AN EXAMINATION OF PATENTABILITY OF ANIMALS AND PLANTS

BY

SAKA ADABALE FATAI[1]
Email:sabdlfatai@gmail.com
Phone Number: +2348030529058

Abstract:

As advancements in genetic engineering and biotechnology accelerate, the traditional boundaries of patent law are continually challenged. This paper delves into the complex and evolving landscape of patentability concerning animals and plants, scrutinizes the legal framework for this contentious issue. The examination focuses on key legal frameworks, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and national patent laws to explore the extent to which animals and plants can be granted patent protection. This paper contributes to the ongoing discourse on intellectual property rights in the realm of biotechnology as it offers a comprehensive overview of the current state of patentability for animals and plants within the regulatory framework of the selected jurisdictions.

Introduction

The intersection of biotechnology, intellectual property, and ethical considerations has ignited a multifaceted debate surrounding the patentability of animals and plants. In an era marked by unprecedented advancements in genetic engineering and the manipulation of living organisms, the traditional boundaries of patent law find themselves confronted with novel challenges. This paper, through the relevant legal regulatory frameworks analyses the evolving discourse on patentability of animals and plants. Within the ambit of intellectual property rights, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and various national patent laws play pivotal roles in defining the scope of patent eligibility for living organisms. As biotechnological innovations accelerate, legal frameworks must grapple with questions of novelty, utility, and the unique challenges posed by the patenting of animals and plants.

Protection of Intellectual Property Right (IPRS) guarantees that every man has the right and potential benefit from the proceeds of his sweat and ideas. It accordingly, spurs and invigorates the dawn of industrialization in the world. Patent is one of the machineries that helped to ensure this consistency in the area of protecting ideas and inventions over the years. The purpose of patenting is essentially economic. The state, in order to encourage technological development assures an inventor of a monopoly right to exploit the invention for a limited period of time. It is envisaged that the inventor, during the period of such monopoly would have derived maximum financial benefit from the exploitation of the invention. The state thus, ensures that inventions which could improve the quality of life of citizenry are exploited to the good of the greatest number of people.
There is growing worldwide opposition to the granting of patents on biological materials such as genes, plants, animals and humans. Thus, this opposition represents the attitude of the public to

[1] He is a lecturer and at present , the Head of Common Law Department of Kwara State College of Arabic and Islamic Legal Studies Ilorin, Nigeria.

the extension of patents to plants animals and other biological materials. Groups, religious leaders, and parliamentarians are intensifying their campaign against corporate patenting of living things. This paper therefore examines the patentability or otherwise of plants and animals. In achieving this, it considers the history of Nigerian patent law and the patentable invention under the Act, among others.

Nigerian Patent Law In Retrospect

The Patents Ordinance[2] and the Patents Proclamation Ordinance[3] were the first patent legislation enacted in Nigeria. These statutes applied to the colony of Lagos and Southern protectorate of Nigeria. Afterwards, similar provisions were made applicable to the Northern protectorate of Nigeria by virtue of the subsequent Patents Proclamation Ordinance[4]

Actually, these laws provided for the establishment of a developed patents administration system for Nigeria. However, the situation was radically reversed after the amalgamation of the southern and Northern protectorates in 1914. The Patents ordinance and Patents proclamation ordinance was repealed and replaced with the Patents ordinance of 1916 later renamed and re-enacted as the Registration of United Kingdom Patents Ordinance[5] of 1925 (Cap 182 Laws of the Federation of Nigeria and Lagos 1958.

The provision of the 1925 Ordinance was simply to extend the validity of patents granted in United Kingdom to Nigeria if an application to register same is made to the registrar of patents in Nigeria within three years of the grant of the patent in United Kingdom. Thus, the independent patenting system provided for under the 1900 ordinances was terminated, and Nigeria became an extension of application of a United Kingdom patent.

Perhaps this legislative development is really not jarring within the period of its experience. Perhaps the 1900 ordinances were indeed too ambitious, considering the standard of western civilization and level of western technological know how available within the indigenous population at the time. Again, since at that time, personnel for a patent office will have to be provided by the colonialists in any case, it must have been rationalized that to save cost, it was better to have persons interested in being granted patent protection in Nigeria to first obtain a grant in the UK where there was adequate personnel to evaluate such applications. Thereafter, registration of grant could be done in Nigeria to extend the validity of the UK patent to Nigeria.

Curiously however, the Registration of the United Kingdom Patents Ordinance was not repealed until 1970, ten years after independence. If one could understand why the colonialist enacted the United Kingdom Patents Registration Ordinance in 1925, one finds it difficult to understand how the government of independent Nigeria allowed the law to subsist in our statute books for ten years after independence. Eventually however, in 1970, the Patents and Designs Decree[6] was enacted. The Act which created a Nigerian patent system and administration is still in force till today, and available as chapter 344 of the Laws of Federation of Nigeria 1990[7].

[2] No. 17 of 1900

[3] No. 27 of 1900

[4] No.12 of 1902.

[5] of 1925 (Cap 182 Laws of the Federation of Nigeria and Lagos 1958.

[6] Decree N0 60 of 1970(now patents and Designs Act)

[7] Patents and designs Act Cap P2 Laws of Federation of Nigeria 2004

Nigerian Patent

Under the Act, a patent may be granted either for a product or for a process. An example of a process is the process known as electroplating or indeed any chemical reaction which may give rise to a product. Whichever the case may be, the life of the patent lasts for 20 years provided the annual renewal fees are paid for the duration of its potential life[8]. Where the patentee defaults in the payment of the annual renewal fee, the patent of establishing patentability from the registrar to whoever wishes to oppose the patent. This system, apart from saving the government revenue it might otherwise pay out to experts who will assess the application, it is also speedy. One does not waste any time waiting for the application to complete the laborious process of assessment.

Patentable Inventions

Section 1 (1) of the Patents and Designs Act, prescribes the conditions for patentability of an invention. It provides:

1 (1) Subject to this section, an invention is patentable;

a. if it is new, results from an inventive activity and is capable of industrial application or;
b. if it constitutes an improvement upon a patented invention, and also is new, results from inventive activity, and is capable of industrial application.

Three conditions are primarily set by this provision for patentability namely;

1. The invention must be new
2. The invention must involves an inventive step
3. The invention must be capable of industrial applicability

The secondary provision which is made under section 1(1((b) is that an invention will still be patentable if it is an improvement on an already patented invention

We shall now examine each condition for patentability to understand whether plants and animals are patentable under the Act. In this process, reference will be made mainly to judicial pronouncements of the English court on provisions of the English Patents Act which coincide with the provisions of the Nigerian Law. There has been very little patent litigation in Nigeria; therefore there is a paucity of judicial pronouncements on the interpretation of our legislative provisions[9].

The invention must be new or an improvement on a patented invention

The requirement of novelty is the primary focus of the law of patents. In other words, for an invention to be validly patented, the discovery must be completely unknown anywhere in the world at the time the application for the patent is filed. Thus, if anybody else had made the discovery before the applicant, or even if the applicant himself had disclosed the discovery prior to the filing of the patent application, a valid patent cannot be granted to him.[10]

In defining novelty, the Act adopts a two step approach. The Act first provides in section l (2) (a) that an invention is new, if it does not form part of the state of the art. Then it goes further to define "the art" and "state of the art" in section 1(3) as follows:

> *"the art" means the art or field of knowledge to which an invention relates and "the state of the art" means everything concerning that art or field of knowledge which has been made available to the public anywhere and at any time whatever (by means of a written or oral description, by use or in any other way) before*

[8] See generally section 7 of the Act

[9] See A Brief Analysis of Intellectual Property Law in Nigeria http://www.thelawyerschronicle.com/brief-analysis..>accessed on 3rd may 2021

[10] An overview of the law of patents in Nigeria http://www.nigerianlawguru.com/.../Accessed on 3rd May 2021

> *the date of the filing of the patent application relating 'to the invention or the foreign priority date validly claimed in respect thereof so however that an invention shall not be deemed to have been made available to the public merely by reason of the fact that, within the period of six months preceding the filing of a patent application in respect of the invention, the inventor or his predecessor in title has exhibited it in an official or officially recognized exhibition."*

Thus, the parameters for determining novelty would seem to be fairly objective so long as the invention has not been made available to the public. This has been judicially interpreted in **Gentech Inc's Patent**[11] as follows:

> "thus to form part of the state of the art, the information given (by the user) must have been made available to at least one member of the public who was free in law and in equity to use it"

The implication of the judicial interpretation is that if the information regarding the invention is disclosed confidentially to a person or a group of persons, under circumstances which makes it obvious that they are not expected to disclose to any other person or to make use of the information, then the invention has not been made available to the public as to form part of the state of the art. The courts have tended to be very willing to declare that an invention has been made available to the public once the possibility has been established that relevant information about the invention has been made available to at least one person. Thus, it had been held that if an invention is disclosed in a book which has not been sold but only displayed for sale in a bookshop, sufficient disclosure had been made to make the invention part of the state of the art.

Disclosure to the public could also be by prior use. It has been held though, that where the invention is used such that an analysis of the product will not disclose the nature of the invention, disclosure to the public would not be said to have been made. An obvious example is where a new process is employed in the manufacture of an established product; an analysis of the product will not reveal any information about the process. Therefore the process still remains patentable though it had been used prior to the date of the application for a patent.

In **Merrell Dow Pharmaceuticals Inc. Vs. Norton & Co. Ltd.**[12] it was held that the prior use of a product was to be considered in the same way as a prior published document. In both cases prior use will not invalidate the patent where information available will not enable a person skilled in that field of knowledge produce the substance[13].

Prior Applications or Grants:

Included in the body of sources that must be considered on the question of novelty are prior applications or prior grants of patents. The position of the courts is that where a patented invention coincides with an earlier application filed or patent granted, the subsequent patent will be rendered invalid. The test for determining when such a situation arises was succinctly put by ***Lord Westbury L.C. In Hills v. Evans***[14] that :

> *"The antecedent statement must, in order to invalidate the subsequent patent, be such that a person of ordinary knowledge of the subject would at once perceive and understand and be able practically to apply the discovery*

[11] (1989) R.P.C. 147 at 204
[12] (1994) RPC 1
[13] See http://www.hg.org/article.asp?id=21399>Accessed on15th May 2021
[14] (1860) 31 LI. Ch. 457 at 463

> *without the necessity of making further experiments the information given by the prior publication must, for the purpose of practical utility, be equal to that given by the subsequent patent"*

The conclusion under this head is that the earlier patent or application must be such that it exactly coincides with the subsequent application or grant. It is not enough to state that the subsequent grant or application logically follows from the previous application or grant. Such an argument justifies nullification on the ground of obviousness, and not on the ground of anticipation.

Improvement on Prior Invention

The subject of disclosure by prior use is closely related to the secondary provision for novelty contained in our law. Thus it can be stated that if an invention is related to an existing patented invention but could not have been anticipated based on information available regarding that existing patent, it would qualify as a patentable improvement on the existing patented invention.

Thus the invention of the jet propulsion engine was based on the initial invention of the internal combustion engine but could not have been anticipated by an ordinary person having possession of the knowledge of internal combustion engine. It required a spark of inventive genius to take that leap from one level of the same technology to the other. This then brings us to the next condition of patentability which is the requirement that the invention must evolve from an inventive activity[15].

Inventive Activity

The Act defined an inventive activity in Section 1 (2) (b) of the Act as follows:

> *"an invention results from an inventive activity if it does not obviously follow from the state of the art, either as to the method, the application, the combination of methods, or the product which it concerns, or as to the industrial result it produces"*

In **Technograph Printed Circuits Ltd. -v- Mills & Rockley (Electronics) Ltd[16].** It was held that in considering whether an invention is obvious, it is necessary to examine the question whether the new product or process could have been suggested to persons skilled in the art and undertaking a study of other relevant documents which a diligent researcher would know about. It has however been argued that all published documents have to be assumed to be available for study of persons to whom the patent specifications has been addressed.

Industrial Applicaability

As a matter of fact, It is not every invention which is new or results from an inventive activity that can be patented. Patent laws are especially design to promote industrial development. They are to provide incentive for creativity for persons involved in industrial endeavours. Therefore, an invention will not be patentable, if it is not industrially applicable. Section 1.(2)(c) defines the concept of industrial applicability as follows:

> *"an invention is capable of industrial application if it can be manufactured or used in any kind of industry including agriculture".*

However, as the definition of industry has been extended in the provision to include agriculture, it has been suggested that the intention of the legislature is to allow patenting in respect of product or processes used in almost all kinds of commercial enterprise. There is no judicial pronouncement on this issue, to which one can readily refer; therefore one would say that the point is moot as to

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[15] An overview of the law of patents in Nigeria http://www.nigerianlawguru.com/.../Accessed on 3rd May 2021

[16] (1972) R.P.C. 346.

those areas of endeavour outside the traditional industrial activities in which patents can be granted. It has also been suggested that the requirement for industrial applicability may be referring to utility of the invention. In other words, an invention will not be patentable, it is argued, if it has no practical application

A last point under this head is to draw attention to the fact that methods of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human body or animal body have been specifically excluded from the definition of industrial applicability under the English 1977 Patents Act. Though there is no such specific exclusion in our law, one can surmise that such matters should not in any case fall under the definition of matters which are capable of industrial application[17].

International Obligations under the TRIPs Agreement on Plants and Animals

The agreement on trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) mandates that member state must establish minimum standards of intellectual property protection, and includes the requirement that member states protect product and process inventions in all fields of technology[18]. However, the TRIPs Agreement permits members to exclude from patentability inventions which should be prohibited in order to "protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment[19]. The TRIPs Agreement also allows member states to exclude plants and animals from patentability but provides that members must provide for the protection of plants either by patents, or an effective sui generis system, or by a combination thereof[20]. The obligation to provide some type of protection allows members to choose what kind of protection to adopt. The TRIPS Agreement gives no guidance as to what is an "Effective sui generis system" and there is no agreed interpretation of this term among WTO members[21]. This article of the TRIPS agreement was modeled on the similar provision in the EPC (it was adopted due to pressure from EC member states and developing countries) but the exception goes beyond the EPC exclusion of plant and animal "varieties". Australia has implemented the plant Breeders Right's Act 1994 as an effective sui generis system in accordance with the TRIPs Agreement and the UPOV Convention 1991.

The Commission on intellectual property rights has issued a report which recommends that developing countries should not provide patent protection for plants and animals but should consider different forms of sui generis systems due to restrictions that patents may place on the use of seed by farmers and researchers.[22]

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[17] An overview of the law of patents in Nigeria http://www.nigerianlawguru.com/.../Accessed on 3rd May 2021

[18] see Article 27(1) of TRIPS Agreement

[19] see Article 27(3)&(2) of TRIPS Agreement

[20] see Article 27(3) of TRIPS Agreement

[21] Interestingly, the council and the office of the Union of UPOV maintain that the UPO Act is the only internationally recognized sui generis system for the protection of plants varieties. CEAS Consultants, The Relationship Between the Agreement on TRIPS and Biodiversity Related Issues (Report for DG Trade European Commission) at 25http://www.europa.eu.int/comm/trade/pdf/ceas-final.pdf accessed on May, 2021

[22] Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy,(London 2002)

Article 27.3 (b) of the TRIPs Agreement provides that the potential for exclusion from patentability of plants and animals should be reviewed four years following the date that the TRIPs Agreement enters into force. The review is currently underway, and it is likely that some countries (mostly developing nations) will support maintaining or expanding its section while other countries (such as the United States) may campaign for a narrowing or elimination of the section[23]

OBJECTIONS TO ALLOWING THE PATENTING OF ANIMALS

The main ethnical objections to allowing the patenting of animals are:

- Interference with nature
- Devaluation of animal life
- Suffering of agricultural and laboratory animals

The first objection, relating to interference with nature, encompasses the concern that the patenting of animals will lead to a decline in the genetic diversity in commercialized species. Animal patenting supporters noted the possibility of this occurring but added that this development was already occurring with animal husbandry. A further response is that research and cryopreservation of DNA samples can aid in the improvement of the genetic diversity of endangered animals.

The second objection is that the value of animals would be undermined by patenting, due to a human center view of the world where all resources (including living things) exist for human exploitation. However, humans have 'objectified' animals for many thousands of years by treating animals a property to possess, and using them for such purposes as eating or trading.

The third objection derives from a fear that the issuance of patents on animals will contribute to the suffering of animals in both research and agricultural contexts. The creation of transgenic animals by the introduction of foreign genes could cause animal suffering. However, these technologies could also speed the development of preventions and cures for animal diseases. Another consideration is whether the potential for animal suffering could be outweighed by the possible benefits to mankind from the research[24].

In response to all these concerns, many commentators ague that the patent law is not the appropriate realm to assess moral and public policy objections to scientific research. Instead, regulatory bodies should be used to control scientific, technical or medical practice and research due to ethical, health, safety and environmental concerns[25]. If an activity is deemed to be unacceptable, then the legislature has the power to make such an activity illegal rather than attempting to regulate and control it by way of patenting[26]. Indeed, patents only confer the right to prevent the activities of people other than the patentee and thus refusing to grant a patent would not provide the requisite control to prohibit further research and development. An example of

[23] The review has raised broader issue of the relationship between intellectual property rights under TRIPS and biodiversity under the Convention on Biodiversity

[24] See generally, Animal Patents: The Legal, Economic and Social Issues. Ed. W.H. Lesser, Macmillan Publishers Ltd, 1989 New York E.S. Van de Graaf, "Patent Law and Modern Biotechnology', 1997 at 68

[25] C. Colston, Principle of intellectual property law, Cavendish Publishing Ltd, London1999

[26] AIPPI Report, United Kngdom, Report Q159 "The Need and Possible Means of Implementing the Convention on Biodiversity into Patent Laws

legislative control of scientific activity in Australia is found in the Gene Technology Act 2000, which provides a regulatory framework for managing gene technology in order to protect the health and safety of people and the environment.[27]

The converse argument to the provision of legislative measures for regulation of research is that patents provide an incentive to research and development of new technology and thus the state cannot adopt a morally neutral stance about what kinds of inventions are protected by patent law. Instead, the state should define which inventions are morally repugnant and exclude such inventions from eligibility for patenting. A response to this argument is that patent examiners often do not possess the relevant expertise to make ethnical decisions and such cases are often prolonged and clog up the patent examination process.

The main ethnical objections to allowing the patenting of plants are:

- Life should not be regarded as a commodity and thus living organisms and living matter should not be patented;
- Genetic resources are our common heritage and a monopoly should not be granted over such resources.
- Patents on biological inventions derived form plants and animals should not be granted without recognizing traditional knowledge

In Australia, the requirements of novelty and inventive step can help to ensure that resources that form part of our common heritage are not patentable. Indeed, the House of representatives standing committee on Primary Industries and Regional Services Report On Primary Producer Access To Gene Technology stated that the current practice in Australia of regarding the identification of genetic sequences as mere discoveries "meets some of the objections of those opposing patents on living organisms while still encouraging innovation[28]. There is currently a considerable movement underway to formulate an international norm for protecting traditional knowledge and providing for equitable benefit sharing[29].

OVERVIEW OF EXTENTION OF PATENTS TO ANIMALS AND PLANTS IN SOME SELECTED JURISDICTIONS

(1) European Patent Convention [EPC] and International Union for the Protection of New Varieties of Plants [UPOV]

EPC and UPOV on Plant

[27] Another example is in Europe, the European Commission's Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology, as mandated by Article 7 of the Directive on the Legal protection of Biotechnological inventions.

[28] House of representatives standing committee on Primary Industries and Regional Services Report On Primary Producer Access To Gene Technology titled " Work in Progress, Proceed with caution",(2000) 109

[29] See for instance, Draft EC submission to WTO TRIPS Council, Review of Article 27(3)(b) of the TRIPS Agreement and the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge and Folklore(Working Document of the Commission Services 2002) http://www.wipo.int/eng/meetings/2001/igc/index.htm>

In the 1960's, in Europe, patent law was considered unsuitable for protecting new plant varieties that were created using traditional breeding methods[30]. Although plan varieties were not considered suitable for patenting, it was recognized that there was a need to provide an alternative form of protection. Plant variety rights schemes were developed in some countries as well as the international Convention for the protection of New Varieties of Plants (UPOV Convention)[31]. The Strasburg Convention of 1963[32], provides patent for plant and animal varieties. In 1973, the European Patent Convention (EPC) was signed, creating a regional arrangement that allows patent protection to be obtained in 19 member states[33] by filing a single patent application at the European Patent Office (EPO). For legislative simplicity, the EPC[34] adopted the wording of the Strasbourg Convention and specifically excluded "plant varieties" form patentability since they are protected under the UPOV Convention and National Plant Breeders' Rights Laws. At the time when these legislative instruments were developed, the potential importance of biotechnology could not have been foreseen.

While the exclusion of "plant varieties" in article 53 of the EPC might seem to prohibit the patenting of plants in any form, the practice of the EPO has been to narrowly interpret this exclusionary provision as functioning to prevent conflict between patent and PVR systems. The EPO considers that the purpose of the EPC exclusion was that European patents should not be granted for subject mater under which patentability is excluded by the prohibition of dual protection under the UPOV Act.

Article 2 of the 1961/1972 and the 1978 UPOV Act bans state parties from providing protection both by means of a "special title of protection" and a patent, for the same botanical genus or species[35]. The Board of Appeal in Novartis noted that the preparatory documents of the EPC did

[30] The product of plant breeding were considered not to fulfill the patentability requirements of novelty, inventive step and disclosure due to certain practical aspects. The first practical aspect is that plant breeding depends on sexual reproduction, which is susceptible o genetic mutation according to Mendelian hereditary laws. The second consideration was that the development of a plant variety necessarily required testing at public testing lots, and thus the plants are publicly availably at an early stage. Thirdly, new plant varieties are often distinct from another plant variety but without an improved characteristics and thus may not be considered "inventive" in the sense of patent law. E.S. Van de Graaf, Patent Law and Modern Biotechnology (1997) 81.

[31]International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, 33 U.S.T. 2703, 89 T.I.A.S. 100199.

[32] Council of Europe, <http://conventions.coe.int/Treaty/EN/Treaties/Html/047.htm>

[33] Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Nettherlands, Portugal, Spain, Sweden, Switzerland, United Kingdom (19). Extension States (expected to become members in die curse): Albania, Latvia, Lithuania, Romania, Slovenia, The Former Yugoslav Republic of Macedonia (6)

[34] EPC, Art. 53. The exclusion was originally formulated in the Strasbourg Harmonization Convention of 1963, Art 2.

[35] This article was removed in the 1991 Act, such that dual protection by plant variety rights or patents is no longer prevented (in order to allow Japan and the United States to ratify the UPOV Convention). The allowance of dual protection opens the way for members to allow patenting of animal and plant varieties. Of the 50 UPOV member, however, only 19 are signatories to the 1991 Act.

not suggest that the EPC should exclude subject mater for which there was no plant variety right protection – indeed, the EPC and the 1961 UPOV Convention were intended to be complementary.

Thus, the Board of Appeal held that a claim is in respect to plant varieties (and therefore should not be granted) only where the claimed subject matter is directed to plant varieties. Claims in which specific plant varieties are not individually claimed are not excluded from patentability. This examination practice is considered to be equally applicable to animal varieties. This approach has been adopted by the EPO implementing Guidelines, which provide that an invention concerning plants and animals is patentable so long as the "technical feasibility" is not confined to a particular plant or animal variety.

The prevailing interpretation by the EPO seems to be that the provisions do not exclude claims for plant "per se" but only claims for "varieties" of plants. Transgenic plants can be patented, so long as they are not expressed in "plant variety" terms and the invention is not confined to the medication of a particular plant variety. There seems to be increasing awareness that plant variety rights are more equipped to protecting plants at the varietal level while patents are suited to protecting products of plant biotechnology.

EPC and UPOV on Animal

Article 53 of the EPC also excludes "animal varieties" from patentability. There is no international system for the protection of animal varieties and no particular justification for treating plant varieties and animal varieties in the same way. The preparatory documents for the EPC do not refer to the purpose of excluding animal varieties from patentability. It seems that animal varieties were excluded from patent protection under the EPC on ethnical grounds, because there was no well founded legal or economic reasoning for the exclusion and it does not seem to be in accordance with original intention of contracting states.

As with plant varieties, the EPO has construed the article narrowly, showing a Willingness to grant patents for animals. Since there is no established system for protecting animal varieties, there is no established definition of what exactly constitutes an animal variety. Indeed, it has been noted in the first Board of Appeal decision dealing with the patentability of an animal (Harvard Oncomouse case) that the terminology of "Animal varieties" has a different meaning in the three official languages[36]. This was used as an indication that the legislature intended to exclude patents on "animal varieties" rather than animals generally.

The technical Board of Appeal of the EPO held that the expression "animal variety" refers to the lowest subdivision of species rather than something more general. Therefore, a claim for a mouse that was genetically manipulated to be sensitive to carcinogenic substances was not an animal variety and thus could be patentable under the EPC. It seems that the EPO transferred the reasoning applied in relation to plant varieties to animal varieties. The Board addressed the concept of "order public" or "morality" by applying a balancing test which involves a "careful weighing up of the suffering of animals and possible risks to the environment on one hand, and the invention's usefulness to mankind on the other. The benefit of the Harvard Oncomouse invention to mankind in facilitating cancer research was found to outweigh possible animal suffering or environmental

[36] In German the term could refer to an entire animal species whereas in English and French it would only refer to a subspecies. Harvard/oncomouse (1990) O.J. EPO 476

risks. Thus, the Harvard Oncomouse constituted patentable subject matter. Oppositions to this patent have been filed by many individuals, animal rights groups and church organizations, and are still yet to be resolved.

(2) European Directive on the Legal protection of Biotechnological Inventions

The objectives of the European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions (1998) are to clarify the distinction between what is patentable and what is not, to harmonize national patent laws in the EU, and to provide uniform legal interpretation of specific points in relation to the patenting of living materials. The directive ensures the patentability of living matter ("biological material") in general and establishes a narrow and specific exclusion in relation to plants and animals. The Directive provides that "plants and animal varieties are essentially biological processes for the production of plants or animals, including crossing or selection, are not patentable. Thus parts of animal varieties or animals produced by a patented method such as genetic engineering can be patented in the EU. However, the Directive authorizes EU member states to exclude biotechnology inventions from patentability where their commercial exploitation conflicts with "order public" or morality. The Directive contains an illustrative list of examples of such inventions, which includes processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Plants and animals could also be excluded from patentability under the public policy and morality exception in the Directive. This exception is also included in the EPC in relation to standard patents and has caused much debate. The EPO guidelines interpret the public policy exception as a test of whether the public would consider the invention so repugnant that the grant of patent rights would be inconceivable.

The Directive entered into force in July 1998 and was to be implemented by member states by July 2000[37]. Although the Directive does not possess binding force on the EPO, it has an indirect effect on the practice under the EPC.

(3) The United States on Patentability of Plants

The United States Provides patent protection for "Anything under the sun that is made by man" following the decision of Diamond v. Chakrabarty[38] in 1980 where the Supreme Court held that genetically altered bacteria constituted statutory subject matter. The court further stated that when determining patentability, the relevant distinction is not between living and inanimate things, but whether living products could be seen as 'human-made' inventions. According to the Supreme Court, a determination of patentability based on public safety concerns should be left to the legislative sphere rather than the court system. While patents have been granted since 1930 in the United States for plants under the Plant Patent Act because it deemed products of nature not to be within the terms of the utility patent statute, the subsequent decision of *Ex parte Hibberd* further extended the scope of patent protection in the US. The 1985 case of *Ex parte Hibberd* followed

[37] Art. 15 of the Directive mandated the date of implementation. As of April 2001, the UK has implemented articles 1-11 and the implementation of articles 12-14 were expected and Denmark, Ireland and Finland have implemented the directive.

[38] Diamond v. Chakrabarty 447 US 303 (1980)

the *Chakrabarty* principle and held that US utility patents could be granted for genetically modified plants regardless of the protection available under the Plant Patent Act of 1930 and the Plant variety protection Act of 1970. In 2001, the Supreme Court held that newly developed plant breeds (and thus sexually reproduced plants) are patentable subject matter, and that utility (Standard) patents may be issued for plans.

The United State on Patentability of Animals

The decision in Chakrabarty provides the grounds for granting patents for higher life forms. In 1987, the Board of Appeal in EX parte Allen[39] considered animals to be patentable subject matter by holding that polyploidy oysters were a non-naturally occurring manufacture or composition of matter and satisfied the criteria for proper subject matter. The court relied on the Chakrabarty decision and placed little emphasis on the ethical and moral objections to the granting of patents for living matter. Soon after the Allen decision, the USPTO issued an announcement that the US patents would be granted for "non-naturally occurring non-human multicellular living organisms including animals[40]. Subsequently, the USPTO issued a patent in 1988 to a transgenic mouse known as the Harvard Oncomouse. Although heated debates ensued concerning the patentability of an animal, the USPTO has accepted transgenic animals as patentable subject matter.

Public outrage surrounding animal patenting was evidenced in the 1989 Animal Legal Defence Fund challenge,[41] when animal and farmers rights groups argued that the USPTO did not possess the authority to issue the 1987 statement on the patentability of animals. The court held that the appellants lacked standing and rejected their arguments that the general public has an interest in limiting patentability by statute. The court did not address wider societal concerns regarding animal patenting but stated that the appellant's action may not have the desired effect of preventing animal development research because excluding subject matter from patentability does not prohibit research or development on animals. The court noted that under the principles espoused by the chakrabarty decision, the question in determining patentability is simple whether the "subject matter is made by man".

(4) Patentability of Plants and Animals in Canada

At present in Canada, there seems to be no common understanding regarding whether patent law extends to higher life forms. The Canadian Patent Office has consistently held the view that while the Canadian Patent Act 1985 does not exclude plant and animal subject matter as such, the Act does not allow the patenting of higher life forms such as plants and animals. The government of Canada supports this interpretation[42].

However, in august 2000, the Federal Court of Appeal in the "Harvard Oncomouse" case, interpreted the definition of "invention" in the Act as including genetically modified, non-human mammals, and placed considerable reliance on the majority opinion of the United States Supreme Court in chakrabarty. The "Harvard Oncomouse" case has caused much controversy in Canada. The claim was filed by Harvard University in Canada in 1985 and it was rejected by the Canadian

[39] Ex-parte Allen, 2 U.S.P. W. 2d (BNA) 1425-27 (PTO Bd. Pat. App. & Inter. 1987)
[40] Animal-Patentability, 1077 Official Gazzette of USPTO 24 (1987)
[41] Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 924 (Fed. Cir. 1991).
[42] http://www.srategies.ic.gc.ca/sc_mrksv/corp/corp_appeal-e.html>accessed 4th May,2021

Patent Office in 1993, who held that the animal was made primarily by nature rather than humans. The Commissioner of patents upheld the rejection in 1995, as did a federal trial court in 1998. A majority of the Canadian Federal Appeals Court reversed these decisions in August 2000 and approved the patent, stating that the patenting of animals was not prohibited by the Canadian Patent Act. The Federal Appeals Court held that there may be policy reasons against the patentability of higher life forms, however, such arguments are for parliament and not the courts. This decision set a new precedent, making higher life forms patentable in Canada.

However, the Canadian Federal Government has appealed to the Supreme Court of Canada, arguing that parliament is a more appropriate place to address such a complex question and emphasizing the need for public dialogue on the patenting of higher life forms. The government has recognized the issue as one of significant public interest and established the Canadian Biotechnology Advisory Committee in September 1999. The committee was given a mandate to provide the government with policy advice on matters relating to biotechnology. The committee released a report on the patenting of Higher Life Forms and Related Issues[43] in June 2002, which recommended that higher life forms (Seeds, plants and non-human animals) that meet the criteria in the Patent Act, should be patentable, subject to certain limits.[44] This is the interpretation that the Federal Court of Appeal endorsed in the "Harvard Oncomouse" case. The Canadian government has not yet responded to this report.

[43] Canadian Biotechnology Advisory Committee, Patenting of Higher Life Forms and Related Issues (2002).

[44] Limits include exceptions for farmers, innocent bystanders and research and experimental use

(5) **JAPAN**

Like the EPC and the European Directive, Japanese patent law excludes from patentability inventions that are contrary to public order or morality.[45] However, unlike the EPC and the Directive, the Japanese Patent Office (JPO) considers that morality and safety issues are irrelevant for the purposes of determining whether animals are eligible for patenting; rather these should be addressed by other legal measures. Thus, in Japan, as in the US, animal and plant inventions constitute patentable subject matter. Japanese patent law makes no distinction between plant and "Varieties" and plants and animals themselves.

CONCLUSION

This discourse has examined the patentability of plants and animals. A careful examination of the Nigerian patent law unveils that animals and plants are not patentable. As regards plants, the Nigerian government enacted a Plant Variety Protection Act. The Act now gives the breeders intellectual property rights over a new plant variety with exclusive rights to commercialize seeds and propagate materials[46]. It is observed further that patenting of plant and animal has raised a plethora of moral and ethical questions relating to animal rights, biodiversity, recognition of traditional knowledge and the commoditization of life. In such a controversial area where there has been so much public resistance to patenting, the legislature should bear the burden to prove that the benefits of the stimulation of innovation in this area outweigh the possible risks involved. Indeed, under the EPC, Japanese patent law and the TRIPs Agreement, inventions can be excluded on the grounds of public policy or morality.

Most member countries of the Organization for Economic Co-operation and Development (OECD), including the US and the European Union, allow for the patenting of plants and animals. In the European Community "plant varieties" are excluded from patentability under the EPC due to the existence of an alternative form of protection under the UPOV Convention and Plant Variety Rights legislation[47]. While the prohibition on dual protection under the UPOV Convention no longer exists, it still provides the historical, underlying justification why the patenting of plants is prohibited. Animal varieties are treated in the same way even though there is no other means of patent protection for animals. It is hard to justify their exclusion from patenting, except for reasons of ethics and morality, as discussed above. In relation to standard patents, the EPO courses the exception of "plant and animal varieties" narrowly, and shows a willingness to grant claims to plant and animal subject matter.

In Japan and the US, plants and animals constitute eligible patentable subject matter. The US Supreme Court in the famous case of Chakrabarty held that the only question in determining patentability is simply whether the "subject matter is made by man".

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[45] Japanese Patent Law, Law No 121 of 1959, amended by Law No. 220, Article 32

[46] The Bill was passed by the National Assembly and assented to by President Muhammadu Buhari in the year 2021. The Act contains fundamental segments that highlight the active participation of the private sector and inter-governmental agencies in the Nigerian seeds industry. The act will promote increased staple crop productivity for smallholder farmers in Nigeria.

[47] This alternative form of protection has been replicated in Nigeria courtesy of the recent enactment of Plant Variety Protection Act, 2021.

Therefore, the legal regulatory frameworks surrounding the patentability of plants and animals play a fundamental role in shaping the ethical boundaries of biotechnological advancements. As legislation evolves to keep pace with scientific developments, it becomes imperative to ensure that patent laws provide clear guidance, prioritize ethical considerations, and uphold the principles of equitable access and environmental sustainability. Moreso, a robust legal framework is crucial to navigate the complexities of patenting living organisms, fostering responsible innovation within the bounds of societal values and environmental stewardship.