Abstract: Patenting of medical methods involve the patenting of the techniques such as surgical methods as distinct from the patenting of the medical products. Medical methods are excluded from the purview of patentability in a large number of countries today. One of the most prominent justification for the exclusion is that such patents are likely to restrict the freedom of the doctors and will prevent them from curing patients with the least medical advances. The grant of protection to the medical methods will definitely stall the dissemination of the knowledge of the professional attainment and skills. Methods of medical treatment are most often seen as an excluded subject matter in the light of public policy rather than the patent eligibility criteria as the exclusion has an undertone of the hybrid of the patent law and medical jurisprudence. Though the situation is different in countries, as most of them exclude methods of medical treatment from patentability and some of them grant the patent but not the protection. This article analyses the varied nature of protection given to the medical methods in different jurisdiction and also role of the provision of TRIPS agreement in determining the nature and scope of its protection. The article also discusses that whether the Article 27 of the TRIPS agreement is flexible enough to allow its member states to exclude the protection based on the ground of order public and morality according to the suitability of their local customs and needs. For the purpose of understanding the exclusion of the medical methods from the purview of patentability, some significant factors are needed to be considered such as the ‘patent system’ of the particular country, in the sense that how it is different from other countries and what all are policies and conceptions relating to the grant of protection to the medical processes on the very touchstones of public order and morality because of the contextualized and subjective interpretation of such ‘notions’. The other significant factors are international practices and the justifications given by the member states for the grant of protection to the medical methods. The approach of the United States is unique in this arena as it is built on the edifice of the ‘balancing the interest approach’ which is discussed in detail in the paper. Some suggestions are also provided in the last portion of the article which are significant in the light of the determination of the patentability of the medical methods.

I. INTRODUCTION

It is asserted that why the protection is granted to the person who has invented something and denied to a person whose endeavor has contributed to the mankind. Patent is a right granted exclusively to the inventor for his disclosure of the invention to the public at large. The monopoly is given for 20 years so that the inventor can exclude others from exercising the same right as he himself has and after the fix span of the twenty years, invention comes out in the open space so that the public can be benefitted as it is freely available to others. More than eighty countries across the world does not grant the protection to the surgical or medical processes, though patenting of the medical method is a complex issue as is does not only involve the patent law but also has an essence of the medical jurisprudence. One of significant objective of medical jurisprudence is the protection of human life and hence it implies that doctors should always have a choice for the method of medical treatment.\(^1\) Grant of protection to the surgical processes includes public policy concerns and so the medical practitioners should not be restricted in their area of work and should be allowed to operate freely. The traces of such competing concerns can be found in some of the judicial pronouncements such as Justice Jacob mentions in *Bristol-Mayer Squibb Co v. Baker Norton Pharmaceuticals Inc.* that the purpose of the limitation is … merely to keep patent law from interfering directly with what the doctors actually does to the patients.\(^2\) Some of the WTO members had initially construed the current patentability criteria to oust the new medical processes,\(^3\) they after duration started basing such exclusions on the basis of public order and morality. In the course of time, methods of medical treatment were considered more as patent eligibility criteria rather those patentability criteria.\(^4\) In this article, nature and scope of the exclusion of medical methods from the purview of patentability is discussed with respect to various jurisdictions and also in the light of provision of the TRIPS agreement wherein the ‘ordre public and morality’ phrase has been used.

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2. [1999] RPC 253 (Pat Ct) [51], aff’d in part [2001] RPC 1 (CA).
II. STATUS UNDER VARIOUS JURISDICTION

Although the position of the medical method exclusion from patentability is almost similar in most of the countries, nevertheless some of the jurisdiction has had a different view with regard to such exclusions.

Status in United Kingdom:

If we look into the history of UK, the surgical methods were excluded from the purview of the patentability on the ground of not having ‘industrial utility’ or not being ‘vendible products’ or not having ‘manner of manufacturing’. C & W’s application is relevant in this regard wherein the claim of taking the elements of lead from the human body was held to be non-patentable on the ground not having any industrial or commercial utility. As an aftermath of the decision, surgical methods were regarded as outside the purview of the patent protection because of their being not having the characteristics of the products which are vendible, but the situation got changed in the case of Elli Lilly & Company’s Application wherein court categorically applied the restriction regardless of the changes in the law (related to NRDC) on the ground of the proviso to section 6 of the Statute of the Monopolies which mentions the ground of public policy. The facts of the case are as such the applicant found out some substance that has already been discovered, had some properties of anti – inflammation, which could be used for various treatments of living beings. The court clarified that the ground of refusal was based on ‘ethics’ rather than ‘logic’. In 1970, when the patent system was reviewed by the committee, UK had an opportunity to change its idea towards the exclusion of surgical process. But it was criticized for toeing the lines of the established rules and practices for refusing the grant of protection and not contributing something unique of its own. In the aftermaths of the report of the aforesaid committee, the surgical processes were kept outside the purview of the grant of protection. It is to be noted that the UK patent law only excludes such methods which are technical in nature and not adopted for example ‘diagnostic methods’ and also methods which are not suitable for the recovery or curing of the disease or for the restoration of the physical integrity.

Status in United States of America:

The situation in USA with regard to the medical process is unique in itself as the protection is granted to the medical methods but curtails the scope by providing the defense for its infringement. Till 1954, the patent on medical methods was not allowed in America, however in Ex parte Scherer, by overruling its earlier decisions, Board held that surgical procedures are patentable as they are covered within the purview of the term ‘useful purpose’ (s. 101). It was a case related to the surgery of cataract eye in which the real controversy came into light, when it was observed that the same method of surgery was adopted by more than half of the United States in consequence of which Dr. Samuel Pallin sued others for using his invented method for the surgery of eye cataract. US government, in response to the upheavals created by the patent taken resort to the defense by invoking the provisions of the Omnibus Act which laid down that in the cases of such infringement by the practitioners in the medical field, the liability will not arise. The medical practitioners can be absolved of the liability by taking the defense of the provisions of the act based on the ground of balancing of the public interest on the one hand and the individual interest on the other.

Status in Australia:

Australia is one of such countries which provide patent protection for medical methods. If we look into the section 18 of the Patents Act, 1990 wherein the clear mandate has been provided for the grant of protection to the ‘manners of manufacture’. In the case of Joos’s Court limited the scope of exclusion of medical method by restricting the exclusion to the processes of curing disease, malfunctioning or disabilities. On this ground, court has distinguished between the methods involved in the cosmetic surgeries and therapeutic processes, by emphasizing that such cosmetic processes, strengthening of hair or nails are in no way related to the methods of medical process and are not adopted for the purpose of curing of the diseases.

Status in India:

Section 3 of the Indian Patent Law mentions the subject matters that are excluded from the purview of the patentability, it entails medical, surgical, curative, prophylactic or any other treatment of human body or any other method for the treatment of animals or plants to make them free of disease or increase its economic value. Till now, the provision does not seem to be categorically analyzed by the Courts in India; nevertheless the interpretations have been made clear in some cases by the patent board in India. In Benitec Australia Ltd’s patent, the issue was with regard to the process of mitigating the effect of target gene in a human vertebrate cell by inscribing some acidic molecules, it was held by the patent examiner that for the purpose of application of section 3 (i) of the Patent Act, three conditions must be satisfied which are:

   a. For what purpose the method has been used,
   b. To whom the process is directed,

5Re G.E.C.’s Application, 60 RPC 1 (1942).
6C & W’s application, 31 RPC 235 (1914).
7Elli Lilly & Company’s Application, RPC 438 (1975).
8National Research Development Corporation V. Commissioner of Patents, (1959) 102 CLR 252.
10Joos v. Commissioner of Patents, 126 CLR 611 (Austl. 1972)
11Joos v. Commissioner of Patents, supra n. 184, 623
12Section 3 (i) of the Indian Patent Act
c. The method which is used should be used for the purpose of curing the disease or increment in the economic value of either themselves or their product. However, if any matter is related to the increase in the efficiency of the therapeutic process, it was held by the patent office that matters for the purpose of mitigating the toxicity or improvement of the insolubility are within the purview of the Act.\(^{14}\) The phrase “other treatment” as used in the said provision of the Patent act created controversy with regard to the interpretation and inclusion of the ‘intervention in the cosmetics’. In M/s Golderma Research and Development S.N. C’s. Patent Application\(^{15}\), the issue was in relation to the improvement in the appearance of the body and hair and was not related to the curing of the disease, it was held by the patent examiner that the process is covered within the purview of section 3(i) of the Act, hence, is excluded from the purview of the patentability. Hence, based on the above analysis of the various jurisdictions such as US, UK, Australia and India, it is clear that the position in US is unique in relation to the protection of the medical processes, position in UK and Australia is more or less similar but with regard to Indian scenario it appears that the situation in India is much broader than that of other countries, consequently leads to the exclusion of huge number of invention from the purview of patentability.

### III. CONUNDRUM OF THE CONTEXTUALISED PHRASE WITHIN THE AGREEMENT

The phrase ‘ordre public’ has its origin in the French law and is not amenable to be translated into the English\(^{16}\) although it has been interpreted as relating to the matters as affecting the social structure.\(^{17}\) Morality on the other side implies conformity to the idea of moral principles.\(^{18}\) It is not feasible to confer a definite of subjective meaning to the phrases. The phrases public order and morality are inherently ambiguous and not easy to interpret. These phrases are left open to the domestic courts for their respective interpretation according to their local suitability and culture and practices. An important question arises as to whether law has a content of morality of it is devoid of it? On the one hand, positivistic school of jurisprudence will argue that the law can be devoid of morality however the natural law school will argue that the law should have the content of morality and it cannot be justified only on the ground of logic and reason.\(^{19}\) Positivists argue that the inventor should be given a patent right for his efforts if it fulfills the basic criteria such as novelty, inventiveness and depicts industrial utility irrespective of the fact that it does not have a content of morality, on the other hand, argument given by the naturalist is totally opposite to the positive school and it implies that the invention should not be given patent if it is against the social values and against the public order and morality even if it satisfies the test of novelty, inventiveness and industrial utility. It can be said that it is the oversimplification of the debate of law and morality which is inscribed in the concerned provision of the agreement, specifically Article 27.2 which does not expressly bar the states to exclude such subject matters from the purview of patentability which have tendency to affect or may offend the moral conscience. The exclusion is not based upon a consideration that the subject matter is proscribed by the local law of the state rather it should also be based upon some extraneous consideration as moral concern of the particular locality, which itself has not been defined by the TRIPS. A question arises as to what would have been the reason that TRIPS agreement has not given a coherent interpretation of the phrases like public order and morality. There seems a plausible answer to the questions which says that just to provide the enough flexibility to the member states to delineate the ambit of the term public order and morality suiting to the needs of local culture and conditions. The term provided under the TRIPS agreement has been given to ensure the existence of minimum standard of moral element into the agreement. The debate of positive law and natural law can be seen to be reflected in US and European Union Patent law regime in contrast. Commercial exploitation: A specific reading of sentence ‘the prevention within their territory of the commercial exploitation’\(^{20}\) used in Article 27.2 of the TRIPS implies that a state can utilize the provision when it, within its domestic law, banned the commercial exploitation, though there is difference of opinion with regard to it, one side is skeptical about the invocation of the provisions, when the product or the process itself can be produced or use of which is disseminated in the country which does not have a willingness to give it a patent. The other side asserts that an expressed ban for the purpose of commercial exploitation is not warranted for the purpose of excluding the matter from the purview of patentability.\(^{21}\) On the premises that a state is using a particular product or the process in its jurisdiction and allowing its commercial exploitation, it would rather be contrasting for it to exclude the subject matter from the purview of the patentability. By analyzing the Article 27.2 of the TRIPS and sub clause (i) of section 3 of the Patent law in India it can be asserted that public order and moral concern is expressly provided by the TRIPS agreement without conferring any objective meaning to it so that the member states can interpret and apply them according to the suitability of their cultural and local needs. It has also been argued that the patent offices are not the best places to adjudicate the morality\(^{22}\) which implies that one of the reasons why patent office are vested with the power to decide the morality is that they may not have such mandate to exclude the protection of the patent right on the grounds of moral concerns. Hence it can be said that the exclusion under clause (i) of section 3 of the Indian Patent Act is based on the touchstone of the basic test of ordre

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\(^{14}\) M/s Signature R&D Holdings LLC’s Patent Application, P.A. No. 942/DELNP/2006 decided on 01.05.2009.

\(^{15}\) P.A.No.2196/DELNP/2003/ decided on 31.03.2010.


\(^{17}\) Ibid.


\(^{20}\) Article 27 of the TRIPS


public and morality and TRIPS agreement, specifically Article 27.2 is flexible enough to allow the member country to delineate area and scope of the phrases like ‘ordre public and morality.’

IV. REASONING OF THE EXCLUSION OF THE MEDICAL METHODS FROM THE PURVIEW OF THE PROTECTION OF PATENT LAW
Whether the exclusion of medical processes is justified on a ground of general inconvenience or ordre public or morality? For the purpose of such determination it is imperative to look into public policy considerations and impact which it leaves into the society at large. It is possible that if there is no exclusion of the medical methods then the physicians may be reluctant to perform the operations or processes on patients because of the fear of the infringement. Patenting of medical method may also affect the relationship between the doctor and patient as it hinders the right to privacy of the patient when the suit for infringement is passed in violation of the right. Another significant concern can be that patenting of medical processes may also affect the dissemination of information, as it is the basic feature of the patent law to disseminate the information and hence, the purpose of the law will get forfeited.

- The ground of exclusion of medical method is purely based on the public policy concerns deriving its source directly from the Article 27.2 of the TRIPS agreement.
- Ordre public and morality has always been in constant radar of various jurisdictions for the purpose of exclusion of medical methods.

V. CONCLUSION AND SUGGESTIONS
Though there have been arguments from both the sides, in favor and in against, for the patenting of the medical methods, but the adverse consequences of the patenting outweigh the advantages gained from it as the protection of it may lead to stagnancy in information, high cost of treatment because of the monopoly granted to the inventor as there is a possibility that he may abuse the monopoly. It can also be asserted that the patenting of medical methods can also encourage the inventors on the ground that whatever they have invented is going to be protected and their efforts are not going in a public domain without any protection. Indian patent law has a broader connotation as regard to the interpretation of the provision related to the exclusion of medical methods as compared to other jurisdictions. TRIPS agreement has also provided the subjective criteria for the purpose of determination whether medical process is against the notion of public order and moral concerns and left it open to its member states to determine the subjectivity involved in it. In order to assess whether medical methods should be excluded as a subject matter from the patentability, a subjective analysis of historical and current, domestic and international debates must be look into. The lawmakers should proceed very cautiously in order to consider such issues particularly because they involve the questions of right to life, health and also benefit from scientific progress. The alteration in such laws should only be made after careful and contextual discussions.