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"Exclusion of Methods of Medical Treatment from Patentability: A Global Perspective"

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The exclusion of medical methods from patentability has been a globally contested issue since the early times. Objections to granting exclusive rights over medical methods have their roots in morality – where it is considered wrong to limit the availability of potential lifesaving treatments to individuals in need.[1] "Patent offices and courts around the world generally agreed with the assessment of the medical community and effectively prohibited patents on methods of medical treatment through the nineteenth and early twentieth centuries."[2] This paper will aim to analyse the purpose, limits and morality of the exclusion of medical methods from patentability - globally as well as in India. Further, this paper will examine the ways in which countries have sought to limit the grant of patents to certain categories of subject matter in a bid to promote access to public health goods in contrast to some countries which have decided to grant patentability for medical treatments. This paper will also review the scope and ambit of Section 3(i) of the Patents Act in India.

In India, Section 3 of the Patents Act, 1970 enumerates "what does not qualify as inventions" with regard to patents and subsection (i) states that "any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products" is not considered an invention that is patentable.[3] Internationally, the World Trade Organisation's Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement provides discretion to its Member States in Article 27(3) by giving them the freedom to decide whether patents may be granted to "diagnostic, therapeutic and surgical methods for the treatment of humans or animals. The TRIPS Agreement, which went into effect in 1995, requires that signatory states provide minimum requirements for patentability, such as a 20-year term, non- discrimination among subject areas, national treatment for foreign applications, and the like."[4]

"The European Patent Convention (EPC) is a multilateral treaty among 38 European signatory states[5] which establishes a system whereby patent applications may be filed and examined for patentability by a common agency, the European Patent Office (EPO) based in

[1] Luis Gil Abinader & Jorge L. Contreras, *The Patentability of Genetic Therapies: CAR-T and Medical Treatment Exclusions around the World*, 34 AM. U. INT'l L. REV. 705 (2019).
[2] *Id.*
[3] Patents Act, 1970, Section 3 (India).
[4] Agreement on Trade Related Aspects of Intellectual Property Rights Act, 1995 (TRIPS) Art. 27(3), Art. 33.
[5] Representing both members and non-members of the European Union.

Munich, and then issued as national patents in each of the signatory states."[6] "After several debates and amendments Article 53 states medical treatments as an exception to patentability."[7] "It has been further confirmed "that the exclusion of methods of medical treatment from patentability is "based on social-ethical and public health considerations" and that doctors should be able to choose the best medical treatment for the patient without being restricted by exclusive patent rights with the rationale that patents shouldn't interfere with the saving of a human life."[8] "Therefore, the method of treatment by surgery or therapy and diagnostic methods practised on human or animal body are excluded, while methods outside the body and products for medical use are allowable subject matter under Article 53; and subsequent medical use of known products is also allowable under Article 54 of the EPC."[9] "Though Article 53(4) EPC leaves no room for medical treatments to obtain patents, the courts found a way around it and decided that new types of claims, directed to the "use of compound X in the manufacture of a medicament for a new therapeutic use", are outside exclusion."[10] Another international treaty that deals with the treatment of intellectual property was the General Agreement on Tariffs and Trade (GATT), it was signed by the US, the EU and Japan in 1988.[11] The Trans-Pacific Partnership (TPP) also enumerates this exception clearly in its Article 18.37.[12] Most other bilateral and multilateral treaties also provide flexibility with this exception by referencing Article 27(3) of TRIPS.[13]

Approximately 80 countries around the world prohibit methods of medical treatment from being granted patent protection – all European countries and countries in Asia, Africa, North America and South America.[14] Some countries however, do not limit patentability of medical methods through statutes but with judicial doctrines. The Canadian Patent Act does not explicitly exclude medical treatment from patentability. "The Canadian Supreme Court has refused patents in all claims which "does not lay in the field of the manual or productive arts nor, when applied to the human body, does it produce a result in relation to trade, commerce or industry, or a result that is essentially economic.""[15] "The courts in New Zealand have also held that methods of treatment of human disease do not meet the requirement that patentable methods describe a manner of manufacture."[16]

[6] Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 199
[7] EPC art. 53(c), Id.
[8] *Supra* note 1.
[9] Enrico Bonadio, *Medical Methods, Risks to Public Health and Exclusion from Patentability*, EUROPEAN JOURNAL OF RISK REGULATION, Vol. 1, No. 2 154-156 (2010).
[10] O. Mitnovetski, D. Nicol and T. Piper, *Are Patents for Methods of Medical Treatment Contrary to the Ordre Public and Morality or "Generally Inconvenient"?* JOURNAL OF MEDICAL ETHICS , , Vol. 30, No. 5, 470-477. Oct., 2004.
[11] *Supra* note 1.
[12] *Id.*
[13] *Id.*
[14] *Supra* note 10.
[15] Apotex Inc. v. Wellcome Found. Ltd. [2002] S.C.R. 153 (Can.)
[16] *Supra* note 1.

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"The United States of America, Australia and Japan are some of the very few countries that grant patents for medical methods. In 1954, the US Patent and Trademark Office overturned an 1883 decision prohibiting the patenting of medical procedures."[17] In 1996, the Congress added Section 287(c) to the Patent Act which does not prohibit patenting of medical treatments, rather it creates a limited immunity from patent infringement for medical practitioners and healthcare professionals who practice a patented "medical treatment." US recognises the patentability of medical treatment claims, subject only to the limited healthcare practitioner immunity under Section 287(c)."[18] "In 1959 the Australian High Court ruled that a method need not result in a "vendible product" in order to be patentable, expressly departing from the earlier rule expressed in the UK. Australian courts are empowered to consider whether the patenting of an alleged invention is "generally inconvenient.""[19] Novel therapeutic inventions have been patentable in Japan since 1976.[20]

A rather crucial question is to be highlighted at this point – What is the reasoning behind not granting patentability to medical methods. This question can be answered by looking at the various public policy considerations and the impact of granting these patents on the society as a whole. "It is argued for granting patents to medical treatments that dissemination of information will only happen if the inventor has some protection and is rewarded for disclosing his information to the society. However, if an inventor starts charging a royalty or license fee every time a doctor performs his procedure, this would only discourage the doctors from opting for that method of treatment and underplaying it to the patient (even if they are obliged to disclose it under oath). This hinders the purpose of the invention, especially in a medical context – which is for the alleviating the sufferings of humans. Another reason why patents shouldn't be granted is that if an infringement suit is filed by the patent holder, it grossly violates the privacy of the patient involved."[21] Further, granting of such patents will only increase the already high cost of healthcare and the goal – globally should be the make healthcare more affordable and accessible to all classes. Another potential issue with the granting of patents is the reluctance of doctors to perform these patented methods due to fear of infringement suits – which can last for years, especially in India. Therefore, in my opinion due to the above mentioned reasons, the almost globally concurred view of granting exclusion to medical methods from patentability is a wise and much needed position.

The Indian Patent Office (IPO) has held "inventions claiming surgical methods, therapeutic methods and diagnostic methods" to be non-patentable.[22] Section 3 (i) previously ruled out

[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Supra* note 10.
[21] *Id.*
[22] Dr. Deepti Malhotra, Dr. Malathi Lakshmikumaran, *Scope of Section 3(i): An analysis on diagnostic methods of treatment,* LAKSHMIKUMARAN AND SRIDHARAN ATTORNEYS, (2018) https://www.lakshmisri.com/insights/articles/scope-of-section-3-i-an-analysis-on-diagnostic-methods-of-treatment/#

medical methods of treatment of not only humans but also animals and plants. However, post the 2002 amendment any process for treatment of plants has now become patentable.[23] Section 3(i) has not be subject to judicial review or interpretation, hence its application varies in the IPO. Due to the absence of judicial guidance, the granting and rejecting of patents is done by the IPO without a proper structure.[24] "In Lalit Mahajan's patent application[25], the issue was whether "a device for detection of antibodies to HIV and p24 antigen of HIV in human serum or plasma" was excluded under Section 3(i). It was contended that there was a diagnostic aspect of the device however, 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) was found to be inapplicable."[26] "Diagnosis is defined in Manual of Patent Office Practice and Procedure, as "the identification of the nature of a medical illness, usually by investigating its history and symptoms and by applying tests. Determination of the general physical state of an individual (e.g. a fitness test) is considered to be diagnostic." Therefore, diagnostic methods are intended to ascertain the presence (or absence) of a disease; and are decisive for treatment decisions in otherwise symptomatic patients."[27] However, detection tests- which are mere susceptibility markers in healthy individuals do not fall under the ambit of Section 3(i). This can be observed in another patent application[28] where this exclusion was held to be inapplicable "in case of a device for the rapid detection of presence of IgG and IgM antibodies against dengue viral antigens in a sample (human serum) for a diagnostic purpose.""[29] "However, patent applications such as a method of discovering compounds suitable for the treatment and or prophylaxis of obesity...', and 'kit for the treatment of infertility in women comprising multiple doses of FSH ...' – the Patent Examiner concluded that these were diagnostic treatments and would fall under the exclusion in Section 3(i)."[30] Another patent application regarding the method of detecting the presence or absence of Chikungunya virus strain in a biological sample was rejected under Section 3(i) even though this method stopped at detecting the mere presence or absence and offered no diagnostic value. It was argued that the Section should be read entirely and not by choosing selective parts and disregarding the other part.[31] "By observing these cases, we can see that the IPO through Section 3(i) creates a blanket exclusion on any methods of treatment as opposed to the EPO provision applying Article 27 of TRIPS, by reciting additional methods of treatment and ending with a non-limiting recitation of "or other treatment."[32] However, no guidance or

[23] Priyanka Rastogi, *World Wide Legal Status Of Medical Method Patents: An Overview*, MONDAQ, (2014). https://www.mondaq.com/india/patent/311404/world-wide-legal-status-of-medical-method-patents-an-overview
[24] *Supra* note 22.
[25] *Patent Application No. 693/KOL/2007 decided on 11.01.2010.*
[26] *Supra* note 23.
[27] *Supra* note 22.
[28] *Patent Application No. 2484/DEL/2007 decided on 24.07.2009.*
[29] *Supra* note 23.
[30] *Patent Application No. 195/MUMNP/2003 decided on 18.05.2006; Patent Application No. 404/MUMNP/2005 decided on 28.09.2007*
[31] Patent Application No. 1492/CHENP/2010.
[32] *Supra* note 22.

direction is given for screening methods or probability methods. There has been no clear distinction made between in-vitro and in-vivo treatments, therefore leaving room for differential interpretation on a case to case basis. Further, the phrase, "render them free of disease or to increase their economic value or that of their products" in Section 3(i) is interpreted as "implied without any basis for the same being present in the claims or specification of an application" thereby adding to the ambiguity."[33]

In light of the above concerns with the existing discourse on patentability of medical methods, there is a dire need for laying down foundational jurisprudence in the Court to clarify the legislative intent, the purpose, ambit and guidelines for the application or interpretation of this section which will reduce the ambiguity and discrepancy in interpreting this Section. While the law is absolutely necessary to discourage exclusivity over commercial use and exploitation over inventions which hold high stakes such as human and animal life, it is also important that Indian patent law finds a balance between public health, socio-economic growth while striving to support medical technological innovation to be competent and survive at the global scale. Globally, even in countries which offer patents for medical methods, the patents granted a relatively rare due to logistical difficulties in enforcement. However, in most countries, this exclusion of patentability of medical methods has been adopted and enforced, and rightfully so, with varying degrees of clarity and discretion due to public policies or judicial decisions in place because of ethical reasons.

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[33] *Id.*

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