ABSTRACT

Contrary to the belief that the U.S. is the only country in the world, in addition to Australia, allowing medical method patents, Europe allows medical method patents as well. In Europe, medical methods are interpreted differently than those in the U.S. In fact, many patent experts fall into the trap. This paper selected three well-known U.S. cases involving diagnostic method patents, and searched for the corresponding European patents. After examining the patents and the claims, it was found that some of the diagnostic method patents in Europe have broader scope than their U.S. counterparts. Instead of invalidating diagnostic method patents altogether, broadening the scope of “medical immunity” is a better way to protect medical practitioners from being sued, since the endless interpretation of diagnostic methods in Europe simply caused more confusion.

KEYWORDS: diagnostic method, medical method, patent, medical immunity, infringement
I. INTRODUCTION

The skyrocketing healthcare cost is a global issue. The situation in the U.S. appears to be one of the worst. One theory emerged recently suggests that an important factor contributing to the high healthcare cost in the U.S. is because it is one of the few countries granting medical-method patents. A simple way to test the theory is by proving that the U.S. allowed such patents while others didn’t.

The controversy raised by the patents directed to gene sequences capable of detecting the predisposition of certain cancers has been closely examined both in the U.S. and Europe. ¹ Specifically, commentators have devoted large volume of literature discussing Myriad Genetics’ gene patents.² However, little attention has been paid that, among those patents, a method patent granted in Europe claiming the comparing and analyzing of gene sequences is a diagnostic method in essence. Few, if any, has attempted to explain why patents directed to diagnostic methods could be easily found in a jurisdiction blatantly prohibiting such patents. Apparently there is a missing link between the law and the practice.

Because of the lack of attention, some have continued to argue that the U.S. should follow or learn from the European approach and ban diagnostic method patents altogether,³ without noticing the fact that diagnostic method patents granted in the U.S. could easily find their corresponding method patents in Europe. As a consequence, recently, the U.S. Supreme Court in Mayo Collaborative Servs. v. Prometheus Labs., Inc. has made a similar mistake and erroneously believed that the U.S. is alone in the world allowing patents directed to medical methods.⁴

This paper is a comparative study between American and European patent systems. The comparison was conducted on four levels. The first level is statutory provisions. The literal provisions of relevant statutes were examined. The second level is case law. This paper examines how statutory

² See, e.g., Williams-Jones, supra note 1; Paradise, supra note 1; Kane, supra note 1; Murray & Zimmeren, supra note 1; Sarnoff, supra note 1.
⁴ Mayo Collaborative Serv., 132 S. Ct. at 1305.
provisions were interpreted by relevant authorities. The third level is focused on patents issued. U.S. patents involved in representative cases were searched for their European counterparts. The fourth level is claims. Claims in U.S. patents and their European counterparts were examined and compared, so as to confirm that the claims granted are directed to diagnostic methods.

In this paper, Part II provides a general view regarding healthcare cost and the rationale of theories suggesting that medical-method patents are an important factor contributing to the rising cost. Part III examines statutory provisions concerning medical-method patents in the U.S. and Europe, respectively. This Part also examines U.S. patents and their European counterparts involved in three selected cases: Prometheus Lab. Inc. v. Mayo Collaborative Serv., Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office [hereinafter Myriad], and Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.

In Part IV, this paper explores how the European Patent Office interpreted diagnostic methods and how the interpretation was applied in later cases.

In conclusion, this paper identifies the irony in patenting diagnostic methods. Contrary to the general belief, Europe did not prohibit patenting diagnostic methods in a broad sense. Rather, diagnostic methods were defined narrowly and patents were granted to medical processes outside the narrow scope, including those being considered diagnostic methods in other jurisdictions. This paper suggests that providing a broad infringement exemption for medical practitioners is a better way, once for all, to settle the dispute over the patent eligibility of diagnostic methods. As the technology continues advancing in an unpredictable manner, attempting to incessantly define and redefine diagnostic methods, as well as other medical processes, would be futile.

II. HEALTHCARE COST

The rising cost of healthcare is a global issue. However, the situation in the U.S. seems worse than other developed countries. Specifically, U.S. healthcare spending is among the highest of all industrialized countries. Healthcare expenditures in the U.S. were more than 40% higher than the

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per capita costs in Switzerland which had the next highest cost per capita.\textsuperscript{9} In 2005, the U.S. spent $6,041 per capita on healthcare, which is more than double the median per capita spending of the 30 industrialized countries that form the Organization for Economic Cooperation and Development [hereinafter OECD].\textsuperscript{10}

Some commentators believed that overutilization and misuse of new technology have led to excessive spending and resulted in higher cost for patients.\textsuperscript{11} New and increased use of medical technology has contributed 40-50% to annual healthcare-cost increases.\textsuperscript{12} Therefore, for instance, Daniel Callahan argued that controlling the technology is the most important factor in reducing the rising healthcare cost.\textsuperscript{13}

Similar but more specific than Daniel Callahan’s viewpoint, American Association of Retired Persons [hereinafter AARP] and the Public Patent Foundation [hereinafter PUBPAT] singled out the monopoly of a particular type of technology, medical correlations, as an important factor causing excessive healthcare costs. In their amicus brief to the Supreme Court for \textit{Mayo Collaborative Serv. v. Prometheus Lab. Inc.}, AARP and PUBPAT argued that allowing patents on pure medical correlations have threatened doctors with claims of patent infringement, burdened the public with excessive healthcare costs, and dulled incentives for real innovation in medical care.\textsuperscript{14} AARP and PUBPAT defined medical correlations as processes including, but not limited to, “an overly high or low level of some chemical in the body correlates to an unhealthy condition.”\textsuperscript{15}

Medical correlation is understood as a category of diagnostic methods. It can also be part of a therapeutic method. The premise for an argument asserting that medical-correlation or diagnostic-method patents further burdened the healthcare costs in the U.S., but not other countries, is that countries other than the U.S. must have considered diagnostic methods as patent ineligible. Europe is among the regions or countries which have explicitly banned patenting diagnostic methods on the statutory level. As explained in next part, the situation is not so clear in practice.

\textsuperscript{12} Id.
\textsuperscript{13} Id.
\textsuperscript{14} Brief of AARP and Public Patent Foundation as Amici Curiae Supporting Petitioners at 2-3; \textit{Mayo Collaborative Serv.}, 132 S. Ct. at 1305.
\textsuperscript{15} Id. at 2.
III. PATENTING DIAGNOSTIC METHOD

The majority of countries or regions in the world have banned patenting diagnostic methods, which is a measure consistent with the provisions under the Agreement on Trade-Related Aspects of Intellectual Property Rights [hereinafter TRIPS Agreement]. The U.S. and Australia are exceptions. Instead, U.S. Congress created certain rights sought to protect medical practitioners from being sued for patent infringement in their practice, though it has been argued that the measure is ineffective in protecting physicians' right to practice.

U.S. patent law allows two types of conducts or medical activity involving patented medical products or processes which would otherwise constitute an act of infringement because the implication of Food and Drug Administration [hereinafter FDA] approval processes and the need of medical practitioners for treating their patients. The “FDA exemption” is provided under 35 U.S.C. §271(e) (1) and the “medical immunity” is provided under 35 U.S.C. §287(c).

Under the Food, Drug, and Cosmetic Act, it is not an act of infringement if the act is reasonably related to the development and submission of information. The U.S. Supreme Court in Merck KGaA v. Integra Lifesciences I, Ltd. interpreted the statute that, as long as the alleged infringer has “a reasonable basis for believing that the experiment will produce the types of information” relevant to FDA submissions, then the otherwise infringing act is excused. The statute only protects otherwise infringing acts before the medical product or technology receiving FDA approval. It does not help to protect medical practitioners from being sued since medical practitioners are not allowed to use products or technology without FDA approval.

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17 Brief of AIPPI & AIPPI-US, supra note 3, at 5.
18 35 U.S.C. §271(e) (1) provides:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

The statute at the center of the debate is 35 U.S.C. §287(c) (1). The statute provides immunity from infringement liability for medical practitioners’ medical activity otherwise would violate the patent law. However, the scope of “medical activity” defined under the statute is narrow on its face. Under 35 U.S.C. §287(c) (2) (A), medical activity is defined as “the performance of a medical or surgical procedure on a body” but excluding “the use of a patented machine, manufacture, or composition of matter in violation of such patent”; “the practice of a patented use of a composition of matter in violation of such patent; or “the practice of a process in violation of a biotechnology patent.” It is highly doubtful if there is anything left a medical practitioner can do to use a patented product or technology without “violating such patent” (emphasis added).

As the court in *Emtel Inc. v. LipidLabs Inc.* [hereinafter *Emtel*] has stated, the application of the medical immunity provision of 35 U.S.C. § 287(c) (1) is an issue rarely addressed in the case law. The *Emtel* court contributed to clarify the breadth of the medical immunity provision by answering, *inter alia*, whether it is necessary to infringe every step of a medical-method claim, including nonmedical steps, to be infringement falling within the scope of 35 U.S.C. § 287(c) (1).

In *Emtel*, the patent in dispute was for a business method to provide medical care to patients in remote healthcare locations through the use of videoconferencing equipment. In the independent claims at issue, medical activities make up only some of the steps claimed in the nine- or ten-step business method. In the court’s view, it is not necessary to practice every step of a claim to constitute infringement under section 287(c) immunity if the nonmedical steps in the claim is merely incidental. Examples of incidental steps, as the court has provided, include “washing hands” or “obtaining informed consent.” The court’s interpretation was a deviation from the rule that “every limitation set forth in a claim must be found in an accused product or process exactly or by a

20 35 U.S.C. § 287(c) (1) provides that “with respect to a medical practitioner’s performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.”


23 *Id.* at 825.

24 *Id.*

25 *See id.* at 826. If the nonmedical steps in a medical method claim are incidental, then the infringement of the claim falls within the scope of the medical immunity. On the other hand, if the nonmedical steps in a medical method claim are not incidental, then the infringement of the claim falls outside the scope of the immunity.

26 *Id.*
substantial equivalent” to constitute infringement. The court found that the claimed non-medical steps of the patent in suit are not an incidental part of medical practice. Though the Emtel court found that the medical immunity provision of section 287(c) does not apply in this case, nonetheless, the court has essentially broadened the scope of the immunity by creating an exception to the rules of infringement.

Instead of arguing patent ineligible, it appears to be a new trend arguing that section 287(c) should apply when a suit involving alleged infringement of diagnostic-method patents. For instance, in the amicus brief filed by the International Association for the Protection of Intellectual Property [hereinafter AIPPI] to the Supreme Court for Mayo Collaborative Serv. v. Prometheus Lab. Inc., AIPPI suggested that both the method claims and the named defendants in this case fall within the specified classes under section 287(c), therefore federal subject matter jurisdiction is lacking.

In addition, the AIPPI also attempted to serve the Court by providing a global perspective on the issue of patent eligibility for medical methods. Specifically, in all 33 countries studied by AIPPI, “the societal objective of allowing medical treatment of patients to be unfettered by exclusive patent rights is achieved by excluding methods of medical treatment of patients from patent eligibility altogether,” except the U.S. and Australia.

Under the TRIPS Agreement, member states have the discretion to decide whether to permit patenting diagnostic, therapeutic, or surgical methods. For instance, the patent eligibility of medical methods is literally prohibited under the European Patent Convention [hereinafter EPC]. The provisions were previously placed in Art. 52(4) EPC 1973, and later in Art. 53(c) EPC 2000. Either way, the proscription exists since

28 Emtel Inc., 583 F. Supp. 2d at 826.
29 Id. at 815.
31 Id. at 5.
32 Id. at 4-5.
33 Id. at 5.
34 Art. 27 of the TRIPS Agreement provides that, inter alia, “[m]ember may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals.”
37 Amendment of the European Patent Convention (Nov. 29, 2000), available at http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/ma5b.html. Art. 53 of the EPC 2000 provides that, “European patents shall not be granted in respect of . . . “(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.”
the EPC entered into force in 1977.\textsuperscript{38} Therefore, it is reasonable to infer that no medical-process patent has been granted since the EPC entered into force.

Medical correlations can be all or part of either a diagnostic method or a therapeutic method. In \textit{Prometheus Lab. Inc. v. Mayo Collaborative Serv.}, the patents at issue claimed methods that seek to optimize therapeutic efficacy while minimizing toxic side effects.\textsuperscript{39} Titles of the patents are “method of treating IBD/Crohn’s disease and related conditions wherein drug metabolite levels in host blood cells determine subsequent dosage”\textsuperscript{40} [hereinafter ’623 patent] and “methods of optimizing drug therapeutic efficacy for treatment of immune-mediated gastrointestinal disorders,”\textsuperscript{41} respectively. Surprisingly, the patents have a corresponding European patent whose title is “method for optimizing the use of 6-mercaptopurine in the treatment of Immune-mediated gastrointestinal disorders.”\textsuperscript{42} Nonetheless, whether a patented invention is a diagnostic method is determined by its claims, rather than the title or the specification.

The Federal Circuit considered claim 1 of the ’623 patent as representative of the independent claims asserted in this case.\textsuperscript{43} Claim 1 of the ’623 patent and claim 1 of its corresponding European patent are substantially the same, except the former administering “a drug providing 6-thioguanine”\textsuperscript{44} and the latter administering “a 6-mercaptopurine drug”\textsuperscript{45}

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\textsuperscript{39} Prometheus Lab. Inc., 628 F.3d at 1350.

\textsuperscript{40} U.S. Patent No. 6,355,623 (filed Apr. 8, 1999) (issued Mar. 12, 2002).


\textsuperscript{43} Prometheus Lab. Inc., 628 F.3d at 1350.

\textsuperscript{44} See ’623 Patent, claim 1. The claim reads as follows:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising: (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per 8x10\textsuperscript{8} red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per 8x10\textsuperscript{8} red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

\textsuperscript{45} See ’403 Patent, claim 1. The claim read as follows:

An in vitro method for determining efficacy of treatment of a subject having an immune-mediated gastrointestinal disorder or a non-inflammatory bowel disease (non-IBD) autoimmune disease by administration of a 6-mercaptopurine drug, comprising determining in vitro a level of 6-thioguanine in a sample from said subject having said immune-mediated gastrointestinal disorder or said non-inflammatory bowel disease (non-IBD) autoimmune disease, wherein said
instead. As defined in the specification of the European patent, 6-mercaptopurine [hereinafter 6-MP] drugs are drugs that can be converted to various metabolites including 6-thioguanine [hereinafter 6-TG]. Nevertheless, 6-TG is thought to be the active metabolite mediating many of the effects of 6-MP drug treatment. Therefore, the breadth of two claims is essentially the same because, though 6-MP can be converted to various metabolites, the treatment is effective only if one of the metabolites is 6-TG.

Another case involving diagnostic-method patents which has drawn nationwide attention is Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office[hereinafter Myriad]. The Federal Circuit summarized the method claims at issue as “[a]ll but one of the challenged method claims cover methods of ‘analyzing’ or ‘comparing’ a patient’s BRCA sequence with the normal, or wild-type, sequence to identify the presence of cancer-predisposing mutations.” Thus, the challenged method claims are “diagnostic methods of identifying mutations in these sequences.”

Claim 2 of the European counterpart of Myriad patents is analogous to the first claim of U.S. Patent 5,710,001 [hereinafter ’001 patent], which is one of the representative method claims in Myriad. The European patent survived an opposition procedure with seven claims left. Claim 2 is one of them and is the broadest claim among the survived.

The most significant differences between claim 2 of the European patent and claim 1 of ’001 patent, which would affect the breadth of the claims, is that the use of the term “an alteration” in the former was substituted with “a somatic alteration” in the latter. Literally, genetic treatment is considered efficient if the level of 6-thioguanine is in the range of about 230 pmol per 8x10^8 red blood cells to about 400 pmol per 8x10^8 red blood cells.

46 See id. ¶ 0003.
47 Id.
48 Ass’n for Molecular Pathology, 653 F.3d.
49 Id. at 1334.
50 Id. at 1335.
52 Ass’n for Molecular Pathology, 653 F.3d at 1335.
54 Id.
55 Id. at claim 2. The claim reads as follows:

A method for diagnosing a lesion of a human subject for neoplasia associated with the BRCA1 gene locus which comprises determining in a sample from said lesion whether there is an alteration that is a frameshift mutation in the sequence of the BRCA1 gene coding for a BRCA1 polypeptide altering the open reading frame for SEQ ID NO:2, said altering being indicative of neoplasia.

56 See ’001 Patent, claim 1. The claim reads as follows:
alteration includes somatic alteration and germline alteration.\textsuperscript{57} Therefore the broadest claim in the European patent is at least not narrower than the broadest claim in its U.S. counterpart if the analysis stops here.

What is intriguing is that, claim 1 of '001 patent was declared invalid in \textit{Myriad},\textsuperscript{58} yet its European counterpart survived the opposition procedure\textsuperscript{59} in a jurisdiction where diagnostic method is statutorily patent ineligible.

Thus, the conclusion that can be drawn from the comparison is that European Patent Office [hereinafter EPO] did grant diagnostic-method patents, regardless of whether the number of patents or the breadth of claims granted is larger or smaller than the United States Patent and Trademark Office [hereinafter USPTO]. Nevertheless, it appears that the USPTO has granted more method patents relating to the gene claimed in \textit{Myriad} than the EPO, therefore broader aggregate scope of protection vested, since only one of the three representative method claims in \textit{Myriad} has a European counterpart available.

Another medical-correlation patent in the U.S. triggered probably one of the most famous dissents in Supreme Court’s history. Justice Breyer’s dissenting opinion, joined by Justice Stevens and Justice Souter, in \textit{Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.}\textsuperscript{60} has far-reaching effects. As Justice Breyer phrased it, the patent at issue claimed “a process for helping to diagnose deficiencies of two vitamins, folate and cobalamin.”\textsuperscript{61} Therefore the patent at issue was claiming a diagnostic-method.

Claim 13 of the patent was the center of the controversy.\textsuperscript{62} The claim

\begin{quote}
A method for screening a tumor sample from a human subject for a somatic alteration in a BRCA1 gene in said tumor which comprises gene comprising a first sequence selected from the group consisting of a BRCA1 gene from said tumor sample, BRCA1 RNA from said tumor sample and BRCA1 cDNA made from mRNA from said tumor sample with a second sequence selected from the group consisting of BRCA1 gene from a nontumor sample of said subject, BRCA1 RNA from said nontumor sample and BRCA1 cDNA made from mRNA from said nontumor sample, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said tumor sample from the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said nontumor sample indicates a somatic alteration in the BRCA1 gene in said tumor sample.
\end{quote}

\textsuperscript{57} Germline mutation is a heritable change in the DNA that occurred in a germ cell, which is a cell destined to become an egg or in the sperm, or the zygote at the single-cell stage. When transmitted to a child, a germline mutation is incorporated in every cell of the body. A germline mutation is in contrast to a somatic mutation which is acquired in a single body cell. \textit{Definition of Germline Mutation}, MEDICINE\textsc{net}.com, http://www.medterms.com/script/main/art.asp?articlekey=15923 (last editorial reviewed June 14, 2012).

\textsuperscript{58} Ass’n for Molecular Pathology, 653 F.3d at 1355-56.

\textsuperscript{59} EPO, Case No. T0080/05 – 3.3.04, at 38 (Nov. 19, 2008).

\textsuperscript{60} \textit{Lab. Corp. of Am. Holdings}, 548 U.S. at 125-39.

\textsuperscript{61} \textit{Id.} at 125.

\textsuperscript{62} \textit{Id.} at 129.
basically comprises of two steps: “assaying a body fluid for an elevated level of total homocysteine;” and “correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.”

Indeed, it is a very broad claim which does not exist in the patent’s European counterpart. Nevertheless, claim 1 of the European patent is essentially the same as claim 1 of the U.S. patent: a diagnostic method for the same purposes as claim 13 of the U.S. patent but having more steps, or limitations. For instance, the claims recite the use of isotope markers and mass spectrometer, which render the claims more specific and narrow in scope compared with claim 13 of the U.S. patent.

It is premature to conclude whether the USPTO granted more and broader diagnostic-method patents than the EPO, or vice versa, simply based on the comparison of U.S. patents involved in three cases and their European counterparts. Nonetheless, the EPO did grant diagnostic-method patents even if the EPC explicitly prohibited doing so. Obviously, there is a missing link between the statutory provisions and EPO’s practice. For instance, diagnostic method under the European patent system may have been defined differently.

IV. DEFINING DIAGNOSTIC METHOD IN EUROPE

The definition of diagnostic methods under the European patent system has been evolving since the EPC entered into effect. Though the EPC has literally prohibited patenting medical methods, the trend of expanding the patent eligibility for medical methods, including diagnostic methods, has continued in Europe.

The policy and consideration behind the trend are best illustrated by the EPO Legal Board of Appeal’s opinion in T1020/03. The Board believed that “[p]hysicians in ordinary practice are not likely to be put off from using new methods of therapy by fear of patent infringement, but rather by fear of being sued for medical malpractice by their patients if something should go wrong.” However, “the knowledge as to the best treatments has to be gained somehow, from in vitro tests, in vivo tests on cells and animals, and clinical trials under specially supervised conditions. This needs to be financed.”

The policy was built upon the assumption or fact that the issuance of patent exclusivity would convince investors to inject more money into the
costly tests and clinical trials and thereby improve the quality of medicine. One way to fulfill the policy without ostensibly contradicting the provisions under the EPC is by interpreting the proscription as a narrow exception to patent eligibility, as the Enlarged Board of Appeal opined in *G0001/04 Diagnostic Methods*.

In making this decision, the Enlarged Board stated that a narrow interpretation of the scope of the exclusion from patent eligibility is equitable because, for reasons of legal certainty, “a comprehensive protection of medical and veterinary practitioners may be achieved by other means if deemed necessary, in particular by enacting legal provisions on the national level of the Contracting States of the EPC,” such as “introducing a right to use the methods in question.” Essentially, the Board in 2005 shared the same view as U.S. Congress in 1996 when enacting 35 U.S.C. 287(c).

The reason why the Enlarged Board was invited to interpret “diagnostic methods” under the EPC was because two lines of decisions rendered by the lower Board had apparently adopted divergent interpretations of diagnostic methods. One line had interpreted narrowly, as represented by *T0385/86 Bruker/Non-invasive Measurement*, while the other had interpreted broadly, as represented by *T0964/99 Gygnus/Diagnostic Method*.

The claimed invention in *T0385/86* was a method for the non-invasive determination of temperature and pH value, inside a whole, intact, living animal or human body. The Technical Board found that the claimed method in *T0385/86* was not a diagnostic method. In the Board’s view, it was a patentable method of measurement, because the measurements of temperature and pH value, by itself, did not directly indicate the diagnosis. The Board reasoned that “methods providing only interim results were not diagnostic methods,” “even if they could be utilized in making a diagnosis.”

On the other hand, *T0964/99* was focused on the presence of a “specific step of diagnostic character,” regardless of whether the step is

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70 See EPO, Case No. G0001/04, at 20-21, 30 (Dec. 16, 2005).
71 Id. at 21.
72 Id.
73 *Emtel Inc.*, 583 U.S. Supp. 2d at 822.
74 EPO, supra note 70, at 15-16.
75 EPO, Case No. T0385/86 (Sept. 25, 1987).
76 EPO, Case No. T0964/99 (June 29, 2001).
77 See EPO, supra note 75.
78 See id.
79 See id.
80 See id.
81 See EPO, supra note 76.
performed in the presence of a doctor or done by the patient herself. The Technical Board found that where a sample is taken from a living human or animal body, the “practiced on the body” criterion is satisfied. In T0964/99, the Board found that the crucial step of a diagnostic nature was “the extraction of a body substance for diagnostic purposes.” As a result, the claim was a diagnostic method and not patentable.

Facing the dilemma, the Enlarged Board nonetheless chose to interpret diagnostic method narrowly for reasons of legal certainty, regardless of socio-ethical and public health considerations.

A. The Enlarged Board’s Two-prong Test

The EPO Enlarged Board of Appeal in G0001/04 developed a two-prong test to determine whether a subject matter would fall within the narrow scope of diagnostic methods, thereby un-patentable. However, the Board’s interpretation seemingly has created more ambiguities waiting to be answered as the technology advances.

The test has an emphasis on the medical practitioner’s decision-making process and the interaction with the subject’s body. First, the claim must include 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. Second, the performance of the preceding steps which are of technical nature must imply interaction with the human or animal body.

The process of making a diagnosis as part of the medical treatment of humans or the veterinary treatment of animals can be broken down into four major method steps: (i) the examination phase involving the collection of data; (ii) the comparison of these data with standard values; (iii) the finding of any significant deviation from the standard values during the comparison; and (iv) the attribution of the deviation to a particular

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82 See id.
83 See id.
84 See id.
85 See id.
86 See id.
87 EPO, supra note 70, at 20-21, 30.
88 Id. at 21, 30.
89 Id. at 17.
90 See id. at 33-34.
91 Id. at 33.
92 Id. at 34.
93 Id. at 18.
94 Id.
95 Id.
clinical picture, which is the deductive medical or veterinary decision phase. Though the Enlarged Board placed more emphasis on the deductive medical or veterinary decision phase in reaching its conclusion, its holding did not stop here. The Board stressed that, in order to find an un-patentable diagnostic method, the claim should include the preceding steps as well. As a result, all method steps in an invention need to fall within the four diagnostic steps mentioned above to be considered an un-patentable subject matter under the EPC.

It has been argued that, in the event of a narrow interpretation, the exclusion of a diagnostic method could be circumvented by missing out one of the essential features of the method. In response, the Enlarged Board stated that, in order to be patentable, an independent claim must recite all the essential features which are necessary for clearly and completely defining a particular invention. The Board’s reasoning is somehow similar to the Emtel court in determining whether a method falls within the scope of 35 U.S.C. 287(c) by examining if the non-medical steps in a claim are merely incidental.

Therefore, in order to find that an invention is a diagnostic method, all steps of the method need to be diagnostic. The Enlarged Board did not agree that merely one diagnostic step in a multiple-step method would render the entire method diagnostic, because the nature of diagnostic methods differs from surgical or therapeutic methods. The Board reasoned that, “due to the inherent and inescapable multi-step nature of such a method,” several method steps are required to define a diagnostic method.

Similarly, for reasons of legal certainty, the Enlarged Board concluded that the determination of diagnostic methods should not be dependent on the involvement of practitioners. The Board suggested that a comprehensive protection of medical or veterinary practitioners would be better achieved by enacting legal provisions on the national level, such as introducing a right to use the methods in question, rather than on a European level, because the definition of medical or veterinary practitioners may vary locally.

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96 Id.
97 See id.
98 Id. at 19-20.
99 Id. at 11 & 25.
100 Id. at 25.
101 Emtel Inc., 583 U.S. Supp. 2d, at 826.
102 EPO, supra note 70, at 21.
103 Id. at 23.
104 Id.
105 Id. at 33.
106 Id. at 21.
107 Id.
Also, it can be inferred from the language of EPC that diagnostic methods serving curative purposes are meant to be practiced on the living human or animal body, as those methods of surgery or therapy. Nevertheless, the EPC did not require a specific type and intensity of interaction with the human or animal body. The Enlarged Board concluded that each and every one of the method steps would satisfy the criterion “practiced on the human or animal body” if its performance “implies” (emphasis added) any interaction with the human or animal body. To prevent overreaching of this requirement, the Enlarged Board set a limitation that the requirement only applies to the method steps of “technical nature” (emphasis added), but not the steps of non-technical nature.

The task for determining whether the performance of a step implies any interaction with the subject’s body and whether a step is of technical nature can be amorphous. The only guidance the Enlarged Board rendered is that the deductive medical or veterinary decision phase and comparing data with standard values do not possess technical nature.

It remains a mystery how an interaction can be implied even if the technical nature of a step can be decided or, whether a deductive medical or veterinary decision phase possesses technical nature if the step is done by a computer. The two-prong test set forth by the Enlarged Board seemingly settled the inconsistency between two lines of cases. However, the Board’s interpretation created more ambiguities waiting to be clarified.

B. Application of the Two-prong Test in Later Cases

After the Enlarged Board’s affirmation of the two-prong test as the new rule, the lower Board rendered two decisions: T0009/04 and T1873/06. The claimed methods in both cases were found not diagnostic methods, though there are other considerations involved in the Technical Board’s reasoning.

The claimed method in T0009/04 Koninklijke Philips Electronics NV/Medical Diagnostic Imaging was directed to a “method of diagnostic imaging.” The Technical Board found that the invention was not a diagnostic method because the claim did not include the feature

\[\text{Id. at } 34.\]
\[\text{Id.}\]
\[\text{Id.}\]
\[\text{Id.}\]
\[\text{Id. at } 28.\]
\[\text{Id.}\]
\[\text{EPO, Case No. T0009/04 – 3.2.02, at 5 (Sept. 8, 2006).}\]
\[\text{EPO, Case No. T1873/06 – 3.5.01, at 3-4 (Sept. 13, 2007).}\]
\[\text{EPO, supra note 113, at 1.}\]
pertaining to the diagnosis for curative purposes as a purely intellectual exercise representing the deductive medical or veterinary decision phase.\textsuperscript{117} The method in this case was referring to a patient handling system moveable between different diagnostic imaging equipments.\textsuperscript{118} The system has data storage means for storing object identification data and imaging data from the different equipments such that two types of data are available to both equipments for subsequent correlation of the object with the diagnostic images.\textsuperscript{119}

In applying the two-prong test,\textsuperscript{120} though the claimed method in T0009/04 implies interaction with the human or animal body by employing angiography and nuclear medicines that involve positioning a catheter in a patient, and then introducing a pharmaceutical into the patient via the catheter, and the injection of a contrast medium,\textsuperscript{121} the Board concluded that the method did not include a deductive medical or veterinary decision phase.

By contrast, the claimed method in T1873/06 appears to include a deductive medical or veterinary decision phase, which can be done by a computer system. The question presented in T1873/06 Optimata/Optimized Drug Delivery was whether a claim directed to “a computer system for recommending an optimal treatment protocol for treating cancer”\textsuperscript{122} was a diagnostic method.\textsuperscript{123} The Technical Board found that it was not, because the claim was directed to a “technical system,” which is not a “method.”\textsuperscript{124}

However, the Technical Board did not answer whether the claim before amended fell within the scope of diagnostic methods as the Examining Division had found it.\textsuperscript{125} The examiner found that the subject matter in the un-amended claim was both mathematical and diagnostic method therefore not patentable under Art. 52 (2) and (4) EPC 1973.\textsuperscript{126} In addition to the finding that the claim was directed to a diagnostic method, the Examining Division objected to the expressions in the claim such as “system for recommending an optimal treatment protocol,” “cancer system model,” “system model modifier,” and “selector” as unclear.\textsuperscript{127}

On appeal, the Technical Board did not agree with the examiner’s

\textsuperscript{117} Id. at 5.
\textsuperscript{118} Id. at 2.
\textsuperscript{119} Id.
\textsuperscript{120} See EPO, supra note 70, at 33-34.
\textsuperscript{121} EPO, supra note 113, at 2-3.
\textsuperscript{122} EPO, supra note 114, at 1.
\textsuperscript{123} Id. at 3-4.
\textsuperscript{124} Id.
\textsuperscript{125} Id. at 3.
\textsuperscript{126} Id. Article 52(2) of EPC 2000 provides that, inter alia, discoveries, scientific theories and mathematical methods should not be regarded as inventions, see European Patent Convention, supra note 53, art. 52(2).
\textsuperscript{127} EPO, supra note 114, at 4.
finding that the claim was unclear, even in its un-amended form.\textsuperscript{128} Instead, the Technical Board found that the claim was “well understandable.”\textsuperscript{129} Hence, the clarity of the claim, whether before or after the amendment, would not affect the analysis of whether the subject matter falls within the scope of diagnostic methods, either for the Technical Board’s decision or for the purpose of discussion in this paper.

However, the Technical Board reasoned that it does not need to determine whether the claimed subject matter is a diagnostic method, because the claim is directed to a technical system and not a method.\textsuperscript{130} If the Technical Board was not seeking to avoid answering the difficult question by stretching the facts that a technical system is not a method, then “technical system” must have been defined differently in Europe compared with its U.S. counterpart, just like the interpretation of diagnostic methods.

In addition to \textit{T0009/04} and \textit{T1873/06}, a few other decisions further interpreted, or complicated, the rule set by the Enlarged Board. For instance, in \textit{T1197/02}, the lower Board held that, additional, intermediate, or preparatory steps may be introduced into a claimed method and it is not necessary for these additional steps which are of a technical nature or are using technical means to fulfill the criterion of practice on the human or animal body.\textsuperscript{131} Thus, patent practitioners and examiners were charged with a new task identifying whether a step is additional, intermediate, or preparatory.

In \textit{T1255/06}, the lower Board found that, “although the acquisition of the temperature data leads to the detection of a deviation from the normal values, it does not allow \textit{per se} attribution of the detected deviation to a particular clinical picture.”\textsuperscript{132} According to the finding, it could be inferred that, symptoms detected by a method do not constitute the diagnosis for curative purposes unless the symptom is unique for a particular illness.

In \textit{T0125/02}, the Technical Board held that an analysis performed on sample of exhaled air removed from the body is a method practiced on the human or animal body.\textsuperscript{133} In essence, the decision brought the requirement “implying an interaction with the human or animal body” to a new level.

However, in \textit{T0080/05 Method of Diagnosis/ University of Utah}, which involved the corresponding method claims in \textit{Myriad}, the Technical Board found the claims not diagnostic methods because “all method steps of

\textsuperscript{128} \textit{Id}. at 5.

\textsuperscript{129} \textit{Id}. In the Technical Board’s view, the generality of the expressions is not a matter of clarity. Thus, the Technical Board found that the Examining Division’s objection under art. 84 EPC was not justified.

\textsuperscript{130} \textit{Id}. at 4.

\textsuperscript{131} \textit{EPO}, Case No. T1197/02 – 3.2.02, at 7 (July 12, 2006).

\textsuperscript{132} \textit{EPO}, Case No. T1255/06 – 3.2.02, at 8-9 (Sept. 23, 2008).

\textsuperscript{133} \textit{EPO}, Case No. T0125/02 – 3.2.02, at 6 (May 23, 2006).
technical nature are performing on a tissue sample of a human subject rather than on the human or animal body.

Hence, it is not surprising that inventions seemingly directed to diagnostic methods were found not diagnostic method in Europe by skipping one or more steps, in particular the initial data-collecting step and the interaction with the human or animal body, resulting in the so-called medical correlation involving only comparing and analyzing steps. As a consequence, an irony was created that broad method claims involving only comparing and analyzing steps are patent eligible in Europe, while narrow claims involving all four steps are diagnostic methods and thereby not patentable. On the contrary, in the U.S., a broad claim reciting only comparing and analyzing would bear a high risk of being found claiming the law of nature, as seen in Prometheus.

It is an irony that an analysis performed on sample of exhaled air removed from the body is a method practiced on the human or animal body, while steps performed on a tissue sample taken from a human subject is not a method practiced on the human or animal body. It is also intriguing that a technical system is not a method in the Technical Board’s opinion.

Eventually, another case relating to the interpretation of diagnostic methods was again referred to the EPO Enlarged Board of Appeal. G0001/07 Treatment by Surgery/Medi-Physics was handed down in February 2010. The main issue can be summarized as whether a physical intervention on the body for data collection, such as an injection of a contrast agent into the heart, is patent ineligible under the EPC. Regardless of the Enlarged Board’s interpretation, the case is expected not the last time the Board interpreting diagnostic methods.

V. CONCLUSION

Defining medical activities is easier than the task defining diagnostic

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134 EPO, supra note 59, at 38.
135 The corresponding European patent of the U.S. patents involved in Prometheus avoided being considered a diagnostic method by claiming an “in vitro method.” ’403 Patent, claim 1. Similarly, the European Myriad patent included a sample from the lesion but did not claim any step interacting with the human body and therefore was not a diagnostic method. ’754 B2 Patent, claim 2.
136 Including more steps in a method claim essentially adds more limitations to the claim and make the claim narrow.
138 EPO, supra note 133, at 6.
139 EPO, supra note 59, at 38.
140 EPO, supra note 114, at 4.
141 EPO, Case No. G0001/07 (Feb. 15, 2010).
142 See id. at 1.
methods. For the former, the definition needs only to identify the goal or purpose where the activities are purported to. For the latter, defining diagnostic methods inevitably has to be able to foresee future technologies, which is a task impossible, and the definition is almost always lagging of time.

The presumption that Europe prohibits patenting diagnostic methods altogether is utterly wrong. The debate over the patent eligibility of diagnostic processes should be based on elaborate information. Even if the Prometheus Court declined to assess the benefit of providing patent protection for diagnostic methods from a policy perspective,\textsuperscript{143} either the U.S. Supreme Court in later cases, the Federal Circuit, or Congress would eventually be asked to strike a balance among legal certainty, physician’s right to practice, public health, and incentive to improve diagnostic technologies, as evidenced by the EPO Enlarged Board of Appeal’s narrow reading of diagnostic methods. However, the difficult question the Prometheus Court refused to answer can be easily avoided by providing a broad medical immunity and at the same time allow diagnostic method patents continue to serve the biopharmaceutical industry.

\textsuperscript{143} \textit{Mayo Collaborative Serv.}, 132 S. Ct. at 1304 (2012).
REFERENCES

Articles
Anderson, Gerard F. & Bianca K. Frogner (2008), Health Care Spending in OECD Countries: Obtaining Value per Dollar, 27(6) HEALTH AFFAIRS 1718.
Gallahan, Daniel (2008), Health Care Costs and Medical Technology, in FROM BIRTH TO DEATH AND BENCH TO CLINIC: THE HASTINGS CENTER BIOETHICS BRIEFING BOOK FOR JOURNALISTS, POLICYMAKERS, AND CAMPAIGNS 79 (Mary Crowley ed.).

Cases
EPO, Case No. G0001/04 (December 16, 2005).
EPO, Case No. G0001/07 (February 15, 2010).
EPO, Case No. T0009/04 – 3.2.02 (September 8, 2006).
EPO, Case No. T0080/05 – 3.3.04 (November 19, 2008).
EPO, Case No. T0125/02 – 3.2.02 (May 23, 2006).
EPO, Case No. T0385/86 (September 25, 1987).
EPO, Case No. T0964/99 (June 29, 2001).
EPO, Case No. T1020/03 – 3.3.04 (October 29, 2004).
EPO, Case No. T1197/02 – 3.2.02 (July 12, 2006).
EPO, Case No. T1255/06 – 3.2.02 (September 23, 2008).
EPO, Case No. T1873/06 – 3.5.01 (September 13, 2007).

Treaties

Statutes

Internet Sources

Others
European Patent No. 0,269,352 (issued March 17, 1993).