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Protection Of Health Care Inventions: An Analysis Of Patent Eligibility Beyond Pharmaceutical Inventions In India

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Abstract

The harmonization of the intellectual property regime has brought in substantive changes in the patent regime in India, making it more industry and innovation friendly. The important changes, such as removing section 5 of the patent act that allows product patents for the pharmaceutical industry, have led to a quick increase in patent applications at the Indian Patent Office for pharmaceutical patents. Further, the recent technological advancements in various fields of research and development relating to medicine and health care technologies are also a reason for the sudden rise in the patent applications.

But, with India being known as the pharmacy of the world, traditionally the focus of the discussions and deliberations was often on pharmaceutical components and other inventions related to medicine. But the recent trends in research and innovation in the field show the scope for personalized medicine, gene therapy, stem cell therapy, etc., which point out the need to focus on the patentability of other categories of inventions like medical devices and medical procedures.

The study focuses on the key provisions of the Indian Patent Law relating to patent eligibility for different categories of medical inventions while balancing public health and public interest concerns. The study focuses on and emphasizes medical innovations beyond the pharmaceutical sector. The study employs a doctrinal framework to analyze major laws and precedents regarding the patentability of inventions in medical devices, medical procedures, and biomedical innovations, while addressing the associated legal, ethical, and policy challenges.

Key Words : Healthcare technology, access to healthcare inventions, medical devices, medical processes, diagnostic methods, Patent classification, Right to health, Medical ethics, surgical procedures, patent eligibility, access to health care technology, right to health, affordable health care

Introduction

Medical innovations are the catalyst for the advancement in the healthcare industry[1], it enables the availability of better and quality healthcare facilities to the public. The health care inventions combined with the enablement of monopoly through patent protection enable the protection of the inventor and his economic interests and ensure the industry's zeal in coming up with novel innovations in the domain. But considering the nexus between public health and medical ethics, there have been regulations on the intellectual property protection accorded to patents through certain medical and healthcare inventions. Often, governments see Intellectual property as a means to incentivize the industry and attract investment and opportunities for economic development. But this often gets into a sore point when the medical and healthcare industry is concerned. Then there emerges a public interest and human rights narrative to the grant of patent protection and the obligations of the government to protect the health of the citizens and to ensure affordable healthcare facilities and access to medicine.

We see the trend recurring even when it comes to international instruments on intellectual property protection. This precarious and unsettled contention keeps emerging in terms of emergency relating to health care. But, in specific trends to the research and innovation in the field of medical innovation and Intellectual property it becomes obvious that the debate pertaining to pharmaceutical substances and their patenting has been gaining much attention in the past few decades. And the focus on other health care and medical innovations and their patenting seems to have taken a back stage.

On asking about patenting of the polio vaccine, Jonas Salk said "well, the people, I would say. There is no patent. Could you patent the sun? "[2]. Though the jurisdictions across the world grants patents for medical devices, pharmaceutical substances and other product based medical inventions, the ethical and moral dilemma over such patents always persisted and will continue to do so. But, a patent free regime for medical innovations and health care technology is sure to slow down the rate of research and hamper access to necessary technology because of unavailability. But, one of the pressing aspects that forces the governments to provide the patent monopoly is because of the exorbitant amounts that are involved in drug development, clinical trials and the manufacturing process.[3]

The study aspires to delve into the patentability of health care innovations in India beyond medicines and pharmaceutical substances. The research focuses on a doctrinal study by conducting an analysis of the relevant provisions of legislators, international precedents and other instruments like patents manuals used by the Indian patent office, judicial decisions rearing the area of study to identify the gaps and the niche areas. Considering the developments in health care technology in the fields focused on the increase in the number of patent applications submitted to the Indian Patent Office from the field. The key components incorporate in

[1] Steffen Flessa & Claudia Huebner, **Innovations in Health Care—A Conceptual Framework**, *PMC8508443* (2020), available at https://pmc.ncbi.nlm.nih.gov/articles/PMC8508443/.

[2] D.M.Oshinsky, *Polio: An American Story 211 (Oxford* university Press 2005)

[3] Joseph M. Reisman, Physicians and Surgeons as Inventors: Reconciling Medical Process Patents and Medical Ethics, 10 HIGH TECH. L.J. 355 (1995), https://www.jstor.org/stable/24122457.

the research study include, statutory interpretation, analysis of international agreements, case analysis, comparative analysis of the decision given by courts and appellate tribunals related to intellectual property with special reference to the European Patent Office and the US Supreme Court. Apart from the analysis of primary sources of data through legal instruments and decisions of various judicial entities, secondary sources of data are also considered to analyse the trends in the international arena and understand the latent developments in the field of technology considered.

IMPORTANCE OF PATENT PROTECTION FOR MEDICAL INVENTIONS *VISA VIZ.* RIGHT TO HEALTH

Unlike other forms of intellectual property, the monopoly rights granted over the patents are granted only by the government on an application by the patentee which facilitates a complete disclosure regarding the invention that is seeking patent rights. This is in reference to the public interest interface that is involved relating to certain inventions, which brings in the government as well as the public a stakeholder when granting of a patent as an intellectual property. Further, the parents are usually granted for a shorter tenure of time to enable that such inventions fall into the public domain and the product or possess becomes more accessible and cheaper to the public and can ensure further research and technology in furtherance of the innovation.

With the strive of the developed world order towards unification of Intellectual Property regime through the World trade organisation [4] by adopting the Agreement on Trade Related Aspects of Intellectual Property[5]. The patentability criteria and the minimum standard for patients throughout the word remains the same. To be eligible for patent an invention has to satisfy the triple test of patentability.[6] But, such a unification through an international organisation can never Led to such organisation granting patents, since through the Bais critters for the triple test akin patentability is being unified through the trips agreement, the standard and essence of the criteria of ‘novelty’, ‘inventive step’ and ‘industrial application’ differ from country to country. Thus, there cannot be universal patents valid in multiple jurisdictions. Further, the situation of patents granted at the state level is intensified with the public interest and public order aspects associated with certain inventions. Which brings in additional restrictions of awarding patents for certain inventions even though they qualify the triple test of patentability. Such restriction arising out of moral, ethical, public interest concerns etc. of a government, are also recognised by the TRIPS agreement.[7] Thus the sovereignty of a government in

[4] **World Trade Organization,** Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154.

[5] **Agreement on Trade-Related Aspects of Intellectual Property Rights,** Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 1197 (1994).

[6] Art. 27.1.**Agreement on Trade-Related Aspects of Intellectual Property Rights,** Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Art. 27.1, 33 I.L.M. 1197 (1994).

[7] Art. 27.3.**Agreement on Trade-Related Aspects of Intellectual Property Rights,** Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Art. 27.1, 33 I.L.M. 1197 (1994).

determining what categories of inventions can be excluded from patents stands paramount, to protect the sovereignty, morality, policy and public interest

When considering patents for medical and health care innovation, the role of TRIPS agreements in enabling such a mechanism is inalienable. As an instance, prior to TRIPS agreements a lot of developers and underdeveloped countries used to restrict the grant of pharmaceutical product inventions.[8] such a move also facilitated the sale of 'generic' version of such drugs at an affordable price. The problem of exercise of rights and the extent of a right relating to medical inventions comes because of the interpretation of claims of medical innovations. Because most often the process is also included in the claims of a product patent which are *per se* violations of the patent act. It was observed in a study in the US that, one of the major problems with the Claims of the patent were that they incorporate and widen the inventions far more that what has been described in the application.[9]

The patent office classifies the patents into different categories in accordance with their subject matter or area. This would help the stakeholders to identify and organise patents based on analogous or identical area, identify related technologies and inventions etc. The Indian Patent Classification Systems[10] more or less follows International Patent Classification (IPC)[11]. The patent classification identifies many categories of inventions which can include inventions related to health care technology and medicines. To consider an example Clause A of the international patent calcification is for "human necessities", divided into 4 categories or classes.

A61 deals with inventions which fall under the category of "medical or veterinary Science; hygiene. This class forms the fundamental class which includes various categories of medical innovations. This category includes those inventions relating to almost all medical inventions like medical devices, pharmaceutical substances, medical procedures etc. Inventions relating to the surgery, includes product innovation like surgical instruments, apparatuses used during the surgery and the procedure for doing surgery.[12]Inventions relating to diagnosis include all methods of doing diagnosis which include the imaging techniques. [13] and it also includes "instalments for taking biological samples, including biopsy and blood sampling".[14]Dental

[8] **World Health Organization,** *Model List of Essential Medicines*, 14th ed. (2005), available at https://www.who.int/publications/i/item/9241206907. *See also* **World Health Organization,** *Model List of Essential Medicines*, 23rd ed. (2023), available at https://www.who.int/publications/i/item/9789240062884.

[9] **Lori Andrews, Jordan Paradise & Timothy Holbrook**, *Patents on Human Genes—An Analysis of Scope and Claims*, 307 *Science* 1566 (Mar. 11, 2005).

[10] Indian Patent Office, *Indian Patent Classification System* (2023), available at https://www.ipindia.gov.in.

[11] World Intellectual Property Organization, *International Patent Classification* (2023).

[12] A61B 5/100

[13] A61B 10/00

[14] A61B 17/100

equipment and other devices or instruments[15] and materials used in the conducting any dental procedures 15, the section also includes anything related to the treatment of throat, nose or ear.[16]

Thus, these patent classifications do not provide concrete class or categories of medical inventions for analysis. Thus, the different categories of medical inventions under the patent classification has been analysed and the paper categories medical innovations into the following major categories for the purpose of understanding the category of patent eligibility contains under the Indian patent law are:

1) Pharmaceutical Substances and Medicines
2) Medical Devices
3) Medical Procedures
4) Diagnostic procedures
5) Biotechnology and biotech related inventions
6) New use of known medical substances
7) Heath care management and analytics

PHARMACEUTICAL PRODUCTS AND MEDICINES

This can involve this category of medical inventions which comes under the category of product patents. They are per se developed from chemical compounds. Thus, the pharmaceutical compositions when they are new chemical compounds, formulations, etc. It could come under the purview of patenting. Under the Indian patent regime, there is no restriction on the patenting of these chemical compounds and substances after the Amendment[17] in 2005 which resulted in the repeal of section 5[18] of the Patent Act, 1970 which removed the restriction of patenting of certain product inventions which are related to pharmaceuticals and chemicals. This amendment was done is in compliance with the TRIS agreement. Post amendment, the pharmaceutical patents are granted in par with inventions belong to the other categories. But, the patents are unique because of their implications on the public health aspects, the Indian patent law strikes a balance between the minimum standards as ascertained by the TRIPS agreement and the right to health aspiration of the public by invoking the exemption to the patentability criteria Under 27(3) of the TRIPS agreement. In reference to these provisions.

The Section 3(e) of the Patent Act, 1970 excludes from patent eligibility any invention which is obtained by combining two existing inventions or discoveries which only results in blatant aggregation of the properties of the substances used or a new process.[19] further in terms of pharmaceutical substances and active ingredient section 3(d)[20] aspires to bring in the scope of section 5 of the Patent Act, 1970 to the extent that evergreening of patents can be avoided by including strict criteria for determining the significant enhancement in the

[15] A61C 5/100
[16] A61C
[17] *Patent (Amendment) Act*, No. 15 of 2002, India (2002).
[18] *Indian Patent Act, No.* 39 of 1970, § 5, India (1970).
[19] *Indian Patent Act*, No. 39 of 1970, § 3(e), India (1970).
[20] *Indian Patent Act*, No. 39 of 1970, § 3(d), India (1970).

therapeutic efficacy of such pharmaceutical inventions in comparison to the existing state of the art to protect the public health and ensure accessibility of medicines.[21]

MEDICAL DEVICES

Patenting of medical devices is permitted, by the Patent Act, 1970 provided such medical devices are included with the product innovations like appliance, apparatus, instrument in the course of doing medical procedures, diagnosis etc. The medical device industry has seen a huge surge in innovation and technological advancement in the last few years. Thus, the government of India and bought medical devices under the purview of the Drugs and Cosmetics Act, 1940, wherein they have included them under the category of drugs emphasising the importance in aspects relating to public health and health care sector. In terms of patentability, like the pharmaceutical products, there are no expressed restrictions existing in the patenting of medical devices under the Indian patent law. But, in terms of patent eligibility restrictions can arise out of provisions to prevent the evergreening of patents, like, section 3(d), Section 3(e) and section 3(f) of the Patent Act 1970 can affect the patentability if the device is formed by combining substances, elements etc. and it does not result in new functionality or properties, where the properties in terms of a medical device can include biocompatibility, flexibility, strength amongst other factors. An in case of combinations it is necessary that they should perform a new or enhanced function. Further, similar Swiss claims if the new use of an existing medical inventions is identified, the same is eligible for patentability only if there is an enhancement of performance or has enabled a novel function or interaction. There in combinations and identifying newer properties or functions, similar to 3(d) for pharmaceutical substances it is necessary to prove the increased efficacy of such combinations.

Further, section 3(f)[22]specifically focuses on evergreen aspects when then invention in consideration specifically falls under the category of "devices" which are already in the public domain. The Instance talks about when the invention in question is "merely arrangement or rearrangement" of already existing devices, but in spite of the integration the device merely performs the functions of the independent devices that were combined. Thus, the involvement of a novel r new functionality is essential to ensure the invention does not become ineligible for patent under the provision. The provision also excludes those inventions which are mere "duplication of known devices", thus inventions were already existing devices merely duplicated without incorporating any innovative aspect or characteristic are also excluded from patent eligibility. Further, the provisions also consider the case of "each functioning independently of one another in a known way" indicates the case when the 'rearranged or duplicated device' does not perform a new function as to increase the efficacy of such combinations. Thus, the provisions have important connotation in determining the patentability of inventions relating to medical devices, ensuring evergreening of patents does not occur in the

[21] *Novartis AG v. Union of India*, (2013) 6 SCC 1 (India)

[22] *Indian Patent Act*, No. 39 of 1970, § 3(f), India (1970). "The mere arrangement or rearrangement or duplication of known devices, each functioning independently of one another in a known way."

sector and the inventions are accessible freely to the public after the patent tenure comes to an end. The provision is also pertinent in the case of medical devices when new or novel technology is being incorporated into existing devices to increase the ease of use etc. like robotics.

Section 3(d) of the patent act deals with patentability aspect pertaining to pharmaceutical and medical compositions mainly. The provision can be applied when the medical device is linked to a pharmaceutical composition, drug delivery systems etc. eg: a novel drug -eluting stent. The provisions can also be attracted when the device uses materials which are merely modified in some way and there is no aggregation of in the efficacy like in case of biocompatible materials. Further new process that will be employed in the manufacture of medical devices which does not result a new product may also come under the purview of section 3(d) of the Patent Act, 1970. Drug delivery or drug eluting devices would be excluded from patentability through section 3 (d) if they merely deliver the drug or a at a specific target in the body without the aggregation of the property or provides a new or additional therapeutic effect. Further, the new uses of substances already in the public domain and the combination if materials or substances without the aggregation of properties may be patentable.

Section 3(d) of the Patent Act, 1970, ensures that patents are not granted in India for trifling modifications, to extend the tenure of patent protection. The provisions ensure that patents, specifically related to the right to health of the citizens are granted on substantiating the efficacy and inventive step of the inventions, thus ensuring the accessibility of the inventions to the public. The importance of the provisions has been reiterated by the Supreme Court of India in the case of *Novartis Ag v. Union of India*[23] though the importance in terms of product inventions such pharmaceutical compositions were considered in the case.

MEDICAL PROCEDURE INVENTIONS

One of the prime prohibitions on inventions relating to health care invention from being patented is section 3(i)[24] of the Patent Act, 1970. While the other provisions restricting patentability are not direct restrictions relating to restricting heath care invention section 3(i) expressly prohibits from patentability those techniques or procedures used by the medical professionals in treating or diagnosing disease in animals or humans. The rationale behind the provisions find its origin from the British patent regime in India itself were the legislative intent[25] used to emphasise that such inventions used to lack industrial application, in reference to the context of usage of such inventions. Currently, the rationale for exclusion of such innovation can be classified under public policy considerations, medical ethics and accessibility and affordability of such inventions.

[23] AIR 2013 SC 1311
[24] *Indian Patent Act*, No. 39 of 1970, § 3(i), India (1970).
[25] Statute of Monopolies 1624, 21 Jac. 1, c. 3 (Eng.)

Though in Novartis Ag v. Union of India[26] and others, the Supreme Court of India did not directly look into the patentability of legislative objective behind section 3(i), but the court emphasised how the public heath aspirations should be given prominence and how the interests of the patentee shall take a back sit in consideration of claims in granting inventions relating to the field of medicine and health care. Further, in *Bayer's Corporation v Union of India*[27] the Delhi high court reiterated the importance of public health and accessibility of health care as one of the objects to be considered while granting patents in India. Thus, the objective of the provisions aligns with medical ethics and ensuring accessibility to health care in India.

The provision incorporates an exhaustive list of medical procedures used for treatment human beings or animals that cannot be patented in India. This includes curative procedures, surgical procedures used to cure diseases in human beings or animals. Any prophylactic procedures indicating preventive health care procedures to ensure human and animals are not affected with a certain disease condition. There provision, includes within itself any treatments related to medicine which can cure a disease or can be used in the due course for human beings or animals. Further those procedures which are used to increase the economic value of animals are also excluded from patentability under the provision. The provision also excludes from the preview, any diagnosis procedures to identify the diseases or disease condition in human beings or animals.

The provision ensures that the medical practitioners are not hesitating from using the state of the art facilities and procedures in the field to provide quality health care in the field due to the fear of patent prosecution. But, the provision has been under debates as to what continues medical procedures, mainly when it comes to diagnostic procedures. Thus, the provision avoids encumbrance sure to patent rights in practicing medicine. These inventions do not go for patent filing independently but are often included as claimed encase of a novel technology, device or any medical for which there in no immediate concern in being patented as long as the patentability criteria is being complied with. Which complicates the grant of such patents because the scope of medical process patents has to be rightly identified by the patent office and denied such claims from the scope of the product patent.

What remains a bone of contention with the increased developments in the areas of medical therapy is the fact that the terminologies are used from the point of a liberal framework and goes for a strict interpretation resulting in denial of patent. For example, medical procedures relating to cosmetic surgery which is not necessarily part of the basic framework of the right to health also gets included in the provision. The new challenges in the interpretation of the provision merge because of the advancement in areas like gene therapy. Stem cell therapy and personalised medicine.

[26] Supra note 22

[27] 2014 SCC Online Del 2853 (Del. H.C.).

DIAGNOSTIC PROCEDURES

Another ground for war is the case of patentability of diagnostic procedures. The word diagnostic was included in the section 3(i) of the patent act post adaptation of the Agreement on Trade Related Aspects of Intellectual Property Rights[28], which results in the amendment[29] and insertion of the word "diagnostic" into the provision. But the extent, scope and coverage of the term is not mentioned in the enactment. Thus, what includes medical diagnosis is often left to the interpretation of the Indian Patent office in furtherance to patent manual. The confusion also exists because the medical fraternity does not define extensively what constitutes 'diagnosis'. The Indian Patent Office guidelines define diagnosis as "diagnosis is the identification of the nature of medical illness usually by investigating its history and symptoms and by applying tests"[30] Further the manual also excludes fitness tests and ones in similar categories unless they do not reveal specific information relating to pathology. Thus, as per the Indian patent office the ability of the diagnostic procedure to identify the determine a disease condition becomes the benchmark to include diagnostic procedure claims within the purview of section 3(i) of the Patent Act, 1970.

One of the major areas of contention regarding the diagnostic process claims is that the Indian laws do not classify diagnostic patents. In European Patent Office for the diagnostic process to be excluded from patent eligibility[31], it should, include examination phase and include data collection, their process should identify ways to compare the data and draw them to standard values, to identify significant deviation from the general situations, and should provide a decision or cause of such deviation.[32] Further, the restrictions exist, if the diagnosis is carried out on the animal or human a body, hence *in- vivo* diagnostic procedures are outside the purview of patenting in Europe while the *in-vitro* methods are patentable provided the reasonable necessities are met.[33] Meanwhile the US courts classified diagnostic procedures not directly as medical procedures to inhibit the scope of patentability, but identified those rely on naturally occurring products or their means or efforts.[34] but, the High Court of Madras in the case of the Chinese University of *Hong Kong & Sequenom Inc. v. Assistant Controller of Patents*[35], clarified that the section 3 (i) of the Patent Act, 1970 nor the current patent guidelines and many of the Indian patent office intents to distinguish between *in-vitro* and *in-vivo* diagnostic procedures. Further, mere source of known process for diagnosis can also come under the purview of Section 2(1)(j) of the patent Act, 1970.

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[28] *Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27*, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, 1867 U.N.T.S. 299.

[29] *Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27(3)*, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, 1867 U.N.T.S. 299.

[30] *Indian Patent Office, Guidelines for Examination of Biotechnology Applications for Patent (Revised), 2016*, Office of the Controller General of Patents, Designs & Trademarks, Ministry of Commerce & Industry, Government of India.

[31] *European Patent Office, Art. 53, European Patent Convention (2020), available at* https://www.epo.org/en/legal/epc/2020/a53.html.

[32] *G 0001/04 (Diagnostic Methods)*, 16 Dec. 2005, European Patent Office, *available at* https://www.epo.org/en/boards-of-appeal/decisions/g0401.html.

[33] *Supra note* 30

[34] *Athena Diagnostics, Inc. v. Mayo Collaborative Services*, LLC, 915 F.3d 743 (Fed. Cir. 2019)

[35] 2023:MHC:4617

BIOTECHNOLOGY AND BIOTECH RELATED MEDICAL INVENTIONS

Post the decision of *Diamond v Chakraborthy*[36] and the TRIPS agreement, the biotechnology related inventions which use genetically modified bacteria and other microorganisms are patentable in India because of the exemption under section under section 2(j) of the Patent Act, 1970. Restrictions for patentability often arise because of not able to substantiate the efficacy than the existing state of the art when the patent is related to new forms of already known biotech substances.[37] Further, higher animals and plants or their parts, even if it does undergo modifications along with the process used for their production are exempted from patenting.[38]These creates a reasonable restriction on the patenting of genes and naturally occurring enzymes used for treatment procedures not sitting out of microorganisms, etc. Further, restriction can also arise with the involvement of aspects relating to traditional knowledge.[39]

Inventions relating to health care.

NEW USE OF KNOWN SUBSTANCES

The patent Act, 1970 in cereals allows patenting on new uses of known substances, provided they fulfil the inventive step criteria of the triple test of patentability. But, the patient eligibility criteria excludes from patentability the inconsequential or lesser discovery of new use of the property of the existing inventions.[40] This is applicable to pharmaceutical components and medicines as well as medical devices. Thus, though the advancement involved in identifying the news use of a known substance, compound or device can be a break though invention in the field of medicine and health care, the same significance is not conferred to such inventions while analysing patentability in India. The claims of patents of pharmaceutical substance which highlight the new use of such already known substance are also known as 'swiss claims', provided such substance has been used previously for the treatment of an entirely different condition or disease. Such Swiss claims or second medical use claims are also exempted from patentability[41]for lack of novelty under section 3(d) and section 3(e) of the Patent act, 1970.

HEALTH CARE MANAGEMENT & ANALYTICS

These categories of inventions are fairest inventions related to the failsafe medicine and health care. They do not directly interfere with access to health care rather enable and facilitate the same. Currently, they are not exempted under the Patent Act, 1970 because of their relation to medical or health care innovations and technology. These inventions when couples with medical procedures related to diagnosis, performing robotic surgery, etc. can become non patentable under provisions like section 3 (i) of the Patent Act, 1970. Further,

[36] 447 U.S. 303 (1980)
[37] *Indian Patent Act, No.* 39 of 1970, § 3(d), India (1970).
[38] *Indian Patent Act, No.* 39 of 1970, § 3(j), India (1970).
[39] *Indian Patent Act, No.* 39 of 1970, § 3(p), India (1970).
[40] *Indian Patent Act, No.* 39 of 1970, § 3(e), India (1970).

[41] *Indian Patent Act, No.* 39 of 1970, § 2(1) (j), India (1970).

with inclusion of various ares of technologies like algorithms, nanotechnology etc., there can be patent eligibility restricts arising out of such relevant areas of technology.

CONCLUSIONS AND SUGGESTIONS

The grant of patents for health care inventions can be a conscious issue that requires careful consideration and deliberation in the right of the increasing populations which needs accessibility to health care technology at an affordable price concurrently protecting the interest of the health care industry. One of the significant drawbacks in the India patent system is the exclusion regarding the medical procedures. Though the provision encompasses the exclusion of the medical professions and enables accessibility to new inventions in the files at an affordable price. The provision is capable of hindering research and development in the area, because of the strict interpretation given to the provision and the scope and extent of the provision not being determined through the legislation, thus increasing the scope of discussion making power of the Indian Patent office in including inventions under the scope of this provisions. The interpretation of the provisions becomes briskly problematic because of the advancements in the area of technology that focuses on various medical and diagnostic procedures.

Further exclusion process using plants and animals, in case of biotech inventions also poses significant challenges to the research and innovation in the area. These provisions hinder the patenting of inventions in the field of bio pharmaceuticals, gene therapy which is considered to revolutionise health care delivery system in the years to come. Thus, the patent eligibility for health care inventions in India poses both opportunities and challenges. But, what is the need of the hour is identifying the nexus and scope of other medical innovations as it was done in the case of pharmaceutical inventions in India.