SUBJECT– MATTER ELIGIBILITY IN AI & MEDICINE: THE NIGERIAN POSITION

Artificial Intelligence (AI) is no longer news. Over the past few decades, the increasing sophistication of digital technologies and AI have crept into the fields of finance, property and real estate and more related to this piece, the field of Medicine. Medical equipment, treatment Machines and computer algorithms are now more frequently designed and intelligently combined to exploit data for the production of meaningful medical outcomes such as the diagnoses of various ailments, therapeutic prescriptions, treatment and prediction of the outcome of clinical scenarios.2

A number of crucial intellectual property law issues arise with respect to AI inventions relating to the medical field. One of these issues is the eligibility of an invention for patentability under Nigerian Law as it relates to its subject matter. This article will address few global developments in AI and Medicine and examine this eligibility issue as it pertains to Nigerian Law.

1. **What is AI?**

   Arguably in its simplest form, programs or features which enable computers to function in ways similar to human or superhuman intelligence may be regarded as AI.3 AI is further defined as ‘a field of science and engineering concerned with the computational understanding of what is commonly called

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1 Olukolade Ehinmosan, NYSC Intern, Corporate and Capital Markets Department, SPA Ajibade & Co, Lagos, Nigeria.
3 Ibid.
Intelligent Behaviour, and with the creation of artefacts that exhibit such behaviour.⁴

Alan Turing, British Mathematician reckoned for his founding and extensive works in modern computer science and AI defined Intelligent Behaviour in a computer as the ability to achieve human-level performance in cognitive tasks.⁵ As would be shown in this paper, AI achieves even super-human level performances and remains an emerging technological field with great and hair-splitting potentials.

Perhaps, AI is better understood in its practical and seemingly magical manifestations than its complex lexical representation. With the interaction of AI and Medicine in the solution of medical problems, AI would be more clearly relatable to the average individual.

2. The Interaction of AI & Medicine

1976 heralded some amazement in the field of Surgery. A surgeon named Gunn explored the possibility of diagnosing acute abdominal pain using unaided or minimally aided computer analysis.⁶ This development marked the incipience of further massive AI inventions and discoveries. One of these inventions is the very popular Artificial Neural Networks (ANNs).

ANNs consist of networks of highly interconnected computer processors called ‘neurons’ capable of performing parallel computations for data processing and knowledge representations. ANNs are known to possess the ability to learn from historical examples, analyse non-linear data and handle imprecise information, rendering them invaluable in medical data analytics.⁷ ANNs are capable of conducting various medical diagnoses and prognosis as well as image analysis, data interpretation and waveform analysis.

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In terms of diagnosis, a classification algorithm called ProstAsure Index was developed with the capability to classify prostate as either benign or malignant. Also, PAPNET, a computerized automated screening system based on ANNs has been developed to assist in cervical screening.

Another example suffices in the operation of Medical Chatbots. Medical Chatbots utilize neural networks to learn from medical textbooks, scientific research, patient records, and messages between actual patients and doctors. The AI chatbot is constantly learning and can be kept up to date on the latest medical research. Baidu, a Chinese search engine, utilizes a chatbot named ‘Melody’ within its Baidu Doctor App. When a patient poses a question to the doctor, the chatbot will request appropriate follow-up questions to learn more about the patient’s symptoms so the doctor can make a more informed decision on treatment.

With respect to prognosis, ANNs have assisted in intelligent and insightful medical planning and action on medical patients depending on their respective level of exposures. It has been demonstrated that ANNs can predict survival in patients suffering from breast and colorectal cancer. Remarkably, ANNs have recorded significant success; they have been shown to perform better than colorectal surgeons in predicting outcomes in patients with colorectal cancer!

Other AI-based inventions in the field of Medicine include Fuzzy Expert Systems, Evolutionary Computations and Hybrid Intelligent Systems. Fuzzy Expert Systems recognizes the phenomenon of “fifty shades of grey” – the

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8 Stamey T.A., Barnhill S. D., Zang Z, Effectiveness of ProstAsureTM in Detecting Prostate Cancer (PCa) and Benign Prostatic Hyperplasia (BPH) in Men Age 50 and Older, J Urol 1996; 155: 436A.


11 Gallego, supra n. 10.

12 Ibid.

factual reality of subjectivity – the fact that things might vary in their characteristics and outcomes. Fuzzy Expert Systems have excelled in the diagnosis of conditions including lung cancer, acute leukemia, breast cancer, pancreatic cancer, et cetera.\textsuperscript{14}

Evolutionary Computations are essentially concerned with search and optimization.\textsuperscript{15} The most widely used forms of Evolutionary Computations are the General Algorithms. They work by creating many random solutions to the problem at hand. This population of many solutions will then evolve from one generation to the next, ultimately arriving at a satisfactory solution to the problem. The best solutions are added to the repository while the inferior ones are eliminated. By repeating this process among the better elements, repeated improvements will occur in the population, survive and generate new solutions.

The Hybrid Intelligent Systems is a product of a combination of the advantages of the earlier highlighted AI-based inventions. This has also been used in resolving a number of medical tasks and problems including the diagnosis and prognosis of breast cancer, coronary artery stenosis and control of the depth of anesthesia.\textsuperscript{16}

3. \textbf{AI & IP : The Eligibility Question}

Flowing from the exposition of the interaction between AI and Medicine, is the common concept of inventiveness. The AI-based Medical solutions highlighted are products of deliberate efforts at creativity and ingenuity. They are clearly inventions; and never before has planet Earth witnessed their sophistication and range of possible applications. They belong to the realm of Intellectual Property Rights (IPRs).


\textsuperscript{15} A. N, Ramesh, supra, 337.

As the impact of AI in Medicine continues to bolster, the intellectual property legal system must gear up for some crucial questions especially regarding the protection of the rights of persons who expend their ‘sweats and calories’ in seeing to the inventions of these medical solutions. Perhaps, one of the most crucial questions to be answered is that of the eligibility of an AI-based medical solution for patent protection. Are the Nigerian IP laws awake to this occasion? Let’s find out.

4. **Subject– Matter Eligibility of AI-Based Medical Solutions**

There is a dearth, if not a total vacuum, of IP judicial authorities bordering on this recondite area. This is clearly understandable in view of the nascent and emerging status of AI in the Nigerian IP space, especially in the health sector. Nonetheless, this piece will consider another common law jurisdiction with arguably one of the most vibrant IP legal systems globally, (i.e., the United States) and critically analyse the patentable subject matter of AI vis-à-vis the relevant Nigerian statute.

Under Nigerian Law, the subject matter of an invention must be eligible for patenting. The Nigerian *Patents and Designs Act* (PDA)\(^{17}\) sets out the criteria for an invention to qualify as patentable. Section 1 PDA provides that an invention may be eligible for patent if such invention:

1. Is new;
2. Involves an inventive step;
3. Is Capable of industrial use or application; and
4. Is not specifically excluded by the Act.

Some U.S. judicial decisions have made this subject more thought-provoking. In *Mayo Collaborative Services v. Prometheus Labs. Inc.*\(^{18}\), for instance, a patent claim was made involving the relationship between the concentrations of certain metabolites in the blood and the likelihood that a drug dosage would prove ineffective or cause harm for failing to meet this requirement. The Court held the invention to be ineligible for patenting as it provided “instructions

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\(^{17}\) Cap. P2, LFN 2004.

[that] add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field.”\(^{19}\) In essence, the Court was of the judicial opinion that a medical invention would not be eligible for patent registration if it is merely a diagnostic method that only recites an indication or a sign to change dosage.

Similarly, in *Alice Corporation Property Limited v. CLS Bank International*,\(^{20}\) the Court spelled out a two-prong test for determining the eligibility of an invention for patentability based on its subject matter as follows:

1. Determine whether the claims are directed to a patent-ineligible concept (laws of nature, abstract ideas, and natural phenomena); and

2. Determine whether the claim’s elements, considered both individually and as an ordered combination, transform the nature of the claims into a patent-eligible application.\(^{21}\)

Apparently following the principles in the above cases, in *Ariosa Diagnostics Inc. v. Sequenom Inc.*, the Court admitted that a method of prenatal diagnosis of foetal DNA “reflects a significant human contribution … that revolutionized prenatal care” but intriguingly held that the claimed method was not eligible for patent.\(^{22}\)

In contrast, it appears that a medical invention would be eligible for patent where it is not merely a diagnostic method but also indicates a method of treatment of a disease. This was the crux of the majority decision in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*.\(^{23}\) Here, the patent was related to a method of treating schizophrenia patients with *iloperidone*

\(^{19}\) Supra, at 69.

\(^{20}\) 134 S. Ct. 2347 (2014).


\(^{22}\) 788 F.3d, 1371, 1376, 1379 (Federal Circuit, 2015).

involving prescriptions and dosage based on the patient’s genotype. The Court held the invention eligible for patent and noted that the patent claim went above and beyond just diagnosing the patient’s genotype to include a capability to disclose specific dosage in the treatment steps of the patient.

It is submitted that the position of the Courts in the United States as revealed above is not likely to be different from a correct interpretation of the PDA in Nigeria. **Section 1(4) PDA** sets out the grounds upon which an invention may be excluded as follows:

“(4) **Patents cannot be validly obtained in respect of**-

(a) Plant or animal varieties, or essentially biological processes for the production of plants or animals (other than microbiological processes and their products); or

(b) inventions the publication or exploitation of which would be contrary to public order or morality (it being understood for the purposes of this paragraph that the exploitation of an invention is not contrary to public order or morality merely because its exploitation is prohibited by law).

(5) **Principles and discoveries of a scientific nature are not inventions for the purposes of this Act.**”

For an invention relating to the field of Medicine to be eligible for patent, it would certainly have to scale through these three important exclusionary provisions.

Delving into the first exclusion, where an AI-related invention has its subject matter relating to plant and animal varieties and/or biological processes for the production of plant and animal varieties, such invention would not be eligible for patent under Nigerian law. Also, by virtue of the second exclusion, an invention that violates public order and morality would certainly not be eligible for invention.
Of utmost importance in this context is the third exclusion. Where an invention is based on principles and discoveries of a scientific nature, then such invention would not be eligible for patent. This exclusion looks particularly problematic when placed in relation to the examples earlier highlighted in this treatise. However, the presence of the words “principles” and “discoveries” are suggestive of the position of the United States Courts. For an invention to enjoy eligibility to a grant of Patent, it must not merely relate to the discovery (diagnosis) of a biological situation or state of things but must be capable of creating (inventing) a method through which a scientific challenge or problem can be tackled.

To sum up the foregoing analysis, the below excerpt by an IPL expert is helpful:

“The question may then be asked whether principles and discoveries of a scientific nature are inventions? The Nigerian PDA specifically excludes these and states that they are not inventions. Indeed, a discovery without anything further cannot amount to an invention. A man who discovers that a known machine can produce effects which no one knew could be produced by it before, or that a known process will produce improved effects if continued for a longer period, or who discovers an advantage in the working of a known scientific process without any modification in that process, may make a useful discovery, but if he does nothing more, his discovery is not a patentable invention.”

5. Review of Subject-Matter Eligibility: Critical Issues

Apart from the substantive issues relating to subject-matter eligibility, medical AI inventions also face practical issues. Indeed, the possibility of a medical invention apparently satisfying the basic requirements for patentability in the

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PDA but falling short of registration cannot be divorced from the subject matter of patentability.

By section 3 of the PDA, every patent application shall be addressed to the Registrar of Patents in compliance with appropriate procedures and formalities. Notably, section 3 of the PDA prescribes procedures to follow for patent applications especially what the application should contain. In essence, full compliance with section 3 PDA does not automatically secure a patent on the invention.

Also relevantly, section 4 PDA clothes the Registrar of Patents with the power to examine every patent application but only for conformity with section 3 PDA. In clearer terms, this power of the Registrar of Patents to examine patent applications is aimed at ensuring that the content of the patent application as well as the procedure for application are complied with in line with section 3 PDA. The power of the Registrar of Patents clearly has nothing to do with examining a patent application on the merits. The PDA states thus:

“(2) Where the examination mentioned in subsection (1) of this subsection shows that a patent application satisfies the requirements of section 3(1) and (3) of this Act, the patent shall be granted as applied for without further examination and, in particular, without examination of the questions-

(a) whether the subject of the application is patentable under section 1 of this Act.”

In essence, by the combined effect of the PDA and the Patent Rules, upon compliance with the procedures and provision as to the content of the application, the Registrar shall grant the patent.

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25 See also, Rules 11 to 15 of the Patent Rules, a subsidiary legislation made in pursuance of the PDA.

26 Section 4(2), PDA (emphasis intended); also, Rule 13 of the Patent Rules (supra).

27 Section 4(2), PDA and Rule 14 of the Patent Rules (supra).
Understandably, the Registrar of Patents is, with due respect, presumed a layman administrator – one skilled in the statutory patent application formalities but bereft of scientific and technical credentials. The Registrar thus has strictly administrative responsibilities with respect to patent applications and cannot enquire into the merits of compliance of an application with the subject-matter eligibility criteria discussed in preceding paragraphs. The PDA allocates the risk of establishing patentability to the patentee, by making the patentee’s proprietary rights subject to the snail-paced and grossly unpredictable vehicle of courtroom litigation.

As F. O. Babafemi notes, there are some IPL jurisdictions where the examination of patent applications are done by the Patent Office and intended to cover all possible aspects of the patent law capable of affecting the validity of such patent, including those of the United States (US) and the United Kingdom (UK), which are in substantial accord with Nigerian laws. In these systems, the Registrar of Patents and the agency staff possess scientific expertise and technical skills for conducting very meticulous inquests into the patentable nature of submitted applications that spans fairly lengthy periods of time.

In addition to the lack of substantial examination in the Nigerian patent system highlighted above, the adversarial system of adjudication may restrict the latitude of the Judge’s powers to conduct wide-ranging inquisitions on the patent claim which is the subject of litigation, if not properly within the scope of the pleadings as filed. This ultimately has a negative toll on the quality and reliability of the IP dispute resolution system.

It is respectfully submitted that the PDA and subsidiary legislations be amended to include substantial expertise in intellectual property law on patents and designs as an eligibility criteria for the appointment of the Registrar of Patents. In addition, the Registrar of Patents should be empowered to review patent applications on the merits in line with international best practices and the peculiar needs of the Nigerian IPL system. The Registrar of Patents should be able to conduct in-depth and meticulous

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inquests on the patent claim sought to be registered and its conformity with subject-matter eligibility as well as other statutory criteria.

6. **Conclusion**

Admittedly, the impact of AI in the field of Medicine in Nigeria has not been pronounced by Nigerian courts. However, the fact that it took only a few knocks on the door for FinTech and PropTech to gain wide recognition and influence in Nigeria suggests a promising future for this field. The reality of medical practice as a global rather than a municipal field also suggests that it would ultimately penetrate and ‘infect’ the Nigerian medical practice. The sooner this is grasped, the better for intellectual property law practice and overall, the medical economy.

In addition, the AI revolution is real and here to stay. With the unstoppable prevalence of technological advancement in medicine and other related fields, it would not be surprising that the Registrar of Patents is overburdened with patent applications. The Patent Registry should therefore be enlarged, computerized and adequately staffed in anticipation of this certain occurrence. A crystal ball is not also required to foresee that specialized IP Courts would soon be a national urgency in Nigeria in the near future. Similar to the National Industrial Court, there should be a specialized Court or Tribunal specifically empowered to adjudicate on IP disputes. A system is developed, not necessarily by quality of its laws, but by foresight and appropriate actions.

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For further information on this review and area of law please contact

**Olukolade O. Ehinmosan** at: S. P. A. Ajibade & Co., Lagos by

Telephone (+234 1 472 9890), Fax (+234 1 4605092)

Mobile (+234.810.370.8623)

Email: oehinmosan@spaajibade.com)

[www.spaajibade.com](http://www.spaajibade.com).