

'Diagnostic Method' Patent Model-Patent Incentives and Socio-Ethical Concerns

Kalyan C Kankanala[†]

Brain League IP Services, No. 18, 2nd Floor, 5A Cross, 24th Main, J P Nagar 2nd Phase, Bangalore

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Medical methods have been excluded from the scope of patentability by most countries in consideration of ethics inherent in the practice of medicine. While the prohibition against patentability of surgical and therapeutic methods in which a doctor would directly be involved at all steps is viewed stringently by patent offices and courts, the exclusion relating to diagnostic methods is given a flexible treatment due to evolution of technology based diagnostics, involvement of technicians and decrease in intervention of doctors. This paper expounds the law relating to patentability of diagnostic methods, compares the differences in patent laws of various countries with the help of examples and concludes with suggestions for a diagnostic method patent model for India.

Keywords: Patent, diagnostic methods, patent model

The incentives offered by the patent system for advancement of science and technology has been precluded to certain inventions based on social and ethical considerations. One of such excluded category of inventions relate to medical methods¹, which have been excluded from the scope of patentability by most countries in consideration of ethics inherent in the practice of medicine. The exclusion of medical methods from the scope of patentability is sanctioned by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under Paragraph 3 of Article 27, which allows members to exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals from the scope of patentable subject matter.² 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.

Among inventions relating to medical methods, all types of medical methods are not treated equally by patent offices and courts. While the prohibition against patentability of surgical and therapeutic methods in which a doctor would directly be involved at all steps is viewed stringently, the exclusion relating to diagnostic methods is given a flexible treatment. In addition to ethics inherent in the practice of medicine, evolution of technology-based diagnostics, involvement of technicians and decrease in intervention of doctors makes diagnostic methods

unique from the patent perspective when compared with other medical methods. With the development of technology-based diagnostics, the process of diagnosis has become easier, faster, convenient and accessible. As a result, the intervention of doctors in medical diagnosis has decreased appreciably. While development of technology based diagnostic methods require patent incentives for rapid advancement, it is important to ensure that diagnostic methods that include involvement of a doctor are not impeded by patents. Bearing in mind the interests of technology progress and interests of medical profession, different countries have come up with different 'diagnostic method' patent models to balance patent incentives to organizations for advancement of diagnostic science and technology with the social and ethical considerations in the practice of medical profession.

Under such a backdrop, this paper expounds the law relating to patentability of diagnostic methods in USA, Europe and India and analyses their suitability for balancing the socio-ethical interests of doctors and the promotion of progress of diagnostic science and technology through patent incentives. It then compares the differences in patent laws of the countries with the help of examples. The paper finally concludes with suggestions for a 'diagnostic method' patent model that would be best for India.

Patentability of Diagnostic Methods

USA

Section 101 of the Patent Act, which deals with patentable subject matter provides that any process,

[†]Email: kalyan@brainleague.com

machine, manufacture, composition of matter or improvement is patentable if it is new and useful.³ As a method of medical treatment is a process, it falls within the scope of patentable subject matter and is patentable if it satisfies all other patentability requirements. The right to get a patent over a method of medical treatment is available under the Patent Act, but the statute under Section 287(c) (1) abrogates the remedy available for its infringement. Section 287(c) (1) of Title 35 of the United States Code provides that civil remedies for patent infringement are not available against medical practitioners or a health care entity for carrying out a medical or surgical procedure on human body or organ or cadaver or a nonhuman animal used in medical research or instruction directly relating to the treatment of humans.⁴ Only a medical practitioner licensed by the state to perform medical or surgical procedures or any person acting under his direction falls within the scope of this exemption.⁴ The exemption from civil remedies does not extend to the use of a patented machine, manufacture, or composition of matter in violation of a patent, the practice of a patented use of a composition of matter in violation of a patent, or the practice of a process in violation of a biotechnology patent.⁴

The Section was incorporated in Title 35 in the year 1996 through an Omnibus Consolidated Appropriations Act after the hue and cry sparked off by Pallin's case.⁵ Pallin acquired a patent over a method for making surgical incision in the eye in a manner that would allow the wound to self-heal and requires no sutures to heal in a cataract surgery. He filed an infringement suit against Singer, an ophthalmologist and Hitchcock Clinic alleging that they carried out hundreds of operations that infringe on his patent. In response, Singer and Hitchcock claimed for patent invalidity on the grounds of lack of novelty and non-obviousness.⁵ After hearing both parties, the court held that the patent was invalid as it lacked novelty and non obviousness and that Pallin cannot take any action to enforce any feature of the patent against the parties, any physician, health care provider, hospital, clinic, teaching institution, or other entity or person of any kind.⁶ It further declared that Singer and Hitchcock did not infringe the patent.⁶

The American Medical Association and the doctors being dissatisfied with Pallin's acts expressed a need for a legislation to protect the doctors from such suits, as they would have a devastating effect on the practice of medical profession by restricting access of

a doctor to a treatment, affecting autonomy of a doctor, breaching patient confidentiality and so on.⁷ Due to immense lobbying and pressure from the medical profession, the US Congress brought about an amendment in Section 287(c) making medical methods unenforceable.⁸

Patent Model

The US patent law does not differentiate between diagnostic methods and other methods of medical treatment when it comes to patentability or enforceability. All medical methods are considered patentable and not enforceable against licensed medical practitioners. However, differences in involvement of doctors in a diagnostic method when compared to other medical methods result in variations in application of the law. While a medical practitioner is involved in all steps of a surgical or therapeutic method, most steps in many diagnostic methods are carried out by a technician and only the final deduction is made by the medical practitioner. In such a scenario, the patent law prohibits enforceability of patents against medical practitioners but not against technicians, institutes or companies that perform steps in a patented diagnostic method. Such technicians, institutes, companies, etc. can be made liable as direct or contributory infringers and civil remedies can be availed against them under the US patent law.

In a recent case, involving a diagnostic method patent, the Federal Circuit held a company liable as a contributory infringer for supplying data necessary for diagnosis to a medical practitioner.⁹ The patent claim at question in the case related to a method for detecting a deficiency of cobalamine or folate in warm-blooded animals comprising the steps of: assaying a body fluid for an elevated level of total homocysteine and correlating the values to an elevated level of total homocysteine in said body fluid with a deficiency of cobalamine or folate.¹⁰

The patent holder and the exclusive licensee sued Laboratory Corporation of America Holdings (Laboratory Corp) for supplying the assay data to the doctors.¹⁰ The Court held that the doctors by correlating levels of homocysteine to cobalamine or folate deficiency infringed the patent claim directly.¹⁰ As Laboratory Corp supplied the data to make such an analysis, the Court held that Laboratory Corp was liable for contributory infringement and granted damages to the tune of seven million dollars.¹⁰

As it stands today, the US patent law does not distinguish between diagnostic and other medical methods. However, the application of the law results in differential treatment due to variation in levels of involvement of a medical practitioner in a diagnostic method when compared to other medical methods. A 'diagnostic method' patent can be enforced against any person other than a medical practitioner, which would include a technician, company, institute and so on. Therefore, patent incentives that are not available to surgical, therapeutic or other methods are available to diagnostic methods because they can be patented and enforced. Consequently, the patent law in USA results in a balance between the patent incentives necessary to promote the progress of diagnostic technology and the right of medical profession to provide medical care unimpeded by existence of patents.

Europe

The European Patent Convention (EPC) excludes medical methods from the scope of patentable subject matter. Paragraph 1 of Article 52 of the European Patent Convention states that patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.¹¹ Paragraph 4 of the same article provides that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body are not regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1.⁴ The provision does not apply to products, in particular, substances or compositions, for use in any of the methods. The Convention excludes methods of medical treatment by surgery, therapy or diagnosis from the scope of patentable subject matter by legal fiction due to socio-ethical considerations.

While the meaning and scope of surgical and therapeutic methods has been quite clear and unambiguous, the scope of and extent of prohibition with regard to diagnostic methods has been uncertain. The Board of Appeals has been giving conflicting opinions relating to patentability of diagnostic methods until the issue was referred to enlarged Board of Appeals, which clarified the law relating to the scope of the exclusion. The conflicting opinions of the Board and the decision of the enlarged Board of Appeal are discussed below.

Bruker/Non-Invasive Measurement

Claim 1 of the patent application in suit related to a method for the non-invasive determination of

chemical and/or physical conditions inside a living animal or human body using local magnetic resonance, in which the temperature within selected areas of the body was determined from a parameter of the resonance spectrum. Claim 2 of the patent application also related to a similar method, in which pH within selected areas was determined. The application was rejected as being related to a method of diagnosis under Article 52(4) of EPC and the applicant appealed.¹²

The Board started its reasoning by pointing out that Article 52(4) of EPC was intended to exclude only methods of therapeutic treatment from patentability, so that no-one could be hampered in the practice of medicine by patent legislation and that the exclusion should be narrowly construed.¹³ The Board was convinced that the only diagnostic methods to be excluded from patent protection were those whose results immediately make it possible to decide on a particular course of medical treatment.¹³ Moreover it observed that a method would be excluded from patentability only if it contained all steps involved in arriving at a medical diagnosis and that methods providing only intermediate results were not diagnostic methods.¹³ All steps for making a diagnosis according to the Board include, the examination and data gathering phases and comparing the test data with normal values, recording any significant deviation (symptom) and, finally, attributing the deviation to a particular clinical picture (deductive medical decision phase).¹³

As the methods in the patent claims result in obtaining body temperature or pH value at a given body location, which require a couple of steps such as comparing to a standard and attributing a clinical situation for making the diagnosis, the Board concluded that the claim does not include all the steps and is therefore not a diagnostic method.¹³ Furthermore, as the methods in patent claims can be implemented by a technician and do not require a doctor, the Board stated that the method has industrial application and is not excluded from patent protection.¹⁴ The Board went on to state that a diagnostic method would be excluded from patentability only if it is directly practiced on human body such as an allergy test in which the abnormal deviation can be detected from a change to the skin; a method for determining the patency of a body duct whereby liquid is injected into the uterus with a catheter and the pressure build-up in the uterus

observed; a method in which scarlet-fever spots are directly observed or photographed; or an endoscopic examination carried out to ascertain liver damage.¹⁴ In the light of its reasoning, the Board concluded that the diagnostic method in the present case was not excluded from patentability under Article 52(4).

R v CYGNUS

The patent application in the case was directed to iontophoretically sampling a substance from the living human or animal body for diagnostic purposes. The Examining Division rejected the application on the ground that the subject matter was excluded from patentability by reason of being a diagnostic method within the meaning of Article 52 (4) of the EPC and the applicant appealed.¹⁵

The Board started its analysis by stating that the expression 'diagnostic methods practiced on the human or animal body' in Article 52 (4) was not limited to those methods which comprised all the steps necessary to reach a medical diagnosis.¹⁶ The Board was of the opinion that Article 52 (4), EPC was meant to exclude from patent protection all methods practiced on the human or animal body which relate to diagnosis or which are of value for the purposes of diagnosis.¹⁶ The Board further stated that the taking of a body sample for the purpose of a medical examination belonged to a fundamental diagnostic activity, regardless of the technical means used, be it a spatula for taking a swab or smear, a syringe for taking a blood sample, or, as in the present case, an ionophoretic current forcing a substance through the skin.¹⁶ As all method claims in the patent application comprised the step of sampling a substance from a living human or animal body, the Board stated that the claimed step of sampling a substance related to diagnosis and constituted an essential diagnostic measure practiced on the living human or animal body and was therefore a diagnostic method.¹⁷

It observed that the fact that a method could be performed by a patient himself and that its execution would not have a significant impact on the body nor involve a serious health risk was irrelevant for determination under Article 52(4). The Board also observed that a process, the claimed steps of which amounted to nothing more than the (internal) operation of a technical device and thus without exception fell within the competence and under the exclusive control of a technician, may be regarded as patentable, even if it generated and detected physical signals on a living body and its results might be

evaluated for diagnostic purposes.¹⁷ As per the Board, the crucial step in the patent application that was of diagnostic character was the extraction of a body substance for diagnostic purposes, which had to be considered as constituting an elementary diagnostic activity performed under the ultimate responsibility of a physician.¹⁷ In the light of its reasoning, the Board held that the step of ionophoretically sampling a substance from the living human or animal body for diagnostic purposes was a diagnostic method within the meaning of Article 52 (4) of EPC.

Reference to Enlarged Board of Appeals

Considering the conflicting decision of Board of Appeals regarding the meaning of diagnostic methods practiced on human or animal body mentioned under Article 52(4) of the European Patent Convention, the President of the European Patent Office referred the issue to the Enlarged Board of Appeals (Board).¹⁸

The Board started its analysis by stating that diagnostic methods practiced on the human or animal body referred in Article 52(4) of EPC are inventions within the meaning of Article 52(1) EP, which by means of a legal fiction, are regarded as not susceptible of industrial application because of socioethical and public health considerations including impediment of medical or veterinary practitioners by such patents.¹⁹ It stated that as per the established jurisprudence of the (European Patent Office) EPO, the method steps to be carried out when making a diagnosis as part of the medical treatment of human beings or the veterinary treatment of animals for curative purposes include the:

- (i) examination phase involving the collection of data,
- (ii) comparison of these data with standard values,
- (iii) finding of any significant deviation and
- (iv) attribution of the deviation to a particular clinical picture.²⁰

The Board then pointed out that the question to be answered in the context was whether the diagnostic methods referred to in Article 52(4) of EPC comprise only the deductive medical or veterinary decision phase consisting in attributing the detected deviation to a particular clinical picture or whether they are also meant to include one or more of the preceding steps related to examination, data gathering and comparison.²⁰

To begin, the Board opined that the intelligent act of deduction of a disease condition is not patentable

but if such a deduction is done by a diagnostic tool, it may be patentable.²⁰ It then stated that the exclusion relating to diagnostic methods under Article 52(4) should be interpreted narrowly because the article talks about diagnostic methods practiced on the human or animal body but does not make reference to particular steps pertaining to such methods.²¹ The board then went on to state that the provision should be interpreted narrowly because it is very tough to define the group of medical or veterinary practitioners to whom the exclusion applies and the technology involvement in diagnosis is very high that the role of practitioners is limited and diagnostic tool companies require patent incentives.²¹

The Board then differentiated methods of surgery or therapy from diagnostics by pointing out that a method of therapy or surgery can be defined by one step in the whole process, which is not the case in diagnosis that requires steps of data collection, comparison and deduction, thus necessitating a narrow interpretation.²² It went on to state that steps of intermediate diagnosis would not be sufficient to form a diagnostic method and would not warrant exclusion from patentability.²² As defining an exclusion based on persons practicing it rather than the method gives rise to legal uncertainty, the Board observed that a diagnostic method should be defined based on the steps involved, essential or non-essential, and not involvement of medical practitioners, technical staff or patients.²³ The Board further stated that practice of a step on the human or animal body under Article 52(4) should not be strictly construed as certain non-technical steps that require deduction are not applied on human or animal body and are completely intelligence based.²³ It further stated that a step need not directly interact with the human body or have direct contact but if it can be implied that the step is linked with human or animal body or requires presence of human or animal body that would be enough.²³

In the light of its reasoning, the Board finally concluded that a diagnostic method practiced on the human or animal body containing the feature pertaining to the diagnosis for curative purposes as a purely intellectual exercise representing the deductive medical or veterinary decision phase as well as the features relating to the preceding steps which are constitutive for making the diagnosis and the specific interactions with the human or animal body which occur when carrying those out among said preceding

steps which are of a technical nature are excluded from patentability under Article 52(4) of EPC.²⁴

Patent Model

Based on the decision of the enlarged Board of Appeals, it can be concluded that the meaning of 'diagnostic methods' under Article 52(4) would be narrowly construed in Europe. A diagnostic method would be excluded from patentability only if the method involves all steps such as data gathering, comparison, deviation and deduction. If a method involves only one of the steps or if all steps are carried out by a diagnostic tool, it would not be excluded from patentability. The involvement of a doctor or a technician is not relevant for determination of patentability in Europe and the only question is whether the step is essential for making the diagnosis.

By construing the scope of diagnostic methods excluded from patentability limited to methods involving all steps, the European patent law makes the exclusion narrow. Considering the involvement of technology in diagnosis, it makes methods in which diagnosis is made by a tool and a method which includes only intermediate steps patentable. So, in Europe, the patent law ensures availability of patent incentives to promote progress of diagnostic technology by construing the scope of excluded diagnostic methods to be narrow. It also safeguards the interests of the doctors to provide health care without impediments from patents by excluding diagnostic methods that involve all steps including deduction by doctors from scope of patentability.

India

The Indian patent law also excludes medical methods from the scope of patentable subject matter. Section 3(i) of the Indian Patent Act provides that any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human being 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 patentable.²⁵ The Manual of Patent Practice and Procedure (Manual) provides that a method is considered to be a diagnostic method if it identifies the presence of a disorder in a person or animal suffering from a medical disorder.²⁶ A diagnostic method would be excluded from patentability only if it is practiced on a living body.²⁶ If a method is practiced or performed on tissues or fluids, which have been permanently removed from

the body or on a dead body to determine cause of death, such a method is not excluded from patentability.²⁶

Patent Model

As per the interpretation of the Manual, any method that identifies the existence of a medical disorder would be excluded from patentability irrespective of whether the method is performed by a machine or a doctor. However, if the method does not result in identification of a disorder, in other words, if the steps in the method do not include the deduction of a disorder, then the method would be patentable. Furthermore, *in vitro* diagnostic methods are also not excluded from patentability.¹⁸ Though, the Indian patent law relating to diagnostic methods is similar to that of Europe with slight variations, due to dearth of legislative history and judicial interpretation, the exact scope and extent of the exclusion is not clearly defined.

Analysis and Conclusion

Patent law in all three countries balances the patent incentives for development of diagnostic technology and the interest of doctors to offer medical care without patent hurdles. While USA achieves this objective by limiting enforceability of diagnostic methods against medical practitioners, Europe accomplishes this goal by construing the scope of diagnostic methods excluded from patentability narrowly. India provides incentives to advancement of diagnostic technology by allowing *in vitro* diagnostic methods and intermediate steps in a diagnostic method to be patentable but the scope and extent of excluded methods is not clear. The balance between the interests of medical practitioners and progress of diagnostic technology is maintained by US patent law through regulation of enforceability with no restrictions on patentability and by European law through exclusion from patentability. Consequently all diagnostic methods are susceptible to patent protection in USA and only certain diagnostic methods such as intermediate steps, diagnosis by a machine, etc. are patentable in Europe. The table 1 elucidates the variance in patentability of diagnostic methods in USA and Europe.

The table shows a sample list of patents filed by European assignees in US. These patents were granted in US but they were either not filed or were filed but withdrawn in Europe. The reason for such non-filing or withdrawal could most probably be the

narrow scope of patentability for diagnostic method inventions in Europe.

The diagnostic method patents listed in the table that have been granted patent protection in USA cannot be enforced against medical practitioners. However, they can be enforced against any person other than a medical practitioner such as technician, company and so on. The US model allows patents to all diagnostic methods, thus ensuring their advancement through patent incentives and protecting the doctors from patent infringement suits by making the patents unenforceable against them.

On the other hand, Europe allows only a few diagnostic methods to get patent protection, thus restricting the scope and extent of patent incentives to diagnostic methods. It provides patent incentives to only limited 'diagnostic method' inventions such as technology based inventions and so on, which do not involve intervention of the medical practitioner for diagnosis. By excluding essential steps for diagnosis such as deduction of a disease based on data and deviations, it safeguards the interests of medical

Table 1-Diagnostic method patents- European assignees (sample study of class 435/4 of US classification)

S. No.	US Pat No	Title	Status in Europe
1	US 4,985,353	Method for the diagnosis of whooping-cough and a test kit for carrying the method into effect	Deemed to be withdrawn
2	US 6,040,134	Method of diagnosing preclinical diabetes	Deemed to be withdrawn
3	US 5,858,697	Method for rapid diagnostic of urinary tract infections	Deemed to be withdrawn
4	US 6,261,796	Method and kit for measuring mitochondrial activity	Deemed to be withdrawn
5	US 4,880,732	Process for the rapid determination of sperm cell count and/or living sperm count	Not filed in EU
6	US 6,824,972	Diagnosis and treatment of medical conditions associated with defective NFkappa B (NF-.kappa.B) activation	Not filed in Europe
7	US 6,399,748	<i>In-vitro</i> method for prognosticating the illness development of patients with carcinoma of the breast and/or for diagnosing carcinoma of the breast	Deemed to be withdrawn

Source: USPTO and EPO patent databases

practitioners.

US follows an approach with a broad subject matter for diagnostic methods and restrictions with regard to enforceability and Europe follows an approach with narrow subject matter, where certain diagnostic methods are excluded from patentability prima facie. By allowing patents to all diagnostic methods, the US approach extends the patent incentives to progress of diagnostic technology in all areas without any discrimination. As a result, companies and inventors would be incentivized to develop new methods, as they know that they can get a patent. The interests of the doctors and patients are adequately safeguarded under the US philosophy because no one can claim a remedy against them for infringement while carrying out a medical activity. However, damages can be claimed against them if their activities fall outside the scope of medical activity.

As per the European approach, the incentives to progress of diagnostic methods are limited to certain inventions because diagnostic methods including all steps of diagnosis are excluded from patentability. Though the scope of exclusion has been read narrowly by the Board, lot of inventions still fall within the scope of the existing exclusion. The result is limited patent incentives to advancement of diagnostic methods and enforceability of patentable diagnostic methods against doctors. As a result, a doctor might be liable for infringement and damages while carrying out a medical activity.

The Indian position, as it stands today, is very vague and ambiguous due to lack of legislative history and judicial interpretation. Though India follows the European model by excluding diagnostic methods from the scope of patentable subject matter, determination of the scope and extent of such prohibition depends on the interpretation of the judiciary. It is important for the Courts and Patent Office to bear in mind the need for progress of diagnostic technology and the right of doctors to have access to diagnostic methods while interpreting the scope of the exclusion. The interpretation should ensure rapid progress of diagnostic technology by granting patent incentives to diagnostic companies without disturbing the right of medical profession to access diagnostic methods in order to provide high quality health care.

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