Exclusion of Diagnostic, Therapeutic and Surgical Methods from Patentability

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The article deals with the exclusion of diagnostic, therapeutic and surgical methods from patentability. Ambiguities and uncertainties still loom large in the air with respect to exclusions of patentability relating to medical or surgical processes or those relating to the pharmaceutical or biotechnological industry. Uniformity in this area is still a distant dream even in this post-TRIPS era. Here, an analysis of the present scenario of patentability of the diagnostic, therapeutic and surgical methods is attempted. The distinct differences among the developed and developing economies with regard to the criteria and policies of exclusions from patentability, particularly pertaining to areas having a strong relation to the public health realm are discussed. An attempt of comparative analysis in this area has also been undertaken. A strong patent regime in consonance with the principles of human rights and ideals of public health is the need of the hour. The benefits of enabling and exclusion clauses in the patent legislations should be balanced and constructed in such a manner as to protect the interests of the developed nations as well as to fulfill the needs and aspirations of the so called third world.

Keywords: Exclusion, patentability, diagnostic, surgical, therapeutic methods, public health, TRIPS

‘The works of founders of states, law givers, tyrant destroyers and heroes cover but narrow spaces, and endure but for a little time, while the work of the inventor though of less pomp is felt everywhere and lasts forever.’

……Francis Bacon†

Intellectual property law regulates the creation, use and exploitation of mental and creative labour. Patents are one among the most prominent of these intellectual property rights. Perhaps in the modern era of science and technological advancements it is the most used (and more often than not ‘abused’) intellectual property. Patents are expected to stimulate economic and technological development and promote competition by creating financial motivation for invention. Reward to original creativity would foster advanced research and development leading to further inventions and progress.

TRIPS and Patents

The TRIPS Agreement which came into effect on 1 January 1995 is to date the most comprehensive multilateral agreement on intellectual property and it, in clear terms talks about the concept of patents, the idea of patentable subject matter, the substantive and procedural aspects of patentability, term of patents and so on.

TRIPS and Patent Exclusions

The Article 27 of the TRIPS Agreement deals with the concept of patentable subject matter. TRIPS talks of two kinds of subject matter exclusions:

(a) the one ‘necessary to protect ordre public or morality’, including when intended to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that necessity is at stake, and not just convenience; and

(b) a second group including: (i) diagnostic, therapeutic and surgical methods for the treatment of humans or animals, as well as (ii) plants and animals other than microorganisms, and (iii) plant or animal production essentially biological processes other than non-biological and microbiological processes. But on the same platform the Agreement makes it clear that products or processes that are deployed during the course of medical treatment are patentable in their own right, since they do not amount to ‘methods of treatment’ ipso facto.

It is still a debatable topic as to whether or not the patent systems foster a higher rate of new ideas, and if so, to what extent. And perhaps a bigger controversy lies in the patent regime-implications on the developing and least developed countries that are the net importers of technology. The pertinent question is whether the patent system promotes technology transfer to these countries or whether it has effectively curbed the potential growth that these
countries might have experienced, had they had the freedom to imitate and learn; freedoms that many of the developed countries enjoyed in the pre-TRIPS era. One can take the example of the Indian space technology which had reaped huge benefits and advancements from the process of reverse engineering in the early 1970s. It is doubtful whether such techniques would be legally good in the post-TRIPS era.¹⁸ So therein lies the question as to whether these countries would benefit more from the exclusions and exception clauses in TRIPS than they would from the enabling clauses. This is evident from the fact that study of case law from developed economies would suggest a restricted reading of eligibility exclusions.⁹ However, developing countries such as India opt for a wide reading of such eligibility exclusions, reflecting their specific national priorities.¹⁰ In the case of developing countries like India, patentability not only relates to innovation and advancements but also to the concept of access to technology goods. This concept of access mostly relates to pharmaceuticals and public health.¹¹ The patent regime cannot be sealed off from the public policy concerns such as health. The State has the difficult task at hand to balance the conflicting and competing concerns of patent rights on one hand and social values, public policy and fundamental rights on the other while upholding important values such as health.¹² Katherine Sands notes: ‘There is an inherent conflict between protecting patent rights and protecting a right to health. In order to connect the two concepts, we need to find a concept that bridges the gap itself.’¹³

Exclusion of Medical, Diagnostic and Therapeutic Methods from Patentability

‘Patenting of methods of medical treatment of human beings is, however, a complicated issue for it is not only based on patent law but also on medical law. Medical law has its origins in the Hippocratic Oath, and the goal is the preservation of human life. Since the goal of patent law is to encourage innovation by rewarding inventors, it is quite distinct from the goal of medical law. Thus, there is a public policy concern that in order to ensure the best possible health treatment, physicians must always be free in their choice of treatment.’¹⁴ The commentary clearly brings out the multifaceted dimensions of the patent regime and the idea of exclusions of medical, surgical and therapeutic methods from it.

The concept of exclusion from patentability has a great impact on the socio-economic, medical, ethical as well as other grounds. Especially when one looks at the exclusion of medical, diagnostic and therapeutic methods from patentability, the dimension becomes multifaceted. The TRIPS Agreement itself clearly says in its provisions about exceptions and exclusions; the objective sought to be achieved is big. But the drawback of non-uniform application of the TRIPS Agreement and the lack of stringent and stricter methods of interpretation of the exclusion clause of the TRIPS has led to many difficulties at the application and implementation levels. Detailed studies too have not come a long way with regard to the good and bad of patent exclusions; especially of medical, diagnostic and therapeutic methods.

The idea behind exclusion of medical, surgical and therapeutic methods from patentability is itself based on the principles of human rights. The fundamental right to life of a person is to be given maximum importance. The right of a person to get adequate and proper methods of treatment becomes a fundamental human right of every human being from the outset. The reason for exclusion of medical methods from patentability is to ensure that patents would not impede and restrict doctors from fulfilling their duties towards patients, which is of paramount importance for the medical profession and the public.¹⁵ But misinterpretation of ideology behind such exclusivity from patentability along with a pro-capitalistic approach have resulted in many developed countries deviating from the well-defined path of exclusion of medical, diagnostic and therapeutic methods from patentability. The balance between the right awarded to the inventor and benefit to society seems to be at peril. The principle of reward to the investor seems to blindfold the humanitarian aspects of patent exclusions.

Medical, Diagnostic and Therapeutic Methods – Definitions and Meanings

The Encyclopaedia Britannica defines diagnosis as the process of determining the nature of a disease or disorder and distinguishing it from other possible conditions. Medical diagnosis or diagnosis is the process of determining the nature of a disease or disorder and distinguishing it from other possible conditions. The term comes from the Greek term ἀναγνώσις, meaning knowledge. A diagnostic procedure can be regarded as an attempt at classification of an
individual’s condition into separate and distinct categories that allow medical decisions about treatment and prognosis to be made.

Surgery, as defined by the Encyclopaedia Britannica is a branch of medicine that is concerned with the treatment of injuries, diseases, and other disorders by manual and instrumental means. Therefore surgery basically involves the management of acute injuries and illnesses as differentiated from chronic, slowly progressing diseases, except when patients with the latter type of disease must be operated upon.

The Oxford Dictionary defines therapy as treatment intended to relieve or heal a disorder. The definition of therapy used by both the UK courts and the EPO includes both treatments to cure or prevent disease, and so methods of, for example, vaccination of healthy individuals are considered to be methods of treatment by therapy.

According to their dictionary meanings, a prophylactic method refers to any medication or treatment designed and used to prevent a disease from occurring, while a curative refers to any product or process used in the cure of diseases.

A look into some international and national legislation clauses relating to exclusions from patentability and in particular the exclusion of medical, surgical and therapeutic methods, some really interesting facts come up. It is surprising to see that some of the developed nations have not bothered to provide patentability exclusions to medical, diagnostic and therapeutic methods thereby, emphasizing their capitalistic approach even in those service sectors which directly pertain to public health and social welfare. And on the other side it is really heartening to see the interpretations of patent exclusion claims of some developing countries.

**EPC and Exclusion of Medical, Diagnostic and Therapeutic Methods from Patentability**

The European Patent Convention (EPC) Article 52, Section 4, Clause 1 (the former EPC law) provided that surgical, therapeutic, and diagnostic methods have no industrial applicability, and because these medical methods do not meet the statutory requirement of industrial applicability (Article 52 Section 1), they are not eligible for patent protection. In 2000, the EPC was amended (came into effect in 2007), and Article 52, Section 4 is now repealed. However, the deleted provision can now be found exactly in its original wording in Article 53, Section (c). The purpose of Article 53 is to list the exceptions to patentability: Section (a) provides for inventions the publication or exploitation of which would be contrary to public order and morality; Section (b) provides for biological processes for the production of plants or animals; and Section (c) provides for medical methods. According to case law, their exclusion from patentability requires that the treatments are performed on the living human or animal body. Method of treatments by surgery, therapy or diagnosis on dead human or animal bodies is thus not excluded from patentability. In line with this, the treatment of body tissues or fluids outside of the human or animal body or methods of diagnosis practised thereon are not excluded by Article 52(4) EPC unless the tissues or fluids are recycled to the donor body.

**Patentability of Medical, Surgical and Therapeutic Methods – A Study across Nationalities**

**India**

The Indian Patent Act of 1970 excludes from patentability 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. The Indian Patent Act interprets the concept of exclusion from patentability in a more or less strict manner. The literal rule of interpretation applied in this regard has always had a human right dimension to it. The ideals of public health and social welfare in consonance with advancement in technology enshrined in the Indian Constitution is given due importance and relevance in the interpretation of the exclusion clause (exclusion of medical, surgical and therapeutic methods from patentability) of the Indian Patent Act 1970.

**United Kingdom (UK)**

The old practice in UK with regard to requirement for a patent was that an invention be industrially applicable and it was clearly stated that a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body is not industrially applicable.

The Patents Act, 2004 which amended the Patent Act of 1977, introduced a new Section 4 (A) to its predecessor, to implement the European Patent Convention as revised in 2000. This section removed
the legal fiction of having to connect patentability of medical and surgical methods with industrial applicability as these were made unpatentable in their own right.\textsuperscript{23}

In addition, the new Section 4A states that patents may be granted for a known substance or composition for use in medicine, or for a specific medical use. These provisions therefore explicitly allow patent protection for the first medical use of a known substance or composition.

**Republic of Korea**

In Korea, patenting medical, diagnostic and therapeutic methods have been construed as being injurious to public health. As per Article 32 of the Korean Patent Act\textsuperscript{24} which deals with the concept of non-patentable inventions, those inventions liable to contravene public order or morality or injure public health are not patentable. The ideals of public health and social welfare have been given their due in this section.

**Germany**

The German Patent Act, 1981 (*Patentgezetz*) provides for the grant of patents for inventions that are new, involve an inventive step, and are susceptible to industrial application. Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible to industrial application within the meaning of invention. This exclusion however shall not apply to products, in particular substances or compositions used in any of these methods [Section 5(2) of *Patentgezetz*]. Thereby surgical, therapeutic and diagnostic methods for treating humans or animals are excluded from the ambit of patentability under German Law. The legislation provides for exclusion from patentability the human body, at various stages of its formation and development, including germ cells, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene. And also are excluded from patentability, the processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such process, plant or animal varieties as well as essentially biological processes for the production of plants or animals [Section 2(2) of *Patentgezetz*]. Such a wide interpretation of the exclusion clause on patentability by this developed nation is quite surprising. It adds to one’s surprise when it becomes evident that Germany is one of the leaders in the world when it comes to research and development as well as grant of patents. Therein lies a lesson for all those who advocate the theory that exclusions from patentability and procedures like compulsory licensing\textsuperscript{25} will kill research and development and minimize further advancements. The grant of such a licence tends to fulfill one of the three purposes: massive production of patented products (e.g. patented drugs) to cure a disease, through the anti-trust act to allow competition (e.g. between firms) and non-commercial use (e.g. by Government) in the interest of the general public.\textsuperscript{26}

**Malaysia**

Part IV of the Malaysian Patent Act, 1983 deals with patentability of inventions. It provides that an invention must possess the basic requirements of patentability i.e. novelty, inventive step and industrial application. The Act provides a list of non-patentable inventions. Section 13(d) provides that methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body are not patentable. However, the proviso to this clause states that this exclusion from patent shall not apply to any products used in such methods.\textsuperscript{12}

**Australia**

Even though Australian Patents Act, 1990 excludes from patentability human beings, the biological processes for their generation,\textsuperscript{27} anything contrary to law [Section 101B(2)(d)] food or medicine produced by mere admixture\textsuperscript{28}, etc., the health care sector has not found mention in a similar manner.

Australia has adopted an investor-friendly approach in the case of medical, surgical and therapeutic methods. In Australia, provided an invention meets the requirements for patentability set out in the Act, the Patent Office will grant patents on diagnostic, therapeutic or surgical methods of treatment.

The Australian Patents Act, 1990 does not expressly exclude methods of medical treatment from patentability. Before 1972, Australian law recognized surgical or medical treatment of the human body, as well as non-medical procedures (such as cosmetic treatment), as an exclusion from patentability.\textsuperscript{29} The reason for the exception was that such treatment was considered ‘essentially non-economic’ and ‘generally inconvenient’ within the terms of Section 6 of the Statute of Monopolies, 1623 (ref. 30).
Based on case law, IP Australia considers that it is now ‘firmly established that methods of medical treatment are patentable subject matter. IP Australia’s practice is that no objection to a patent application may be made on ‘methods or processes for the treatment, medical or otherwise, of the human body or part of it, only on the basis that the human body is involved.’

The Australian Law Reforms Commission (ALRC) does not support the introduction of a new exclusion from patentability for methods of medical treatment. In particular, the ALRC is concerned that such an exclusion would have adverse effects on investment in biotechnology, medical research and innovation in healthcare.

It is thus, unfortunate that Australia which boasts of a very efficient and well established healthcare system does not give much importance to the concept of public health through patent exclusion of medical, surgical and therapeutic methods. The socio-ethical implications can only be ascertained in the long run. This may be one of the reasons for the comparatively higher costs of health care services in Australia. The bigger question still persists: is it not the duty of a State; that too an economically sound State with ample resources to ensure affordability, and accessibility for the general public in the healthcare sector?

**United States of America (USA)**

The Constitution of United States of America has in its Article, embodied the concept of intellectual property protection which includes patent protection as well. Section 101, Title 35 of the United States Code deals with patentable subject matter. The scope of patentable subject matter as per that section is very wide and open. It states that any process, machine, manufacture and composition of matter is patentable if it is new and useful, subject to conditions of Title 35 (ref. 33). The statute does not lay down specific exclusions other than the general conditions applicable to all inventions or discoveries in order to be eligible for a patent. Under US law, although no statutory provision prohibiting the patenting of medical methods emerged, the practice had long been banned under the judicial doctrine known as the Morton doctrine. However, a period of absolute protection for medical methods began with the 1952 revision of the Patent Act, as if it had created a momentum that acted upon the courts to change the case law, and medical methods became patent eligible subject matter, with no limitations imposed on the enforcement of patent rights on medical methods, as with other types of inventions. The pendulum swing in the judicial approach in USA in the area of patentability of medical methods is evident from the cases of *Ex parte Brinkerhoff*, wherein the Morton doctrine was followed by the Patent Board of Appeals but later in the case of *Ex parte Scherer*, the decision was overturned.

Then came in 1992, the controversial *Pallin* case, where a surgeon sued other surgeons for patent infringement, triggering the Congress to amend the Patent Act in 1996, leaving behind, after nearly half a century, the heavenly period in which medical methods enjoyed absolute protection. Responding to the controversy and uproar over the *Pallin* case, the US government brought the Omnibus Consolidated Appropriations Act for the protection of the medical practitioners using patented methods. In the 1996 amendment, Section 287(c) of the above Act, which does not cover patents on medical products such as devices, medications and biotechnology, was added to provide for the exemption of infringement liability for medical practitioners who infringe on patented medical methods. But there is an exception to the above rule that the defence will not apply to a patented machine, item of manufacture, or composition of matter, biotechnological patents, and importantly, patented uses of a composition of matter. Therefore, although current law does not prohibit the patenting of medical methods, it provides an exception for medical professionals in cases where medical method patents are infringed, thereby limiting the enforcement of patent rights on medical methods. Furthermore, there are many exceptions to the infringement liability exemption, thus triggering doubts as to the effectiveness of such an exemption.

So in a way the US concept of exclusions from patentability of medical, surgical and therapeutic methods is unique. On one hand, they grant patents to medical methods, while on the other they limit the scope of such patents by providing express defences in favour of the medical practitioners who use such patented methods. The most important point lies in the fact as to how the US laws and adjudicating bodies balance the equation of public health and social welfare on the one side and the patent regime on the other in cases of exclusions from patentability of medical, diagnostic and therapeutic methods. It is going to be one tremendous task.
Japan

In Japan, the legal treatment of medical methods inventions is to not patent such inventions. Although the Japanese Patent Act, 1959 does not have provisions that exclude medical methods from patent eligibility, and the Patent Office’s examination guidelines state that medical method inventions lack the statutory requirement of industrial applicability under Article 29, Section 1, and must therefore be rejected. This practice has been confirmed in precedent as well by the Japanese court. But one important difference of the Japanese Patent law with the patent laws of other countries lies in the criteria for patentability exclusions of medical, surgical and therapeutic methods in the case of humans and animals. Whereas a method of surgery, therapy or diagnosis of humans is excluded from patentability as an industrially inapplicable invention (although products such as a medical device, apparatus, and substances for use in such a method are patentable subject matter), a method for treatment (surgery or therapy) or diagnosis of animals is not excluded from patentability in Japan.

Ireland

As per the Irish Patent Act, 1992, methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are not patentable. This exclusion does not apply to products, substances or compositions for use in any of these methods, i.e. medicines or surgical instruments. Being part of the British Commonwealth, the Irish patent law seems to follow the UK model of patent exclusion in matters of exclusion of medical, surgical and therapeutic methods from patentability.

Patenting Methods of Medical Treatment and Diagnostic Techniques - A Complicated Issue

In the patent world, a diagnostic method is a method practised on the human or animal body constitutive for deciding on a treatment or for selecting the appropriate treatment. Methods of medical treatment are excluded from patentability in a large number of countries today. The most commonly cited justification is that such patents are likely to fetter the freedom of physicians and prevent them from helping patients with the latest medical advances. To this extent, this exception best captures the tension between patent law and its innovation inducing rationale on the one hand, and concerns of public health on the other, where doctors must be free to administer the latest medical techniques without fear of patent infringement or incurring costs of licensing such inventions.

While some WTO member states had initially interpreted existing patentability criteria to oust new medical methods, they later began to base such exclusions on standalone ethical and public policy grounds. In other words, methods of medical treatment began to be seen more as a patent eligibility criterion stemming from public policy concerns rather than an inherent patentability criterion.

Diagnostic methods are patentable in India provided they are performed on tissues or fluids which have been permanently removed from the body and not on a living body. The scope of the patentability of diagnostic methods in India is still not clearly defined due to the lack of the judicial interpretations unlike in Europe where the extent of patentable subject matter is litigated a large number of times in courts.

If medical procedures remain patentable, society may gain the benefit of medical procedures that do not have accompanying profitable and patentable devices or drugs, but society will pay the price in the form of significant increases in healthcare costs, accessibility and enforcement problems, and distortion of medical research and patient-physician relationships. The society will therefore be better off if medical procedures remain excluded from patentability.

In addition to considerations of economic efficiency and patent policy, humanitarian concerns should also be addressed. Public health considerations should be ranked higher than the internal consistency of patent law. As between property rights and human health and well being, clearly the choice should be in favour of increasing availability of medical innovations, safeguarding patient privacy, and openly sharing research methodology.

Whether medical procedures should be patentable depends on whether granting a patent monopoly will bring more inventions to consumers more efficiently. Patent monopolies for medical procedures are only justifiable when the benefits of increased invention and innovation attributable to the promise of patent monopolies outweigh the total monopoly costs of all patented medical procedures. The principal rationale for excluding medical methods in most countries appears to be one of ‘ethics’, namely, that doctors
must be free to use the latest medical methods to help patients. The exclusion also appears to be based in some countries on the notion that the medical profession cannot qualify as ‘industry’ and therefore does not come within the proper scope of patentable subject matter.54

Conclusion

‘A young man knows the rules but the old man knows the exceptions’. The principle behind the concept of exclusions from patentability of medical, diagnostic and therapeutic methods (and for that matter other exclusions from patentability too) ought to be interpreted in such a manner that the central theme of such exclusions is not lost. It is high time that some clarity is brought within the international arena of such exclusions from patentability. There should be a detailed research oriented study with regard to the concept of exclusion from patentability of medical, surgical and therapeutic methods. The main objective of the study has to be to examine the lacunae in the existing provisions of exclusion of medical, surgical and therapeutic methods from patentability and to find the remedies thereon. Such a study will help to examine the need of interpreting and devising the provisions of exclusions from patentability in TRIPS Agreement in clear terms, ascertain how effectively the exclusion from patentability of medical, surgical and therapeutic methods can address public health issues and objectives at large, investigate the need of bringing about a uniform approach and procedure in national legislations to categorize inventions under the head of medical, surgical or therapeutic methods and thereby exclude them from patentability.

Findings of the research will add to the existing knowledge and understanding of the concept of exclusions of medicinal, surgical, curative, prophylactic, diagnostic, therapeutic methods or other treatment from the patent regime. The study should be significant in the sense that it will support and enrich the area of exclusions in patentability and devise strategies to overcome the existing difficulties with reference to medical, diagnostic and therapeutic methods, generate public awareness on the concept of patent exclusions. The differing approaches of the developed and the developing nations in this regard can be understood and it will help in establishing a uniform and logical system of exclusions in the patent regime of medical, diagnostic and therapeutic methods, and above all the findings of the study will promote the larger idea of social welfare by advancing the concepts of affordability, accessibility and quality in the healthcare sector.

At a time when developing countries benefit more from the exclusion clauses rather than the enabling ones, at least in the area of healthcare sector, the area needs expeditious attention. There are areas of concerns in the realm which needs to be sorted out at the earliest. A spirited action plan needs to be chalked out through constructive negotiations and deliberations at national, regional and international levels. Public health and social welfare are not areas to be experimented with. At the same time it should be made sure that such exclusions does not affect or negate the research and development activities. The economic and social development should harmoniously co-exist. It is of great relevance in the modern era how the patent regime, either through its enabling clauses or through the exception and exclusion clauses, contributes to public health. A co-existing patent system and social welfare mechanism could do wonders to a country’s social and economic spheres.

It is indeed impossible to devise a common exclusion system in the patent regime with regard to the medical, diagnostic and therapeutic methods because of many political, economic and social factors. But a constructive interpretation of an exclusion clause and incorporation of it in the public policy doctrines of the nations would at least bring about an end to drastic anomalies in this regard.

References

1 As quoted by Felix Liebesny, Mainly on Patents (Butterworths), 1989, p. 1.
5 Part II Section 5 Articles 27 – 34 of the TRIPS Agreement.
9 ‘As the discussion of European case law demonstrates, the legal definition of diagnostic methods does not reflect the true nature of a medical diagnosis. Modern diagnoses are rarely final and few occur without the aid of data and quantitative results from laboratory testing’, Piper Tina, commentary in response to ‘Are patents for methods of medical treatment contrary to the ordre public and morality or “generally inconvenient”?’, Journal of Medical Ethics, 30 (2004) 470 -476; Ho Cynthia M, Patents, patients and public policy: An incomplete intersection, UC Davis Law Review, 33 (1999) 601-621.


16 Unilever (Davis’s Application) [1983] RPC 21.


18 The EPC is a multilateral treaty that provides a legal framework for the granting of European patents via a single, harmonized procedure before the European Patent Office, the Convention on the Grant of European Patents, 5 October 1973, 1065 UNTS 255.

19 Guidelines for Examination within the European Patent Office July 1999, C-IV, 4.3.

20 Decision of the Technical Board of Appeal T 144/83, cf OJ EPO 1986, 301.

21 Inserted by Patents (Amendment) Act, 2002, with effect from 20 May 2003, vide SO 561(E).

22 Words ‘or plants’ omitted, by Patents (Amendment) Act, 2002.

23 Article 4A-(1) of The Patents Act, 2004 of UK reads: ‘A patent shall not be granted for the invention of - (a) a method of treatment of the human or animal body by surgery or therapy, or (b) a method of diagnosis practised on the human or animal body.’

24 Article 32 of the South Korean Patent Act 2005 reads: ‘Notwithstanding Article 29(1) to (2), any invention that is liable to contravene public order or morality or to injure public health shall not be patented.’

25 Compulsory licensing refers to the grant of IP licences, particularly copyright or patent licence by a national government without the owner’s consent for the purpose of wide utilization of the protected rights. Yang Deli, Compulsory licensing: For better or for worse, the done deal lies in the balance, Journal of Intellectual Property Rights, 17 (1) (2012) 76-81.


27 Section 18(2) of The Australian Patents Act 1990 reads: ‘Human beings, and the biological processes for their generation, are not patentable inventions.’

28 Section 50(1)(b) of The Australian Patents Act 1990 reads: ‘(1) The Commissioner may refuse to accept a request and specification relating to a standard patent, or to grant a standard patent: (b) on the ground that the specification claims as an invention: (i) a substance that is capable of being used as food or medicine (whether for human beings or animals and whether for internal or external use) and is a mere mixture of known ingredients; or (ii) a process producing such a substance by mere admixture.’

29 Joos v Commissioner of Patents (1972) 126 CLR 611, 619, where Barwick CJ decided that a process for the cosmetic treatment of hair and nails could be patentable, but distinguished this from medical treatment of disease, malfunction or incapacity.


32 www.ipaustralia/patents/resources.int (3 September 2012).

33 Section 101, Title 35 of the United States Code, 2003 reads: ‘Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.’

34 The Morton doctrine comes from the 1862 case of Morton v New York Eye Infirmary, 17 F.Cas. 879 (C.C.S.D.N.Y. 1862), where the New York Circuit Court held that the patentee’s claimed invention of a procedure for performing surgical operations with the use of ether was unpatentable because both ether and the process of inhaling vapors were not new. Although the court’s rationale seems to have rested on the traditional rule that no patent may issue for the discovery of a new but analogous use of an old product, the case referred to the ‘natural functions of an animal’. This language has given rise to the notion that medical and surgical procedures used to treat the human body are not patentable processes.


36 Ex parte Brinkerhoff, 24 Off Gaz Pat, 349 (Comm’r Pat Off 1883).

37 The Patent Board of Appeal held that ‘methods or modes of treatment of physicians of certain diseases are not patentable’ on the rationale that to ‘grant a patent for a particular method of treatment would have a tendency to deceive the public by leading it to believe that the method therein described and claimed would produce the desired result in all cases.’

38 Ex parte Scherer 103 USPQ (BNA) 107 (Patent Office Board of Appeal, 1954).
While allowing a patent on a method of injecting medicine by a pressure jet, the Board overruled its decision in *Brinkerhoff* and held that medical or surgical processes or methods were patentable since they constituted a ‘useful process’ under § 101 of the United States Code.

Dr Samuel Pallin, the owner of a patented method relating to the performance of cataract surgery without sutures sued others that were using his method. Given that almost half of all cataract procedures performed in the United States involved Dr Pallin’s technique, several associations of physician’s protested the enforcement of this patent and lobbied for legislative change in this regard.


Article 29 of the Japanese Patent Act 1959 reads: ‘(1) An inventor of an invention that is industrially applicable may be entitled to obtain a patent for the said invention, except for the following:

(i) inventions that were publicly known in Japan or a foreign country, prior to the filing of the patent application;
(ii) inventions that were publicly worked in Japan or a foreign country, prior to the filing of the patent application; or
(iii) inventions that were described in a distributed publication, or inventions that were made publicly available through an electric telecommunication line in Japan or a foreign country, prior to the filing of the patent application.’

Section 9(4) of The Irish Patent Act 1992 reads: ‘A method for treatment of the human or animal body by surgery or therapy and a diagnostic method practised on the human or animal body shall not be regarded as an invention susceptible of industrial application for the purposes of subsection (1). This provision shall not apply to a product, and in particular a substance or composition, for use in any such method.’


