crossing the plants) is essentially biological and consequently not patentable. Apparently, the patentability of such product, it would appear, runs in potential conflict with the legal protection accorded to plant varieties under EU plant variety legislation in relation to access to genetic resources.[49]

These decisions no doubt sparked some waves of controversy among various groups, including plant breeders and at the European Parliament, resulting in an instantaneous EPO's issuance of a notice staying proceedings on all patent examination and opposition proceedings in which the product 'depends entirely on the patentability of a plant or animal obtained by an essentially biological process.'[50] The stay order, which had since been lifted, [51] was prompted by a Notice from the European

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[46] See *Broccoli/Plant Bioscience*, OJEPO 2012, p.130 (G 0002/07) and *Tomatoes/ State of Israel*, OJ EPO 2012, p.206 (G1/08), both decided on 9 December 2010.

[47]OJ EPO 2016, A27 (G2/12), which involved EP No. EP 1211926. Available at <http://www.epo.org/law-practice/case-law-appeals/recent/g120002ex1.html>. Accessed on 9 February 2018.

[48]OJ EPO 2016, A28 (G2/13), which relates to EP Patent No. EP 1069819. Available at <http://www.epo.org/law-practice/case-law-appeals/recent/g130002ex1.html>. Accessed on 9 February 2018.

[49] See for instance, see Council Regulations (EC) No. 2100/94 of 27 July 1994 on Community Plant Variety Rights (OJL 227, 1.9, p. 1), Article 15.

[50] See 'Notice from the European Patent Office dated 24 November 2016 concerning the Staying of Proceedings
due to the Commission Notice on certain Articles of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions,' para. 4. Available at <https://www.epo.org/law-practice/legal-texts/official-journal/information-epo/archive/20161212.html>. Accessed on 9 February 2018. See also generally Jennifer Best-Martin and Peng Sun, 'EPO Stays Proceedings over Patentability of Plants and Animals.' *The National Law Review*, 3 January 2017. Available at. <https://www.natlawreview.com/article/epo-stays-proceedings-over-patentability-plants-and-animals>. Accessed on 9 February 2018.

[51] It is noteworthy that on 29 June 2017, the EPO Administrative Council, whose memberships are drawn from representatives of governments of EU member States, adopted changes to the Implementation Regulations to the EPC. The new Rule 28(2) EPC which came into force on 1 July 2017 requires that under Article 53(b) EPC, European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process. See generally, OJEPO 2017, A56- Notice from the EPO dated 3 July 2017. Available at <https://www.epo.org/law-practice/legaltexts/official-journal/information-epo/archieve/20170704.html>. Accessed on 9 February 2018. See also Jim

Commission (EC) concerning Directive 98/44/EC on the legal protection of biotechnological inventions.[52] In the Notice, the EC concluded that plants or animals derived from essentially biological processes are not patentable under the Directive.[53] Whether the end to this controversy is yet in sight is uncertain as there are some muted ideas challenging the legality of the newly introduced Rule 28(2) of the Implementing Regulations in the face of the subsisting Enlarged Board of Appeal decisions of *Tomato 11* and *Broccoli 11*.[54] It is candidly submitted though that this latest emergency innovations introduced into the EPC Rules may possibly have been aimed at bringing the EPC into compliance with the requirements of the Directive, not only by reflecting the commitments of EU member States belonging to the Organization but essentially to conform with the obligation for uniformity in harmonized European patent legislation.[55]

Robertson, 'Is New Rule 28(2) EPC Unenforceable?-Plant Patents at the EPO and Exclusions from Patentability. Available at <https://www.wynne-jones.com/news-events/2017/07/is-new-rule-28-2-epc-unenforceable-plant-patents-at-the-epo-and-exclusions-from-patentability/>. Accessed on 9 February 2018.

[52] The Directive 98/44/EC was adopted on July 6, 1998. It arose from attempts aimed at coordinating patent eligibility criterions for biotechnological inventions among the different member States of the European Union. See generally, '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,' Official Journal of European Union, Available at<http://eur-lex.europa.eu/legal-content.EN/TXT/?qid=1483121771896&uri=CELEX:52016XC1108(01)>. Accessed on 9 February 2018.

[53] See section 4 of the Directive. Section 2(2) of the Directive further defines 'an essentially biological process' as consisting entirely of natural phenomena such as crossing and selection. Nonetheless, the Directive failed to state if plants or plant material (e.g. fruits, seeds, etc.), or animals or animal material obtained through essentially biological processes can be patented.

[54] Jim Robertson, 'Is New Rule 28(2) EPC Unenforceable?-Plant Patents at the EPO and Exclusions from Patentability. Available at <https://www.wynne-jones.com/news-events/2017/07/is-new-rule-28-2-epc-unenforceable-plant-patents-at-the-epo-and-exclusions-from-patentability/>. Accessed on 9 February 2018.

[55] The likely implication of the two sets of legal framework which focus on exclusion from patentability of plant and animal varieties is that the EPO would have to take the two sets of legislation into account while examining the patentability of plant-related or animal-related inventions and in the events of any conflict between the two sets of provisions, it would seem that the EPC, rather than the Implementing Regulations of the EPC, would prevail. See Article 164 (2) of the EPC. See also decisions/opinions of the Enlarged Board of Appeal in '*Replacement of Application Documents/ATOTECH*,' OJ EPO 1996, p. 555 (G2/95), decided on 14 May 1996; '*Interpretations of Rule 71a (1) EPC/ GE CHEMICALS*, OJ EPO 1996, p. 649 (G6/95), decided on 24 July 1996; and '*Formalities Officers' Powers*,' OJ EPO 2003, p. 165 (G1/02), opinion of 22 January 2003.

On the other hand, the implication of *ordre public* and 'morality' was deliberated upon by the EPO in *Plant Genetic Systems/Glutamine Synthetase Inhibitors (Opposition by Greenpeace)*.[56] In the case, the EPO held that the concept of *ordre public* covers the protection of public security and the physical integrity of individuals as part of society, as well as protection of the environment, while the doctrine of 'morality' refers to the totality of accepted norms of conduct inherent in the European society.[57] In the instant case of *Plant Genetic Systems*, Greenpeace opposed the grant of a patent for genetically-modified seeds and plants that were resistant to a particular class of herbicides, namely the glutamine synthetase inhibitors, on the ground that the exploitation of the patent would damage the environment, and thus was contrary to public order and/or morality. This contention was rejected by the Technical Board of Appeal of the EPO.

Similarly, in *Harvard/Onco-mouse*,[58] the EPO applied a 'cost/benefit approach' in determining whether the exploitation of a patent for a genetically-modified mouse that is susceptible to develop cancer was contrary to public order or morality. Evaluating the qualified advantages and costs connected with the proposed use of the invention in cancer research, the EPO held that the potential gains to be achieved from such research overshadowed the harm and suffering occasioned to the mice. The mouse was therefore regarded as patentable.[59]

But contrary to the position it held in the *Harvard/Onco-mouse*, the EPO summersaulted in a later case of *Upjohn's Application (Hairless Mouse)*,[60] which involved a genetically-altered mouse disposed to develop hair-loss that was planned to be employed in a research study intended to discover the treatment for curing baldness. Applying the similar 'cost-benefit or balancing test' adopted in the earlier *Harvard/Onco-mouse case*, the EPO held that the likely harm and suffering to be caused to the mice was more than the likely profit to be gained from such study. It was reasoned by the EPO that hair growth did not constitute 'any serious threat to human beings' and accordingly the exploitation of the claimed invention was regarded as being contrary to public order or morality and was consequently denied patent.[61]

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[56] T356/93 [1995] EPOR 357.

[57] *Plant Genetic Systems/Glutamine Synthetase Inhibitors (Opposition by Greenpeace)* T356/93 [1995] EPOR 357, at p. 366.

[58] T19/90 [1990] EPOR 501.

[59] The patent application was eventually accepted in 2004 when proceedings in the EPO were finally concluded.

[60] (1991) EP 89 913 146.0 (unreported), referred to in Amanda Warren-Jones, 'Vital Parameters for Patent Morality-A Question of Form,' (2007) 2 (12) *Journal of Intellectual Property Law and Practice*, 832 at p. 835.

[61] See also 'Plant Patent Law and Practice: Australia, North America and Europe,' *op. cit*., p.16.

From the conflicting decisions in *Harvard/Onco-mouse* and *Upjohn's Application (Hairless Mouse)* cases, at least in relation to granting patent to animal varieties, it is apparent that there is no clear-cut methodological factor (including the 'balancing test') for determining the scope of the exclusion from patentability of inventions, the commercial exploitation of which would be considered as being contrary to public order or morality as well as the means by which it is to be applied. There is therefore, need for a recognisable process in which this exclusion can be applied reliably, impartially and transparently.[62]

2.3. Plant Variety Patent under UPOV Convention

The International Union for the Protection of New Varieties of Plants (UPOV) is an intergovernmental organisation based in Geneva, Switzerland. UPOV was created in 1961 by the International Convention for the Protection of New Varieties of Plants (the UPOV Convention).[63] The primary task of UPOV is the provision and promotion of an operative system of plant variety protection (PVP), with the goal of encouraging the development of new varieties of plants,[64] for the benefit of the society.[65]

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[62] See generally, Amanda Warren-Jones, *op. cit.,* pp.832-846. See also Cynthia M. Ho, 'Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men,' (2000) 2 *Washington University Journal of Law & Policy*, pp. 247-285. Available at http://openscholarship.wustl.edu/law_journal_law_policy/vol2/issl/9. Accessed on 18 March 18, 2017.

[63] The Convention was subsequently revised in 1972, 1978 and 1991. Although the first two revised versions of the Convention did not significantly change the system of plant variety protection (PVP), the 1991 revised version substantially introduced modifications. It extended and reinforced the rights granted to breeders while also curtailing the rights of farmers to save, use and exchange seeds. See Carlos M. Correa and Sangeeta Shashikant and Francios Meienberg, *Plant Variety Protection in Developing Countries*: *A Tool for Designing a Sui Generis Plant Variety Protection System: An Alternative to UPOV 1991*(Association for Plant Breeding for the Benefit of Society [APBREBES], 2015), p.10. See also, André Heitz, 'The History of Plant Variety Protection,' in *UPOV, The First Twenty-five Years of the International Convention for the Protection of New Varieties of Plants* (Geneva, 1987).

[64]The UPOV Convention defined 'variety' as a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one of the said characteristics and considered as a unit with regard to its suitability for being propagated unchanged. See 1991 UPOV Convention, Article 1(vi).

[65]Most countries and intergovernmental organisations that have initiated a plant variety protection (PVP) system have elected to adopt the UPOV Convention system

The UPOV 1991 spelt out the conditions for the grant of breeder's right.[66] The stipulated criteria are:

(i) **Novelty**
The plant variety must be new. The variety would be considered to be novel if at the material time of filing the application for a breeder's right, propagating or harvested material of the variety has not been sold or otherwise disposed of to others by or with the consent of the breeder, with the intention of exploitation of the variety within a period of one year in the territory of the contracting party or within a period of four years (six years with regard to trees or of vines) in another country.[67]

(ii) **Distinctiveness**
In this respect, the variety must be obviously distinguishable from any other variety whose existence is a matter of general knowledge at the material period of filing of the application.[68] The yardstick for measuring the distinctiveness of the variety may be seen as occupying an inaccurate correspondence to the patent law concept of prior art. Distinctive factors, it should be noted include colour, shape, leaf-length and mildew resistance.[69]

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of protection. As of October 31, 2016, UPOV had 74 members; fifteen States (including Egypt, Ghana and Zimbabwe) and one intergovernmental organisation (African Regional Intellectual Property Organisation (ARIPO) had commenced the procedure for acceding to the UPOV Convention; whilst twenty-five other States and one intergovernmental organisation had been having interaction with the office of the Union for vital assistance towards the development of laws based on the UPOV Convention. Nigeria is not listed as a member of UPOV; Kenya became bound by the 1991 revised version on May 11, 2016. For a list of membership of the UPOV Convention, see <http://www.upov.int/members/en/>. Accessed on 18 March 2017.

[66] It is noteworthy that the breeder's right does not extend to acts done (i) privately and for non-commercial purposes, (ii) for experimental purposes and (iii) for the purpose of breeding other varieties. See 1991 UPOV Convention, Article 15.

[67] 1991 UPOV Convention, Article 6.

[68] 1991 UPOV Convention, Article 7.

[69] Jeremy Phillips, *et. al*., *Introduction to Intellectual Property Law* (3rd ed., Butterworths, 1995), p. 357; *Maris Druid-Spring Barley* (1968) FSR 559. It is to be noted that the 1978 UPOV version spelt out various factors that may be taken into consideration in determining the distinctiveness of a variety (such as, 'cultivation or marketing already in progress, entry in an official register of varieties already made or in the process of being made, inclusion in a reference collection, or precise description in a publication'). But no such possible factors are mentioned in the 1991 UPOV revised version. This flexibility accordingly provides opportunity for UPOV contracting parties to decide the extent of the 'common knowledge' requirement. However, the 1991 revised version, unlike its immediate predecessor, limits the

(iii) **Uniformity**

The plant variety must be uniform. The variety shall be considered to be uniform if, subject to the variation that may be expected from the particular features of its propagation, it is satisfactorily uniform in its relevant characteristics.[70]

(iv) **Stability**

The variety shall be deemed to be stable if its material features remain unchanged after repeated propagation or in the case of a particular cycle of propagation, at the end of each such cycle.[71] The stability condition is closely associated with uniformity as it means in practice, 'continuous uniformity.'[72] The stability requirement further reinforces the pattern towards uniformity and the erosion of the genetic origin and genetic diversity.[73]

It is worthy of note that the grant of breeder's right under the UPOV Convention shall not be subject to any further or additional conditions, except that the variety is designated by a denomination in accordance with the requirement of Article 20 of the Convention, that the applicant complies with the bureaucracies required by national law of the contracting party with whose authority the application has been filed and that he pays the necessary prescribed fees.[74] In this regard, it is submitted that the Agreement on Trade-Related Aspect of Intellectual Property Rights (TRIPS Agreement) is more relaxed than the UPOV Convention as the former does not state what criteria are to be applied to grant PVP.

2.4. Plant and Animal Variety Patentability under the TRIPS Agreement

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) is a multilateral agreement on intellectual property that

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possibility of deeming as part of that knowledge a variety in the process of obtaining breeder's right protection or being entered in an official register of varieties, since the variety will only become part of 'common knowledge' if breeder's right is ultimately granted or the variety is registered. See generally 1991 UPOV Convention, Article 7.

[70] 1991 UPOV Convention, Article 8.

[71] 1991 UPOV Convention, Article 9.

[72] Dan Leskien and Micheal Flitner, 'Intellectual Property Rights and Plant Genetic Resources: Options for a *Sui Generis* System,' *Issues in Genetic Resources*, No. 6 (International Plant Genetic Resources Institute, Rome, June 1997), p.52. Available at http://www.bioversityinternational.org/publications/Pdf/497.pdf. Accessed on 21 March 2017.

[73] Carlos M. Correa and Sangeeta Shashikant and Francios Meienberg, *op. cit*., p. 33.

[74] 1991 UPOV Convention, Article 5(2).

was produced in 1994 as part of the 'Uruguay Round' negotiation of the General Agreement on Tariffs and Trade (GATT).[75] In its preamble, the TRIPS Agreement mirrors the aspiration of WTO Members:

> ... to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.

In addition, the notable aim of the TRIPS Agreement is to 'contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare, and to a balance of rights and obligations.'[76]

As a means of accomplishing its stated aspiration and goal of improved trade liberalisation, the TRIPS Agreement foists a responsibility on all WTO Members to afford minimum criterions of intellectual property (IP) protection. Thus, members are mandated to provide and enforce a variety of intellectual property rights (IPRs), including copyright, patents, trademarks, industrial designs and geographical indications, without discrimination as to the nationality of the right holder.[77] The TRIPS Agreement made the protection of plant varieties compulsory. Countries that are neither member of the World Trade Organisation (WTO) nor of UPOV have discretion of determining whether or not to create a PVP. If they make such a decision, they are equally at liberty to elect the extent or other features of such protection.

On the other hand, WTO members[78] are required by the TRIPS Agreement to protect plant and animal varieties.[79] In this respect, the Agreement states that '…patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they

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[75] For a detailed discussion see D. Gervais, *The TRIPS Agreement: Drafting History and Analysis*, (2nd ed., Sweet & Maxwell 2003). See also Gerard, Porter, *Human Embryos, Patents and Global Trade: Assessing the Scope and Contents of the TRIPS Morality Exception*, (Edinburg School of Law Working Paper Series No. 2010/27), p.1. Available at <http://ssrn.com/abstract=16633027>. Accessed on 20 March 2017.

[76] TRIPS Agreement, Article 7.

[77] TRIPS is administered by the WTO, and disputes between WTO members regarding the interpretation of TRIPS and its implementation in national laws are subject to the WTO dispute settlement system. See Gerard, Porter, *op. cit*.

[78] As of July 2016, the WTO has 164 members. Nigeria became a member of WTO on 1 January 1995.

[79] TRIPS Agreement, Article 27(1).

are new, involve an inventive step and are capable of industrial application.'[80] Moreover, subject to the provisions of Articles 65(4), 70(8) and 27(3), patents shall also be available and patent rights enjoyable without discrimination as to the place of inventions, the field of technology and whether products are imported or locally produced.

It is worthy of note that the obligation to grant protection to plant varieties does not however, cover WTO members which are 'least-developed countries' (LDCs) as they are permitted a provisional period of grace till 1 July 2021 within which period they are not bound to adopt the TRIPS standards. This window period is subject to further extension upon duly motivated request by an LDC member.[81]

To the general rule of patentability granted under Article 27(1) of the TRIPS Agreement, Articles 27(2) and 27(3) thereof make provision for a number of limitations to the rule. For instance, Article 27(2) mandates that WTO members may decline granting patents for inventions, the commercial exploitation of which would be contrary to *ordre public* or morality. As a consequence of this, WTO members may deny their consent or refuse to grant patents for inventions where this is vital to protect human, animal or plant life or health or to prevent grave influence to the environment.[82]

The wordings and core guiding principles or objective of the 'TRIPS morality exclusion' contained in Article 27(2) has been described as lacking in clarity and 'shrouded in ambiguities' thereby leading to 'low-intensity academic debate.'[83] Some divergent views have been expressed regarding the meaning of the provision. A survey of literature discloses four divergent academic opinions. Some groups have expressed the opinion that WTO members must first disallow the commercial exploitation of an invention within its territory before it is authorised to exempt the invention from patentability on moral grounds.[84] Another group reasons that the provision

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[80] This is similar to the provision under the EPC, Article 52. It is submitted that for the purposes of this provision, the terms, 'inventive step' and 'capable of industrial application' may be deemed by a member to be interchangeable with the terms, 'non-obvious,' and 'useful,' respectively.

[81] See for instance, TRIPS Agreement, Article 66.

[82] 'Plant Patent Law and Practice: Australia, North America and Europe,' *op. cit*., p.7.

[83] Gerard, Porter, *op. cit*, pp. 1, 7.

[84] P. Van Den Bossche, *The Law and Policy of the World Trade Organisation: Text, Cases and Materials*, (2nd ed., Cambridge University Press, 2008), p. 785, where he postulated that, 'the link between the use of the exception and the prevention of commercial exploitation of the invention in the territory of the member aims to ensure that this exception is not used to deny patent protection to an invention on public order or morality grounds, while the invention itself is in fact commercially exploited in the member.'

merely entails the decision of a competent authority[85] that a prohibition is vital to protect morality, but does not foist any legal condition for the members to adopt constructive steps to bar the actual commercial exploitation of the invention.[86] A third divergent opinion is that WTO panel, while reconsidering a member's decision to exclude an invention from patentability on grounds of *ordre* public or morality, would adopt the 'necessity test' used in scrutinising processes applied under the 'exceptions clauses' applicable in other WTO agreements.[87] Finally, according to a fourth group, 'morality test' of the provision would be determined by the 'morality jurisprudence' of the European Patent Office that has been developed regarding Article 53(a) of the EPC.[88]

It is submitted that it is crucial that the provisions of Article 27(2) should be read and considered carefully in conjunction with Article 27(1) and Article 30[89]to arrive at a possible reasonable interpretation and understanding of that provision. Thus, the most reasonable interpretation of Article 27(2) is the suggestion put forward by Bossche to the effect that a WTO member must

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[85] Like a legislative body or an individual patent examiner.

[86] Dan Leskien and Micheal Flitner, *op. cit*. Leskien and Flitner submitted that the TRIPS Agreement 'does not require an actual ban on the commercialization as a condition for exclusion; only the necessity to patent-by whatever means-the commercial exploitation of the invention. Yet the member state would not have to prove that under its national laws the commercialization of the invention was or is actually prohibited,' *ibid*, at p.15. See also Carlos M. Correa, *Trade-Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford University Press, 2007), p. 291.

[87] Like Article XX of GATT as well as Article XIV of the General Agreement on Trade in Services (GATS). GATT and GATS are multilateral agreements that stipulate the fundamental principles for global trade in goods and services, respectively. The two agreements seek to remove barriers to trade through the creation of a non-discriminatory trading arrangement. See generally Gerard Porter, *op. cit.* pp.2-17. See also C. Henekels, 'The Ostensible Flexibilities in TRIPS: Can Essential Pharmaceuticals Be Excluded from Patentability in Public Health Crises? 32 *Mosnash U. L. Rev*. 335-356 at pp. 348-351; P. Van Den Bossche, *op. cit*., pp. 639-640.

[88] This group's view is simply that since the term, '*ordre* public or morality' was imported from the EPC's Article 53(a), the latter's judicial interpretation in some case laws would certainly influence the intrepretation under the TRIPS Agreement. See N. Pires de Carvalho, *The TRIPS Regime of Patent Rights*, (Kluwer Law International, 2002), pp. 171-172. For an overview of the morality interpretation under the EPC, see generally Amanda Warren-Jones, *op. cit*., pp. 832-846.

[89] Which states that '[m]embers may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.'

first exclude the commercial exploitation of the invention within its domain before legally preventing its patentability. Failure to do so will imply that it cannot later purportedly fall back on Article 27(2) to rationalise diverging from its central responsibility under Article 27(1) of making patents available without discrimination as to the field of technology.[90]

Furthermore, by Article 27(3), WTO members are additionally authorised to exclude from patentability: (i) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and (ii) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.[91] But members are enjoined to make allowance for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. [92] This requirement encouraged a large number of developing countries to join UPOV and to adopt national statutes fashioned after the UPOV Convention, whose membership considerably increased since 1995. A few developing countries like, Egypt, India,[93] Malaysia and Thailand, enacted *sui generis* laws that,

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[90] This line of reasoning equally corresponds with a primary standard cutting across the whole WTO agreement, namely, that departure from WTO requirements should not be treated lightly. See Appellate Body Report, *United States-Measures Affecting the Cross-Border Supply of Gambling and Betting Services (US-Gambling)*, WT/DS285/AB/R (Adopted 20 April 2005), para. 308. See also Gerard Porter, *op. cit.* pp. 3, 18.

[91] This provision of the TRIPS Agreement was clearly stimulated by the EPC of 1973. Article 53(b) of the EPC stipulates that European patents shall not be granted in respect of 'essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.' Indisputably, although the TRIPS Agreement has factually followed this EPC text, there are two significant dissimilarities with the EPC version. On the one hand, the exclusion under the latter is mandatory, while it is only optional under the TRIPS Agreement. This is a vital distinction, since members of the EPC are obliged to respect the exclusion. Secondly, the TRIPS Agreement initiates the idea of 'non-biological' processes which is absent in the EPC. Carlos M. Correa, *Patent Protection for Plants: Legal Options for Developing Countries* (South Centre, Geneva, October 2014) Research Paper 55, p.15.

[92] Although no definition was given to the phrase, "effective *sui generis* system," nonetheless potential member states were mandated to make such system available as far back as the end of 1999 if they chose this as a substitute to patenting and also if they intended to avoid punitive trade sanctions. See generally, TRIPS Agreement Article 27(3)(b).

[93] For instance, India enacted the Protection of Plant Varieties and Farmers' Rights (PPVFR) Act, 2001. The Act, a *sui generis* system, is an attempt by the Indian government to recognise and protect the rights of both commercial plant breeders and farmers in respect of their contribution made in conserving, improving and making available plant genetic resources for development of new plant varieties and

though are not absolutely conforming to the requirements of UPOV, became subject to the disciplines of the TRIPS Agreement.[94]

Since the TRIPS Agreement does not specify the concept of 'plant varieties,' WTO members are therefore, free to adopt a narrow[95] or broad definition of the term,[96] depending on each particular countries' conditions and the goals being sought. This is a decisive in-built flexibility of the Agreement.[97]

2.5. Plant and Animal Variety Patentability under Nigerian Statute

In Nigeria, it must be stated that though she is a member of the World Intellectual Property Organisation (WIPO) and many other regional and international organisations as well as a signatory to many international Conventions, yet by virtue of Section 1(4) of the Patents and Designs Act,[98] patent cannot be validly obtained in respect of:

(a) plant or animal varieties, or essentially biological processes for the production of plants or animals (other than microbiological processes and their products); or
(b) inventions the publication or exploitation of which would be contrary to public order or morality (it being understood for the purposes of this paragraph that the exploitation of an invention is not contrary to public order or morality merely because its exploitation is prohibited by law).

Given the above statutory provisions surrounding the patenting of plant and animal varieties in Nigeria, it is perhaps not an exaggeration to contend that in Nigeria, though an invention is patentable if it is new, results from inventive activity and is capable of industrial application; or if it constitutes an improvement upon a patented invention and also is new, results from

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to encourage the development of new plants varieties. Four types of plant varieties can be registered under PPVFR Act, 2001. The following plant species can be registered under the Act, namely, Cereals (Rice, wheat, maize, sorghum, pearl millet); Legumes (Chickpea, *mungbean*, *urdbean*, field pea, *rajmash*, lentil, pigeon pea) and Fibre Crop(cotton and jute, etc.). See generally Malathi Lakshmikumaran and Rajani Jaiswal, 'Plant Variety Protection in India,' (2009). Available at<www.lslaw.in>. Accessed on 23 March 2017.

[94] Carlos M. Correa, *ibid*, p.7.

[95] Like, restricting protection to plant varieties as defined under UPOV on the basis of uniformity, distinctiveness, novelty or stability.

[96] Based on equity or other reasons, to plant groupings that are comparatively heterogeneous and not stable, such as farmers' varieties. The only condition for introducing such wide-ranging protection is that it should not be inconsistent with other requirements of the TRIPS Agreement. See TRIPS Agreement, Article 1 (1).

[97] Carlos M. Correa and Sangeeta Shashikant and Francios Meienberg, *op. cit*., p. 16.

[98]Cap. P2, Laws of the Federation of Nigeria, 2004.

inventive activity and is capable of industrial application,[99] nonetheless, with respect to plant and animal varieties' patent, the application would not be granted.

While there are no decided case laws regarding the patentability of plant and animal varieties or the imports of the phrases, 'essentially biological processes' and 'public order or morality' in the Nigerian context, yet it is submitted that their legal implications would not be too dissimilar from what those terms have been help to imply in other foreign jurisdictions examined. For instance, with respect to the 'morality jurisprudence approach' under Article 53(a) of the EPC, the EPO have adopted different tests such as weighing and balancing the harms and benefits of the commercial exploitation of the invention, [100] the 'standard of morality inherent in European society and civilisation,' [101] and 'public abhorrence' test [102] to determine the patentability of new varieties.

3. INFRINGEMENT AND REMEDIES FOR PATENT RIGHTS

Section 25 of the patent and designs Act defines infringement of a patent as the doing or causing the doing of any act, without the licence of the patentee, of any act which that 'other person is precluded from doing under sections 6 or 9' of the Act. For instance, a patentee's right can prevent any other person from doing any of the following acts:

(i) where the patent has been granted in relation to a product, the act of making, importing, selling or using the product, or stocking it for the purpose of sale or use;[103] and

(ii) in respect of patent granted for a process, the act of applying the process or doing in relation to the product obtained directly by means of the process, any other acts mentioned in paragraph (i) above.

It is worthy of note in this regard that the rights under a patent extend only to acts done for industrial or commercial purposes. They do not apply to acts done in relation to a product protected by the patent after the product has been validly sold in Nigeria unless in the case of the patent making provisions for a special application of the product, in which circumstance, the special application shall continue to be reserved to the patentee.[104]

Where a patentee's right has been infringed upon, the law allows him to seek appropriate remedies from the court of law. As a matter of fact, some

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[99] *Ibid*, section 1(1)(a) and (b).
[100] *Harvard/Oncomouse* (1990) OJ EPO 476.
[101] *Plant Genetic Systems* (1995) EPOR 357.
[102] *Howard Florey/H2 Relaxin* (1995) EPOR 541.
[103] Patents and Designs Act, section 6 (1)(a).
[104] *Ibid*, section 6 (3)(a) and (b).

international agreement[105] and national laws[106] also make provisions for such remedies. Such available remedies include order of injunctions, [107] damages, [108] account of profits, [109] delivery up or destruction, [110] and a

[105] See for instance, the TRIPS Agreement, which in its Article 42 requires members to make available to 'right holders civil judicial procedures concerning the enforcement of any intellectual property right' protected by the Agreement.

[106] Patents and Designs Act, *op. cit*., section 25(2).

[107] *Pfizer Inv. v. Polyking Pharmaceutical Ltd* (1992) FHCL 372; *Crossley v. The Derby Gas Ltd Co*. (1834) 4 LT Ch. 25, where the court held that an order of injunction to prevent a person selling after expiration of patent an article made during the subsistence of the patent can be granted. See also TRIPS Agreement, Article 44 which states thus: '[t]he judicial authorities shall have the authority to order a party to desist from an infringement, *inter alia* to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.'

[108] See TRIPS Agreement, Article 45. For assessment of damages, see *General Tire & Rubber Co. v. Firestone Tyre & Rubber Co. Ltd* (1975) 2 All ER 173 at 185, where Lord Wilberforce stated the basic principles as follows: ' [a]s in the case of any other tort…the object of damages is to compensate for loss or injury. The general rule at any rate in relation to "economic" torts is that the measure of damages is to be, so far as possible, that sum of money which will put the injured party in the same position as he would have been in if he had not sustained the wrong.' See also *South Australia Asset Management Corp. v. Montague Ltd* (1996) 3 WLR 87; *Gerber Garment Technology Inc v. Lectra Systems Ltd* (1997) RPC 443 at 453, where Lord Justice Staughton further stated thus: '…at first impression the Patents Act is aimed at protecting patentees from commercial loss resulting from the wrongful infringement of their rights....' However, it must be added that if the patentee has been exploiting the patent by granting licences to others in return for royalties, then his loss would be the capitalised value of the royalties that the infringer would have paid had he obtained a licence. See, *Catnic Components Ltd v. Hill & Smith Ltd* (1983) FSR 512, (1982) RPC 183. See also David Bainbridge, *op. cit*, pp. 418-419.

[109] The intendment of seeking such a relief from the court is not merely to punish the defendant or infringer of the patent's right but to prevent his unjust enrichment. An action for account of profits is restricted to the profits actually realised and traceable to the infringement and the claimant must take the defendant's business as it is. But this type of claim is rarely made in patent's cases due to their complexity. See, *Potton Ltd v. Yorkclose Ltd* (1994) FSR 567. See also David Bainbridge, *op. cit*, p. 415.

[110] In this respect, the Article 46 of the TRIPS Agreement provides thus: [i]n order to create an effective deterrent to infringement, the judicial authorities shall have the authority to order that goods that they have found to be infringing be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to avoid any harm caused to the right holder, or, unless this would be contrary to existing constitutional requirements, destroyed.' Where this claim is

declaration that the patent is valid and has been infringed upon by the defendant.

3.1. Possible Defences

A violator sued for infringing a patentee's right has a number of possible defences. He may contest the legality of the patent and therefore urge the court to declare it null and void.[111] Where the legality of a patent has been put in issue and evidence has been led, the court must decide on it, even if the parties are no longer interested. The rationale for this position is that third parties may be affected.[112]

Secondly the infringer may also raise the defence that the act which was a subject matter of the patent was done privately and not for commercial purposes or that the act was done for experimental purposes regarding the subject matter of the invention. Thirdly, it could also amount to a defence by the defendant to contend that the alleged infringing product or process lacks newness or is obvious. In such a situation, the defendant would be contesting that the patent claims are invalid if they cover the alleged infringement or if valid, they cannot apply to the alleged infringement.[113]

4. CONCLUSION

The article critically assessed the legal protection of new plant and animal varieties under intellectual property law. It was discovered that while the biological tampering with nature began as far back as the Bible days, yet the provision for legal protection of plant and animal varieties began only in the nineteenth century. In the United States of America, such protection started about 1930 and in Europe, much later. Although the EPC provides for patentable inventions, yet the patentability neither extends to patents in respect of 'essentially biological processes for the production of plants or animals' nor in respect of inventions, the commercial exploitation of which would be contrary to '*ordre*' public or morality.

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granted by the court, the infringing goods would be ordered to be delivered up to the claimant so as to be destroyed. See the Nigerian case of *Beecham Group Limited v. Esdee Food Products Nigeria Ltd.* (1981) FHCL 177.

[111] See for example, *JEM Ag Supply v. Pioneer Hi-Bred International Inc, op. cit*, where the defendant challenged the validity of the patent of the plaintiff. See also Patents and Designs Act, *op. cit*, section 9 which entitles any person to apply to the court to declare a patent null and void based on the statutorily stipulated grounds.

[112] *Ocular Sciences Ltd v. Aspect Vision Care Ltd.* (1997) RPC 289.

[113] In *Mabuchi Motor KK's Patent* (1996) RPC 387, the patent was held to be valid but not infringed. See also *Gillette Safety Razor Co v. Anglo-American Trading Co Ltd* (1913) 30 465. For a detailed discussion on the possible defence in patent infringement action, see David Bainbridge, *op. cit*, pp. 406-411.

It is crucial to add that even if claims are made to an essentially biological process for the production of plants or animals, they are patentable if the process is micro-biological (and not macro-biological process). The exclusion of varieties and essentially biological processes in part articulates ethical objections to human interventions in the production of animals and plants,[114] which may also be associated with the moral and public policy grounds.[115] On the other hand, under UPOV 1991, a protectable variety must be new, distinct, uniform and stable ('NDUS').

Moreover, in relation to plant variety protection, the TRIPS Agreement authorises its members to either use patent, or an *effective sui generis* system or a combination thereof. In most cases the patent option is not considered. Mostly, developing and LDCs have recourse to the *sui generis* option so as to achieve some elements of flexibility to accommodate local contexts and to align plant variety protection into their socio-economic policy objectives. However, the lack of lucidity in the agreement as to what it takes for a member to comply with "effective" *sui generis* system has reduced the portrayed flexibility unreliable.[116]

Finally, as noted earlier, it is indisputable that ethical and moral questions will inexorably arise in the exploitation of inventions. The more central question, however, is how they should be addressed. This article has made an effort in establishing that splicing a morality provision into the patent laws result in an unstable fusion. Although from the various legal frameworks examined in this work, there is interplay between morality and patentability, yet the case law proves that consideration is at best perfunctory. What is more, the concepts of morality differ greatly from country to country. What is acceptable in one country may be seen as offensive or injurious to prevailing moral standards in another. In this light therefore, it is high time that Nigeria, like other developing or LDCs should embrace the flexibility approach of the TRIPS Agreement to either use patent, or an *effective sui generis* system or a combination thereof to promote the patents of plants and animal varieties.[117]

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[114] Silvia Salazar, 'The World of Biotechnology Patents,' in Christophe Bellmann *et al* (eds.), *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability* (Earth Scan Publications Ltd, 2003), p.124. See also Barbara A. Claffey, 'Patenting Life Forms: Issues Surrounding the Plant Variety Protection Act (of US),' *Southern Journal of Agricultural Economics* (December, 1981), pp.33-36.

[115] W. R. Cornish, *op. cit*., pp. 226-227.

[116] Gizachew Silesh, *The Ethiopian Legal Regime on Plant Variety Protection: Assessments of Its Compatibility with TRIPS Agreement, Implications and the Way Forward*, (Unpublished Master's Thesis, Addis Ababa University, 2010), p. iii.

[117] Such a move by Nigeria would have a constitutional basis as section 24 (d) of the Constitution of the Federal Republic of Nigeria 1999 (as amended) encourage Nigerian citizens to 'make positive and useful contribution to the advancement, progress and well-being of the community where he resides.' Unfortunately, the

provision of section 1(4) of the Patents and Designs Act is not an encouraging statutory condition for a citizen who may be interested in biotechnology and genetic engineering of propagating plant and animal varieties.