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Yūsuke Satō

Jiameng Kathy Liu

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PATENT PROTECTION OF MEDICAL METHODS —FOCUSING ON ETHICAL ISSUES—*

**From Current Situation and Problems on Intellectual Property Law,
Annual of Industrial Property Law, June 2007**

**Written by Yūsuke Satō[†]
Translated by Jiameng Kathy Liu^{††}**

Translator's note: The following is a translation of “Patent Protection of Medical Methods—Focusing on Ethical Issues—,” an article written by Professor Yūsuke Satō in the June 2007 issue of the Japanese periodical *Annual of Industrial Property Law*. In Japan, despite the lack of an explicit statutory prohibition, methods of medical treatment have never been patentable. The Japan Patent Office (“JPO”) has rejected patenting medical processes on ethical grounds, interpreting that they do not fulfill the statutory requirement of “industrial applicability” in the main sentence of Article 29, Section 1 of the Patent Act, and courts have been confirming this practice. In light of recent developments in biotechnology, this prohibition is now in question. Reforms are being discussed from the perspective that Japan’s patent system should encourage the development of new medical technology.

In this article, Professor Satō examines the underlying ethical reasons for excluding medical methods from patent protection and discusses whether they are appropriate. He compares the treatment of medical methods under the Japanese patent system to that of the European Patent Convention (“EPC”), where Article 52, Section 4 explicitly provides that medical processes do not have “industrial applicability.” He also compares the same to the United States Patent Act (“U.S. Patent Act”), 35 U.S.C. § 1 *et seq.* where, while medical processes are patentable, Section 287(c) immunizes medical practitioners from liability from medical process patent infringements.

After reviewing a wide range of theories, Professor Satō argues that the ethical issues surrounding Japan’s patent system should be viewed from the standpoint of whether the patent system could be socially justified and whether it would lead to industrial development. To do so, the elements of “industry,” as well as limitations of patent rights enforcement, should be kept in mind when considering patentability requirements.

* This article includes subsequent findings and is the continuation of the discussion of ethical issues in *Patent Protection of Medical Methods (1)-(3)*. See Yūsuke Satō, *Patent Protection of Medical Methods (1)*, 3(1) HITOTSUBASHI HÖGAKU 285 (2004); *Patent Protection of Medical Methods (2)*, 3(2) HITOTSUBASHI HÖGAKU 281 (2004); *Patent Protection of Medical Methods (3)*, 3(3) HITOTSUBASHI HÖGAKU 283 (2004).

[†] Dr. Yūsuke Satō is a professor at Iwate University. He is also the associate director of the Center for Regional Collaboration in Research and Education at Iwate University. Dr. Satō specializes in intellectual property law, particularly patent law and copyright law.

^{††} Juris Doctor expected 2011, University of Washington School of Law. The translator wishes to thank the editors and staff of the *Pacific Rim Law & Policy Journal* for their linguistic and editorial assistance.

I. A LEGAL SYSTEM THAT EXCLUDES MEDICAL METHODS FROM PATENT PROTECTION—DEFINING THE ISSUE

A. *Introduction*

In legal systems that protect inventions as patents, there is a global trend to exclude inventions of therapeutic methods, diagnostic methods, and surgical methods (collectively, “medical methods”).

To describe further, medical method inventions are discoveries or inventions of methods for treating, diagnosing, or performing surgery on humans (including animals under the TRIPS Agreement and EPC as discussed below), which are different from inventions of medical products. Larger examples of medical product inventions include medical facilities and patient management systems; smaller examples include surgical tools such as scalpels, therapeutic medicine, therapeutic devices and tools, diagnostic medicaments, diagnostic devices, and other various inventions. In contrast, surgical methods include methods of operating on the human body using tools such as scalpels, as well as ways of collecting blood samples; therapeutic methods include methods for treating humans using medical products such as medications; and diagnostic methods include methods of collecting various data from the human body by measuring, for example, the organs’ structures and functions for the medical purposes of discovering ailments and assessing health conditions, as well as judging conditions and progression of disease.

Within inventions related to medical technology, diagnostic devices and medications are patentable and protectable, whereas medical methods alone are, as discussed below, unpatentable or subject to limited enforcement and thus excluded from protection.

B. *The Exclusion of Medical Methods from Patent Protection in Each Legal System*

1. *The TRIPS Agreement*¹

While Article 27, Section 1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”)² provides that “patents

¹ [FN 1] Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application.”³ Section 3 also provides that member countries “may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals.”

2. *EPC*

In Europe, the European Patent Convention (“EPC”)⁴ Article 52, Section 4, Clause 1 (the former EPC law)⁵ provides that surgical, therapeutic, and diagnostic methods have no industrial applicability, and because these medical methods do not meet the statutory requirement of industrial applicability (Article 52, Section 1), they are not eligible for patent protection. In 2000 the EPC was amended,⁶ and Article 52, Section 4 is now repealed (the revised EPC law). However, the deleted provision can now be found exactly in its original wording in Article 53, Section (c). The purpose of Article 53 is to list the exceptions to patentability: Section (a) provides for inventions the publication or exploitation of which would be contrary to public order and morality; Section (b) provides for biological processes for the production of plants or animals; and Section (c) provides for medical methods.

3. *U.S. Law*

Under U.S. law, although no statutory provision prohibiting the patenting of medical methods emerged, the practice had long been banned

² *Translator’s note:* The extent of protection and enforcement of intellectual property rights (hereinafter “IP rights”) varies around the world. As IP rights became more important in trade, these differences became a source of tension in international economic relations. The World Trade Organization’s (“WTO”) TRIPS Agreement is an attempt to narrow the gaps in the way these rights are protected around the world, and to bring them under common international rules. It establishes minimum levels of protection that each government has to give to the intellectual property of fellow WTO members. See TRIPS Agreement, *supra* note 1.

³ *Translator’s note:* For the purposes of Article 27 of the TRIPS Agreement, the terms “inventive step” and “capable of industrial application” may be deemed by a Member to be synonymous with the terms “non-obvious” and “useful,” respectively. See TRIPS Agreement, *supra* note 1, at Article 27 n. 5.

⁴ *Translator’s note:* The EPC is a multilateral treaty that provides a legal framework for the granting of European patents via a single, harmonized procedure before the European Patent Office. See Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 255 [hereinafter European Patent Convention or EPC].

⁵ [FN 2] Although the current law is still in effect, it has been amended as mentioned below. For convenience purposes, I will call it “former EPC law.”

⁶ [FN 3] Although the amended law is commonly called EPC 2000, it is scheduled to take effect in December 2007 due to delays in the ratification process in various countries.

under the judicial doctrine known as the *Morton* doctrine.⁷ However, a period of absolute protection for medical methods began with the 1952 revision of the Patent Act,⁸ as if it had created a momentum that acted upon the courts to change the case law, and medical methods became patent eligible subject matter, with no limitations imposed on the enforcement of patent rights on medical methods, as with other types of inventions. Nevertheless in 1992, the *Pallin* case,⁹ where a surgeon sued other surgeons for patent infringement, triggered Congress to amend the Patent Act in 1996, leaving behind, after a nearly a half a century, the heavenly period in which medical methods enjoyed absolute protection.¹⁰

In [the 1996] amendment, Section 287(c),¹¹ which does not cover patents on medical products such as devices, medications and biotechnology, was added to provide for the exemption of infringement liability for medical practitioners who infringe on patented medical methods.

Therefore, although current law does not prohibit the patenting of medical methods, it provides an exception for medical professionals in cases where medical method patents are infringed, thereby limiting the enforcement of patent rights on medical methods. Furthermore, there are many exceptions to the infringement liability exemption, thus triggering doubts as to the effectiveness of such an exemption.¹²

⁷ *Translator's note:* The *Morton* doctrine comes from the 1862 case of *Morton v. New York Eye Infirmary*, 17 F.Cas. 879 (C.C. S.D.N.Y. 1862), where the New York Circuit Court held that the patentee's claimed invention of a procedure for performing surgical operations with the use of ether was unpatentable because both ether and the process of inhaling vapors were not new. Although the court's rationale seems to have rested on the traditional rule that no patent may issue for the discovery of a new but analogous use of an old product, the case referred to the "natural functions of an animal." *Id.* This language has given rise to the notion that medical and surgical procedures used to treat the human body are not patentable processes. *See id.* at 884.

⁸ *Translator's note:* The Patent Act of 1952 reflects the basic structure of the present law. The 1793 Patent Act defined the four classes of patent eligible subject matter as "art, machine, manufacture, or composition." The 1952 Patent Act replaced the term "art" with "process," resulting in the current language of 35 U.S.C. § 101. As a result of this replacement, there has been a substantial expansion of the subject matter being claimed in issued U.S. patents. *See* Act of Feb. 21, 1973, ch. 11, § 1, 1 Stat. 318 (codified as amended at 35 U.S.C. § 101).

⁹ *Translator's note:* *Pallin v. Singer*, 36 U.S.P.Q. 2d 1050 (D. Vt. 1995).

¹⁰ [FN 4] *See generally* Yūsuke Satō, *A Theme on the Patent Protection of Medical Methods* (2), 55(3) PATENT 31 (2002) (discussing in detail the history and reform of U.S. law related to medical issues).

¹¹ *Translator's note:* 35 U.S.C. § 287(c) (1996).

¹² [FN 5] *See* Cynthia M. Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. DAVIS L. REV. 601, 641-44 (2000).

4. *Japanese Law*

In our country, the legal treatment of medical methods inventions is to not patent such inventions. I refer to legal treatment because the Patent Act does not have provisions that exclude medical methods from patent eligibility, and the Patent Office's examination guidelines¹³ state that medical method inventions lack the statutory requirement of industrial applicability under Article 29, Section 1, and must therefore be rejected. This practice has been confirmed in precedent¹⁴ and thus can be called case law.

5. *Classification of Legal Systems*

In sum, systems that exclude medical methods from patent protection can be divided into two categories: 1) systems that deny patent eligibility itself, and 2) systems that recognize patent eligibility but limit enforcement of patent rights. Further, systems that deny patent eligibility can be further divided into systems that deny patent eligibility by determining whether the claimed invention lacks industrial applicability on the one hand, and on the other, systems that deny patent eligibility by explicitly excluding medical methods based on special reasons, thereby denying patent eligibility on the sole basis that the claimed invention is a medical method.

In this article, as does Professor Nakayama, I will refer to patent systems that limit patent eligibility itself as "upstream systems," and patent systems that limit the enforceability of patent rights as "downstream systems."^{15,16} Further, the line of thinking that denies patent eligibility based on industrial applicability will be referred to as "industrial applicability requirement theory," and the line of thinking that denies patent eligibility not

¹³ [FN 6] See Japan Patent Office, *Examination Guidelines on Patents and Utility Models*, <http://www.jpo.go.jp/shiryu/index.htm> (showing that the Guidelines published in December 2000 have been amended in August 2003 and April 2005) (last visited Oct. 7, 2010).

¹⁴ [FN 7] *Surgical Navigation Technologies Inc. v. Japan Patent Office Commissioner*, Kōzō Oikawa, 1828 HANREI JIHŌ 99 (Tokyo High Ct., Apr. 11, 2002).

¹⁵ [FN 8] NOBUHIRO NAKAYAMA, *INDUSTRIAL PROPERTY LAW PART I: PATENT LAW*, 117 (Kōbundō, 2d ed. 1998).

¹⁶ *Translator's note*: Patent rights do not arise until a patent has been procured from the government. Thus, if the issuance of patent is the peak of a river, then patent procurement could be considered upstream and patent enforcement could be considered downstream. The author's use of the term "upstream system" to refer to patent systems that limit patent eligibility and the term "downstream system" to refer to patent systems that limit enforceability of patent rights, as adopted from Professor Nakayama, illustrates the difference in approach used by different patent systems to limiting patent protection on medical methods.

based on industrial applicability but on some other special reason will be referred to as “special reason theory.”¹⁷

Based on this categorization, the TRIPS Agreement, the former EPC law, the revised EPC law, and the Japanese law are upstream systems, whereas the U.S. law is a downstream system. In addition, the former EPC law is based on the industrial applicability requirement theory, but as discussed below, this could also be viewed as a mere legal fiction. The revised EPC law is indeed based on the special reason theory. As for Japan, although the official treatment by the Patent Office seems to be based on the industrial applicability requirement theory, as with the former EPC law, it has been seen as legally fictitious.

C. Objective of This Article

In any event, the various forms of legal systems that exclude medical methods from patent protection are based on ethical reasons. As such, ethical reasons are appearing in the patent laws of various legal systems, and are acting as obstacles to the patent protection of medical methods.

However, depending on what the particular ethical reason is, the way in which the obstacle arises differs. In other words, there is an intimate relationship between the position of the obstacle on patent protection of medical methods and the ethical reason behind it.

The primary focus of this article is to examine the underlying ethical reasons for excluding medical methods from patent protection and determine whether they are appropriate. Next, [this article] will delve into how such ethical reasons should be incorporated into the Patent Act, namely, whether the industrial applicability requirement theory or the special reason theory should be given more weight, keeping in mind whether the legal system is upstream or downstream.

As a roadmap for the comprehension of the systematic positioning of ethical reasons in Patent Act, after discussing Europe’s changing case law formed by the appeal cases at the European Patent Office (“EPO”), [this article] will touch on the arguments observed in the United States and Japan

¹⁷ *Translator’s note:* Patent eligibility can be rejected based on two theories. The first theory is to reject patent eligibility based on the lack of industrial applicability, which is a statutory requirement. The author refers to this theory as the “industrial applicability requirement theory.” The second theory is to reject patent eligibility based on other special reasons. For example, even if an invention is in fact industrially applicable, it could nevertheless be denied patent eligibility due to ethical concerns. The author refers to this theory as the “special reason theory.”

(Part II), and then examine the ethical concerns surrounding medicine in light of its relationship with the patent system using the recent accomplishments of biomedical ethics (Part III), and finally, it considers the systematic positioning of these ethical concerns on the patent system and touch on the question of upstream and downstream legal systems (Part IV).

II. THE REALITY OF EXCLUDING FROM PATENT PROTECTION BASED ON ETHICAL REASONS

A. *The Transformation of EPC Case Law*

1. *Overview*

Although Article 52, Section 4, Clause 1 of the former EPC law provides that surgical, therapeutic and diagnostic methods are not industrially applicable, and that statutorily this is based on the industrial applicability requirement theory, there are two opposing theories for this interpretation. The “non-industrial medicine theory” seeks to relieve medical activities that are non-business and non-industrial from patent restrictions,^{18,19} while the “socio-ethical theory” is based on the ethical and public health concern that anyone who wishes to offer medical methods on humans (and animals) should not be hampered by patents to use such methods.^{20,21}

Looking at the case law of EPO appellate decisions, it is noticeable that the non-industrial medicine theory is powerful in the beginning and is later replaced by the socio-ethical theory.

2. *The Non-Industrial Medicine Theory*

The non-industrial medicine theory probably focuses on the special ethics of healthcare provided by doctors since Hippocrates, and considers that such activities should not be recognized as an industry from an ethical perspective. According to this theory, the medical industry should not be thought of as an “industry,” and therefore any medical activities should not

¹⁸ [FN 9] See case G-5/83, 1985 OFFICIAL J. EPO 64.

¹⁹ *Translator’s note:* The prefix “G” in note 18 indicates that the case was heard before the Enlarged Board of Appeal of the EPO. See *infra* note 33.

²⁰ [FN 10] See case T-24/91, 1995 OFFICIAL J. EPO 512.

²¹ *Translator’s note:* The prefix “T” in note 20 indicates that the case was heard before the Technical Board of Appeal of the EPO. See *infra* note 33.

be eligible for patent protection. As such, the dividing ridge of patent protection and exclusion is whether such medical activities can be performed by persons other than a doctor, or whether such activities can be used for slimming and beauty parlor types of businesses. Unless the activity satisfies both requirements of 1) non-industrial medical activity and 2) exclusive use by doctors, the activity should not be excluded from patent protection under Article 52, Section 4.

i. Non-Industrial Medical Activity

Whether or not an activity is a non-industrial medical activity is determined as follows. For example, in the 1985 appeal of the *Thenoyl Peroxide* case,²² the Board of Appeal decided that a limited claim on a method of using a drug for cosmetic products was eligible for patent protection because the use occurred at a beauty parlor, which was an industrial use, and in the 1986 appeal of the *Appetite Suppressant* case,²³ the Board of Appeal decided that a claim on a method of body beautification, which had both cosmetic effects (slimming) and therapeutic effects (amelioration of obesity), should not be denied patent protection because of the mere fact that it is hard to distinguish cosmetic effect from therapeutic effects. The Board of Appeal also denied the use of such reasoning against the patent applicant.²⁴

ii. Exclusive Use by Physicians

If a medical activity is seen as non-industrial because it is performed by a doctor, then the activity performed by a non-doctor would no longer be non-industrial. To illustrate this, the Technical Board of Appeal in the 1987 appeal of the *Non-invasive Measurement* case²⁵ decided that if the premise of Article 52, Section 4, Clause 1 is to prevent the patent system from distracting the practices of medical doctors, then only those method claims which are to be practiced by doctors should be deemed impossible for

²² [FN 11] Case T-36/83, 1986 OFFICIAL J. EPO 295.

²³ [FN 12] Case T-144/83, 1986 OFFICIAL J. EPO 301.

²⁴ [FN 13] There are also cases that rejected patent protection based on Article 52 Section 4 of the EPC. In a 1990 case, for example, a claim on the use of a composition containing lantern salt for removing and cleaning plaque from human teeth was found to inevitably provide both cosmetic effect and therapeutic effect (at least in the sense of disease prevention), and because such claim was not limited to providing cosmetic effect and required treatment to the human body for the purpose of therapy, the court held that it was excluded by Article 52 Section 4. See case T-290/86, 1992 OFFICIAL J. EPO 414.

²⁵ [FN 14] Case T-385/86, 1988 OFFICIAL J. EPO 308.

industrial application. In the same case, the Board of Appeal decided that the claimed measurement method was industrially applicable because it could be performed without medical knowledge and skills in a commercial environment.

Furthermore, in the 1987 appeal of the *Flow Measurement* case,²⁶ where it was decided that a measurement method (claim 1) that used an implanted drug dose control unit was eligible for patent protection, the Board of Appeal established that the non-commercial and non-industrial medical and veterinary activity should not be limited because the doctor was not able to use his professional skills to prevent in any way the disease prevention, curing, or symptom-alleviation effects offered by the method.

Similarly, in the 1990 appeal of the *Image Information Creation* case,²⁷ the Board of appeal decided that the claimed method could be used without medical knowledge or special skills, and thus should not be excluded under Article 52, Section 4.

3. *The Socio-Ethical Theory*

In contrast, according to the socio-ethical theory, as discussed above, Article 52, Section 4 should not prevent the use of medical methods, and even if the claimed method is in fact industrially applicable, it is excluded from patent protection if it corresponds to a medical method.

Within EPC case law, this theory peaks in the 1987 appeal of the *Pigs I* case,²⁸ which held that for methods provided under Article 52, Section 4, even if the method is industrially applicable, it must be excluded from patentability due to policy reasons. As such, Section 4 vaguely admits that industrial applicability is possible for medical methods, and yet by legal control from the policy perspective denies its patentability by asserting the lack of industrial applicability. As such, this standpoint is also known as the quasi-industrial applicability requirement theory.

In the 1994 appeal of the *Birth Control I* case,²⁹ the Board of Appeal announced that even if the claimed method satisfies the requirement of industrial applicability under Article 52, Section 1, it is nevertheless excluded from patentability under Article 52, Section 4.

²⁶ [FN 15] Case T-245/87, 1989 OFFICIAL J. EPO 171.

²⁷ [FN 16] Case T-400/87, 1991 OFFICIAL J. EPO 47.

²⁸ [FN 17] Case T-116/85, 1989 OFFICIAL J. EPO 13.

²⁹ [FN 18] Case T-820/92, 1995 OFFICIAL J. EPO 113.

Moreover, in the 1994 appeal of the *Artificial Lens* case,³⁰ the Board of Appeal stated that because the exclusion provision in Article 52, Section 4 is based on social ethics and public health concerns and aims to ensure that anyone wishing to perform medical treatment on humans and animals not be prevented by patents from using such methods, [such methods] do not require that doctors be the only people who qualify to use the methods.

Finally, the 2001 appeal of the *Biological Sampling Methods* case³¹ also applied the policy justification for Article 52, Section 4 as announced in the *Pigs I* case.³²

4. *Conflict Settlement*

As discussed above, there are two opposing views in case law, with the socio-ethical theory appearing to have gained more power. However in 2005, the Enlarged Board of Appeal³³ stated that the exclusion of medical methods from patent protection for the lack of industrial applicability under Article 52, Section 4 is legal fiction, that the lack of industrial applicability should not be considered to be the real reason for exclusion, that Article 52, Section 4 does not require that doctors or medical practitioners practice the method, and thereby put an end to this long lasting conflict.³⁴

Integrating this trend, the revised EPC law amended the old provision that excludes medical methods from patentability based on the lack of industrial applicability, shifting to a new provision that excludes medical methods from patentability based on special reasons that are separate from industrial applicability, thereby allowing a reasonable explanation for such exclusion on the basis of social ethics. Today, Europe has come to settle this issue legislatively, and the legal fiction of the quasi-industrial applicability requirement theory has become a thing of the past.

³⁰ [FN 19] Case T-24/91, *supra* note 20.

³¹ [FN 20] Case T-964/99, 2002 OFFICIAL J. EPO 4.

³² *Translator's note*: See [FN 17], *supra* note 28.

³³ *Translator's note*: In Europe, decisions of the first stances of the European Patent Office ("EPO") can be appealed to the Boards of Appeal. Although the Boards of Appeal are integrated in the organizational structure of the EPO, they are independent from the EPO in that decisions are bound only by the European Patent Convention ("EPC"). There are currently twenty-six Technical Boards of Appeal, plus the Legal Board of Appeal, the Enlarged Board of Appeal, and the Disciplinary Board of Appeal. To ensure uniform application of the law, or if an important point of law arises, a question can be referred to the Enlarged Board of Appeal, either by a board of appeal or by the President of the EPO. See EPO Homepage—Boards of Appeal, <http://www.epo.org/about-us/boards-of-appeal.html> (last visited Oct. 7, 2010).

³⁴ [FN 21] See case G-0001/04, 2006 OFFICIAL J. EPO 334.

B. *U.S. Law*

In the United States, Congress introduced Section 287(c)³⁵ in 1996 in order to limit the enforceability of patent rights on medical methods by exempting medical professionals from infringement liability. Although this amendment was proposed by the Senate, the legislative history reveals that the House of Representatives' proposal was to ban all medical methods inventions from patenting. There was little debate as to which proposal was better, but it seems that Congress ultimately adopted the Senate's proposal to limit the enforceability of patent rights because a complete ban on patenting medical methods was considered too drastic. In any case, Congress knew something had to be done, and it looked for the solution through congressional debate.³⁶ Several regulatory reasons can be found, but a few of them are more than twenty years old. The legislative history is very interesting in that it dates back to the patent reform issues of the early Twentieth Century³⁷ and contains an extensive discussion of the issue.

In the United States, there is no statutory requirement for industrial applicability, and although stated strongly, the equivalent is the "utility" requirement of Section 101.³⁸ Because none of the following ethical concerns would amount to the failure of meeting the utility requirement, they can be considered obstacles to patent protection under the special reason theory.

1. *Rule of Information Sharing*

According to the Oath of Hippocrates, physicians have the responsibility of providing the best care to patients, and in order to protect this principle, doctors must be able to share information among each other. This is known as the rule of information sharing.

A clear illustration of this rule can be found in "The Principles of Medical Ethics" published by the AMA³⁹ in 1957. Section 2 provides that "[p]hysicians should strive continually to improve medical knowledge and skill, and should make available to their patients and colleagues the benefits of their professional attainments." The patent system, which allows people

³⁵ *Translator's note:* 35 U.S.C. § 287(c).

³⁶ [FN 22] *See* [FN 4], *supra* note 10.

³⁷ [FN 23] Although amendments were proposed in both 1902 and 1903, they were both rejected. *See id.*

³⁸ *Translator's note:* 35 U.S.C. § 101.

³⁹ [FN 24] "AMA" is short for American Medical Association.

who hold information related to revolutionary medical knowledge and skills to monopolize and exclude others from accessing such information, directly runs afoul of the principle of medical ethics and should be discarded all together.

2. *Increased Healthcare Costs—Preventing the Public from Accessing Healthcare*

If medical methods were patentable, then the use of such methods would require the signing of a licensing agreement. Consequently, physicians would charge a higher rate from patients in order to recover the licensing fee. This would inevitably lead to higher healthcare costs and prevent the public from accessing healthcare.

3. *Privacy of Patients*

If medical methods were patented and such patents were infringed, the process of proving infringement or remedy by disclosing which patient received the care under the patented medical method would inevitably infringe on the patient's privacy rights. For example, the U.S. Supreme Court ruled that Connecticut's anti-birth control law (state law), which prohibited the use of birth control rather than the manufacture or sale of birth control, was a constitutional violation of a couple's privacy rights.^{40, 41}

4. *Autonomy of Patients and Physicians*

The respect for autonomy is a very important principle and the very first principle out of the four introduced in the standard textbook for biomedical ethics—"Principles of Biomedical Ethics"⁴² by Beauchamp and Childress. Autonomy is the control over one's own decision; it is the freedom from coercion in deciding to act, and is satisfied when one: 1) acts intentionally, 2) with understanding, and 3) without controlling influences

⁴⁰ [FN 25] See *Griswold v. Connecticut*, 381 U.S. 479, 485 (1965).

⁴¹ [FN 26] See George J. Annas, *Surrogate Embryo Transfer: The Perils of Patenting*, HASTINGS CENTER REPORT 25, 26 (1984). In this article, Annas brings up the U.S. Supreme Court case *Griswold v. Connecticut* and argues that the patent (U.S. Patent No. 4,816,257) obtained on the method of surrogate embryo transfer ("SET") violates patient privacy.

⁴² [FN 27] TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (5th ed., Oxford University Press 2001). See also TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (Yukimasa Nagayasu & Norio Tachiki trans., Shōbundō, 3d ed. 1997).

that would affect against a free and voluntary act.⁴³ This is also the basis for informed consent.

The existence of a patent system would endanger autonomy. In other words, if a physician holds a patent or a license to a patented medical method, his act would be influenced in that he would want to use the patented medical method. If, on the other hand, a physician does not hold a patent or a license, his act would also be influenced in that he would avoid using the patented medical method. Such person would thus not be acting free of controlling influences.

5. *Fidelity of the Physician-Patient Relationship*

The Geneva Oath of the World Medical Association states that “the health of my patient will be my primary concern,” and imposes a fidelity obligation on physicians with regards to their patients. However, the existence of a patent and licensing obligation would place the physician under contractual obligation, which would inevitably lead to conflicting obligations, where the physician would not be able to meet his fidelity obligation to the patient.⁴⁴ Moreover, the incentive to gain profit from patenting would also run afoul of the fidelity obligation.⁴⁵

C. *Japanese Law*

The Japanese Patent Office (“JPO”),⁴⁶ without offering any reason, unexpectedly placed “surgical, therapeutic, and diagnostic method practiced on humans” in the exception category to “inventions that are industrially applicable.” Consequently, under the patent examination guidelines, it is unclear why medical methods lack industrial applicability.

Judicial decisions provide some clarification. In the *Method for Assisting Surgery* case,⁴⁷ the Tokyo High Court emphasized the difference in

⁴³ [FN 28] See [FN 27] BEAUCHAMP & CHILDRESS, *supra* note 42, at 58-59.

⁴⁴ [FN 29] See Gregory F. Burch, *Note: Ethical Considerations in the Patenting of Medical Processes*, 65 TEX. L. REV. 1139, 1152-53 (1987).

⁴⁵ [FN 30] See Joseph M. Reisman, *Physicians and Surgeons as Inventors: Reconciling Medical Process Patents and Medical Ethics*, 10 HIGH TECH. L. J. 355, Section II.C (1995).

⁴⁶ *Translator's note:* The Japan Patent Office (“JPO”) consists of the General Affairs Department, the Examination Department, the Appeals Department, and other sections and departments. The main functions of these departments include: (1) granting adequate rights for patents, etc.; (2) drafting plans for IP policies; (3) international exchange and cooperation; (4) review of the IP system; and (5) dissemination of information on IP. These functions provide for the positive advancement of industrial development. See JPO Homepage—The Role of the Japan Patent Office, <http://www.jpo.go.jp> (last visited Oct. 7, 2010).

⁴⁷ [FN 31] See [FN 7], *supra* note 14.

infringement liability that arises from patents on medical products and from medical methods. For a patented medical product, the existence of the product would determine the physician's ability to use the product. In other words, the existence of a patent on a medical product would not be constraining because the physician would use whatever available product to continue his medical activity. In contrast, with a patented medical method, the physician would worry about whether the medical method he is about to practice is patented, and if it is, whether there is a valid license that allows him to practice the method, and would undertake medical activity with the fear that he may be liable for infringement. Physicians who treat patients in emergency situations should not have to deal with these concerns. Although this is not to say that medical industry is not industrial, practical reasons exist for interpreting medical methods as lacking industrial applicability.

This viewpoint is similar to the EPC socio-ethical theory (quasi-industrial applicability requirement theory) as discussed above in Part II.A.3. However, this viewpoint is also different from the EPC socio-ethical theory because it suggests that only physicians need be relieved from the restriction of the patent system, whereas the EPO socio-ethical theory suggests that everyone needs to be relieved.

While theories are categorized under the quasi-industrial applicability requirement theory because they tend to come from ethics, raise moral reasons, and do not view medical industry as non-industrial, there remains ambiguity and vagueness because there is nothing more to say about the ethical reason behind such interpretation.

Unlike pharmaceutical inventions that are mainly developed by private businesses for profit, because medical methods are developed by universities and do not necessarily involve a patenting incentive, it is not unreasonable to say that such development is non-industrial.⁴⁸ Consequently, some interpret the patenting of medical methods in ways similar to the non-industrial medicine theory and the industrial applicability requirement theory.

III. ANALYSIS OF ETHICAL DISCOURSE

A. *Criticisms of Hippocratic Medical Ethics*

The Oath of Hippocrates states:

⁴⁸ [FN 32] See [FN 8], *supra* note 15, at 116.

I will prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone. I will not give a lethal drug to anyone if I am asked, nor will I advise such a plan. In every house where I come I will enter only for the good of my patients, keeping myself far from all intentional ill-doing.⁴⁹

In Japan, the remarks of Pompe⁵⁰ should also be remembered: “Physicians must be aware of their lifework. Once a person chooses this profession, he no longer exists for himself but must exist for the patients. If he is reluctant, he shall choose a different profession.”⁵¹

There are two criticisms on medical ethics that arise from these origins. First, the disease structure is changing in developed countries due to the improvement in nutritional and sanitary conditions as well as medical care systems. In Japan, for example, although the primary medical concern since the Meiji era⁵² has long been acute and chronic infectious diseases (such as tuberculosis, Hansen’s disease, luetic infection, and acute pneumonia), malnutrition, and endemic diseases, these were overcome by 1960, and attention is shifting to adult and geriatric diseases such as cancer, stroke, and cardiac disorder.⁵³

Because these chronic diseases cannot be cured immediately, healthcare today is serving more in the form of symptom management and control rather than therapy. From the viewpoint of a patient, healthcare is a way of improving his quality of life because the patient must live with the lifelong ailment. As such, patients now have the right to decide their own treatment strategy, and the patient-physician relationship is changing to a service requester-consumer-service provider relationship. Ethical issues including the physician-patient relationship are now present as biomedical ethics.⁵⁴

In the context of patient autonomy and informed consent, physician-centered healthcare is criticized and the policy suggested by the Hippocratic Oath, where the physician’s attitude in unilaterally providing care in a self-

⁴⁹ [FN 33] HIPPOCRATES, VOLUME 1 579 (Shinichirō Ōtsuki ed., Enterprise, Inc. 1988).

⁵⁰ [FN 34] Pompe is the founder of Nagasaki Medical School, and is known in Japan as the father of modern western medicine.

⁵¹ [FN 35] See Nagasaki Medical School Homepage, <http://www.med.nagasaki-u.ac.jp> (last visited Oct. 7, 2010).

⁵² *Translator’s note*: The Meiji era extended from 1868 to 1912.

⁵³ [FN 36] TAKESHI KAWAKAMI, TECHNOLOGICAL ADVANCEMENT AND HEALTHCARE COSTS 124, 163-65 (Keisoubunbō 1986).

⁵⁴ [FN 37] AKIHIRA KOMEMOTO, REVOLUTIONARY STATE-OF-THE-ART MEDICINE 7-13 (Chūkō Shinsho 1988).

righteous manner based solely on his or her medical knowledge and skills, is especially criticized as Hippocratic paternalism.^{55, 56}

The second criticism is reflected in changes in social awareness. While the Hippocratic Oath states that a physician has a nonmaleficence obligation, in which he or she must not do any harm to anyone (“*primum non nocere*”), and a beneficence obligation, in which he or she must actively do good to everyone, and many professional ethics guidelines adopt these principles, there are criticisms that too few people within the medical profession actually believe that these principles are merely a code of ethics within the small group of medical association, that these principles fail to consider patient perspectives from an external point of view, and that the collision between these principles, the theory of patient autonomy, and informed consent may trigger the medical paternalism criticism.⁵⁷

B. *Regarding the Rule of Information Sharing*

The criticisms mentioned above⁵⁸ also apply to the rule of information sharing, which is one of the rules provided by the code of medical ethics. Indeed, as the Geneva Oath of the World Medical Association provides, since physicians have the duty of providing the best care to their patients, they should be able to freely choose the best method of medical care. However, criticisms based solely on the fact that patenting of medical methods would take away this freedom lack social considerations.

The patent system aims to encourage innovation by granting monopoly rights with a limited term [to the inventor], and with improvement in technology, the patent system ultimately provides benefits to the public. Thus, the problematic situation is where the duty of the physician conflicts with this social benefit.

Let us consider the situation of medical research where humans are the subjects of experiment. In such a situation, there would inevitably be a conflict between the obligation of the physician, which is to provide the best medical care to the patient, and the obligation of the researcher, which is to improve medical care for the benefit of the future public. Would it be possible to adhere to the Geneva Oath under such circumstances? Article 2

⁵⁵ [FN 38] KAZUMASA HOSHINO, *ETHICS OF MEDICINE* 73 (Iwanami Shinsho 1991).

⁵⁶ *Translator's note*: Hippocratic paternalism means “having the physician do what he or she thought was best for the patient.” Robert M. Veatch, *Autonomy's Temporary Triumph*, 14(5) *HASTINGS CENTER REP.* 38-40 (1984).

⁵⁷ [FN 39] See [FN 27] BEAUCHAMP & CHILDRESS, *supra* note 42, at 7.

⁵⁸ *Translator's note*: See *supra* Part III.A.

of the Nuremberg Code provides, “The experiment [involving human subjects] should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.”⁵⁹ As such, the Nuremberg Code implies that the duty of providing the best care to patients must yield to social benefits.⁶⁰

Under the condition that the patent system gives equal opposition between the goal of providing benefits to the future public and the expense of disadvantage for the current public, the rule of information sharing is not necessarily absolute and thus should not be the basis for rejecting patent protection of medical methods. The problem is the legitimacy of the patent system from a public policy standpoint; it is not with the code of medical ethics within medical associations.

C. *Regarding the Sociol-Ethical Theory*

The assertion that patent protection of medical methods is against social ethics can also be rephrased as having no social justification. Besides ethical considerations, justification of law and public policy requires accounting for other factors such as cultural pluralism, political processes, and experimental data. In contrast, the objective of ethical principles is to solely provide moral guidance on every act an individual would take. Thus, even if an act is morally correct, the law that encourages such an act may not necessarily be correct. For example, the assertion that active euthanasia is morally justified does not conflict with the government’s assertion that this practice should be legally banned because it would be difficult to regulate the abuse once a ban is signed into a law. However, ethical notions are used to provide moral considerations for policy-making and legislative processes as well as judicial decisions.⁶¹ (As in this article, it is not meaningless to take ethical considerations for problems regarding the patent system.)

If a system uses patents to restrict physicians or laymen from freely using medical methods or to put physicians in a dilemma, then based on the principle of ethics, can we still say such a system is justified? In this situation, it becomes necessary to balance the disadvantages from such a patent system with the social benefit that it could provide. The question is whether the technological advancement and industrial development from

⁵⁹ *Translator’s note:* Nuremberg Code (1947); Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, Vol. 2, 181-82 (1949), available at <http://ohsr.od.nih.gov/guidelines/nuremberg.html>.

⁶⁰ [FN 40] See [FN 27] BEAUCHAMP & CHILDRESS, *supra* note 42, at 319-20.

⁶¹ [FN 41] See [FN 27] BEAUCHAMP & CHILDRESS, *supra* note 42, at 7-9.

such a patent system could outweigh the disadvantage for physicians and laymen trying to use the medical methods. There is no doubt that this question can be answered for other areas of technology even if the technology relates to emerging life and safety issues, but it is not the case when the technology involves medical methods. Some point out that no restriction has really been imposed, and that problems could be resolved by providing legal redress.⁶² Others point out that since physicians could become liable for infringing patents on medical products, it is meaningless to distinguish products from methods.⁶³

D. Regarding Increase in Medical Costs

This problem relates to how we think about the principle of justice. Let us consider it from the viewpoints of utilitarian justice, liberal justice, and egalitarian justice.

From the utilitarian point of view, justice is realized as long as the majority has achieved happiness. Thus, even if the cost of medical care increases due to patenting of medical methods, justice is still realized because the increase of healthcare cost is only partial and temporary. If viewed in the long term, the resulting technological advancement would bring much benefit and happiness to the people.

From the liberal point of view, justice does not exist as the result of enhanced public benefit; rather, it exists in allowing a fair course of action without confinement. If a person in a free market can distribute wealth based on his or her free will without any restriction, then justice is considered realized. It would not be considered problematic if the fluctuations of healthcare costs were due to the market principles. Rather, the meaning of justice would be misled if the market were interfered with for the purpose of achieving justice.

Egalitarian justice is divided into equality of result and equality of opportunity. However, since the ability of each individual is different, it is impossible to achieve equality of result, and we can only be satisfied with equal opportunity. If people are ensured with equal opportunity to satisfy their basic health needs with an appropriate standard of care, justice is considered achieved, even if some people seek better services such as

⁶² [FN 42] See Rainer Moufang, *Methods of Medical Treatment Under Patent Law*, 24 INT'L REV. INTELL. PROP. & COMPETITION L. 18, 47-49 (1993).

⁶³ [FN 43] See *Patent Protection of Medical Methods in MODERN DEVELOPMENT IN INTELLECTUAL PROPERTY LAW AND COMPETITION LAW, IN MEMORY OF PROFESSOR NOBUO MONYA* 167, 182-83 (2006).

luxurious hospital rooms and expensive dental treatment because they can afford them.

When considering the justification of public policy, there may be hesitation in focusing heavily on only one of the above justice theories. If the ideal is to have the right to receive the minimum necessary healthcare, then as long as this right is not taken away, services beyond such needs may be left to market principles and justice could be achieved in the most realistic sense.⁶⁴

Under this perspective, because the increase in healthcare cost is due to the novel patented invention on medical care, access to healthcare for fulfilling basic health needs is not necessarily encumbered and an increase in costs should not be the reason to prevent justifying patent protection of medical methods.

E. Regarding Patient Privacy

The patients' right of privacy is based on the principle of self-autonomy—it serves as a wall to protect patients from having their information disclosed and accessed.⁶⁵

Physicians have the duty to maintain secretly any information obtained in a physician-patient relationship and cannot disclose such information to a third party without the patient's consent.⁶⁶

However, this right is not absolute. For example, if a patient receiving psychological treatment tells the doctor that he or she plans to kill someone, the doctor would have difficulty deciding whether he or she should breach his or her duty and inform the police and the potential victim. Accordingly, the patient's privacy right and the physician's duty to maintain secrecy are recognized under the condition that there is no other bigger obligation to protect.⁶⁷

Then, how about in a situation of patent infringement? Would the patient's privacy right and the physician's duty to maintain secrecy fall back for enforcing patent rights? This is a difficult question.

However, since judicial proceedings are equipped with confidentiality orders (Patent Act Article 105, Sections 4-6, Article 200, Section 2, Section 201, etc.) to prevent the leaking of trade secrets for the duration of the lawsuit, privacy rights should not be a problem.

⁶⁴ [FN 44] See [FN 27] BEAUCHAMP & CHILDRESS, *supra* note 42, at 230-50.

⁶⁵ [FN 45] See *id.* at 296.

⁶⁶ [FN 46] See *id.* at 303-04.

⁶⁷ [FN 47] See *id.* at 305-12.

F. Regarding Physician-Patient Autonomy

Physicians and patients select medical methods based on various conditions, such as insurance and financial capability, which affect their decision-making processes. Therefore, even if a patent affects their decision-making processes, it is merely an addition to the already existing conditions. Given this perspective, patent protection of medical methods would not strongly affect the physician-patient autonomy.⁶⁸

G. Regarding Honesty between Physician and Patient

Besides the duty of honesty to patients, physicians also have other contractual obligations with the hospital and in other social relationships. These obligations may conflict with their obligation to remain honest with patients. Consequently, as mentioned in the autonomy section above,⁶⁹ even if additional obligations arise in patent licensing and other contracts related to the patent, honesty between physicians and patients is not enough to be regarded as a problem.⁷⁰

H. Regarding the Non-Industrial Medicine Theory

Because my analysis above is based on ethical theories, it is no longer appropriate to take the viewpoint of the Hippocratic Oath, which vaguely defines medicine.

As such, the opinion that the development of medical methods occurs in universities with public funds and is different from the development of medical products which are conducted in private companies for profit, and that the development of medical methods is not necessarily “industrial” because it does not involve the incentive of obtaining patent protection becomes problematic.

The problem from a biomedical ethical point of view is how to distribute the limited resources and to which area of healthcare to distribute such resources. In other words, when public funds are limited, which medical field should receive the funds? Beauchamp argues that in such circumstances, funds should be allocated to areas such as kidney dialysis,

⁶⁸ [FN 48] See [FN 29], *supra* note 44, at 1152-54.

⁶⁹ *Translator's note: See supra* Part III.F.

⁷⁰ [FN 49] See [FN 30], *supra* note 45, at Section II.C.

kidney transplantation, and heart transplantation.⁷¹ Accordingly, distributive justice and even utilitarian justice cannot be achieved without a detailed cost-benefit analysis, and the problem is clearly quite difficult.

However, this problem could be avoided if we let market principles take care of where to invest, and justice could be achieved from a libertarianism standpoint. To illustrate this point, George J. Annas, criticizing the patenting of surrogate embryo transfer (“SET”), introduces the statement made by Dr. John Buster, the team leader of SET: “But for private investor financing, he [Buster] maintains, he would not have been able to do the research that led to SET since NIH [National Institute of Health] would not fund the research, and he could not charge private patients.”⁷²

Healthcare needs have diversified according to the change in disease structure, as discussed above in Section A. Resource allocation based on market principles is considered justified in areas where governmental funds cannot be counted. Essentially, it is the same basis as having private security firms in addition to police, and having private schools in addition to public schools.⁷³ Therefore, medicine should be approved as being industrial.

IV. PLACEMENT OF ETHICAL HURDLES IN THE PATENT ACT

A. *Argument of Systematic Positioning*

As discussed above from the biomedical ethics point of view, ethical obstacles facing patent protection of medical methods are reduced to the problem of finding social justifications.

The Patent Act achieves utilitarian justice by granting a monopoly right with a limited term for inventions that would enhance technological advancement and industrial development. In other words, information on technological ideas, which at its natural state would immediately enter the public domain, is artificially made personal property by equipping it with the principle of exclusion. As a result, the information is made tradable in a free market, distributed optimally and produced maximally through the principle of free market, and thereby achieves utilitarian justice. Additionally, because such a result is achieved through the principle of free market, liberal justice is achieved as well.

⁷¹ [FN 50] See [FN 27] BEAUCHAMP & CHILDRESS, *supra* note 42, at 250-59.

⁷² [FN 51] See [FN 26], *supra* note 41, at 25.

⁷³ [FN 52] SUSUMU MORIMURA, HOW FAR COULD FREEDOM EXTEND —INTRODUCTION TO LIBERATARIANISM 114 (Kōdansha Gendai Shinsho 2001).

Accordingly, although when such bases of justification is rejected, in situations where results of technological advancement and industrial development are not achieved, or where utilitarian justice and liberal justice, as discussed above, collide with the justification based on some other principles, that the ethical issues surrounding medical methods are not limited to only these situations.

However, there are still some points left to be mentioned regarding the non-industrial medicine theory because it is possible that there may be technologies that would not result in industrial development. For example, in contrast to what I have discussed above, if medical advancement resulting from public investment actually leads to the development of the medical industry and yet it does not become socially justified, then we must reserve a backup for rejecting patent protection of medical methods by asserting that it does not fall in the category of industry.

Given this point, it seems that it is meaningful to save some room for deciding whether medicine is industry under the industrial applicability requirement theory.

If we take the special reason theory in which the special reason has no relationship with the industrial applicability requirement theory, however, then it is difficult to explain why the patent system cannot be justified. Therefore, it is more appropriate to consider the positioning of these ethical issues in the patent system under the industrial applicability requirement theory.

B. Upstream or Downstream System?

The next question is whether the system should be upstream or downstream when deciding whether patent protection should be given to medical methods under the industrial applicability requirement theory.

In an upstream system, patent protection is denied when the system determines that an invention cannot be applied industrially. In other words, the patent application would be rejected when it has been determined that the invention would not lead to industrial development or is limited in areas that do not aim for industrial development. However, it is questionable whether such decision-making is possible. Even if such a decision was made during the examination process, the system may not be able to deal with the change in the industry structure later on, and thus may omit some important technologies from protection.

In contrast, such a problem may be avoided in a downstream system. Even if a patent exists on inventions with no industrial applicability, while

the patent rights have no effect in areas of industrial development, they could have some effect in other areas.

Accordingly, it seems necessary to add new provisions in Article 69 of the Patent Act to limit the effectiveness of patent rights. However, patent rights are basically only to be “enforced as industry” (Patent Act Article 68). “Enforcement as industry” does not mean personal or domestic enforcement;⁷⁴ it should be interpreted to mean business and industrial enforcement. As such, it becomes possible to reject the protection of inventions that would involve no business and industrial enforcement of patent rights. Further, such interpretation of “enforcement as industry” would not only lead to more flexible responses to distinct cases but also would allow a more clear distinction between patent protection and non-protection in a downstream system.

C. *Importance of the Key Word “Industry”*

As discussed above, ethical issues surrounding the patent system should be viewed from the standpoint of whether the patent system could be socially justified and whether it would lead to industrial development. Therefore, the elements of “industry” are important and should be kept in mind when considering patentability requirements as well as limitations of patent rights enforcement. I believe these are the α and the ω of the Patent Act.⁷⁵

⁷⁴ [FN 53] See [FN 8], *supra* note 15, at 311.

⁷⁵ *Translator’s note:* α refers to “alpha” and ω refers to “omega.” In other words, because the elements of “industry” are the most essential part of the Japanese patent law, they should always be kept in mind when considering patentability requirements and the limitations of patent rights enforcement.