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MEDICAL METHOD PATENTS: TREATING “THE PHYSICIANS’ IMMUNITY STATUTE”*

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I. BACKGROUND

Although there is no exclusion of medical methods in U.S. Patent Law with regards to their ability to be patented,³ both the medical profession and the courts have long held that therapeutic and surgical procedures are not patentable processes.⁴ This trend was reversed by the Patent Office Board of Appeals in its decision in *Becton-Dickinson & Co. v. Robert P. Scherer Corp.*⁵ In *Becton*, the court held that not only are the improvements for the medical device, hypodermic injector, patentable, but the method of hypodermic injection was also patentable even when the method consisted of medical or surgical methods involving treatment of the human body.⁶ After this case, the United States Patent and Trademark Office (USPTO) started granting medical method patents even for pure medical procedures.⁷ In 1980, the United States

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³ 35 U.S.C. § 101 (2009).

⁴ *Morton v. New York Eye Infirmary*, 17 F. Cas. 879, 884 (S.D.N.Y. 1862) (No. 9,865) (“Neither the natural functions of an animal upon which or through which [a new force or principle] may be designed to operate, nor any of the useful purposes to which it may be applied, can form any essential part[s] of [a patentable] combination”). The Court held the use of sulfuric ether during surgical operations is not patentable; *see also* Wendy W. Yang, *Patent Policy and Medical Patents: Case for Statutory Exclusion from Patentability*, 1 B.U.J. SCI. & TECH. L. 5 (1995).

⁵ *Becton-Dickinson & Co. v. Robert P. Scherer Corp.*, 106 F. Supp. 665, 676 (E.D. Mich. 1952).

⁶ *Id.*; *see also*, U.S. Patent No. 2,322,245 (filed Jun. 22, 1943).

⁷ U.S. Patent No. 5,410,769 (filed May 2, 1995) (Method for immobilizing a patient’s arms overhead in a prone position during a medical procedure); *see also*, U.S. Patent No. 5,383,886 (filed Jan. 24, 1995) (Method for performing a percutaneous medical procedure without a trocar).

Supreme Court, in deciding *Diamond v. Chakrabarty*⁸, expanded patentable subject matter to include “anything under the sun that is made by man”⁹ with limited exceptions for laws of nature, natural phenomena, and abstract ideas.¹⁰ It immediately followed that an “isolated and purified gene”¹¹, DNA sequences¹² and Expressed Sequence Tags (ESTs)¹³ became patentable subject matter. As a consequence, genetic diagnosis and therapeutic methods also became patentable. In keeping with the spirit of the Hippocratic Oath, researchers and physicians obtained medical method patents mainly to claim credit for their inventions without the expectation of any financial reward.¹⁴ The result of this tradition was that patents on medical methods were rarely enforced until 1994.¹⁵ In *Pallin v. Singer*¹⁶, for the first time a physician, Samuel Pallin, sued another physician, Jack Singer, alleging infringement of his medical procedure patent for a single stitch cataract surgery technique.¹⁷ As a result of Pallin’s litigation, the medical community became concerned about the negative consequences of similar litigation involving medical procedure patents and sought to limit the patent owner’s ability to enforce his patent rights against a practicing physician.¹⁸ Eventually, in 1996, with certain exceptions, the

⁸ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

⁹ *Id.* at 309.

¹⁰ 35 U.S.C. § 101 (2009).

¹¹ Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) (“The body does not contain the patented, isolated and purified gene”).

¹² *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995) (DNA sequences could be patented even if the methods the scientist used to obtain these sequences were routine and obvious).

¹³ CATHERINE M. POLIZZI & DEBRA A. SHETKA, PATENT ISSUES OF GENOMICS RESEARCH (DRUG DEVELOPMENT RESEARCH) 41, 205-217 (1997)) (“At the narrowest, the EST claims will be limited only to the sequence of the EST claim itself. At the broadest, EST claims would also encompass the full-length gene, as well as the protein encoded by the gene.”).

¹⁴ Linda Rabin Judge, *Issues Surrounding The Patenting Of Medical Procedures*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 181, 202 (1997). [hereinafter Judge]

¹⁵ *Id.* at 188.

¹⁶ 36 U.S.P.Q. 2d 1050 (D. Vt. 1995) (The court partially invalidated Pallin’s Patent, and Pallin agreed not to enforce the remaining valid claims against Singer).

¹⁷ *Id.*

¹⁸ Representative Greg Ganske and other physicians in Congress introduced H.R. 1127, attempting to exclude a technique, method, or process for performing a surgical or medical procedure or making medical diagnosis from

“physicians’ immunity statute” was enacted into U.S. Patent Law to protect physicians and health care facilities from patent infringement suits when they performed medical procedures on the human body.¹⁹ Arguments to amend the “physicians’ immunity statute” continue today.²⁰ Some scholars recommend replacing this statute with alternatives such as licensing or monetary incentives,²¹ while others suggest expanding the scope of this immunity to include disease diagnosis methods.²²

This paper will discuss the patentability of medical methods and will endeavor to address the potential defects of the “physicians’ immunity statute.” In order to preserve the merits and limit the drawbacks of the statute, it proposes replacing the statute by establishing a new “Medical Method Patents” regime. In such a new patent regime, the rights of patentees, freedom of the physicians, benefits to the general public, and efficiency of government agencies are better balanced and more easily enforced.

Part II will briefly discuss the patentability of medical methods and the feasibility and necessity of granting such patents in the United States today. Part III will discuss the problems solved by the “physicians’ immunity statute,” the substantive, hidden and unsolved problems in the statute and possible new problems created by the statute. Part IV will propose replacing the

patentability. Senator William H. Frist introduced bill 1334, attempting to exclude medical practitioners’ medical performance from infringing patent. Neither bill passed in Congress. See, Yong-Kang Yang, *The Comparison Among the Patent Laws of China, the United States, and the European Patent Convention Regarding Methods for the Diagnosis of Diseases*, 89 J. PAT. & TRADEMARK OFF. SOC’Y 887, 891 (2007).

¹⁹ 35 U.S.C. § 287(c) (2009).

²⁰ See, Jeff S. Rundle, *The Physician’s Immunity Statute: A Botched Operation or a Model Procedure*, 34 IOWA J. CORP. L. 943 (2009).

²¹ Steve Dirksen, *Patents & Technology: A Reconsideration of the Physicians’ Immunity Statute*, 2001 DUKE L. & TECH. REV. 27 (2001) (Congress has the power to provide a limited remedy to a medical procedure patentee by allowing her licensing the technology or create a nominal damages provision allowing other physicians to use the procedure by paying small, nominal damages). [hereinafter Dirksen]

²² Gregory P. Lekovic, *Genetic Diagnosis and Intellectual Property Rights: A proposal To Amend “The Physician Immunity Statute”*, 4 YALE J. HEALTH POL’Y L. & ETHICS 275 (2004) [hereinafter Lekovic] ([T]he provisions of the Physician Immunity Statute that prevent enforcement of patent infringement actions against physicians performing patented procedures or methods of diagnosis can be applied to genetic diagnoses as well).

statute by creating a new “Medical Method Patent” regime, list possible new terms for this patent and discuss how the new patent regime inherits the merits and solves the problems of the current “physicians’ immunity statute”. Part V will briefly introduce patent examination procedures for “Medical Method Patents” and indicate the changes compared to ordinary examination procedures.

II. THE PATENTABILITY OF MEDICAL METHODS AND THE NEED TO HAVE MEDICAL METHODS PATENTS

According to current U.S. Patent Law, for an invention to be patentable, it must be within the category of patentable subject matter,²³ it must have “utility”,²⁴ it should be new or “novel”,²⁵ it must be “non-obvious”,²⁶ and it must be adequately disclosed so as to enable a person of ordinary skill in the art to make and use the invention without “undue experimentation”.²⁷ In exchange for the patent disclosure, the patent owner obtains market exclusivity for a limited period of time, during which others are excluded from making, selling, offering for sale, using, or importing the patented subjected matter.²⁸ Anyone who violates these exclusion rights infringes the patent rights. For the infringement of a patent, the patent owner can seek both monetary damages and injunctive relief.²⁹

The Patent Act allows an inventor to patent “any new and useful process, machine, manufacture, or composition of the matter, or any new and useful improvement thereof”.³⁰

While naturally occurring phenomenon is not per se patentable, any such material, which has

²³ 35 U.S.C. § 101 (2009).

²⁴ *Id.*

²⁵ 35 U.S.C. § 102 (2009).

²⁶ 35 U.S.C. § 103 (2009).

²⁷ 35 U.S.C. § 112 (2009).

²⁸ 35 U.S.C. § 163 (2009).

²⁹ 35 U.S.C. § 271 (2009).

³⁰ 35 U.S.C. § 101 (2009).

been manipulated by an inventor, can be considered new and non-obvious and is therefore patentable.³¹ Therefore, a broad class of technological inventions and methods of using them are also potentially within patent protection. A medical method for the diagnosis or treatment of disease is generally patentable subject matter regardless of whether it is used in biotechnology, pharmaceuticals, medical devices, computers or genomics.³² If a patent application satisfies all of the other statutory requirements, a patent will be granted.³³ This is precisely the approach followed by the USPTO.³⁴

Domestically, the patent system of the United States plays a very important part in encouraging, fostering and promoting the development and progress of science and technology, including medical methods.³⁵ The commercial marketplace, safeguarded by patent rights, encourages investment in the high cost and high risk area of medical research³⁶ and induces inventors to develop commercial inventions.³⁷ The enhanced reputation created by patent ownership and the ability to commercially market the invention are incentives to the inventors' efforts to further develop commercially viable devices.³⁸ Patent law also induces patent owners

³¹ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

³² Greg Borzo, *Method Patent Fails; Court: Surgeon Doesn't Have to Pay Royalties*, AM. MED. NEWS, Apr. 15, 1996, at 1. (The subject matter of medical and surgical procedure patents includes, but not limited to, using ultrasound to determine the sex of a fetus, treating impotence, combining drugs and vitamins to treat cancer, treating pain, suturing internal organs, grafting skin, and diagnosing and treating heart problems).

³³ A new technique with little or no investment is patentable if it satisfies the statutory requirements, while a complex new technique may be not patentable if it is not novel or obvious. *See*, Judge, *supra* note 14, at 189.

³⁴ *Id.*

³⁵ Yong-Kang Yang, *The Comparison Among the Patent Laws of China, the United States, and the European Patent Convention Regarding Methods for the Diagnosis of Diseases*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 887, 888 (2007). [hereinafter Yang]

³⁶ The average cost of researching and developing a new medicine is around \$ 800 million, but it is very easy to imitate; for other medical treatment it may cost more. *See* J.A. DiMasi, R.W. Hansen, and H.G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Cost*, J. HEALTH ECON. 22, 151-85 (2003).

³⁷ Steven Cherensky, *A Penny for Their Thoughts: Employee Inventors, Pre-invention Assignment Agreements, Property, and Personhood*, 81 CAL. L. REV., 636 (1993).

³⁸ *Id.* at 636-37.

to disclose their inventions to the public rather than relying on trade secret protection law.³⁹

While the United States may have the most advanced science and technology in the fields of medical diagnosis and treatment methods, undoubtedly, the patent protection given to these medical methods plays an important role in keeping the United States a world leader in the field.⁴⁰ With the development of biotechnology, many countries have begun to realize the social and economic importance of genetics and have started to offer patent protection for isolated, modified and purified genes, DNA sequences and even ESTs, if the ESTs have independent utility.⁴¹ Granting patents to medical methods, especially in regard to gene diagnosis or gene treatment will also greatly benefit the U.S. in the face of global competition.

Medical method patents also raise ethical concerns. The American Medical Association (AMA) argues that the United States' patent policy poses a dilemma for physicians since it is their ethical duty to freely exchange medical knowledge and skills without the expectation of financial reward for advancing medical science.⁴² Some argue that since patent rights by definition are exclusive, there is no positive burden on the patentee to use the invention; a patent simply provides the patentee with the right to exclude others from making, using, offering to sell or importing any patented invention and restricts the licensing of the invention.⁴³ However, applied to medical methods, this reasoning would result in the patent owner having the right to exclude patients from access to their methods for diagnosis or treatment which compromises

³⁹ Steven Cherenksy, *A Penny for Their Thoughts: Employee Inventors, Pre-invention Assignment Agreements, Property, and Personhood*, 81 CAL. L. REV., 636, 636-637 (1993).

⁴⁰ Yang, *supra* note 35, at 888.

⁴¹ The European Patent Convention (EPC) and Patent Law of China (PLC) offer patent protection for isolated, modified and purified gene, DNA sequence whose function can be described; Australia, Japan and the United States also grant patents for gene technology usage for diagnosis and treatment. See Lu Qi, *You guan ren ti ji yin zhuan li de xiang guan fa lv wen ti* [Legal Issues Concerning Human Gene Patents], <http://vip.chinalawinfo.com/newlaw2002/SLC/SLC.asp?Db=art&Gid=335545772> (last visited Mar. 19, 2010).

⁴² *AMA Criticizes Patenting of Medical Procedures*, BNA HEALTH CARE DAILY (Jun. 21, 1995).

⁴³ 35 U.S.C. § 271 (a)(2009).

patients' medical care.⁴⁴ In addition to these concerns, many physicians fear that the investigation of patent infringement allegations may interfere with the patient-physician relationship and may result in violations of patients' privacy rights.⁴⁵ While these problems are not exclusive to medical method patents, what is unique to the medical arena is the element of medical ethics, which requires that improvement in health care be freely shared between medical practitioners which runs counter to the patent holders' privilege to exclude.⁴⁶ The enactment of the "physicians' immunity statute" solved some of the problems by exempting physicians and health care facilities from liability for patent infringement when they perform a medical procedure on the human body.⁴⁷

III. THE "PHYSICIANS' IMMUNITY STATUTE" IS NOT THE BEST SOLUTION

35 U.S.C. § 287(c) was a timely legislation, written just 16 months after the *Pallin*⁴⁸ case, and responded to the ethical concerns highlighted by health care professionals. Section 287(c) provides:

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. ...the term "medical activity" means the performance of a medical or surgical procedure on body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of biotechnology patent.⁴⁹

⁴⁴ Lekovic, *supra* note 22, at 281.

⁴⁵ Gregory F. Burch, *Ethical Considerations in the Patenting of Medical Processes*, 65 TEX. L. REV. 1139 (1987). [hereinafter Burch]

⁴⁶ *AMA Criticizes Patenting of Medical Procedures*, BNA HEALTH CARE DAILY (Jun. 21, 1995).

⁴⁷ 35 U.S.C. § 287(c) (1)(2009).

⁴⁸ *Pallin v. Singer*, 36 U.S.P.Q. 2d 1050 (D. Vt. 1995).

⁴⁹ 35 U.S.C. § 287(c)(1) and (2)(A)(2009).

The “physicians’ immunity statute” responded to the public’s concern over medical methods patents but may have been a hasty reaction to the problems.

A. THE “PHYSICIANS’ IMMUNITY STATUTE” HELPED TO SOLVE SOME PROBLEMS

From the statutory language,⁵⁰ “medical practitioners” are exempted from liability for patent infringement for performing a qualified “medical activity.”⁵¹ The problem of possible restriction of patients’ access to medical care may have been solved.⁵² Without fear of the threat of liability every time physicians seek to modify or use patented medical procedures, physicians may now focus on the best interest of the patient.⁵³ From a practical standpoint, the “physicians’ immunity statute” restricts the lifesaving medical treatment procedure patent owners’ rights by frustrating the effects through such unreasonable limits as the number of licensees allowed to access the procedure or the charging of unreasonable amounts of royalties.⁵⁴

Not only does the “physicians’ immunity statute” provide physicians and patients the right to access patented medical methods, but it can also be used as a tool to help analyze the economic efficiencies of the United States’ medical methods patent protection.⁵⁵ According to the Coase theorem, when trade in an externality is possible and there are no transaction costs, bargaining will lead to an efficient outcome regardless of the initial allocation of property

⁵⁰ 35 U.S.C. § 287(c)(1) and (2)(A)(2009).

⁵¹ *Id.*

⁵² Lekovic, *supra* note 22, at 281.

⁵³ AMA Council on Judicial and Ethical Affairs, *Ethical Issues in the Patenting of Medical Procedures*, 53 FOOD & DRUG L.J. 341, 345 (1998).

⁵⁴ Beata Gocyk-Farber, Note, *Patenting Medical Procedures: A Search for a Compromise Between Ethics and Economics*, 18 CARDOZO L. REV. 1527, 1545 (1997). [hereinafter Farber]

⁵⁵ Wei Yanliang, *Yi liao fang fa de zhuan li bao hu yan jiu* [Patent protection of medical methods both inland and abroad], <http://vip.chinalawinfo.com/newlaw2002/slc/slc.asp?db=art&gid=335577581> (last visited Mar. 20, 2010). [hereinafter Wei]

rights.⁵⁶ Other than completely taking away patent rights for medical procedures to respond to the public opinion, the “physicians’ immunity statute” provides a practical and suitable solution when considering the private patent rights and social costs of medical method patent infringement litigation.⁵⁷ Unlike enforcing utility, design or plant patents whose infringement can be shown by simply purchasing the claimed products, the cost of litigating a medical treatment procedure patent infringement is too high.⁵⁸ In addition, an investigation by presenting the facts surrounding a surgery or interviewing patients about their procedures will undoubtedly invade the patients’ right of privacy.⁵⁹ Researching medical records obtained from insurance companies, clinics or elsewhere generally requires a subpoena, adding to the cost and complexity of the process.⁶⁰ The “physicians’ immunity statute” eliminates the above costs while preserving other patent rights for patentees.

B. THE “PHYSICIANS’ IMMUNITY STATUTE” LEFT SOME PROBLEMS UNSOLVED

While the “physicians’ immunity statute” gives immunity to “medical practitioners” from patent infringement liability when they are performing a qualified “medical activity,” it does not include medical procedures for diagnostic purposes.⁶¹ According to the principles of autonomy and medical ethics, patients have the right to be free of interference in making medical decisions

⁵⁶ The Coase theorem, attributed to Ronald Coase, is an important basis for most modern economic analyses of government regulation. “Government should create institutions which minimize transaction costs, so as to allow misallocations of resources to be corrected as cheaply as possible.” See, Coase theorem, http://en.wikipedia.org/wiki/Coase_theorem (last visited Mar. 20, 2010).

⁵⁷ Wei, *supra* note 55.

⁵⁸ *Pallin v. Singer*, 36 U.S.P.Q. 2d 1050 (D. Vt. 1995) (the action by Plaintiff (Dr. Pallin) was dismissed and each side should bear its own fees and costs. The total litigation costs for Defendant alone were nearly \$500,000.); see also, Nancey McCann & Shelly Hedrick, *Pallin Patent Claims Invalidated: Physicians Free to Perform Sutureless Cataract Surgery without Threat of Infringement Litigation*, PR NEWSWIRE (1996), <http://www.cptech.org/ip/pallin.txt> (last visited May 22, 2010).

⁵⁹ Burch, *supra* note 45, at 1139.

⁶⁰ Wei, *supra* note 55.

⁶¹ 35 U.S.C. § 287(c)(2)(A) (2009). This provision is limited by later § 287(c)(2)(E) to situations where the performance of a medical or surgical procedure directly relating to the treatment of humans.

regarding their own bodies.⁶² Physicians should respect patients' decisions, have a duty to avoid causing harm and bear responsibility when they fail to prevent harm.⁶³ Healthcare decisions not only include means of treatment but also means of diagnosis.⁶⁴ Denying a patient's right to be diagnosed using a patented technology is no different than denying a patient's right of treatment.⁶⁵ It is unreasonable for the "physicians' immunity statute" to only include medical treatment procedures while excluding medical diagnosis procedures.⁶⁶

The "physicians' immunity statute" also excludes immunity for "the practice of a patented use of a composition of matter in violation of such patent" and "the practice of a process in violation of a biotechnology patent".⁶⁷ In other words, "utility patent" rights are still protected.⁶⁸ Accordingly, both "biotechnology processes" defined in 35 U.S.C. § 103(b)⁶⁹ and the process of making or using biological material patents are within the "biotechnology patent" definition, excluding them from the "physicians' immunity statute."⁷⁰ This may lead to restricting a physician's ability to diagnose, research and treat genetically-based diseases.⁷¹ Currently, genetic diagnosis is the only way to identify certain non-curable, genetic-based

⁶² TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 120-21 and 125 (Oxford U. Press 1994) [hereinafter Beauchamp]; *see also*, Thomas R. McCormick, *Principles of Bioethics*, U. of Wash. Sch. Of Med., <http://depts.washington.edu/bioethx/tools/princpl.html> (last visited Mar. 20, 2010). [hereinafter McCormick]

⁶³ Beauchamp, *supra* note 62, at 192.

⁶⁴ 35 U.S.C. § 287(c)(2)(E) (2009).

⁶⁵ Under the principle of beneficence, it is the physicians' duty to prevent harm. *See*, McCormick, *supra* note 60.

⁶⁶ Lekovic, *supra* note 22, at 284.

⁶⁷ 35 U.S.C.S. § 287 (2010).

⁶⁸ MARGARETH BARRET, *INTELLECTUAL PROPERTY* 118 and 145-146 (2nd ed. 2001) (Utility patent is a patent obtained on an invented composition of matter). [hereinafter Barret]

⁶⁹ "Biotechnology process" is defined as either "a process of genetically altering or inducing a single or multi-celled organism"; or the "cell fusion procedures yielding a cell line that expresses a specific protein" and "methods of using a product produced" by above processes. 35 U.S.C. § 103(b) (2009).

⁷⁰ Lekovic, *supra* note 22, at 283.

⁷¹ *Id.* at 283-84.

diseases,⁷² and genetic treatment may be the only effective method of treating certain diseases.⁷³ Leaving biotechnology patents out of the “physicians’ immunity statute” also can lead to the diminished availability of medical diagnosis and treatment for patients.⁷⁴

C. THE “PHYSICIANS’ IMMUNITY STATUTE” CREATED NEW PROBLEMS

While the “physicians’ immunity statute” attempted to mitigate the “negative results” created by the *Pallin* verdict, it has created conflicts with current U.S. patent systems and the U.S.’s obligations as a member of the Paris Convention for the Protection of Industrial Property.⁷⁵

The complete elimination of all remedies for physicians’ medical methods patent infringement has had a substantial, negative impact on the incentives of the inventors.⁷⁶ Most often, a new medical procedure is found by a physician-inventor through routine medical practice.⁷⁷ By investing labor and financial capital, the physician may develop or perfect a new way to eliminate problems or complications in the physician’s medical field. A pure medical treatment procedure patent like this, without an accompanying apparatus patent like machine, manufacture, composition of matter, or biotechnology may earn limited, if any, royalties if routine payments to physicians do not include a concurrent reward for the claimed invention.

⁷² U.S. Patent No. 5,679,635 (filed Oct. 21, 1997). This patent granted exclusive rights to the screening methods to determine if subject is a Canavan carrier or a Canavan patient; *see also*, Lekovic, *supra* note 22, at 278 (“Since there is no treatment for Canavan’s disease, genetic testing of the parents and/ or prenatal screening represent the only options for parents who do not want to have a child with this devastating condition; this technique allows parents either to avoid pregnancy or to terminate affected embryos”).

⁷³ Eight U.S. patents held by Myriad relating to BRCA1 and/or BRCA2 substantially limit the research and testing of genetic treatment to breast cancer. Jordan Paradise, *European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics’ BRCA Patent Controversy*, 59 FOOD & DRUG L.J. 133 (2004).

⁷⁴ Council on Sci. Affairs, *Patenting Genes and Their Mutations* (2000), <http://www.ama-assn.org/ama/no-index/about-ama/13570.shtml> (last visited Mar. 20, 2010).

⁷⁵ Paris Convention for the Protection of Industrial Property, art. 2, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305. [hereinafter Paris]

⁷⁶ Dirksen, *supra* note 21.

⁷⁷ *Id.*

The “physicians’ immunity statute” reduces the financial incentive for research in the above situations. Furthermore, many medical procedures require expensive and extensive clinical research.⁷⁸ This high capital investment must be accompanied by appropriate monetary reimbursement if new or improved medical procedures are to be offered to patients.⁷⁹

Physicians in private practice constitute the majority of practicing physicians in the United States today.⁸⁰ Unlike an academic medical researcher who can obtain funding from a variety of sources⁸¹, private practice physicians must rely on the commercial marketplace to recover their investment in the development of a new medical procedure.⁸² By taking away physicians’ ability to recover financial investments in new medical treatment processes, the “physicians’ immunity statute” may force them to resort to trade secret law for intellectual property protection. In the long run, it will undoubtedly restrict patients’ access to better medical treatments.

Another problem with the “physicians’ immunity statute” is that it limits its application to a qualified “medical practitioner...who is licensed by a State to provide the medical activity”.⁸³ Combining the reading of “State”⁸⁴, a person not licensed by any state or territory of the United States, the District of Columbia, or the commonwealth of Puerto Rico, cannot enjoy the

⁷⁸ Farber, *supra* note 54, at 1551.

⁷⁹ *Id.* at 1554.

⁸⁰ According to The Center for Studying Health System Change (CSHSC), 56% of primary-care physicians owned their practices in 2008. See Ellyn Boukus, Alwyn Cassil, and Ann S. O’Malley, *A Snapshot of U.S. Physicians: Key Findings from the 2008 Health Tracking Study Physician Survey*, (2009), <http://www.hschange.com/CONTENT/1078/#top> (last visited Mar. 21, 2010).

⁸¹ Possible funding sources are: the National Institutes of Health (NIH), private donations, and technology transfers under the Bayh-Dole Act.

⁸² Dirksen, *supra* note 21.

⁸³ 35 U.S.C. § 287(c)(1) and (2)(B) (2009).

⁸⁴ 35 U.S.C. § 287(c)(2)(G).

protection of the statute.⁸⁵ Article 2 of the Paris Convention for the Protection of Industrial Property requires that the enjoyment of the statute should be provided to “all the other countries of the Union”.⁸⁶ Since medical methods are patentable subject matter in the United States and within the scope of industrial property defined by the Paris Convention,⁸⁷ the “medical practitioner” defined by the “physicians’ immunity statute” contravenes the Paris Convention of which the United States is a member.

IV. THE BETTER SOLUTION: REPLACING THE “PHYSICIANS’ IMMUNITY STATUTE” WITH A NEW “MEDICAL METHOD PATENT”

Congress created a separate design patent that protects the visual characteristics embodied in or applied to an article of manufacture⁸⁸ and plant patent protection for invented or discovered plants which are in a cultivated state and asexually reproduced.⁸⁹ Following the legislative history of design and plant patents,⁹⁰ where there is always a two-step patent protection development for special subject matter,⁹¹ Congress should create a new medical methods patent with special terms that has the merits of the “physicians’ immunity statute” but addresses its problems.

First, Congress enacts statutes offering sui generis patent protection, and then the Patent Office and courts interpret the statute to determine whether the claimed invention falls within the

⁸⁵ Yang, *supra* note 35, at 892.

⁸⁶ Paris, *supra* note 75 (“(1) Nations of any countries of the Union shall ... enjoy in all the other countries of the Union the advantages that their respective laws now grant.”).

⁸⁷ Paris, *supra* note 75, art. 1 (The Convention applies to a Union for the protection of industrial property and patents recognized by the laws of the countries of the Union belongs to the objects).

⁸⁸ 35 U.S.C. § 171 (2009).

⁸⁹ 35 U.S.C. § 161 (2009).

⁹⁰ In developing intellectual right protection for designs, Congress enacted design patent law in 1842. The Supreme Court then considered design patents in three decisions. Similarly, the Plant Patent Act of 1930, Plant Variety Protection Act and later Supreme Court decisions help to establish plant patents. *See*, DONALD S. CHISUM, CHISUM ON PATENTS, §§ 23.02, 24.01- 24.04 (Bender 2010).

⁹¹ Anne E. Crocker, *Will Plants Finally Grow Into Full Patent Protection On An International Level? A Look at the History of U.S. and International Patent Law Regarding Patent Protection for Plants and the Likely Changes After the U.S. Supreme Court’s Decision in J.E.M. Ag Supply v. Pioneer Hi-Bred*, 8 DRAKE J. AGRIC. L. 251 (2003).

newly created statutory subject matter.⁹² As described in the Introduction to this paper, medical methods have long enjoyed patent protection through process or apparatus patents although the exact boundaries of eligible patent subject matter is presently uncertain,⁹³ and the Patent Office and courts have found medical methods patentable through interpretations of existing patent law.⁹⁴ In addition, the “physicians’ immunity statute” specifically exempts a qualified “medical practitioner” from infringement of a medical method patent during medical treatment.⁹⁵ This illustrates the uniqueness of medical methods and suggests that a different treatment is required. Altering the “medical method patents” model to provide a separate sui generis patent protection for medical methods is a much needed improvement.

A. DEFINITION OF “MEDICAL METHOD PATENTS”

Section 287(c) defines “medical activity” as “the performance of a medical or surgical procedure on a body” with three limitations.⁹⁶ Unfortunately, this definition is too vague, and a clearer description of the subject matter is needed for the new “medical method patents.” In contrast, the Patent Office of China (CPO) and the European Patent Office (EPO) provide a better definition because both exclude “diagnostic, therapeutic and surgical methods for treatment of humans or animals” from patentability.⁹⁷ A clearer and more precise definition is

⁹² Anne E. Crocker, *Will Plants Finally Grow Into Full Patent Protection On An International Level? A Look at the History of U.S. and International Patent Law Regarding Patent Protection for Plants and the Likely Changes After the U.S. Supreme Court’s Decision in J.E.M. Ag Supply v. Pioneer Hi-Bred*, 8 DRAKE J. AGRIC. L. 251 (2003).

⁹³ In *In re Bilski*, the Supreme Court addressed for a “process” to be patentable, whether the “process” should “be tied to a particular machine or apparatus or transform a particular article into a different state or thing”. See, Kevin E. Noonan, *The Supreme Court, In re Bilski and the Lingering Question of Labcorp v. Metabolite*, June 1, 2009, <http://www.patentdocs.org/2009/06/the-supreme-court-in-re-bilski-and-the-lingering-question-of-labcorp-v-metabolite.html> (last visited Dec. 17, 2010).

⁹⁴ See, *Becton-Dickinson & Co. v. Robert P. Scherer Corp*, 106 F. Supp. 665 (E.D. Mich. 1952).

⁹⁵ 35 U.S.C. § 287(c) (2009).

⁹⁶ 35 U.S.C. § 287(c)(2)(A) (2009).

⁹⁷ The flexibility is offered by Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights. See, e.g., Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, vol. 31, 33 I.L.M. 84 (1994). [hereinafter TRIPS].

needed in U.S. law to identify exclusion. As was explained, new “medical method patents” should include both “medical diagnosis method patents” and “medical treatment method patents.” The proposed definition and exception for the two terms are discussed below. The major parts of the “medical diagnostic method patents” definition and exceptions come from the Patent Law of China (PLC) and the “physicians’ immunity statute” in Title 35 of the United States Code.⁹⁸

1. Definition and exceptions for “medical diagnostic method patents”

Definition:

Inventions belong to medical diagnostic methods and are able to be granted medical method patents when following requirements are satisfied:

- (1) the method is practiced on a living human or animal body; and
- (2) the immediate purpose of the method is to determine if the patient is suffering from a disease or is in good health

An invention should be granted a medical method patent right if the invention, as viewed from the form of its description, is practiced on samples in vitro, but its immediate purpose is to obtain the diagnostic determination of a disease or health for the same subject⁹⁹;

“The practice of a biotechnology process should be granted a medical method patent right if the practice is for no purpose other than to determine the presence or absence of a disease”¹⁰⁰

Exception:

The medical diagnostic method shall not include

- (1) methods of pathological anatomy practiced on a dead human or animal body;
- (2) methods the immediate purpose of which are only to obtain information from the living human or animal body as an intermediate result¹⁰¹ rather than

⁹⁸ 35 U.S.C. § 287(c)(1) (2009).

⁹⁹ *Inventions Belonging to Diagnostic Methods*, GUIDELINES FOR EXAMINATION OF STATE INTELLECTUAL PROPERTY OFFICE OF CHINA, Part II, Chapter I, § 4.3.1.1 (2006). Defining the methods for diagnosis directly practiced on living human or animal bodies avoids susceptibility of industrial application.

¹⁰⁰ Hereby, gene diagnosis or genetic diagnostic testing, separated from other biotechnology patents, belong to the medical method patents. *See*, Lekovic, *supra* note 22, at 296.

to obtain the diagnostic result of the presence or absence of disease, or methods of processing such information;

(3) methods the immediate purpose of which are only to treat or test the body tissues, body fluids or excrements that have been removed from the human or animal body in order to obtain information as an intermediate result rather than to determine the presence or absence of disease, or methods of processing such information¹⁰²;

(4) any use of a patented machine, manufacture, or composition of matter in violation of such patent;

(5) the practice of a patented use of a composition of matter in violation of such patent; and

(6) the practice of a process in violation of a biotechnology patent other than for purpose of diagnosis¹⁰³

as for above items (2) and (3), it should be noted that the information can be regarded as an intermediate result only if the diagnostic determination of the presence or absence of disease, cannot be immediately obtained on the basis of the obtained information per se in accordance with the medical knowledge in the prior art and the disclosure of the patent application.¹⁰⁴

As for above item (5), the “patented use of a composition of matter” does not include a claim for a method of performing a medical or surgical procedure on a body that requires the use of a composition of matter where the use of that composition of matter does not directly contribute to achievement of the objective of the claimed method¹⁰⁵

Although methods for the diagnoses of diseases are directly prohibited from obtaining a patent, the PLC offers a clear definition for a medical diagnostic method which includes diagnostic steps, testing steps and the determination of the presence or absence of disease immediately obtained under certain conditions.¹⁰⁶ Moreover, the revision and adoption of the “physicians’ immunity statute” both exclude utility patents from medical diagnostic method patents and extend the scope of medical diagnosis to cover genetic diagnoses.

¹⁰¹ See, *Inventions Not Belonging to Diagnostic Methods*, GUIDELINES FOR EXAMINATION OF STATE INTELLECTUAL PROPERTY OFFICE OF CHINA, Part II, Chapter I, § 4.3.1.2 (2006) (physique and body parameters, physiological parameters or other parameters, which is more like utility invention).

¹⁰² *Id.*

¹⁰³ 35 U.S.C. § 287(c)(2)(A) (2009).

¹⁰⁴ Barret, *supra* note 68.

¹⁰⁵ 35 U.S.C. § 287(c)(2)(F) (2009).

¹⁰⁶ Yang, *supra* note 35, at 896.

2. *Definition and exceptions for “medical treatment method patents”*

Definition:

Medical treatment methods include both methods of treatment for diseases and methods of surgery

(a) Methods of Treatment for Diseases

Methods of treatment for diseases refer to the processes of intercepting, relieving or eliminating the cause or focus of diseases so that the living human or animal bodies may recover or gain health or relieve pain.

Methods of treatment for diseases include various methods which provide treatment purpose or which provide treatment nature. Prophylactic methods and immunization methods are regarded as methods of treatment for diseases. For a method both possibly serving treatment purpose and possibly serving non-treatment purpose, unless clearly stated that the method serves non-treatment purpose, it shall be deemed as medical treatment method. Although medicines can be used as treatment for diseases, medicines per se should be granted ordinary patent rights.¹⁰⁷ The practice of a treatment process using a biotechnology is also regarded as treatment method.¹⁰⁸

(b) Methods of surgery

Methods of surgery refers to the methods of traumatic or invasive treatment such as incision, resection, stitching, and tattooing practiced on living human or animal bodies with the aid of instruments. Methods of surgery practiced on a dead human or animal body shall be treated as an ordinary utility patent.¹⁰⁹

Exception:

The medical treatment patents shall not include

- (1) methods of making artificial limbs or other or other prostheses, and methods of measurement in making such artificial limbs or prostheses;
- (2) method of stockbreeding by treating animal bodies by a non-surgical means to change their growing trait;
- (3) methods of butchering animals;
- (4) methods of treating dead human or animal bodies, such as methods of anatomy, beautification, antisepsis, or making specimens;
- (5) methods of purely cosmetic nature which are not invasive to the human body or do not produce wounds;

¹⁰⁷ *Methods of Treatment for Diseases*, GUIDELINES FOR EXAMINATION OF STATE INTELLECTUAL PROPERTY OFFICE OF CHINA, Part II, Chapter I, § 4.3.2 (2006). Ten inventions are listed as Methods of Treatment for Diseases in Inventions Belonging to Methods of Treatment for Diseases.

¹⁰⁸ 35 U.S.C. § 287(c)(2)(A) (2009) (This extends medical treatment patent to cover process using biotechnology which is left out from the “physicians’ immunity statute”).

¹⁰⁹ *Methods of Surgery*, GUIDELINES FOR EXAMINATION OF STATE INTELLECTUAL PROPERTY OFFICE OF CHINA, Part II, Chapter I, § 4.3.2.3 (2006) (Restricting the methods only to those directly practiced on living human or animal bodies also avoids susceptibility of industrial application and medical research). [hereinafter *Methods of Surgery*]

- (6) methods for making a human or animal not in a diseased state feel comfortable or pleased, or methods for supplying oxygen, negative oxygen ions or moisture under a special condition such as for diving or for shielding from toxic gas.
- (7) methods of killing bacteria, viruses, lice, or fleas on a human or animal body¹¹⁰

The definition and exceptions for “medical treatment method” are also borrowed from the Chinese Examination Guidelines, with clear language indicating that biotechnology is not excluded from medical treatment.¹¹¹ Machines, manufactures, composition of matter or biotechnology are still treated as apparatus, which receive ordinary patent protection.¹¹² The “medical treatment methods” cover everything in section 287(c).¹¹³ By setting restrictive terms to this method, unsolved problems and newly created problems of the statute can be solved. Free interchanges of medical treatment information among physicians can be promoted through the publication of the patents.¹¹⁴

B. IMPORTANT TERMS OF “MEDICAL METHOD PATENTS” AND POLICY ANALYSIS

In considering the special requirements involved in treating the lives of human beings and animals while balancing medical ethic requirements and economic rights of medical patent rights owners, the authors propose different rules governing “medical method patent” rights as outlined below. The following proposals present important or amended terms which may achieve the above goals more efficiently.

1. *All “medical method patents” should clarify whether they are for medical diagnosis, for medical treatment or for both in the preamble of the first independent claim*

¹¹⁰ *Inventions Not Belonging to Methods of Treatment for Diseases*, GUIDELINES FOR EXAMINATION OF STATE INTELLECTUAL PROPERTY OFFICE OF CHINA, Part II, Chapter I, § 4.3.2.2 (2006). [hereinafter *Inventions*]

¹¹¹ *Methods of Surgery*, *supra* note 109.

¹¹² *Inventions*, *supra* note 110.

¹¹³ 35 U.S.C. § 287(2009).

¹¹⁴ Yang, *supra* note 35, at 915.

This rule is similar to the single claim format requirement for design patents.¹¹⁵ In addition to the brief description of the figures, “medical method patents” require a clear indication of whether the patent is for medical diagnosis, medical treatment, or both in the preamble of the first independent claim. Since both medical method and ordinary utility patents may be granted to an invention if the claimed invention claims both medical diagnosis or treatment use and some other utility,¹¹⁶ this proposal offers patent applicants the opportunity to address precisely which patent rights they desire while reducing the burden on examiners in issuing restriction orders.

2. *All “medical method patents” must be novel¹¹⁷, non-obvious,¹¹⁸ offer sufficient enablement information to practice the invention,¹¹⁹ and applications may also be subject to a restriction requirement when more than one embodiment is disclosed¹²⁰*

All existing statutory requirements must be met for a medical method patent application’s approval. In addition, the claimed medical method must be an eligible “process” for patenting under 35 U.S.C. § 101 and no patent will be granted to an abstract idea. According to the recent Supreme Court decision in *Bilski v. Kappos*¹²¹, the current Federal Circuit’s “machine-or-transformation” test¹²² is not the sole test for the patentability of a “process”.¹²³ The Supreme Court then granted *certiorari*, vacated judgment and remanded to the Federal Circuit for

¹¹⁵ 35 U.S.C. § 171 (2009) (All design patents have the same single formal claim which refers to the drawing: “(The) ornamental design for (the article as specified in the Title of the invention) as shown”).

¹¹⁶ This is same as both design and utility patents may be obtained on an article when it has both utility and ornamental appearance. *See*, MANUAL OF PATENT EXAMINING PROCEDURES § 1502.01 (2006). [hereafter MPEP]

¹¹⁷ 35 U.S.C. § 102 (2009).

¹¹⁸ 35 U.S.C. § 103 (2009).

¹¹⁹ 35 U.S.C. § 112 (2009).

¹²⁰ Similar to restriction requirements for ordinary patent application, restriction may be applied when there are more than one medical diagnosis methods, medical treatment methods or both in one patent application.

¹²¹ *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

¹²² *Id.* at 3226 (The “machine-or-transformation test” in determining a “process” is to transform a particular article into a different state or thing).

¹²³ *Id.*

reconsideration of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*¹²⁴ and *Classen Immunotherapies, Inc. v. Biogen Idec*,¹²⁵ and the Federal Circuit will develop its case law on what tests are to be used to determine patent eligibility for claims related to medical diagnostics.¹²⁶

3. *All applicants treated as a “small entity” will be charged one half of the established fees*

Similar to the reduced fee charged for patent applications by small entities, fees charged under 35 U.S.C. § 41(a), (b) and (d)(1) should be reduced by 50 percent for medical method patent applications.¹²⁷ Petition and processing fees other than revival,¹²⁸ document supply fees,¹²⁹ certificate of correction fees,¹³⁰ request for reexamination fees,¹³¹ and miscellaneous fees and charges,¹³² which do not occur during the patent application process, are not included as reduced fees.¹³³ However, this reduced application fee should extend to any applicant who files a medical method application. The reduced fee should encourage an inventor to apply for and publish medical method patents as well as remove financial burden on the applicant in obtaining a patent. A reduction in the application fee is justified because the medical diagnosis or medical treatment use of medical method patents will be restricted as discussed below.

4. *No maintenance fee is due on “medical method patents”*

¹²⁴ *Bilski v. Kappos*, 130 S. Ct. 3543 (2010).

¹²⁵ *Id.* at 3541.

¹²⁶ See, Kevin Noonan, *Bilski v. Kappos: What Effect on Biotechnology Patents?* (2010), <http://www.patentdocs.org/2010/07/bilski-v-kappos-what-effects-on-biotechnology-patents.html> (last visited Dec. 19, 2010).

¹²⁷ 35 U.S.C. § 41(h)(1) (2009).

¹²⁸ 37 C.F.R. § 1.17 (f)-(k) (2009).

¹²⁹ 37 C.F.R. § 1.19 (2009).

¹³⁰ 37 C.F.R. § 1.20 (a) (2009).

¹³¹ 37 C.F.R. § 1.20 (c) (2009).

¹³² 37 C.F.R. § 1.21 (2009).

¹³³ MPEP, *supra* note 116, at § 509.02.

Following design patent and plant patents, no maintenance fees should be required.¹³⁴ As will be discussed below, a shortened 14-year term should be granted to medical method patents. The use of varying maintenance fees for a patent depending on its term as incentive becomes unreasonable.¹³⁵ Financial burden on the patent owner is somewhat relieved and physicians' medical patents will be the ultimate beneficiaries since they will not have to reimburse the maintenance fee to the patent owner.

5. *“Medical method patents” last 14 years from the date of issue as opposed to the 20 years from the effective filing date for utility patents*

The proficiency of medical diagnosis and treatment of diseases in the United States is ahead of most other countries and is improving at tremendous speed.¹³⁶ In particular, DNA analysis methods widely used today could explore the potential weaknesses of diseased cells and interactions between them.¹³⁷ Many new or alternative methods of treating diseases come out relatively quickly.¹³⁸ A shortened design patent term of 14 years from the issuing date appears to be a better approach than the normal 20-year term. Medical method patents will also enter the public domain earlier with the shortened term, which will benefit the public for the unique diagnostic or treatment methods of certain diseases. The cancellation of maintenance fees also justifies a shortened term for medical method patents.

6. *Restriction agreement for medical diagnosis or medical treatment use of “Medical method patents”*

¹³⁴ 37 C.F.R. §1.362(b) (2009).

¹³⁵ For ordinary utility patents, patent owners have the right to choose suitable terms (either 3.5 years, 7.5 years, or 11.5 years) for their patents by paying or refusing to pay the maintenance fee. *See*, 37 C.F.R. § 1.362 (a) & (d) (2009).

¹³⁶ Yang, *supra* note 35, at 888.

¹³⁷ Gene Trace Systems, Inc., *Development of Rapid DNA Medical Diagnostics*, Status Report 95-05-0006 (2004), <http://statusreports.atp.nist.gov/reports/94-05-0006.htm> (last visited May 26, 2010).

¹³⁸ Harold Schmeck & Maya Pines, ed., *The Future of Genetic Research, Blazing the Genetic Trail* (1991), http://www.accessexcellence.org/RC/AB/IE/Future_Of_Genetic_Research.php (last visited May 26, 2010).

Just as Congress created the “physicians’ immunity statute” offering zero compensation to patent owners for a “medical practitioner’s” medical activity,¹³⁹ Congress must have the power to provide reasonable restriction of the use of medical method patents in medical diagnosis or medical treatment¹⁴⁰ while the patent owners have the right to choose the most suitable agreements themselves.

For general “medical method patents” with options for the patient to select, reasonable license fees offering a modest return on the investment should be granted while sudden huge profits should be prohibited.

The first solution is to provide a suggested charge, which has the following aspects:

(1) Require that all applicants submit information regarding the amount of investment for development of the medical methods, the potential number of patients and possible charges to each patient for reimbursement of the investment at the time of the medical method patent application. If the application is subjected to a restriction requirement, applicants may resubmit the above information for the selected invention. Applicants have the right to expunge this information from the 18-month period publication.

(2) At the time the notice of allowance is sent, the examiner can provide suggested charges to “medical practitioners” for their use of this patent in medical diagnosis or medical treatment.

The charge should be reasonable based on the costs of implementing the patented medical methods plus reasonable nominal profits. The USPTO could include a formula for the profit amount based on the cost of implementing the patented medical methods and the original research investment in their Examination Manual. It can be a suggested charge for each

¹³⁹ 35 U.S.C. § 287(c)(1) (2009).

¹⁴⁰ Dirksen, *supra* note 21.

diagnosis or treatment, or an overall reimbursement in the patent term after which only implementing costs can be charged. The applicant is free to choose from the two suggested charges and reserve the right to petition the reasonableness of the amount.

The second solution is to provide licensing of the invention to the government “at will”.¹⁴¹ This deems the federal government immune from injunction for the medical method patent infringement while requiring it to pay the patent holder “reasonable and entire compensation” for the use thereof.¹⁴²

For a special “medical method patent”, which provides the only unique diagnosis method or treatment for a disease, the same solutions for general “medical method patents” shall be provided to the patent owner while the federal government shall reserve the right to require “compulsory licenses” under limited conditions.¹⁴³ “Compulsory licenses” are licenses for implementing the patented medical diagnosis method or patented medical treatment method which become automatically effective upon receipt of the request of patent owners to implement the patented medical methods by the USPTO.¹⁴⁴ However, even for a medical method without alternatives, “compulsory licenses” can be granted only under certain circumstances and the scope and duration shall be strictly limited. Article 31 of TRIPS provides a good guideline for use of “compulsory licenses.”

¹⁴¹ 28 U.S.C. § 1498 (2009) (When the United States is using or manufacturing an invention “described in and covered by” a U.S. patent, the patent owner can recover “reasonable and entire compensation” for such use and manufacture).

¹⁴² *Id.*; *see also*, Judge, *supra* note 14, at 211.

¹⁴³ There are a number of situations where the government requires compulsory licenses on equitable terms. *See*, Plant Variety Protection Act, 7 U.S.C. § 2404 (1988) (The Department of Agriculture may grant compulsory licenses when there is need to supply “fiber, food or feed” if the owner cannot or will not supply the public needs); *see also*, Clean Air Act, 42 U.S.C. § 7608 (1988) (The Attorney General may forward a certification to a Federal District Court ordering compulsory licensing for an invention necessary to comply with the Act when there is no alternatives and failure to license may tend to create a monopoly).

¹⁴⁴ Yang, *supra* note 35, at 889.

Proposed terms and restriction to use “compulsory licenses” are as follows:

- (1) Only medical method patents with no other alternatives currently may be subject to “compulsory licenses”.
- (2) Such “compulsory licenses” can only be granted “in cases of national emergency or other circumstances of extreme urgency” without “successfully obtaining authorization from the patent right owner”.¹⁴⁵ Patent holder shall be given prompt notice.¹⁴⁶
- (3) The use of “compulsory licenses” shall be non-exclusive and non-assignable, and such use shall only be authorized for the supply of the domestic market.¹⁴⁷
- (4) The authorization of such use shall be terminated “if and when the circumstances which led to it cease to exist and are unlikely to recur”.¹⁴⁸
- (5) The patent owner “shall be paid adequate remuneration in this circumstance”.¹⁴⁹
- (6) Both the decision relating to the use of “compulsory licenses” and the decision relating to the remuneration shall be “subject to judicial review or other independent review.”¹⁵⁰

Appropriate restricted use of “compulsory licensing”, approving it for use during a national emergency, protects the general public during emergency health crises. Reasonable exploitation fees and limited duration of the exploitation of the patent keeps the patent owner’s rights from excessive exploitation.¹⁵¹

V. PATENT EXAMINATION PROCEDURE FOR PROPOSED NEW “MEDICAL METHOD PATENTS”

¹⁴⁵ TRIPS, *supra* note 97.

¹⁴⁶ *Id.*

¹⁴⁷ *Id.* at 31 (d)-(f).

¹⁴⁸ *Id.* at 31 (g).

¹⁴⁹ *Id.* at 31 (h).

¹⁵⁰ TRIPS, *supra* note 97, at 31 (i) & (j).

¹⁵¹ After the implementation of “Compulsory Implementing Rules of Patents relating to Public Health”, the application for pharmaceutical products grew as well as patients getting new and better pharmaceutical products. Both the aims of patent law and socio-ethics of public health have been achieved. *See Yang, supra* note 35, at 897.

Compared to the patent examination procedure for ordinary utility patents, there is no significant change for “medical method patents” because they are now patented in the form of a “process”. However, medical method patents should be separated from other inventions to obtain such a patent either through the applicant’s election or subject to a restriction. Disclosure of the proximate investment and the market is required as part of the specification, and the applicant reserves the right to expunge it from publication. The only differences between the two methods after the examination are that an agreement for use shall be provided, and the applicant has to select an appropriate restriction before the issuance of the patent. The appendix sets forth the major steps of patent examination for medical methods.

VI. CONCLUSION

Offering patent protection for medical methods, either for diagnosis or treatment, is necessary to foster and encourage these inventions. In response to the ethical concerns raised by health care professionals, the “physicians’ immunity statute” has been put in place to protect the public. Although it protects “medical practitioners” from infringing on patent rights while performing medical care, the statute limits the inventor’s incentive to patent a medical method, and discourages the investment of new medical method research.¹⁵² At the same time, the exclusion of medical diagnosis from the statute may still raise the issue of public interest. A new “medical method patent” better addresses and resolves conflicts between patent law and public interest. Under the new proposed patent regime, patent owners shall have patent rights similar to other patent owners and enjoy adequate economic profits from it while the patients’ right of access to the patented medical methods shall be guaranteed by appropriate restriction agreements for use of medical method patents. Thus, by establishing a new patent for medical diagnosis

¹⁵² Dirksen, *supra* note 21.

methods and medical treatment methods and by canceling the “physicians’ immunity statute,” the rights of patent holders, the ethics of medical professionals, and the interests of the general public can be better balanced and protected.

APPENDIX

Flow Chart for “Medical Method Patents” Application Examination Procedure

