THE LEGAL AND ETHICAL IMPLICATIONS OF PATENTING MEDICAL TECHNOLOGIES ON HEALTHCARE SERVICES IN NIGERIA*

Abstract

Patenting an invention gives the patentee the right to exclude others from making, using, or selling such invention for a period of 20 years from the date of filling a patent application. The requisite factors for patent eligibility include novelty, obvious inventive process and industrial applicability of the invention. Interestingly, the patent laws in some jurisdictions like Europe, USA, exclude both medical and surgical procedures for patient care from patentability based on morality and absence of technical or inventive activity, while granting same to medical devices and gadgets used for therapeutic and surgical purposes as well as medicines. Technological inventions in the healthcare sector have undoubtedly made significant contributions to improving public health. These inventions in the healthcare sector aid the healthcare practitioners to provide more efficient healthcare services through early diagnosis, less invasive treatment options and also reduces the duration of hospitalisation and recuperation. Therefore, this paper seeks to determine the legal and ethical issues associated with granting patent protection to inventions in the medical field; should all or a certain category of medical inventions be patented and what would be the effect on the medical practitioners and the quality of service delivered to healthcare consumers in Nigeria.

Keywords: Ethics, Healthcare, Medical Procedures, Medical Technologies, Patent Protection, Right to Health.

1. Introduction

If every invention suitable for public use and does not contravene public morality is patentable, as opined by Matthew [1] then almost every invention under the sun would be patented. However, this is not the case because patent is a statutory protection of intellectual properties with stipulated criteria for patentable inventions. Moreover, statutory provisions of nation states are influenced by the social mores (public morality and opinion) prevalent among citizens of that state, as propounded by the German jurist; Von Savigny [2] For instance, in Europe, patenting a method of human treatment may be considered to be against public morality but this may be convenient in Australia. Although patents are available in these states for medicines and medical devices for diagnosing or treating patients, patents on methods of treatment, which could be enforced in such a way as to prohibit doctors from practicing their profession and providing life-saving services, are considered to contravene public morality. A patent is a monopoly over an invention or an exclusive right to control the way the patented invention is exploited over a stipulated period of time. [3] The rationale for patenting inventions is that an inventor of a product or process for which monopoly is granted can generate revenue from either sale or licensing or use of the invention to recoup the money invested in the research that led to the invention. In return, the inventor or patentee discloses or shares the knowledge in the invention with the public as part of his patent application requirement [4] by explaining in detail the process, utility and industrial application of the invented product. Thus, while the inventor enjoy exclusive right to control his inventions, derive financial benefits from his intellectual sweat and resource investments, which motivates him to create more inventions on one part, the public on the other part benefit from both the knowledge of the inventive process and the utility in the products, all in the spirit of social contract as propounded by John Locke and Thomas Hobbes.

Medical inventions encompass surgical and medical procedures or methods of treatment, [5] Medicines, healthcare products and medical devices, aimed at improving the delivery of quality healthcare service to healthcare service consumers to achieve better disease prevention techniques, improved diagnostic accuracy, efficient patient care management, advanced surgical and restorative procedures. [6] Thus, the utility of medical inventions are for diagnosis, treatment of diseases or medical conditions and surgical interventions to promote

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[1] Matthew Latimer, 'Patenting inventions arising from biological research' [2005] (6) *Genome Biol* 203.

[2] A protagonist of the historical school of thought

[3] Trade Related Aspects of Intellectual Property (TRIPS) Agreement, Article 33.

[4] TRIPS Agreement, Article 29

[5] Also called invasive and non-invasive procedures or techniques respectively

[6] Richard Patent Law, 'Medical Innovation' [2009] <https://www.richardspatentlaw.com/industries/medical/.> Accessed 25 September 2019.

health conditions. [7] According to Michael A & ors, [8] disease was viewed with mystery and was a common occurrence that claimed many lives in the early days of human existence. Hippocrates and Galen were the first documented western physicians to actively engage in a rudimentary science of medical care when medical practitioners relied primarily on signs and symptoms presented for treatment. [9] Subsequently, medical technology evolved in response to the high mortality rates associated with disease conditions. For instance, some medical innovations were introduced for diagnosis or treatment of diseases, such as the sphygmomanometer, x-ray, prosthetic devices such as artificial heart valves, blood vessels etc. Recently, inventions on robotic devices, minimal access surgery are being used in healthcare service delivery. From the days of Hippocrates and Galen, medical practitioners have freely exchanged scientific knowledge, discoveries and inventions made for advancing medical practice, without expecting any financial reward[10]. This antecedence led to scientific development of the profession, knowledge transfer and validation of medical and surgical techniques invented for patient care [11]

Inventions on medical procedures have been predominantly used by the inventors to claim credit without necessarily expecting any financial reward. [12]. For instance, Dr. Willem Einthoven of the Netherlands invented the first electrocardiogram for which he received a Nobel Prize in 1924. [13] . Edward and Steptoe are acclaimed as founding fathers of Artificial Reproductive Technology by virtue of the birth of the first baby conceived through *in vitro* fertilization. [14]. The duo claims the credit but they did not patent the medical technology, neither is any financial reward attached to the recognition. Today thousands of children are products of this unpatented method of conception and there has been an extensive incremental invention in this regard. [15] Similarly, Murphy's sign is a terminology for the positive sign seen on abdominal examination before diagnosing a patient with acute cholecystitis, [16] while positive McBurney sign diagnoses acute appendicitis. [17] These terminologies are named after the inventors. In addition, pfannenstiel and Joel-Cohen incisions are methods of making obstetrical surgical incisions for surgical delivery of babies. [18] These incision methods are named after the surgeons who first described and used them. The inventors shared this knowledge amongst other practitioners and today, these methods are freely and widely used on pregnant women who for any reason could not have vaginal delivery.[19] These incision methods represent an incremental invention on the pre-existing (traditional) vertical incision for abdominal surgeries. Moreover, the afore-mentioned medical and surgical procedures are freely used by medical practitioners, in performing medical activities which includes diagnosis and treatment of patients. Assuming they were patented by the inventors and these inventors enforced their rights against medical practitioners and other healthcare staff for infringing on their patent rights by using the inventions without permission, what would be the fate of healthcare service and state of human health today?

Medical devices involve use of raw materials to manufacture novel products such as medicines, implants, surgical instruments, software automated gadgets and systems as well as improvements on existing products which are used in hospitals [20] . These tangible products can be subjected to patent protection like other technological products, but they are different from procedures which are basically skills acquired over time through learning and practice.[21]

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[7] A Attaran, 'How Do Patents And Economic Policies Affect Access To Essential Medicines In Developing Countries?' [2004] (23) Health Aff . 155.

[8] A Michael, A De Miranda, M Doggett, T. Evans, 'Medical Technology Contexts and Content in Science and Technology' [2005] <https://www.researchgate.net/publication/42831446_Medical_Technology_Contexts..> Accessed 25 September 2019

[9] Koutsouris Dimitris, 'The Evolution of Medical Care: from the Beginnings to Personalized Medicine' [2017] (7) *Health Technol* 3.

[10] Linda Judge, 'Issues Surrounding the Patenting of Medical Procedures' [1999] (13) *Santa Clara High Tech. L.J* 202 .

[11] Ibid

[12] Ibid 188

[13] Monique Ellis, 'Top 10 new medical technologies of 2019' [27 February 2019] <https://www.proclinical.com/blogs> Accessed 29 September 2019.

[14] R. Edward & P Steptoe, *A matter of life. The story of a medical breakthrough* (London: Hutchinson 1980.)

[15] Victoria Assisted Reproductive Authority (VARTA) 'Types of Assisted Reproductive Treatment.' www. varta.org.au. Accessed 2 March, 2017. Cited in C Ekechi-Agwu 'Law and Ethics of Medically Assisted Reproduction in Nigeria' LLM Dissertation 2017.

[16] K Musana, S Yale, 'Murphy's Sign' [2005](3)(3) *Clinical Medical Research*.132.

[17] S Moses, 'McBurney's Point' [10 June 2012] <https://fpnotebook.com. >Accessed 30 September 2019.

[18] O Naji, Y Abdallah & Ors, 'Cesarean Birth: Surgical Techniques'[2010] *Global library of women's medicine*

[19] Ibid

[20] Richard Patent Law, n6.

[21] O Naji, Y Abdallah & Ors n 18

Medical practice is predicated on the premise of saving lives and avoiding preventable deaths as such, any act or decision that undermines this, attacks the basic foundation of the profession. This is evident in the principle enunciated in the Hippocratic Oath…

> to reckon him who taught me this Art equally dear to me as my parents, to share my substance with him, and relieve his necessities if required; to look upon his offspring in the same footing as my own brothers, and to teach them this Art, if they shall wish to learn it, without fee or stipulation; and that by precept, lecture, and every other mode of instruction, I will impart a knowledge of the Art to my own sons, and those of my teachers, and to disciples bound by a stipulation and oath according to the law of medicine, but to none others. I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients... Into whatever houses I enter, I will go into them for the benefit of the sick, and will abstain from every voluntary act of mischief and corruption….

2. Legal Issues

All human rights instruments and national laws [22] recognize and seek to protect the right to life which is sacrosanct and is not easily alienated from right to health. Under international law, the legal basis for intellectual creations, protection and use stems from Article 27.2 Universal Declaration of Human Rights. The right of every person to enjoy the utility of any invention made and the right of inventors to benefit from their work are both recognized and secured in Articles 15.1(b) and (c) of International Covenant on Economic Social and Cultural Rights (ICESCR) respectively, and the utility of inventions to the general public is further reiterated in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) 1994. [23] States are enjoined to grant patent protection to qualified inventions and to also apply discretion to exclude some inventions from patent protection on grounds of public order or morality in their specific national patent laws. [24] This is so because what state A may consider to be against public order and morality may not be so in state B. There has been a general notion that medical procedures or method of treating diseases and surgical procedures are not patentable because they are deemed to be incapable of industrial application and have no inventive process. [25] The United States Code (U.S.C.)[26] provides that whoever invents or discovers any new and useful process, or any new and useful improvement thereof, may obtain a patent, subject to the conditions and requirements of this title. Consequently, the court in the case of *Becton-Dickinson & Co. v. Robert P. Scherer* [27] relied on the utility of the new method for injecting a medication using a pressure jet to hold that processes involving medical or surgical techniques of treatment are patentable. Pursuant to this decision, patents were granted for other medical and surgical techniques, for instance a method for performing a percutaneous medical procedure without a trocar. [28] Conversely, in a patent infringement lawsuit between *Pallin v Singer*, [29] the plaintiff sought to enforce his patent right by claiming damages and entitlement to royalties against some doctors for using his invented self-sealing episcleral incision method in performing eye surgeries on their patients, but the court held such claim invalid and dismissed the suit. Thereafter, the legislature took a further step by amending the patent code. [30] to preserve sanctity in healthcare service, protect both patients and healthcare staff from frivolous litigations. Though US patent law does not prohibit patenting methods of medical and surgical treatment, it nonetheless denies enforcement where the infringed right relates to the performance of a medical activity. The law [31] protects medical professionals and the healthcare facilities where they work from liability of damages claimed for use of medical and surgical procedures in performing their medical activities. But this exclusion does not cover liability for infringing on patent rights for other medical inventions which may or may not be used in conjunction with the procedures. The statutes of monopolies 1623 [32] also limits the exclusion of non- patentable inventions to: Human beings and biological processes for their generation.

[22] Constitution of the Federal Republic of Nigeria (CFRN) 1999 (as amended) s 33.
[23] Article.
[24] TRIPS Agreement, article 27.2
[25] B Meier, 'The new patent infringement liability exception for medical procedures' [1997](23) *J Legis* 265.
[26] 35 U.S.C. (1988) s 101. Note: the word "art" in 1952 was replaced by "process" in the revised statute thereby clarifying that processes are patentable subject matter.
[27] 106 F. Supp. 665 (E.D. Mich. 1952)
[28] U.S. Pat. No. 5,383,886. See also Linda, Judge n 10.
[29] No Civ A 2:93-CV202 1996.
[30] 35 USC (Supp II 1996), s 287(c)
[31] 35 USC, s 287 (c)(1)

[32] S 18(2)

Literarily, the exclusion of medical and surgical procedures from patentability is absolute but some procedure-related medical devices may be patented under certain conditions [33] Such as where the procedure is a method or part of the method or an improvement in the use of an invented medical device - which is a product of an inventive process, not being part of an existing prior art and can be used by a person skilled in that art. Methods of medical treatment were excluded from patent protection in the UK since 1914 i*n the Matter of C & W's Application for a Patent.* [34] Here, the solicitor general refused an application for patent protection for a process of extracting toxic lead from living human beings on grounds that the alleged invention related simply to a medical treatment. The basis for such refusal was that a medical treatment process did not employ any form of manufacture or trade, thus lacks commercial value. In *Eli Lilly & Company's Application* [35] the court stated that the restriction still applied and the patent application was refused based of the public policy proviso to section 6 of the Statute of Monopolies. The court affirmed that the law intends at that time to prevent grant of patent on any new method that claimed to be a cure or prevention of disease in human beings. Subsequently, the parliament of the United Kingdom codified exclusion of methods of medical treatment from patent protection. [36] This implies that grant of patent or denial of same also depends on the technical details disclosed in the claims on the patent application.

In Australia, the law is not quite explicit but no statutory provision prohibits the grant of a patent for a medical or surgical procedure for treating human beings, except to the extent of excluding ''Human beings and biological processes for their generation from patentability.[37] The Patents Act 1990 contemplates invention according to section 6 of the Statute of Monopolies 1623, such that an invention is patentable in Australia, if it is not generally inconvenient. Thus the courts have unfettered jurisdiction to decide whether or not it is generally convenient for an invention to be patented based on public order. However, the opponents to the patentability of methods of medical and surgical treatment rely on the proviso of 'manner of new manufacture'**,** [38] and statutory exclusion of Human beings and biological processes, [39] to argue that granting a patent to these methods of treatment are generally inconvenient on grounds of public policy and morality. Nevertheless, the Federal Court in the case of *Anaesthetic Supplies Ltd v Rescare Ltd* [40] held that it was not generally inconvenient to patent a device for treating snoring and the method of treatment. In the court's opinion, it is unreasonable to patent products (devices) for human treatment but deny same for methods of treatment. In a similar case between *Bristol Myers Squibb Co v F H Faulding & Co Ltd,* [41] the federal court held that it was generally inconvenient to patent the method of administering taxol medicine for cancer treatment, based on public policy reasons. However, on appeal, the decision was set aside by majority opinion and the court held that it was not generally inconvenient to patent the medical procedure. [42] Is it therefore proper to conclude that the courts took the right approach on this issue in arriving at the above decisions? Be that as it may, the Australian courts in a recent decision has confirmed the position of law in the state on this issue in the case of *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd,* [43] where the Federal Court held that methods of treatment are patentable under the section 18(1)(a) of the 1990 Patents Act.

The Patents (Amendment) Act, 2005,[44] excludes medical and surgical diagnostic and therapeutic procedures from patentability in India. In *Lalit Mahajan's* patent application,[45] the issue was whether a device for detection of antibodies to HIV and P24 antigen of HIV in human serum was excluded from patentability under section 3(i) of the Act. The opponents argued that the applicant had hidden the diagnostic aspect of the device hence the invention

[33] Article 52(4) of the European Patent Convention (EPC) 1978, provides that methods of medical treatment of the human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body are excluded from patentability, because they are not susceptible to industrial application. Even the second medical use idea (Swiss type claim) which was used to circumvent the exclusion in article 52(4) EPC 1978 and secure patent protection for methods of medical treatment that involve the new medical use of drugs, still left treatment methods and surgical procedures unpatentable.
[34] RPC 235 (1914).
[35] [1975] RPC 438**.**
[36] Patents Act 1977 s 4(2) (UK).
[37] Statute of Monopolies 1623, s 6.
[38] Patents Act 1990, s 18 (1).
[39] Statute of Monopolies 1623, s 6.
[40] (1994) 50 FCR 1.
[41] (1998) 41 IPR 467
[42] Though Sheppard J in dissent, argued that granting a patent for a method of medical treatment would be ''generally inconvenient'' within the public policy proviso in section 6 of the Statute of Monopolies, 1623. Yet, majority decision held otherwise.
[43] [2013] HCA 50
[44] S 3(i)
[45] Patent Application No. 693/KOL/2007 decided on 11.01.2010

falls within the excluded category. The patent examiner observed that the invention in question was a device and not a diagnostic or therapeutic method. As a result, the ground raised by the opponent was not sustainable and section 3(i) of the Act was held to be inapplicable to the invention. Similarly, in *M/s. Applied Research Systems Ars Holding, Netherland's* patent application[46] the issue was whether the claim related to a kit for the treatment of infertility in women comprising multiple doses of FSH could be excluded from patent protection under section 3(i) of the Act. The Patent Examiner concluded that the said invention was merely a method of medical treatment in the guise of the claimed kit (a product), and was not patentable under section 3(i) of the Act. It therefore appears that in US and UK, healthcare products, medicines and invented devices used for invasive and non-invasive procedures in the healthcare facilities either for diagnostic or therapeutic purposes, may be patented if they meet the statutory requirements, but the medical or surgical procedures are not patentable as inventions on their own, though they can be included as part of the claims in the patent application, such that the patent right will encompass them. While in Australia, medical and surgical procedures may be granted patent protection as sole inventions.

3. Ethical Issues

Ethics as a code of professional conduct in healthcare basically provide guidelines for patient care and the ethical use of medical technologies for medical practitioners and other healthcare staff.[47] Perhaps that's why the World Medical Association adopted the version of the Hippocratic Oath[48] which reads: I swear to fulfill, to the best of my ability and judgment, this covenant: I will respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow. The ethical questions therefore are: What is the right thing to do? Is it morally right for claims to be made for medical inventions used for medical activity? What medical inventions should be patented- both procedures and devices or devices only? Where does the healthcare staff obligation lie? To use patent protected procedures and save lives or refrain from using same and risk endangering human life? Are medical practitioners obligated by the Hippocratic Oath (Geneva Code of ethics) to respect patent rights of their colleagues in lieu of patient care? Should breach of patents rights on procedures be enforced on healthcare staff? Does patent protection of medical and surgical procedures not negate the part of the oath on sharing of knowledge and teaching without a fee among medical practitioners? These issues can be resolved by determining whether it is morally right and positively promotes public good to patent all medical inventions whether products or procedures or a certain category of the inventions, bearing in mind that the purpose of creating patents as a protective tool for intellectual inventions is to contribute to the promotion of knowledge acquisition and transfer and technological advancements for the mutual social and economic welfare of the inventors and the public, thus achieve a balance of rights and obligations.

Given that procedures are skills acquired from practice and sharing such knowledge is essential for saving human lives, would it be ethical to patent such procedures and seek to enforce same on fellow medical practitioners who use the skill to provide healthcare service to patients? The authors certainly think otherwise, having conceived the medical profession to have more of a paternalistic approach than a contractual relationship. The later approach supports the mutual benefit purpose of establishing patent laws for inventions other than procedures because it doesn't merely negate the spirit of the Hippocratic Oath, but a healthcare staff would most likely refrain from incurring liability from patent infringement claims than use the patented procedure to treat a patient. Indeed, any attempt to enforce patent on medical and surgical procedures will constitute an affront on medical practice and healthcare service delivery. It is therefore the authors' recommendation that medical activities which involve the above procedures should be statutorily excluded from patent protection to promote public good and morality. In *Mayo Collaborative Services v. Prometheus Laboratories Inc*.[49] Prometheus's patent involves a process of administering thiopurine compound to patients with autoimmune diseases like ulcerative colitis, Crohn's disease, and comparing the difference in concentration of the resulting metabolite in the patient's blood with the metabolite limits as contained in the patent to determine whether the patient is reacting to the drug as desired or not. The Court invalidated the claims, on the grounds that the content of the claims sought to protect laws of nature as it did not add enough inventiveness to the law of nature and granting patent protection on laws of nature would inhibit future innovations premised on them. In view of the fact that prior art for medical and surgical procedures is basically established at the medical school during lectures, clinical postings to various departments in the medical profession, scientific seminars and conferences, in the operating theaters, are medical and surgical procedures eligible for patent protection under patent Act in Nigeria?

[46] Patent Application No. 404/MUMNP/2005 decided on 28.09.2007.
[47] A.S Taubman, 'A framework for looking at IP and Bioethics' Life Sciences symposium September 2007, *Global IP Issues Division, WIPO*.
[48] The Geneva Convention Code of Medical Ethics in 1949
[49] 132 S. Ct. 1289 (2012) at 1293

According to the Patents and Designs Act Cap P 2 Laws of Federation of Nigeria, 2004,[50] an invention is patentable if it is new, result from inventive activity and is capable of industrial application; or if it constitutes an improvement upon a patented invention but also new, results from inventive activity and is capable of industrial application. For the purposes of this section, an invention is new if it does not form part of the state of the art.[51] Therefore, the requirement of novelty relates to both availability of the product of that invention to the public as well as descriptive information of same. [52]An invention is said to result from 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, while the industrial applicability of an invention is satisfied if the invention can be manufactured or used in any kind of industry. Section 1(4) of the Act excludes the following from patentability under the Act: plant or animal varieties, or essential biological processes for the production of plants or animals (other than microbiological processes and their products); 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). Principles and discoveries of a scientific nature are also not patentable under this Act.[53] The question then is, would it not be against public order and morality to patent medical and surgical procedures used for treating patients, such that physicians and healthcare practitioners will require to obtain permission from the patent right owners before treating the patients, bearing in mind that time is of essence in patient care management. The intendment of the lawmakers would not have been to encourage such hardship, where parents may watch their children die or husbands lose their pregnant wives and unborn babies because the procedures needed to save their lives are patented and the health facility they could access have no permission to use those procedures. On the other hand, medical devices and medicines have definite inventive process and industrial applicability which are important requirements for patentability. Unlike the procedures, manufacturing these healthcare products is financially and manpower intensive. Thus, it is understandable and in accordance with public order and morality that the inventors or research and development industries that sponsored the invention patent these products to recoup the investments made to develop the products. Section 2 of the Act secures the right of inventors to be written as the owner of the invention such that their intellectual effort is acknowledged in the event that an inventor is not the one filing the patent application. This provision is highly commendable because an inventor may not have the resources to patent his invention but he retains the credit for his work through this provision. According to Section 3(3) of the Act, a patent application shall relate to only one invention, but may include claims to other products or processes. This is to say that patent protection may extend to procedures that are included as part of the claim on the patent application made for medical inventions other than medical or surgical procedures alone.

All inventions need to be new, involve an inventive step and be industrially applicable. If that is the case, do the invasive and non-invasive (surgical and medical) procedures in healthcare service meet the criteria for patentability?

Surgical and medical methods of treatment are skills performed by healthcare professionals which are intended to produce specific desired effects on human beings, as such they lack both inventive process and industrial applicability. Moreover, being that the skills are acquired over time from observation and training they cannot be entirely novel but may at best be described as having been incrementally refined and advanced by knowledge. If this be the case, it implies that methods of human treatment are not patentable for not meeting the requirements of patentability under the Nigerian law. Moreover, the code of medical ethics in Nigeria,[54] which incorporates the Hippocratic Oath, enjoins the practitioners to share medical knowledge among themselves for the benefit of their patients and not for personal gain.

[50] Section 1(1)

[51] 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 (by means of a written, oral description or use) before 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 successor in title has exhibited it in an official or officially recognised international exhibition.

[52] George Etomi, *An Introduction to Commercial Law in Nigeria* (Text, Cases and Materials), (Lagos: MIJ Professional Publishers Limited, 2014).

[53] Patents and Designs Act Cap. P 2 Laws of Federation of Nigeria, 2004 s 1(5).

[54] 2004. See the Preamble: oath section, s 8 and 9

The scope of rights granted the patentee is provided in section 6 of the Act. However, these rights are subject to the exclusions: Compulsory licensing, [55] Ministerial authorization to exploit the patented invention in the interest of the public, [56]and during any period of emergency. [57] In the case of *welcome Foundation Ltd v Lodeka Pharmacy Ltd*,[58] the court held that there is no provision in the Patent Act to exclude anyone from liability of infringement; neither does the minister have such powers. If patent rights must be enforced, it implies that infringements on patent protected procedures would also be enforced, which will jeopardise the utility of the invented medical and surgical procedures. Assuming without conceding that the procedures are eligible for patent protection, then the patentees must be subjected to the above proviso restricting the exclusivity of their rights. Such that despite the patent protection granted those procedures, they would still be beneficial to the public in saving lives without obstructing healthcare service delivery [59] and any threat to life constitutes an emergency because right to life is sacrosanct. [60] Moreover section 17(3)(c-d) [61] specifies the commitment of the government at all tiers to ensure that there is adequate medical and health facilities for all persons. Therefore, the authors are of the opinion that surgical and medical methods of treatment were not intended to be patentable under the Patent and Designs Act Cap P 4 Laws of Federation of Nigeria, 2004.

Some legal and ethical considerations that may arise in patenting medical and surgical procedures for patient treatment include: Breach of patients right to privacy and good quality healthcare: because the patient's details have to be disclosed in applying for license to use the procedure in treating the patient or during a law suit as a result of non-permitted use. Undue delay in securing such permission, especially where it is sought from another nation state may cause loss of life and invariably increase mortality rate in the healthcare sector. All these ultimately derogate from a person's right to enjoy the highest attainable form of health. *Affordability:* patents are secured with a fee hence grant of permission to use either as assignment or license also comes with a fee. Hence in applying the patent protected procedure for treating a patient, the cost of securing the use of such patient will be inputted into the patient's hospital bill which will certainly be higher than what would ordinarily have been the bill. It would then give rise to a situation where the rich in the society gets better healthcare than the average persons. *Jeopardizing patient–physician relationship:* Patients will be made to move frequently and unnecessarily from one physician to another in search of those with the permission to render specific or desired healthcare service. Also in emergency situations like road traffic accidents, medical personnel would be wary of using certain procedures to save lives of the injured persons without a guarantee that the liability for patent infringement be waived on a doctor who applies a patented procedure to save a patient's life but without the patentee's permission. *Patient's Autonomy:* because the patients need to scout for the medical facility or practitioner with permission to use the specific procedure necessary for his treatment, he loses his right of autonomy to choose a desired health facility or practitioner. Rather availability of the healthcare service is the controlling influence that strips them of their autonomy and determines their source of healthcare service.

The precedent of knowledge sharing in medical practice promotes medical research, new and improvements on (incremental) existing inventions. Assuming the foremost procedures were patented by the inventors, the knowledge would not have been freely transferred which is one of the basic principles in the Hippocratic Oath. The ethical principle of nonmaleficence asserts an obligation of not causing harm to others. Where the fear of patent infringement litigation deters a healthcare staff from giving the appropriate healthcare service to a patient which results in health deterioration or death of such a person, harm has already been caused which may be irreversible. The proximate cause of this harm is the patent protection granted the procedure not necessarily the inability to secure a permission to use same. Hippocrates says '… make a habit of two things – to help or at least do no harm.' [62] This underscores the principle of beneficence. Hence, patenting a medical procedure which ought to be used for human treatment but it's not being used for human treatment due to patent rights issues, defeats the ethical principle of beneficence. The justice inherent in patenting inventions is the mutual benefit derived from the inventions by both the public and the inventor. While the inventor is acknowledged for his invention on either medical surgical procedure for therapeutic or diagnostic purposes, the knowledge should be freely disseminated and used for medical activity. However, where it is obvious that the inventive process placed much financial burden on the inventor and the invention being important for human treatment has no available substitute,

[55] First Schedule to the Patents and Designs Act 2004, Part 1, Par 2-3 & 8-11.
[56] First Schedule to the Patents and Designs Act 2004, Part 2, Par 15-11.
[57] First Schedule to the Patents and Designs Act 2004, Part 2, Par 20.
[58] (1971) All NLR 536
[59] CFRN 1999, (as amended) s 17 (1)(b)
[60] CFRN 1999 (as amended) , s 33
[61] CFRN 1999(as amended)
[62] W H Jones(ed) *Hippocrates in Epidermics* (Cambridge: Harvard University Press, 1923) 165.

compulsory licensing may be implemented to ensure the inventor is adequately compensated for his intellectual sweat, while public good is achieved.

From the above discourse, patenting medical and surgical procedures apparently undermine the very essence of medical practice and healthcare service delivery, wherein lies the utility? It has been argued [63] that public policy considerations do not provide a sufficient basis to justify discrimination against patenting of methods of medical and surgical treatment. Since the inventions provide potential relief to patients, they have industrial applicability and should not be regarded as being contrary to public order and morality or said to be generally inconvenient. As such, medical and surgical procedures should enjoy equal patent protection as other medical devices. It is also argued that patenting such procedures for treatment will attract investments in costly clinical trials in medical research and advance medical knowledge by encouraging the development of new procedures which in turn increases the quality of the patients' health care. The biotechnology sector also supports the opinion that granting patent protection for medical procedures is necessary to promote future scientific innovations in the healthcare sector, by stimulating new ideas for improving on existing technologies. [64] It was this controversy of whether or not to patent medical and surgical procedures as part of medical inventions that occasioned the cause of action in the suit filed by Dr. Samuel Pallin [65] alleging that other doctors infringed on his patent; [66] which is a surgical procedure used to perform cataract surgery without sutures, as such he claimed right to royalties. It is therefore argued that if such patents are allowed, patients and insurance companies will face significant increases in health care costs. [67] In spite of the above view, it is believed that patent protection was intended to provide incentive for technological innovations in the interest of the public, especially for inventions requiring significant investment of time and resources such as medicines, medical devices and equipment. [68] Thus, while the inventors benefit from their intellectual sweat, they are motivated to contribute to medical research and healthcare service delivery.[69] Some medical organizations such as the American Medical Association have deemed the practice of patenting medical and surgical procedures unethical. [70] The association opines that proprietary interests should not interfere with dissemination of medical or surgical procedures for saving .human lives, which would make medical practitioners worry about infringement lawsuits while deciding the best treatment plan for their patents, so as to ensure that access to all methods or techniques of human treatment are available to the public as healthcare service.[71] It is worthy of note that litigations to enforce patent rights on medical and surgical procedures are uncommon, especially in Nigeria. This can be attributed to the following reasons:

1. An infringement on medical procedures patent right is not quite obvious, unlike an infringement of patented medical devices or medicines which are evidenced by the presence of the infringing products.[72] Thus, enforcing such patent without evidence would be an arduous task.
2. It is also believed that any act to enforce such patent by claiming exclusive rights to the invention would be contrary to the ethics of the medical profession and inconsistent with the principles declared while taking the Hippocratic Oath.

Some opinionists have argued that grant of patent for medical and surgical procedures negate the medical tradition of sharing knowledge and techniques for public benefit. [73] Being that patents are granted as a motivating factor to inventors to enable them recoup the financial investments made on their discoveries, inventions relating to medical and surgical procedures for treatment are skills which are not quite financially demanding or research intensive as to warrant grant of exclusive right to such inventions, unlike other medical inventions such as

[63] Linda Judge n 10, 181

[64] Ibid 188

[65] *Pallin v. Singer*, No. 93-202, 1995 U.S. Dist. LEXIS 20824 (D. Vt. May 1, 1995).

[66] U.S. Patent No. 5,080,111

[67] Ron Stodghill II, *First, Do No Harm. Then, Get a Patent*, BUS. WK., July 24, 1995. 86.

[68] Evan Ackiron, 'Patents Critical for Pharmaceuticals, the AZT Case,' [1991](17) *AM. J. L. & MED*. 145. Cited in Linda Judge, n 10, 186

[69] Rebecca Eisenberg, 'Proprietary Rights and the Norms of Science in Biotechnology Research' [1987](177) *YALE L.J* 97

[70] The House of Delegates passed a resolution condemning the practice in 1994. Other medical organizations in this category include the American Urological Association, American Society of Cataract and Refractive Surgery, and the American Association of Medical Colleges.

[71] Linda Judge, n 10, 188

[72] William Noonan, 'Patenting Medical Technology' [1990] (11) *J. LEGAL MED*. 263

[73] Medical procedures hearing WL 615780 Reprinted 1995. See statement of Donald R Dunner, chair of intellectual property section.

medicines and medical devices which involve high costs for developing, manufacturing or testing same.[74] Generally, patent rights are granted upon application and assessment of the invention by the patent office of the nation state, to ensure that the invention sought to be patented meets the required conditions for patentability. Once this is established the patentee has the sole right to the invention to the exclusion of any other person, except to those he grants permission or other statutory restrictions. In the event that anyone infringes on such patent right, the patentee is empowered by the law to institute legal proceedings against the infringer and claim damages for the breach of right. This general provision is also applicable to inventions made in the medical field. Thus, the following are envisaged as the possible effect patent protection of medical technologies may have on the healthcare sector and service delivery.

1. Bearing in mind the implication of patent rights on inventions, physicians may not be inclined to share medical information for fear of allegations, law suits and claim of damages for patent right infringement. For instance where a patent owner files a suit for infringement and claims damages for use of his patented medical or surgical procedure, as was the case in *Pallin v. Singer*. [75]
2. With the growing trend towards extensive patenting of such procedures accompanied with the financial personal gain, there will be a tendency to horde medical knowledge because incremental inventions would be subject to patent rights as well, and these will inhibit medical research.
3. In addition, there would be an unhealthy competition amongst practitioners as to the number of medical patents filed, shifting the focus from patient care to vie for high patent portfolio, thereby jeopardizing the health and lives of the patients and undermining the service of the healthcare sector due to reduced availability of new treatments for patients.
4. Ultimately, the quality of healthcare will be compromised and the cost of healthcare services will be higher. Such that affordability determines the quality of healthcare one receives. The implication would be that the healthcare facilities that provide healthcare services at a cheaper cost will have more patients and a long waiting list of patients than the less affordable facilities.
5. On the other hand, access to improved technological inventions can increase a patient's chance of survival by aiding early and accurate diagnosis. This utility may be undermined where a practitioner or the healthcare facility that patents a particular technique may decide to exclude others entirely from using their invention so as to monopolise the treatment and charge high fees, such that they can gain from the treatment fee what they would have benefited from royalties if they had given license to the patent to other practitioners or facilities.
6. A pseudo passing-off situation may be established by granting such patents, because the public may be misled into believing that the patent certifies such health facility or medical practitioner as the best expert in that particular field of practice. [76]

4. Conclusion

Proponents for excluding patents on medical and surgical procedures argue that such patents will result in high cost of healthcare service either due to monopoly of the procedure, royalties charged by patentees or the cost of patent infringement lawsuits. Rather, the incentives offered to such inventors should be the traditional rewards that are available for scientific inventions. So that patents would not be needed to encourage invention of these procedures. On the other hand, opponents of this exclusion argue that patent does not interfere with the development or transfer of knowledge amongst practitioners in the medical profession. For instance medicines, biological products and other medical devices are part of medical inventions used for patient treatment. The medical practitioners and other scientists in the healthcare sector should encourage and benefit from patents as a means of promoting research and development. But, excluding medical and surgical procedures from patentability is not arbitrary. The authors concede that patent may be a good incentive for new inventions or improvements in existing medical technology, being that medical and surgical procedures predominantly constitute an improvement on existing prior art, and does not necessarily involve significant financial investment to make it a research intensive venture, the reward ought to be restricted to scientific acknowledgements without any right of enforcement, so that medical practitioners can freely use the invention for patient care because the primary purpose of such inventions in medical practice is for healthcare. In the alternative, healthcare professionals and facilities should be statutorily exempted `from liabilities of infringement on patented procedures as in the US. Such that,

[74] Dr. Greg Ganske, sponsor of H.R. 1127, speaks in support of Medical Procedures Innovation and Affordability Act, H.R. 1127, 104th Cong. 1995.

[75] No. 93-202, 1995 U.S. Dist. LEXIS 20824 (D. Vt. May 1, 1995); see also Hearings (testimony of Dr. Jack Singer, ophthalmologist from Dartmouth-Hitchcock Medical Center, Randolph, Vermont).

[76] ASCRS Files Complaints Over Deceptive Advertisements by Samuel Pallin, MD Regarding Invention of Surgery, PR NEWSWI E, May 24, 1996, available in LEXIS-NEXIS, NEWS Library, PRNEWS File. See also Linda Judge, n 10, 195

patentees will have no remedies where the infringement on the patented procedure; not the use of a patented medical device, is for the purpose of healthcare service delivery (a medical activity). However, while it is hoped that the Patent and Designs Act 2004 in Nigeria may yet be amended to reflect the above suggestions, compulsory licenses which are non-assignable and non-exclusive may be granted to all health facilities and healthcare professional upon being licensed to for patentees to file claims on infringed patent rights against healthcare professionals for using medical and surgical methods of human treatment, though there has been no such litigation in Nigeria. In addition, the patent filing fee for such inventions should be much less than that for others. On a balance of scale, saving human lives (serving public good) should be of greater priority than individual proprietary interest.