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Patenting in Biotechnology: An Analysis of the Three Tests of Patentability under the Nigerian Patent Law

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Abstract

Biotechnology has the potential to address some of the problems, including food insecurity and malnutrition, the emergence and re-emergence of infectious diseases, and climate change, besetting developing countries such as Nigeria. However, it poses a significant challenge to the existing patent system in Nigeria due to its inherent connection to naturally occurring substances. Therefore, this paper provides a legal analysis of the applicability of the patent standard tests of novelty, inventiveness and industrial application to biotechnology in Nigeria. The analysis draws on the interpretations of similar provisions in the European Union, the United States and the United Kingdom. The primary purpose is to identify and clarify possible issues that could arise in the bid to apply relevant provisions of the existing patent law to biotechnological inventions in Nigeria. The paper found that biotechnological inventions and innovations have proven challenging to the requirements of novelty, inventiveness and industrial applicability under the globalised patent standards. This is because patent laws evolved primarily in response to the development of machines and chemical processes, so they do not necessarily contemplate the peculiarities of biotechnological inventions and innovations. It is recommended that for clarity, there is a need for Nigeria to formulate principles that would guide the application of the patent law to biotechnology as obtained in other jurisdictions, bearing in mind the possible implications of biotechnology patents on public health, food security, traditional knowledge and the environment among other factors.

Keywords: biotechnology, patent, Nigeria, novelty, inventiveness, industrial application

1. Introduction

Continuing challenges such as food insecurity, malnutrition, the emergence and re-emergence of infectious diseases, and climate change, among others, have made biotechnology very attractive to developing countries and the world. It can drive improvements in the quantity and quality of agricultural produce, health care delivery, environment and the quality of life by using biological organisms, processes or systems to create or modify products and processes.[1] As a result, there have been an increasing number of contributions to the discourse on biotechnology. The contributions addressed the subject from various perspectives, including human rights, biosafety, bioethics, food security, medicine and intellectual property rights.

This paper focuses on the aspect of intellectual property rights, particularly patents. Although it remains contentious, it is believed that patenting has a critical role in stimulating research and

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[1] See Nigerian National Policy for Biotechnology 2001;European Patent Office, 'Biotech Patent' <https://www.epo.org/en/news-events/in-focus/biotechnology-patents> accessed 29 February 2024.

innovation in biotechnology.[2] However, as discussed shortly, the application of patent standards to biotechnological inventions or innovations poses a number of peculiar challenges due to their inherent connection to substances or processes occurring naturally. Thus, this paper analyses the applicability of the patent standard tests of novelty, inventiveness and industrial application to biotechnology in Nigeria. The analysis draws on the interpretations of similar provisions in selected jurisdictions, including the United States and the United Kingdom. The main purpose is to identify and clarify possible issues that could arise in the bid to apply relevant provisions of the existing patent law to biotechnological inventions in Nigeria.

2. The Nigerian Patents and Designs Act 1970

The Nigerian Patents and Designs Act of 1970 provide the principal legal framework for patent protection in Nigeria. This law draws primarily on the Model Law for Developing Countries on Inventions developed by the United International Bureaux for the Protection of Intellectual Property (BIRPI).[3] It is administered by the Intellectual Property Office, also known as the Trademarks, Patents and Designs Registry under the Commercial Law Department of Nigeria's Federal Ministry of Industry, Trade and Investment.[4] To this end, the Minister for Industry, Trade and Investment is empowered to make rules that will facilitate the effective implementation of the patent law.[5]

In addition, it is significant to note that patents may be secured through the Nigerian National Office for Technology Acquisition and Promotion (NOTAP). The office facilitates the preparation and processing of patent applications at the Intellectual Property Office in Nigeria and other countries, especially with respect to indigenous inventions and innovations resulting from government-funded research and the private sector.[6] More particularly, NOTAP encourages universities and research institutions in Nigeria to patent and commercialise their inventions. To spur the culture of patenting among the Nigerian scientists and innovators, various Intellectual Property and Technology Transfer Offices (IPTTOs) are being established by NOTAP across the universities and research institutions in Nigeria. In the same vein, it is important to note that the World Intellectual Property Organisation (WIPO) has also been actively promoting the commercialisation to research and innovation from universities and research institutions in Nigeria and other developing countries through the establishment of various Technology and Innovation Support Centres (TISCs).[7]

The Nigerian Patents and Designs Act, 1970 is arguably a technology-neutral patent law, applicable to all fields of technology including biotechnology, although this may not have been

[2] M Herder and E R Gold, 'Intellectual Property Issues in Biotechnology: Health and Industry'8 -12 <https://www.oecd.org/sti/futures/long-termtechnologicalsocietalchallenges/40181372.pdf> accessed 29 February 2024.

[3] See O Oyedepo, 'Patent and Economic Development in Nigeria'. (2012) 16 (1) *Nigerian Law Journal* 144, 150. (arguing that the Nigerian patent law 'was a quick fix that doomed failed as it lacks proper basis for its operation); See also, A Adebambo, 'Public Health, Access to Medicines and the Role of Patent System in Nigeria' (2011) NIALS Journal of Intellectual Property, 164, 171.

[4] See the Intellectual Property Office, Nigeria. 'About IPO Nigeria: About the Registry'. <https://www.iponigeria.com/AboutUs> accessed on 30 January 2024.

[5] S 30 of the Nigerian Patents and Designs Act, 1970, and the Nigeria Patent Rules, 1971.

[6] The Nigerian National Office for Technology Acquisition and Promotion, 'Patenting Inventions through NOTAP'. <http://www.notap.gov.ng/content/patenting-inventions-through-notap> accessed 30 January 2024.

[7] WIPO, 'Technology and Innovation Support Centers', <https://www.wipo.int/tisc/en/> accessed 30 January 2024.

intended given that the system was originally created for the protection of mechanical and subsequent chemical inventions.[8] The law sets out the requirements for patentability and who can claim patent, the patent-application process, and the patent-granting process. It also contains provisions regarding the rights granted to a patent holder, the duration and how a patent may be surrendered, nullified or voluntarily licensed, and infringement and enforcement of patent rights. In addition, it regulates matters concerning compulsory licensing and the use of patents by the government as well as the relationship between the Nigerian patent system and international conventions or arrangements. Nevertheless, the discussions in this paper focus on the patentability requirements of novelty, inventiveness and industrial applicability as set forth in the Nigerian Patents and Designs Act in relation to biotechnology.

2.1 Relevant Provisions on Novelty, Inventiveness and Industrial Applicability

Section 1 of the Nigerian Patents and Designs Act, 1970, sets out the requirements for patentability and the scope of subject matters that could be eligible for patent protection. Without specifically defining the concept of 'invention', the law makes patent protection available for inventions (including those constituting improvements upon patented inventions) that are new, result from inventive activities, and are capable of industrial application.[9]

An invention is required to be new in the sense that it does not form part of the state of art.[10] The 'state of art' under the Nigerian Patents and Designs Act, 1970 means everything concerning the art or field of knowledge to which an invention relates and, which at any time, had been made available to the public in Nigeria or elsewhere. The disclosure could have been either by 'a written or oral description, by use or in any other way', prior to the date of a patent application or foreign priority date validly claimed in relation to the invention.[11] It is important to note that an invention does not lose its status of newness by reason of it being displayed at 'an official or officially recognised international exhibition', provided a patent application is filed within six months after its display.[12] As to the requirement of inventive activity, it means that, having regard to the state of art, the invention must not have been obvious, more particularly to a person versed in the art or field of knowledge to which the invention relates.[13] Under the Act, a patentable invention is capable of industrial application 'if it can be manufactured or used in any kind of industry, including agriculture'.[14]

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[8] See generally, I Mgbeoji and B Allen, 'Patent First, Litigate Later! The Scramble for Speculative and Overly Broad Genetic Patents: Implications for Access to Health Care and Biomedical Research'. (2003) 2(2) *Canadian Journal of Law and Technology*, 83, 85 (pointing out that patent systems around the world, including that of the United Kingdom which had historically influenced the establishment of patent system in Nigeria, were originally designed not for the protection of biological inventions but mainly mechanical inventions).

[9] S 1(1)(a-b) of the Nigerian Patents and Designs Act, 1970.

[10] S 1(2)(a) Ibid.

[11] S 1(3) Ibid. It is important to note that in this regard there are no geographical limitations. In other words, a patent application for an invention in Nigeria may be anticipated by the state of art in Canada, Austria, United States or any part of the world, rendering the invention ineligible for patent protection in Nigeria. Adopts a geographically limiting approach in certain regards vs biopiracy).

[12] Ibid.

[13] S 1(2) (b) of the Nigerian Patents and Designs Act, 1970; See also W R Cornish and D Llewelyn, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (5th Ed., London: Sweet & Maxwell, 2003)192; A O Oyewunmi, *Nigerian Law of Intellectual Property*. (Lagos, Nigeria: University of Lagos Press and Bookshop Ltd., 2015) 153. Citing Re Johns Manville's Patent (1967) RPC 479 at 494.

[14] S 1(3) of the Nigerian Patents and Designs Act, 1970.

Notwithstanding the focus of this paper, it is worth noting from the onset that a biotechnological invention that falls under any of the exempted subject matters listed under section 1(4) and (5) of the Nigerian Patent and Designs Act, 1970, will not be protected under the patent law despite being new, inventive, and capable of industrial application. The exemptions are as follows:

> *(a) plant or animal varieties, or essentially biological processes used for the production of plants or animals as opposed to microbiological processes and their products;*
>
> *(b) an invention that its publication or exploitation would be contrary to public order or morality, although in this context, inventions are not to be considered as contrary to public order or morality by the mere fact that their exploitation is prohibited by law; and*
>
> *(c) principles and discoveries which are of a scientific nature.*

In the context of biotechnology, the above standard tests for patent protection have remained largely controversial due to the inherent connection of biotechnological inventions with substances and processes occurring in nature.[15] Particularly, the applicability of each of the standard tests of patentability briefly described above to gene-related inventions raise a number of complex issues. For instance, it could be difficult to see what is new or inventive about a gene isolated from the human body, given that it has always been present in nature. Accordingly, a broad question with regard to biotechnology patentability is whether an invention relating to a naturally occurring substance or process could be said to be available to the public so as to form part of the prior art or obvious to a person skilled in the art and thereby rendering the invention ineligible for the grant of patent?

More specifically, can a gene or any other biological material already existing in nature (or a living organism) by mere isolation be considered novel or inventive? In the same vein, biotechnological inventions have also proven challenging to the industrial applicability requirement, with questions arising on whether they are useful or capable of practical application and not purely speculative or theoretical?

In Nigeria, there is no concrete guidance for determining the patentability of biotechnological inventions. The situation is further exacerbated by the fact that Nigeria operates a purely patent registration system.[16] As a result, patent applications are merely subjected to formal examination as opposed to some form of substantive examination to determine the merits of patent applications. Yet, some scholars have maintained that substantive examination is at the heart of patent systems.[17] In the case of Nigeria, it can be argued that because no substantive examination is required, there is hardly in existence examiners who are trained for such purpose or who could have the requisite knowledge of the state of art especially in a multidisciplinary field such as biotechnology.[18] This

[15] Generally, critics have argued that 'extensive IPRs are being granted for innovations that are not novel or are obvious to anyone skilled in the relevant arts'. – A G Isaac and W G Park, 'Open Development: Is the "Open Source" Analogy Relevant to Biotechnology?' In D Castle (ed), *The Role of Intellectual Property Rights in Biotechnology Innovation* (United Kingdom: Edward Elgar, Cheltenham, 2009) 231.
[16] S 4 of the Nigerian Patents and Designs Act 1970.
[17] See Oyedepo (n3) p.150.
[18] Ibid. pp.150 – 151.

increases the chances of registration of 'undeserving inventions' that do not satisfy the patentability criteria of novelty, non-obviousness and industrial application.[19]

In any case, to attempt the questions raised earlier, it would be helpful to look at other jurisdictions, such as the European Union[20], the United Kingdom[21] and the United States where issues relating to biotechnology patentability have had to be dealt with by their patent offices and courts.

a. Novelty

With respect to corresponding provisions on novelty contained under Articles 52 and 54 of the European Patent Convention, 1973 (as amended), it is established that a naturally occurring substance such as a gene sequence will not lack novelty when isolated for the first time and having no previously recognised existence.[22] In this regard, it is significant to note the difference between the objection that a product or process lacks novelty and the objection that it is non-patentable subject matter on the grounds that it is a mere discovery. The concept of 'newness' in the sense as used under the novelty requirement is not construed as 'not pre-existing' but 'novel' in a prior art sense so that the unknown but natural existence of a substance does not preclude it from patentability.[23]

Also, in principle, it is understood in the context of the European Patent Convention, 1973 (as amended), that an invention cannot be said to have been 'made available to the public' and thereby

[19] Ibid. Citing G S Yankey, *International Patents and Technology Transfer to Less Developed Countries*. (Adershot, Avebury, 1987) 222.

[20] Discussions as regards the European Union are based not only on the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions ('Biopatent or Bio-Directive') OJ L 213, 30.7.1998, but also the Convention on the Grant of European Patents (European Patent Convention) 1973 (as revised),and the European Patent Office. Even though both the European Patent Convention and European Patent Office are not part of the European Union's legal and institutional frameworks, they are binding on all the 27 European Union Member States. – See the European Patent Office. 'The EPO at a Glance'. <https://www.epo.org/en/about-us/at-a-glance> accessed 31 January 2024; Besides, the provisions of the Biopatent Directive, 1988, were incorporated into the European Patent Convention in 1999 through the amendments to the Implementing Regulations of the European Patent Convention. See 'Decision of the Administrative Council of 16 June 1999 amending the Implementing Regulations to the European Patent Convention'. 7/1999 OJ EPO, 437. <http://archive.epo.org/oj/issues/1999/07/p437/1999-p437.pdf> accessed 31 January 2024.

[21] It is worth noting from the onset that, the regulation of biotechnology patents in the United Kingdom and practices of the Intellectual Property Office, draw significantly on the European Union Biopatent Directives 1988, and cases from the European Patent Office. As a result, reference to the United Kingdom are merely to support the discussions under the European Union where necessary, and also to take account of different interpretation, if any. See generally, United Kingdom Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office, 2016. <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/512614/Guidelines-for-Patent-Applications-Biotech.pdf> accessed 03 January 2024, the United Kingdom Manual of Patent Practice (MPOP) 2016 (as updated in 02January, 2024). <https://www.gov.uk/guidance/manual-of-patent-practice-mopp> accessed 23 January 2024and the United Kingdom Patents Act 1977 (as amended). <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/950221/consolidated-patents-act-1977.pdf> accessed on 23 January 2024.

[22] See *Howard Florey Institute's Application/Relaxin* (V 0008/94) (1995) OJ EPO, 388, 394 (The Opposition Division of the European Patent Office held that 'it is established patent practice to recognise the novelty for a natural substance which has been isolated for the first time and which had no previously recognised existence').

[23] See UNCTAD-ICTSD. *Resource Book on TRIPS and Development*. (Cambridge University Press, Cambridge 2005)392.

constituting a state of art or lacking in novelty merely by the disclosure of its existence. A disclosure destroys the novelty of an invention only if the available information is sufficient enough to enable a person skilled in the art to reproduce the invention.[24] In addition, in considering novelty within the context of gene sequence, it is important to note that the existence of large sequences or gene banks would not impugn the novelty of specific sequences. The question often considered in this regard is whether the invention is merely an arbitrary selection or a purposive selection with new technical effects.[25]

The novelty requirement, as provided for under section 2 of the United Kingdom Patents Act, 1977 (as amended), is considered in the same light as discussed above with regard to biotechnological inventions.[26]In *Kirin-Amgen Inc. and others v Hoechst Marion Roussel Ltd and others*[27]the House of Lords particularly held thus:

> *I think it is important that the United Kingdom should apply the same law as the EPO and the other Member States when deciding what counts as new for the purposes of the EPC… It would be most unfortunate if we were to uphold the validity of a patent which would on identical facts have been revoked in opposition proceedings in the EPO.*

In the United States, the courts hardly offer any clearer or predictable guide as regards questions on prior art and novelty in relation to biotechnological inventions. To begin with, section 102(a) of the United States' Patent Act, 1952 (as amended), sets out conditions that could negate the novelty of an invention. These include when the claimed invention has already been patented, 'described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention'.[28] But the Courts have tended to rest their decisions concerning biological-based inventions on the subject matter patent eligibility test under section 101 of the United States' Patent Act, 1952 (as amended).[29]

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[24] See the decision of the Technical Board of Appeal of the European Patent Office in *Thickness of Magnetic Layers/Toshiba* (T 0026/85) (1988); *Collaborative/Prepro Rennin* (T 0081/87) (1990) OJ EPO, 250; G-IV, 2 Guidelines for Examination in the European Patent Office, 2024.

[25]*AGREVO/Triazoles* (T 939/92) (1995) OJ EPO 309*; Generics [UK] Ltd. (Trading as Mylan) v. Yeda Research and Development Co. Ltd & Anor* (2013) EWCA Civ 925, (2014) RPC 4; *Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Co Ltd* (2010) RPC 8.

[26] See paragraphs 9-24 of the United Kingdom Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office, 2016; In *Asahi Kasei Kogyo KK's Application* (1991) RPC 485, 539, it was held in the House of Lords as follows: ' ... I do not see how an invention can be said to have been made available to the public merely by a published statement of its existence, unless the method of working is so self-evident as to require no explanation.'

[27] (2004) UKHL 46.

[28] See particularly, section 102(a)(1) of the United States' Patent Act, 1952 (as amended by the Leahy-Smith America Invents Act 2011).

[29] See for instance, *Diamond v Chakrabarty* (1980) 447 U.S. 303.; *Mayo Collaborative Services v. Prometheus Laboratories Inc.* (2012) 132 S.Ct. 1289; *Association for Molecular Pathology and others v. Myriad Genetics, Inc. and others*(2013)133 S.Ct. 2107, (2013) 569 U.S. 576; As reflected in these cases, it is believed that, with specific regard to biotechnological inventions, the patent eligible subject matter requirement under Section 101 of the United States' Patent Act, 1952 (as amended), tends to overlap with the requirement of novelty and other standard tests such as nonobviousness due to their connection to naturally occurring substances. See Singh K.K, *Biotechnology and Intellectual Property Rights: Legal and Social Implications* (Springer, India 2014) 50; Some contributors have

Even so, some literature suggests that with reference to biotechnology, a claimed invention may not be anticipated by the pre-existence of the biological material. It is believed to be obtainable when the invention process involves the isolation and substantial purification of the biological material so much as to make the claimed invention quite distinct from that which exists in nature.[30] But there is little or no authority to support this interpretation of section 102 of the United States' Patent Act, 1952 (as amended). This means the issue as to when or whether a naturally occurring biological substance or process of no previously recognised existence can be said to be a prior art or available to the public in light of section 102 of the United States' Patent Act, 1952 (as amended) remains unclear.

In actual fact, the view mentioned above is more consistent with some of the patentable subject matter decisions of the United States' courts concerning claimed biotechnological inventions which, often than not, appear to rest in part on the patentability requirements of novelty and non-obviousness.[31] Arguably, if the interpretation of novelty in the context of biotechnology is to rest entirely on section 102 of the United States' Patent Act, 1952 (as amended), the position of the United States would more likely align with that of the European Union, in that naturally occurring substance such as genes the existence of which were unknown do not qualify as prior art.[32]

As some cases illustrate however, the United States Patent and Trademark Office (USPTO) and courts appear to treat naturally occurring substances as prior arts which are already in the public domain. This assertion is based on the fact that, both the patent office and courts of the United States have maintained that substances derived from nature must be modified by human intervention in order to be transformed from a non-patentable subject matter to patentable subject matter under section 101 of the United States' Patent Act, 1952 (as amended).[33] As a result, it could be argued that a claimed invention relating to a naturally occurring substance as such lacks novelty in the United States' context. In fact, in failing the 'threshold test' of patentable subject matter under section 101 of the United States' Patent Act, the question of novelty would not arise.[34]Notwithstanding, it is worth noting that, with particular reference to genetic sequence, it

in fact suggested that, 'most if not all of the Court's patentable subject matter precedents could be better understood in terms of other requirements for patent protection such as novelty, nonobviousness, or limitations on claim scope'. – See Eisenberg R.S, 'Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods After' (2012) 3(1) *Journal of Law, Technology & the Internet*, 1, 7 (citing Duffy J.F, 'Rules and Standards on the Forefront of Patentability'. (2009) 51 WM. & MARY L. REv. 609, 622-23; Osenga K, 'Ants, Elephant, Guns, and Statutory Subject Matter' (2007) 39 ARIZ. ST. L.J. 1087, 1115-18).

[30] See Kankanala K.C, 'Complications in Patenting Biotech Inventions: A Peek at US Law' (2018) 5 <https://www.bananaip.com/ip-news-center/complications-in-patenting-biotech-inventions-a-peek-at-us-law/> accessed February 2024.

[31] As in the case of *Diamond v Chakrabarty* supra note 264.; For extensive discussion in this regard see, R S Eisenberg, 'Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods After', pp.1 - 65.

[32] Eisenberg(n31) pp.53-54 (pointing out that 'without assistance from the doctrine of patentable subject matter, newly discovered products and phenomena of nature do not seem to qualify as prior art under § 102 alone').

[33] See *Association for Molecular Pathology and others v Myriad Genetics, Inc. and others*.

[34] See *In re Comiskey*, (2009) 554 F.3d 967, 973 (where the court pointed out that, only if the requirements of section 101 of the United States' Patent Act, 1952 (as amended), are satisfied can an inventor be 'allowed to pass through to' the other requirements for patentability, such as novelty under section 102 and non-obviousness under section 103 of the United States' Patent Act, 1952 (as amended); *In re Bilski*, (2008) 545 F.3d 943, 950-51 (the court held that 'whether a claim is drawn to patent-eligible subject matter under section 101 is a threshold inquiry, and any claim of an application failing the requirements of section 101 must be rejected even if it meets all of the other legal

has been held that the existence of a larger sequence and a method of sequencing in a prior publication would anticipate a fragment or portion of the whole genetic sequence.[35]

b. Inventiveness

The inventive step patentability requirement (defined as no obviousness in the United States' context) is covered by Article 55 of the European Patent Convention, 1973 (as amended), section 3 of the United Kingdom Patents Act, 1977 (as amended) and section 103 of the United States' Patent Act, 1952 (as amended). In considering the inventiveness of a claim in the biotechnology context, the European Patent Office Opposition Division in the case of *Relaxin*[36] pointed out that the requirement of inventiveness would be met by a claim that provides to the public for the first time a product whose existence was previously unknown notwithstanding that its isolation and preparation was through conventional means. In the present case, the isolation of the DNA encoding human H2- relaxin was held to involve an inventive step despite its natural existence in the human body (albeit previously unknown) on the grounds that there was no pertinent real prior art (as opposed to the human body) available to render the claimed subject-matter obvious. Similarly, under the patent system of the United States, it is assumed that genetic information that is novel must also be taken to be non-obvious even though, ordinarily, they are different requirements.[37]

Generally, in evaluating the no obviousness or inventiveness of claimed inventions, including biotechnological inventions, the United States Patent and Trademark Office and the European Patent Office have sought to establish some specific steps. The European Patent Office applies the three steps problem-and-solution approach: (i) determine the 'closest prior art', (ii) establish the 'objective technical problem' to be solved, and (iii) consider whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to a skilled person.[38]With specific regard to biotechnology, it is further provided that:

> *obviousness is considered at hand not only when results are clearly predictable, but also when there is a reasonable expectation of success. In order to render a solution obvious, it is sufficient to establish that the skilled person would have followed the teaching of the prior art with a reasonable expectation of success. Likewise, a mere "try and see" attitude in light of the closest prior art does not necessarily render the solution inventive.*
>
> *On the other hand, a "reasonable expectation of success" is not to be confused with the "hope to succeed". If researchers are aware when embarking on their research that, in order to reach a technical solution, they will need not only technical skill*

requirements of patentability); Even then, in line with the view expressed, some contributors have maintained that 'some patentable subject matter decisions concerning products and phenomena of nature appear to rest in part on considerations of novelty, originality, and nonobviousness that find expression elsewhere in the Patent Act….'- See Eisenberg R.S, 'Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods After', p.56.

[35] See *In re Crish*, (2004) 393 F.3d 1253.

[36] Supra.

[37] See W R Cornish and D Llewelyn, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, p838.

[38] See G-VII, 5. Guidelines for Examination in the European Patent Office, 2024; See also *Biogen Inc/Hepatitis B virus* [1999] EPOR 361 (T 0886/91).

> *but also the ability to make the right non-trivial decisions along the way, this cannot be regarded as a "reasonable expectation of success".*[39]

In determining the question of obviousness under section 103 of the United States' Patent Act, 1952 (as amended), the United States Patent and Trademark Office relies on the framework set forth by the United States Supreme Court in *Graham v John Deere Co. of Kansas City*[40], and reaffirmed in *KSR International Co. v Teleflex Inc.*[41] as follows: (i) determine the scope and content of the prior art, (ii) ascertain the differences between the claimed invention and the prior art, (iii) resolve the level of ordinary skill in the pertinent art and (iv) given the existing circumstances, evidence of secondary considerations, if any, such as commercial success, long-felt but unsolved needs, or failure of others, and so forth, may be utilised.[42]

In the United Kingdom, decisions regarding the inventiveness of biotechnological inventions are reached on a case-to-case basis by relying on the four-step *Windsurfing/Pozzoli* approach for assessing inventiveness generally.[43] Paragraphs 25-56 of the United Kingdom Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office 2016 (as updated) provide, in detail, guidelines on how the *Windsurfing/Pozzoli* test could be applied for the purpose of judging inventiveness in the biotechnology context. These guidelines, as stated in paragraph 25, draw from the decisions of courts in the United Kingdom, as well as the Boards of Appeal of the European Patent Office.

In practical terms, it is questionable whether the steps for determining inventiveness formulated under the various patent systems discussed above would yield different outcomes when applied to the same claim. For instance, in *Teva UK Ltd v LEO Pharma*,[44] a composition consisting of two active ingredients was held by the court in the United Kingdom to be inventive because of a 'long-felt want' of a composition that specifically contains the two active ingredients. It was revealed that researchers had not found any way of putting the active ingredients together until the patent was under consideration, even though that had been their desire for a long time. This decision clearly aligns with the 'long-felt but unsolved needs' test adopted by the United States Patent and Trademark Office, and it could also be aligned with the European Patent Office problem-and-solution approach, which takes into consideration the problem to be solved by the invention.

Notwithstanding the foregoing, biotechnology has continued to pose a significant challenge to the patent systems in the United States, Europe and other jurisdictions around the world, especially as the technology advances at a considerable pace. With particular reference to gene-related invention, there are various bioinformatics tools now available for genetic investigation and vast amounts of information available on the human and other genomes. Hence, determining the gene encoding for specific protein or comparing and assigning functions to genes through automated

[39] See G-VII, 13. Guidelines for Examination in the European Patent Office, 2024.
[40] (1966) 383 U.S. 1, 148 USPQ 459.
[41] (2007) 550 U.S. 398.
[42] For detailed discussion and analysis see section 2141 of the United States Manual of Patent Examining Procedure; See also *In re Kubin*, (2009) 561 F.3d 1351 (the court held that the isolation of the claimed genetic sequences was obvious in light of KSR); Cf *In re Deuel* (1995) 51 F 3d 1552.
[43] See s 3 of the United Kingdom Manual of Patent Practice, 2016 (as updated) outlining the steps.
[44] (2015) EWCA Civ 779; See also *Idenix Pharmaceutical, Inc v Gilead Sciences, Inc &Ors* (2014) EWHC 3916.

methods is increasingly becoming a routine compared to a few years back.[45] Accordingly, the extent to which the products there from can be regarded as new and inventive remains an open question.

c. Industrial Applicability

Concerning the requirement of industrial applicability, some contributors have expressed concerns that biotechnology patents are speculative and of no demonstrable utility, especially with cases involving newly discovered genetic sequences.[46] Determining the usefulness or applicability of biotechnological inventions arguably raises the question of what needs to be disclosed in the patent application as proof that the biotechnological invention is capable of industrial application.

The United States Patent and Trademark Office has sought to address the issue by setting out utility requirement guidelines. Pursuant to the guidelines, patent applications must disclose at least a 'specific and substantial utility that is credible' in relation to claimed inventions, as a way of meeting the utility requirement of section 101 of the United States' Patent Act, 1952 (as amended).[47] This means that the claimed invention is useful for a particular practical purpose in contrast to the general use(s) that would be applicable to the broad class of the invention. With particular reference to genetic sequencing, disclosing the use of a claimed polynucleotide simply as a 'gene probe' or 'chromosome marker' would not in the absence of a specific DNA target be considered to be 'specific' and neither will it be considered 'substantial' where it may prove useful only at some future date after further research.[48]

In contrast, there are no elaborate guidelines specifically set out on how to meet the industrial applicability requirements of Articles 52(1) and 57 of the European Patent Convention, 1973 (as amended). Generally, and with particular regard to claimed inventions relating to genetic sequence, it is understood that a patent application must where it is not self-evident, indicate in the application the way in which the invention is capable of practical exploitation in industry.[49] Significantly, after considering, in some detail, decisions from the Board of Appeals of the European Patent Office, the Supreme Court of the United Kingdom in *Human Genome Sciences v. Eli Lilly*,[50]outline certain principles which should be taken into account when assessing the industrial applicability of biotechnological inventions. For instance, to meet the requirement of industrial applicability in the United Kingdom, the biotechnological invention must disclose a practical application' and 'some profitable use'. This is to ensure that the ensuing monopoly right 'can be expected [to lead to] some … commercial benefit'.[51]

[45]K K Singh, *Biotechnology and Intellectual Property Rights: Legal and Social Implications*, pp.59-60.
[46] I Mgbeoji I and B Allen, 'Patent First, Litigate Later! The Scramble for Speculative and Overly Broad Genetic Patents: Implications for Access to Health Care and Biomedical Research', pp.83-87.
[47] S 2107 of the United States Manual of Patent Examining Procedure.
[48] See *In re Fisher* (2005) 421 F.3d 1365.
[49] See G-III.4 Guidelines for Examination in the European Patent Office, 2024; See also *Harvard/Transgenic Animal*, (2006) E.P.O.R. 31.
[50] (2011) UKSC 51, (2012) RPC 6.; See also paragraphs 60-61 of the United Kingdom Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office, 2016.
[51]Ibid.

3. The Intersection Between Biotechnology Patenting and Traditional Knowledge

While the broader question on the protection of traditional knowledge falls outside the purview of this paper, the nexus between traditional knowledge and the patentability of biotechnological inventions vis-à-vis the standard tests of novelty and inventiveness is worth exploring (albeit in brief). This is because traditional knowledge, particularly those associated with genetic resources, plays a significant role in biotechnology research and development. Accordingly, it is argued that traditional knowledge potentially impacts the novelty or inventiveness of certain biotechnological inventions, particularly in the aspects of medicine and agriculture.

As evidenced in the *Neem* patents, the case of *Hoodia*, the *Enola* beans patent and others involving the use of the Rosy Periwinkle, *Turmeric*, *Jamun* and so on,[52] certain patent claims relating to biotechnology have been challenged and subsequently revoked on the grounds of lack of novelty and inventiveness. This is because they were largely based on traditional knowledge. The cases, in effect, question the adequacy and suitability of the prevailing intellectual property legal standards with regard to the cumulative nature of the innovation process as well as the contributory intellectual efforts of traditional knowledge holders, the majority of whom are in developing countries like Nigeria.

Going further, in the light of the discussions in the preceding section of this chapter, it is quite clear that a biotechnology invention consisting mainly of traditional knowledge ought not to pass the standard tests of novelty and inventiveness since traditional knowledge constitutes prior art. However, the question of how to deal with the misappropriation of traditional knowledge within the patent system is a challenging one, as the views continue to diverge between developed and developing countries.[53] It is not clear what degree of intervention is required to transform a biotechnology claim that is based on or derived from traditional knowledge into a novel and non-obvious invention. This is exacerbated by the fact that it is difficult to define the state of art in the traditional knowledge context, given that traditional knowledge is tacit, hardly documented and sometimes held in secret and considered sacred.[54]

4. Conclusion

A combined examination of the Nigerian patent law and those of other jurisdictions such as the United States, United Kingdom and European Union show the controversies and practical complexities associated with the application of patent standards to the field of biotechnology. As noted, because the law evolved primarily in response to the development of machines and chemical processes, it does not necessarily contemplate the peculiarities of biotechnological inventions and

[52] For more detailed discussions on the above highlighted cases and others see, N D Dewani, and A Gurtu (Eds.) *Intellectual Property Rights and the Protection of Traditional Knowledge* (IGI Global, 2020); P A Ageh, and N Lall, 'Biopiracy of Plant Resources and Sustainable Traditional Knowledge System in Africa' (2019) 8 Global Journal of Comparative Law 162, 178; Queen Mary Intellectual Property Research Institute. 'Report on Disclosure of Origin in Patent Applications'. (Prepared for the European Commission, DG-Trade, 2004) 20-23 <http://trade.ec.europa.eu/doclib/docs/2005/june/tradoc_123533.pdf accessed 31 January 2024.

[53] See World Trade Organisation. 'TRIPS: Reviews, Article 27.3(b) and Related Issues - Background and the Current Situation'. <https://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm> accessed 21 January 2024.

[54] K R Srinivas, 'Traditional Knowledge and Intellectual Property Rights: A Note on Issues, Some Solutions and Some Suggestions. (2008) 3 Asian J. WTO & Int'l Health L & Pol'y, 81 at 84 (pointing out that while innovation do take place in the context of traditional knowledge and it is cumulative and evolving, it is difficult to find the state of art compared to scientific knowledge); See also F Lenzerini, 'Traditional Knowledge, Biogenetic Resources, Genetic Engineering and Intellectual Property Rights'. In D Wuger & Cottier (Eds.) *Genetic Engineering and the World Trade System: World Trade Forum* (Cambridge, United Kingdom: Cambridge University Press, 2008)120.

innovations which are inherently connected with naturally occurring substances and processes. They have proven challenging to the requirements under the globalised patent standard, including the required tests of novelty, inventiveness and industrial applicability. For the purpose of clarity, there is a need for Nigeria to formulate principles that would guide the application of the patent law to biotechnology as obtained in other jurisdictions, bearing in mind the possible implications of biotechnology patents on public health, food security, traditional knowledge and the environment among other factors.