Intellectual Property Rights
and Patentability in Medicine

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and Patentability in Medicine

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Your ears shall hear a word behind you, saying, “This is the
way, walk in it,” whenever you turn to the right hand or
whenever you turn to the left.

Isaiah 30:21

Throughout my short 28-year life, I have realized that my Lord has
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Seon Kui (Erica) Lee
ABSTRACT

Although there has been many BT related researches and studies conducted, not much consideration was put on the intellectual property rights and patentability in medical industry. Nevertheless, the wide expansion and rapid advancement of medical inventions and medical industry demand more thorough review for their intellectual property rights and patentability.

Therefore, this study will first examine the concept of intellectual property and the Korean patent system briefly. Then, the current situation of the medical patent in Korea is introduced and the discussion of the medical patent in the foreign countries will be followed. Finally, the main focus of this thesis, the patentability of medical inventions such as new medicament, medical instruments, medical use and medical treatment process inventions while considering the ethical matters and social consensus issues in the medical industry. Since the patentability of the new medicament and medical instruments is already fully discussed and established in the Korean patent system, this thesis would give just a brief discussion on these two subjects.
The main discussions are that since the patents for treatment process employs the human body as its subject, they lack the industrial applicability; that the exclusion of medical practice from patent subject for the public health is desirable in terms of national economy; and that if it were rational to exclude the treatment process from the patent subjects, the issue would be how to enforce this rationally and co-purposefully.

More specifically, the provision in the Examination Guideline is unreasonable: that is, the exclusion of medical treatment due to its lack of industrial and the entry of medical use inventions as a type of material claims. There would be several alternative plans for this. First of all, the provision that ‘excludes the patent for medical treatment process which does not include the treatment process by drugs due to the ethical reason’ should be stipulated on the Korea Patent Act. Apart from this, another plan would be that the treatment process inventions should be allowed for the patent subject, but in the process of granting the patent, more thorough and specified principles or criteria should be applied: the principles on the Korea Patent Act such as novelty, non-obviousness, and industrial applicability as well as the ethical
considerations or ethical principles as discussed in the previous chapter. In order to enforce this effectively, more rational and reasonable examination of claims would be possible in granting the patents for not only the medical industry but also other industries such as BT industry, which may need the ethical consideration as well, by establishing the ethics review committee under the Korea Intellectual Property Office. In addition, the appropriate protection for the true nature of inventions should be given by allowing expressing the medical use inventions as a type of process claims, not material claims.

However, the most important thing to consider in applying or introducing this is not the government-driven policy establishment but the social consensus because the ethical consideration is necessary in granting the patents in medical industry for its unique characteristics unlike the patent in other areas or fields. In order to accomplish both public interest or goods and industrial development harmoniously, the attitude to consider more carefully is strongly required.

**Key Words:** medical invention, patent system, intellectual property right, medical practice, medical treatment method patent, and medical procedure
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CHAPTER I

INTRODUCTION

1. Background

Stepping into the 21st century, the medical industry has been remarkably developed in bioengineering, bioinformative database, medical supplies (drugs), medical instruments, and medical process. Most of all, due to the striking outcomes in the biotechnology (BT) area, the medical industry, in addition to the informatics industry, is considered as a high-tech area that can determine a nation’s competitive power in the 21st century. For example, the development of human embryonic cloning technology and its applications opened the possibility for curing the incurable diseases such as Alzheimer’s disease and Parkinson’s disease. Moreover, based on a series of biotechnology such as the completion of human genomic map, the genomic function analysis, and the gene modification technology, medicine cherished great expectation for curing the genetic diseases with high potential for manifesting such as diabetes, heart diseases, and cancers through the gene therapy. If these possibilities may become real, their economical and industrial efficiency might be fully revolutionary.
Due to such development and prospect in the area of medical industry, the domestic and international movement to solidify the intellectual property rights for the technology in medical industry has gotten into its stride. Especially, in the area of BT patents, in order to encourage the BT related researches and to preoccupy the economical advantages or benefits resulted from the predominance of level of such technologies, the grant of patents to BT inventions tends to expand around the developed countries including the United States. In addition, the bioinformative database based on the research outcomes of human genome possesses the economical value for itself as a lower rank of the medical industry, so its protection has become a significant matter recently.

However, although there has been many BT related researches and studies conducted, not much consideration was put on the intellectual property and patentability in medical industry. Nevertheless, the wide expansion and rapid advancement of medical inventions and medical industry demand more thorough review for their intellectual property rights and patentability.

Of course, the proper protection of intellectual property rights is the essential requirement for industrial development. If there is no protective
legislation for new inventions, the inventors will be in the unfavorable position and this would further result in the impediment of industrial development by discouraging the will to invent. Moreover, even completed inventions would be hidden, which may not play any role to improve the technology level in the society. Especially, since the development of medical industry carries a big significance in insuring the healthy life of the public and securing the nation’s competitive power, it fully deserves the authorization for intellectual property rights. However, the intellectual property rights in the medical industry shows the characteristics that are clearly distinguishable from the protection of other intellectual property rights recently.

First, the intellectual property rights related to the medical industry cannot be progressed without considering the ethical problems. Especially, the suggestion of bioethics in relation to animal cloning and human embryonic cloning are the most representative examples for that. The reason that the ethical issues are raised in many aspects for medical patents than for the patents in other areas is because the risk for their violation of human dignity has remarkably increased under the names of ‘care, prevention, and welfare’.
Second, the matter of intellectual property rights in the medical industry emphasizes on the social consensus more than any time. Since the medical technology has a huge influence on the entire human beings, the social consensus and social watch on the development, approval, and enforcement of technology is highly demanded.

Third, as seen recently in the radical conflicts on Glivec among multinational corporations, health authorities, and patients, the solidification of intellectual property rights has strong intention to grand the incentives for technology development that can help the human races, but conversely the concern that the development outcomes of medical technology may not be enjoyed universally and equally by giving the exclusive property rights to the universal knowledge of human races.

Last, the harmonization of intellectual property rights is another matter. Originally, the patent system is introduced to pursue the harmony between the public side such as industrial development through sharing the technology at the national level and the private side, the protection of inventor’s interest. However, the national goal such as the modern universal competition system, the unification of global-scale technologies, and the coordination of private and
public interests according to this are made more and more incompetent. As the developed countries with higher position in highly advanced technology tend to insist the universal validity of patent rights and expand the subjects for patent rights, the technologically undeveloped countries become more and more subordinate in technology and patents. As a result, the international disputes for intellectual property rights are becoming more serious than any other times.

Therefore, this study will first examine the concept of intellectual property and the Korean patent system briefly. Then, the current situation of the medical patent in Korea is introduced and the discussion of the medical patent in the foreign countries will be followed. Finally, the main focus of this thesis, the patentability of medical inventions such as new medicament, medical instruments, medical use and medical treatment process inventions while considering the ethical matters and social consensus issues in the medical industry. Since the patentability of the new medicament and medical instruments is already fully discussed and established in the Korean patent system, this thesis would give just a brief discussion on these two subjects.
2. Objectives

Based on the above background information, the objectives of this study are determined as follows.

- To review the current intellectual property rights and the patent system in Korea, especially in the Korean medical industry
- To establish clear definitions and classification of medical inventions and medical subject materials, which can be patentable in Korea
- To investigate the current situation of medical inventions and medical patents in Korea
- To examine the patentability of the medical inventions including medical process and medical product
- To make the suggestions for the new direction of medical patents in Korea.
3. Methods

In order to carry out this study, mainly two study methods for social sciences are applied.

First, the literature review was performed with academic articles on medical or BT patents, official documents from WIPO, KIPO and other foreign patent offices, and laws or agreements related to the medical patent issues.

Second, the comparative study on different patent systems regarding the intellectual property rights in other countries including the United States of America, European countries, and Japan.
CHAPTER II

BRIEF INTRODUCTION TO INTELLECTUAL PROPERTY RIGHTS AND PATENT SYSTEM IN KOREA

1. Intellectual Property

1.1 Definition

Intellectual property, often known as IP, allows people to own their creativity and innovation in the same way that they can own physical property. The owner of IP can control and be rewarded for its use, and this encourages further innovation and creativity to the benefit of us all.¹

According to the WIPO, the definition of intellectual property rights is the property rights in creations of the mind, such as inventions, industrial designs, literary and artistic works, symbols, and names and images.²

² Intellectual property rights include literary, artistic and scientific works; performances of performing artists, sound recordings, and broadcasts; inventions in all fields of human endeavor; scientific discoveries; industrial designs; trademarks, service marks, and commercial names and designations; protection against unfair competition; and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.
In some cases, IP gives rise to protection for ideas but in other areas there will have to be more elaboration of an idea before protection can arise. It will often not be possible to protect IP and gain IP rights (or IPRs) unless they have been applied for and granted, but some IP protection such as copyright arises automatically, without any registration, as soon as there is a record in some form of what has been created.

1.2 Classification

The major forms of intellectual property rights that are recognized around the world are patents, trade secrets, copyrights and trademarks. Each form of intellectual property right is designed to cover a different element of the creative process. Patents are used to protect new inventions; trade secrets recognize the value of proprietary business information; copyrights are used to protect books, records and other tangible forms of creative work from unauthorized copying and misappropriation; and trade marks protect the distinguishing words and symbols developed by firms to identify their goods and services in the eyes of consumers.3

a. Patents

A patent is a grant which is issued by the national government conferring the rights to the holder to exclude others from making, using or selling the patented subject matter exclusively during the term of the patent. While the scope of items which are eligible for patent protection will vary from country to country, a patent usually will be granted for new and useful products and for processes for the manufacture of new or existing products, as well as for methods of use of new or existing products. Some nations, such as the United States, extend patent protection to designs and plants. Any person who makes, uses or sells an invention in violation of the rights of a patent holder is said to have infringed the patent and the holder may be entitled to injunctive relief and damages.

b. Trade Secrets

A trade secret, sometimes referred to as “know-how” or “proprietary information”, is information which is utilized in the business and which affords the user a competitive advantage over others without access to the information due to the fact that the information is neither generally known, nor readily ascertainable by proper means. In order for information to qualify as a trade secret, it must be the subject of reasonable efforts to
maintain its secrecy, although trade secret status is not necessarily lost by disclosing the information to others, provided that they are under a duty to treat the information as confidential and to limit its use. Trade secrets are protected as a matter of statutory or contractual law in many countries and the owner generally has a cause of action against any person who acquires the secret by improper means or uses or discloses it in violation of a duty to limit its use or maintain its secrecy.

c. Copyrights

Copyrights protection is available to authors of original literary, dramatic, musical, artistic and other intellectual works. The owner of a copyright has the rights, for a specified period of time, to exclude other from reprinting, publishing, distributing, copying, publicly performing or publicly displaying the work and from preparing derivative works based on the copyrighted work. However, a copyright does not prevent others from using any of the knowledge set forth in the work to make, use, or sell the idea or invention since copyright protection does not extend to any idea, procedure, process, system, method or operation, concept, principle or discovery. Any violations of the exclusive rights of the copyright owner are referred to as infringement or privacy.
d. Trademarks

A trademark is a word, name, symbol or other similar means which are used by a manufacturer or merchant to identify his goods and distinguish their source from those goods which may be manufactured or sold by others. A service mark is a mark or device used to identify a service, such as transportation or insurance, offered to customers. The owner of a trademark or service mark has a right of action against those persons who use a representation or copy of the mark without authorization from the owner. Moreover, a trademark owner may prevent others from offering for sale or distribution, or from advertising, goods or services using a copy or colorable imitation of a mark which is so similar to the original mark that deception or confusion is likely to result.

e. Special Forms of Intellectual Property Rights

Certain types of technology may be eligible for protection under special laws and regulations designed to take into account some of the attributes of the subject matter that may not lend themselves to traditional forms of intellectual property rights.
1.3 International Intellectual Property Laws

Each of the various forms of intellectual property right extends only to the border of the country in which the rights has been granted. Thus, the holder of patent in one country can preclude others from using, making or selling the invention only in that country because protection in foreign countries may not be derived from that country’s patent grant. If a foreign country has an established patent act regime that covers the subject matter of the invention, the inventor may be able to apply for a patent in that country and thereby preclude other from unauthorized use or sale of the invention in that market. However, if the foreign country does not provide the appropriate patent protection, the inventor will be unable to prevent others in that country from using or selling the invention.4

In the world today, intellectual property laws are far from uniform. This inconsistency reflects the fundamental schism that exists between developed and developing countries regarding the benefits and perceived dangers of property rights in technologies and related items. An inventor in a developed country will seek strong intellectual property protection to prevent those located in developing countries from “free-riding” on his work and to establish

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additional markets through which to recover the costs of development. On the other hand, governments in many undeveloped and developing countries are reluctant to provide any strong degree of protection to foreign inventors and firms, since protection of this sort may work as a disincentive to local innovators to build their own research and marketing capabilities and, perhaps more importantly, allow foreign firms to exercise undue control over the availability and affordability of the protected items.

1.4 Values and Uses of Intellectual Property Rights

As with any form of property right, the value of a firm’s intellectual property rights will generally depend upon a number of different factors: for example, the value of a patent as a device upon a number of different factors. For example, the value of a patent as a device from excluding others from practicing a specified process or invention will depend upon the breadth of its claims. Also, the strength, and attendant value of a trademark varies with the type of mark and the perceptions regarding the product or service to which the mark is related that are created in the minds of consumers. Moreover, as with other property rights, there may be “clouds” on the firm’s title to a specific intellectual property right, particularly in those cases where the underlying invention or work was created by more than one person.
Intellectual property rights can be put to a variety of different uses. The rights can be sold or assigned to a third party in return for cash or other consideration, or can be used as a capital contribution to a new business venture which might be formed to exploit the rights. Intellectual property rights can be pledged as security for the obligations of the owner, such as patent to manufacture the products which are covered by the patent rights. Finally, and perhaps most importantly, an intellectual property right can be loaned or licensed to one or more third parties, thereby giving the third party a limited right to use the property for purposes determined by the owner of the rights.

1.5 Intellectual Property Protection Concerns in Developing Countries

Little doubt exists that developing countries are anxious to reduce what they perceive to be a critical technological gap between developed and developing countries. Even the Committee on Transfer of Technology of the United Nations Committee on Transfer and Development (UNCTAD), which has a decided bias in favor of developing countries, has urged governments to adopt measures, including intellectual property rights protection and technical cooperation, to increase technology flows to developing countries and facilitate access of those countries to technology.
Developing countries become skeptical when developed countries assert that strong intellectual property protection is the proper means to insure economic development, particularly when firms in the developed countries claim that monopoly rights in new foreign markets, such as in less developed countries (LDCs), are necessary to recover their research and development costs. On the contrary, developing countries fear that patent protection for new products and technologies will merely enable large multinational corporations to secure global monopolies, and thereby charge exorbitant prices for their goods.

Lacking the scientific financial infrastructure necessary to create patent-induced innovations, developing countries are far more interested in technology transfer than in the encouragement of domestic innovation. However, while these countries seek to maximize technology imports, they must do so with an only meager transfer payment budget. Therefore, it is not surprising that developing countries have little or no interest in creating a system that impedes their own ability to appropriate new technologies and products developed by foreign innovators.
Some of the concerns of developing countries regarding intellectual property protection can be summarized as follows.\textsuperscript{5}

a. Cultural Attitudes Regarding Private Property Rights

One fundamental problem is that many developing countries do not necessarily share the same cultural attitudes regarding the nature of private rights to own and use various types of tangible and intangible property. For example, some countries, certain forms of intellectual property are viewed as pure public goods. In fact, some cultures are genuinely hostile to any notion that knowledge is a private capital good, a premise that is fundamental to the intellectual property systems of the industrialized economies.

b. Lack of perceived Benefits to Developing Countries

Although certain developing countries have nurtured their own domestic industries, most fail to recognize any potential advantages flowing from granting greater intellectual property protection. Less prosperous countries lack the resources necessary for domestic research and development, and research findings indicate that, historically, the implementation of a new patent regime within a developing country has led to few inventions and fewer

relative benefits. Moreover, developing countries may be unable to bear the cost of lost consumer surplus that is the result of higher prices stemming from the monopolization associated with the beginning stages of intellectual property development. Finally, these countries may be unable to bear the start-up and maintenance costs associated with developing and enforcing new intellectual proper rights although initially these costs generally accrue to foreign innovators.

c. Underutilization of Inventions

A common argument made in favor of granting patent protection is its effect of spurring importation of new products and technologies. Generally, however, the patent holder need not necessarily enter foreign market in which the patent was granted. Rather, the patent may simply be used as a means of preventing others from making or selling the product in that market. As a result, the patent system, in many cases, actually leads to the underutilization of inventions in the patent-granting country.

Developing countries are not without legal remedies in these situations. For example, compulsory licensing and working requirements may be utilized to insure that patented inventions are actually used in the country, either
through licensing or direct investment or manufacturing activities. However, these rights are often viewed as ineffectual, as there may be no local firm capable of independently using the technology without additional technical assistance from the patent owner.

d. Availability of Essential Commodities

Regardless of local attitude toward private property rights, many countries believe that certain products and technologies must not be included in any intellectual property protection regime. In some countries, the markets for these essential commodities may actually be operated by the local government.

e. Autonomy

In most cases, developing countries adopted some form of intellectual property protection regime. However, much resistance exists to the establishment of a uniform global standard simply to conform to the requests of developed countries. For instance, Indian officials have often expressed a high degree of indignation at the suggestion that they pursue a course undirected by their own program of self-reliance and specific needs. Also, the level of protection for intellectual property should keep pace with economic development of the country concerned.
f. Lack Stimulus for Local-Specific Products

Because developed countries create a majority of the patentable inventions and technology, most of the patterns granted in developing countries are issued to foreigners. The largest proportion of inventions covered by patents are thus induced, not by the availability of patent protection in the developing countries, but rather by the domestic patent system of the holder or in conjunction with patent systems in other develop countries. As a result, a developing country cannot expect that implementation of a patent regime will induce foreign innovators to focus their development efforts on new products and technologies that meet the special needs of the developing nations.

g. Effect of Other Factors

Implementation of a patent system does not guarantee that foreign investment and technology transfer will increase. A variety of political, legal, cultural, social and economic factors impacts on the perceived risks of undertaking a particular inbound investment transaction and on the level of foreign investment and technology transfer. For example, a patent is of little value in a country where lack of expendable capital impedes the purchase of patented goods. Also, the ability of the patent holder to successfully
commercialize any product depends, not only on the competitive environment but also on the ability to effectively market the patented product.

h. Local Political Environment

Ultimately, the policies of developing countries must be forged in the context of the local political environment. In some cases, the interest in continued black market copying and pirating activities might overwhelm any attempts at reform. For example, although the best interests of the country as a whole may demand a stronger intellectual property protection system, certain well-entrenched interest groups, including representatives of the pirate industries, possess the necessary political clout to block the proposed changes. These groups often argue that the costs associated with implementing greater protection are too much for the small economy to bear.

1.6 Importance of Intellectual Property in Medical Industry

All countries have an important interest in providing adequate intellectual property protection as a way of encouraging more investment, research and innovation from which they should benefit. This is particularly so in medicine, where new drugs are very expensive and time consuming to research, and where the results of the research are uncertain.
The most common examples are in the areas of pharmaceuticals and chemicals. As the Director of the Philippine Bureau of Patents, Trademarks and Technology Transfer recently stated, “… developing countries have a need requiring special preferential attention on patent systems – such as on medicine – to make it affordable to the poor people…” 7 Similarly, PRC officials believe that pharmaceutical products “ are produced for the health of the people”. 8 Accordingly, copying should be permitted in order to produce them.

2. Intellectual Property System and Patent System in Korea

2.1 Historical Background

The constitutional foundation for the protection of intellectual property in Korea can be found in Article 21(2) of its Constitution, which provides that the rights of authors, inventors, and artists shall be protected by law. In accordance with this provision, Korea has enacted a number of intellectual property laws such as the Patent Act, the Utility Model Act, the Design Act, the Trademark Act, the Computer Program Protection Act, the Semiconductor

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6 See Gutterman, supra note 5.
8 China calls Special 301 Designation Unacceptable, Says Trade Will Suffer. 5 World Intellectual Property Report (BNA) 146 (June 1991)
9 See Gutterman, supra note 5.
Chip Layout Design Act, and the Copyright Act to protect the respective types of intellectual property. In addition, the Unfair Competition Prevention law in order to prevent passing-off practices with regard to intellectual property and to protect trade secrets and trade dresses.

With its industries developing rapidly over the last few decades, Korea had faced a need to modernize its system of intellectual property protection. The pressure from Korea’s major trading partners have also led Korea to meet international standard in protecting intellectual property. Thus, during the last several years, Korea has participated in the World Intellectual Property Organization, the Paris Convention and the Universal Copyright Convention and become a signatory to other international agreements. In addition, the Korean government has made an effort to provide greater protection to foreigners.
2.2 Intellectual Property Laws\textsuperscript{10}

Various types of intellectual property are protected under the relevant acts upon being registered in Korea. The requirements of registration as well as the term of registration differ under each act. Under the Patent Act, to be registrable, an invention must be a highly advanced creation of a technical idea utilizing the law of nature. However, under the Utility Model Act, an invention must be a creation of a technical idea relating to shape, structure or assembly of an article and utilizing the laws of nature.

Under the Trademark Act, signs, characters, figures or a combination thereof which are used on goods by a person who produces, manufactures, processes, certifies or sells goods in order to distinguish his goods from those of another, as well as service marks, collective marks, and emblems are protected for ten year periods. The Copyright Act protects literary, scientific, and artistic works. Computer programs are protected under the Computer Program Protection Act.

\textsuperscript{10} See Yoon, supra note 3.
The protection of an intellectual property may overlap under two or more acts. For example, a design which is protected under the Design Act may also qualify for protection under Copyright Act. In the event of such overlap, a conversion of a registration under, for example, the Patent Act into a registration under the Design Act may be allowed.

2.3 Foreign Applicants

A foreign applicant for the registration of intellectual property who has no domicile or residence in the Republic of Korea shall file an application through a representative who has a domicile or residence in the Republic of Korea. This is to facilitate communication between the applicant and the Korean Intellectual Property Office. Documents, submitted to KIPO, must be written in the Korean language.¹¹

2.4 Korea Patent System¹²

The patent right in Korea is governed by the Patent Act of Korea (hereinafter referred to as the Patent Act), the related administrative decrees adopted by the President (the Enforcement Decrees), the ordinances promulgated by the Ministry of Trade and KIPO’s administrative regulations (collectively, the “Patent Acts”). The Patent Act recognizes the right of a patentee to have an exclusive right to commercial and industrial use of the

patented invention. A patentable invention, under the Patent Act, is defined as a “highly advanced creation of technical ideas utilizing rules of nature”. Korea’s Patent Acts follow the first-to-file rule. The priority of a patented invention is determined by the filing date on which an application for patent was filed rather than the date of the invention itself.

a. Conditions for Patentability

As referred above, the Patent Act defines a patentable invention as a highly advanced creation of technical ideas utilizing rules of nature. It further provides that in order for an invention to be patentable, such invention must possess industrial applicability and must not have been obvious to a person of ordinary skill in the art. Therefore, in order to be patented under the Patent Acts, an invention must be novel, useful, and non-obvious.

The novelty requirement under the Patent Act cannot be satisfied if an invention was publicly known or worked in Korea prior to the date of the application for patent. Similarly, such requirement would not be met if an invention were described in a publication distributed in or outside Korea prior to the date of the application for patent. Judicial precedents in Korea have

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14 Chapter II, Article 29 [Requirements for Patents], Korea Patent Act.
indicated that it is sufficient to prove that the matter in question was actually known by or available to many unspecified persons in order to establish that there was public knowledge of such matter and that it was distributed. According to such precedents, actual public knowledge and actual distribution need not be proven. However, the mere existence of a publication describing the invention without proof of actual distribution may or may not serve as adequate proof of loss of novelty.

Under the Patent Acts, there are three exceptions to the novelty requirement described above. These exceptions apply when a disclosure of an invention is made unintentionally, or such disclosure results from a government-sponsored exhibition or by a scientific publication. However, an applicant claiming such exception must file the application for patent for the disclosed invention within six months of the date of disclosure. Further, the applicant must submit documents which prove that the prior disclosure constitutes one of the recognized exceptions to the novelty requirement.
b. Procedures for Obtaining and Maintaining Patent Rights

Application

In order to obtain a patent with respect to an invention, an application for patent must be first filed with KIPO. In addition to the application, a priority document must also be filed within 16 months of the priority filing date. A power of attorney must be filed within two months after the filing date, with 30-day extensions available on request. Although the provisions of the Acts do not require a submission of a nationality certificate, KIPO sometimes requests that such certificate be submitted with respect to the applicant.

Detailed Description of Invention

The specification of the invention must describe the invention in such manner as to enable to enable a person of ordinary skill to perform the invention. The patent acts do not require that the applicant reduce the invention to practice.

Under Korean Patent Acts, the scope of a patent is determined by the claims. As the practice in Korea is to interpret claims narrowly, the drafting of the claims language for an application is of primary importance for an applicant. The Enforcement Decrees specify acceptable claim format for the
purpose of Korean Patent Acts, and such specification should be carefully followed. If an application was originally filed in another jurisdiction, it is necessary that accurate and technically correct scientific translations be made for the purpose of Korean application.

Request for Examination

In Korea, patent applications are not examined automatically upon filing. A request for examination must be made separately. An applicant may request an examination at any time within five years of the filing date. If a request for examination is not made during such period, the application lapses irrevocably. In the case of converted or divided applications, the original filing date controls for the purpose of determining the request period rather than the date of the conversion or division.15

Under the patent acts, the patent applications are to be examined in the order of their request dates, and other groups designate priority by the filing date. Because of the volume of pending applications, it may take two or three years for the examination to commence with respect to an application. A request for accelerated examination may be made if the invention is being

worked in Korea by an unauthorized third party, or the KIPO determines that
the urgent examination of the application is necessary.

*KIPO Response*  
If the examiners find that an application is not satisfactory after its
examination, they will issue a notice of preliminary rejection.16 Such notice will
contain the description of any matter must respond to such notice. Usually,
the period for responding to the preliminary rejection is 2 months from the date
of notice. Each extension may be requested for a period up to 1 month and
extensions may be requested up to five separate occasions upon request of
applicant.

If the applicant does not adequately respond to the preliminary
rejection, the examiners will issue a notice of final rejection. If the response is
satisfactory, the examiners may then issue decision for grant. However, it is
possible that even if the applicant responds satisfactorily to the first preliminary
rejection, the examiners may discover another ground for rejecting the

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16 In the application process, KIPO may issue a notice of amendment requiring the
applicant to submit additional documents or satisfy certain formalities. For example,
such notices may require that the applicant submit a power of attorney or nationality
certificate. In addition, it is also possible for an applicant to amend an application
during the application process, provided that a request for such amendment is made
within the statutorily prescribed time period.
application. In such event, the examiners will issue another notice of preliminary rejection, and the applicant will need to respond to such notice.

If the final rejection is issued with respect to an application, the applicant may appeal to the KIPO’s appellate trial board within 30 days.\textsuperscript{17} If the trial board finds for the applicant, the application will be remanded to the examiners for reexamination. If the trial board upholds the rejection, the applicant may appeal to the Patent Court of Korea.

If the examiners render a decision for grant, the notice of such decision is delivered to the applicant of a designated agent of the applicant. The complete application is published after the payment of registration fee in the official gazette.

\textit{Opposition}

Once an application is published, any person may file an opposition within three months form the date of its publication.\textsuperscript{18} It is not necessary that an opposing party file complete supporting materials at the time of filing an opposition. It is sufficient that the opposing party file a mere notice of

\textsuperscript{17} At the same time of such appeal, the applicant may also file for an amendment to the application. This is the last opportunity to file for an amendment to an application. If such amendment is filed, the trial board will delay a hearing on the application until the examiners have had the opportunity to reconsider the application in light of the amendment.

\textsuperscript{18} Chapter III, Article 69 [Opposition to the Grant of a Patent], Korea Patent Act.
opposition within such a three-month period and then submit the supporting materials within 30 days from the date of such submission. Once made, the notice of opposition is delivered to the applicant, and thereafter, both the applicant and the opposition is delivered to the applicant, and both the applicant and the opposing parties are free to submit arguments and counter arguments until the examiners reach a decision.\textsuperscript{19} If the examiners dismiss the opposition, the patent will be issued. The opposing party does not have a right to appeal from the examiner’s decision of dismissal. If the opposing party wishes to continue to block the patent, it will be necessary for such party to file a separate action with KIPO to invalidate the issued parent. If the examiner upholds the opposition and issues a final rejection for an application, the applicant may appeal through the procedures discussed above.

\textit{Registration and Maintenance}

Once the patent is granted for an invention, the applicant must pay the annuities for the first three years. Such payment must be made within three months of the notice of the grant of the patent. There is a grace period six months for such payment although a penalty will be assessed for late payment. The amount of such penalty equals the amount of the original filing fee. After

\textsuperscript{19} It is possible for the applicant to amend specification and claims if the applicant believes that such changes will counter the arguments on which opposition is based.
such payment, the applicant must pay annuities starting from the fourth year from the year in which the patent is granted.

**Patent Term**

The term for patent right is generally 20 years commencing from the filing date of the patent application, following the registration of establishment of the patent right.20 However, unless the patent is registered, the patentee cannot pursue remedies to enforce its patent.

In the case of pharmaceutical or agrochemical, the patent term may be extended if it could be shown that the invention cannot be worked in Korea for more than two years due to the review process under the Pharmaceutical Affairs Act or the Agrochemicals Administration Act. Generally, an extension may be granted up to five years upon application to KIPO.

**Scope and Uses of Patent Rights**

Once the application receives the patent for his invention, he has the exclusive right to practice the patent unless such practice would necessarily utilize another person’s earlier filed patent, utility model, or design. In such

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case, the patentee must first obtain a license from the owner of the earlier filed invention, utility model or design.

The patentee’s exclusive right to practice the patent, however, does not prevent another person from using the invention solely for experimentation or research, or in vessels, aircraft or other vehicles that are merely in transit through Korea. Further, the patentee may not interfere with the making, selling, and using of any products identical to the patented product if such product already existed in Korea on the filling date of the application for the patent in question.
CHAPTER III

CURRENT SITUATION OF MEDICAL PATENT IN KOREA

1. Statistics

According to the statistics\textsuperscript{21}, a total of 231,028 applications for Industrial Property Rights (patents, utility models, trademarks and industrial designs) were filed in 1999, which was a 24.7\% increase compared with 185,209 applications filed in 1998 (Table 1).\textsuperscript{22} Especially, considering the industrial development, the increase of applications in Beverage, Medical, & Hygiene shows the comparably high from 4,875 applications in 1998 to 5,446 applications in 1999 (Table 1). As the patent applications and inventions increased in other industrial areas, especially Electrics & Telecommunication, there was also increased development and applications in the area of medical industry.

However, the ratio of registrations to applications is quite low compared to other industries. (Table 2) This may indicate either that the examination process or regulations are very strict or that the scope of patentable invention in medical industry is very small.

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<table>
<thead>
<tr>
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<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Machinery</td>
<td>8,175</td>
<td>22,007</td>
<td>26,146</td>
<td>20,606</td>
<td>11,254</td>
<td>13,532</td>
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<td>Chemicals</td>
<td>7,233</td>
<td>7,787</td>
<td>8,489</td>
<td>9,395</td>
<td>9,112</td>
<td>9,934</td>
</tr>
<tr>
<td>Fibers</td>
<td>1,417</td>
<td>1,521</td>
<td>1,409</td>
<td>1,864</td>
<td>1,637</td>
<td>1,363</td>
</tr>
<tr>
<td>Electrics &amp; Telecommunications</td>
<td>21,741</td>
<td>38,343</td>
<td>44,057</td>
<td>48,989</td>
<td>41,420</td>
<td>41,390</td>
</tr>
<tr>
<td>Civil Engineering &amp; Construction</td>
<td>838</td>
<td>1,441</td>
<td>1,651</td>
<td>1,577</td>
<td>1,507</td>
<td>2,628</td>
</tr>
<tr>
<td>Mining &amp; Metal</td>
<td>1,506</td>
<td>1,887</td>
<td>2,218</td>
<td>2,630</td>
<td>2,442</td>
<td>2,827</td>
</tr>
<tr>
<td>Beverage, Medical &amp; Hygiene</td>
<td>3,254</td>
<td>3,435</td>
<td>3,842</td>
<td>4,595</td>
<td>4,875</td>
<td>5,446</td>
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<tr>
<td>Office Supplies &amp; Printing</td>
<td>306</td>
<td>430</td>
<td>691</td>
<td>926</td>
<td>955</td>
<td>711</td>
</tr>
<tr>
<td>Agriculture, Forestry &amp; Marine</td>
<td>335</td>
<td>355</td>
<td>473</td>
<td>534</td>
<td>590</td>
<td>907</td>
</tr>
<tr>
<td>Miscellaneous Goods</td>
<td>907</td>
<td>1,293</td>
<td>1,350</td>
<td>1,618</td>
<td>1,396</td>
<td>1,904</td>
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<tr>
<td>TOTAL</td>
<td>45,712</td>
<td>78,499</td>
<td>90,326</td>
<td>92,734</td>
<td>75,188</td>
<td>80,642</td>
</tr>
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</table>
Table 2. Patents Registrations by Industries

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Machinery</td>
<td>1,546</td>
<td>1,948</td>
<td>2,644</td>
<td>4,297</td>
<td>10,868</td>
<td>12,716</td>
</tr>
<tr>
<td>Chemicals</td>
<td>1,782</td>
<td>2,014</td>
<td>3,178</td>
<td>3,508</td>
<td>7,210</td>
<td>6,977</td>
</tr>
<tr>
<td>Fibers</td>
<td>329</td>
<td>522</td>
<td>513</td>
<td>862</td>
<td>1,108</td>
<td>1,471</td>
</tr>
<tr>
<td>Electrics &amp; Telecommunications</td>
<td>6,303</td>
<td>6,104</td>
<td>7,324</td>
<td>12,031</td>
<td>26,743</td>
<td>33,117</td>
</tr>
<tr>
<td>Civil Engineering &amp; Construction</td>
<td>234</td>
<td>306</td>
<td>411</td>
<td>610</td>
<td>1,393</td>
<td>1,706</td>
</tr>
<tr>
<td>Mining &amp; Metal</td>
<td>535</td>
<td>606</td>
<td>936</td>
<td>809</td>
<td>1,222</td>
<td>1,954</td>
</tr>
<tr>
<td>Beverage, Medical &amp; Hygiene</td>
<td>599</td>
<td>554</td>
<td>900</td>
<td>1,373</td>
<td>2,669</td>
<td>2,544</td>
</tr>
<tr>
<td>Office Supplies &amp; Printing</td>
<td>110</td>
<td>137</td>
<td>142</td>
<td>322</td>
<td>501</td>
<td>725</td>
</tr>
<tr>
<td>Agriculture, Forestry &amp; Marine</td>
<td>61</td>
<td>92</td>
<td>121</td>
<td>189</td>
<td>319</td>
<td>424</td>
</tr>
<tr>
<td>Miscellaneous Goods</td>
<td>184</td>
<td>229</td>
<td>347</td>
<td>578</td>
<td>867</td>
<td>1,001</td>
</tr>
<tr>
<td>TOTAL</td>
<td>11,683</td>
<td>12,512</td>
<td>16,516</td>
<td>24,579</td>
<td>52,900</td>
<td>62,635</td>
</tr>
</tbody>
</table>
2. Medical Inventions

In a broad sense, the “Medical Invention” means an invention that requires the medicine and its use plays part in the human body either directly or indirectly.\textsuperscript{24} According to the Examination Guidelines of Medical Field, “Medicine” refers any material used to diagnose, cure, reduce, treat and prevent the diseases in humans, and the instruments, the materials not used directly, cosmetics and food supplies are excluded in medicine in terms of universally accepted social view and customs. In deciding which material is medicine, such a material is medical invention either when the invention can be clearly used as a medicine or when it cannot be distinguished, for example when considering its application state, the invention cannot be clearly distinguished medically or when it can be used as a medicine besides other uses except for medical use. When a material has a value to regardless of whether the material is new or known, the medical invention can be established.

According to the above definition and consideration, the “medical invention is classified into four main categories: new medicament invention,

medical instrument invention, medical use invention, and medical treatment method invention. (Table 3)

Table 3. Patentable/Non-Patentable Inventions in Medicine

<table>
<thead>
<tr>
<th>Subject Material</th>
<th>New Medicament Invention</th>
<th>Medical Instrument Invention</th>
<th>Medical Use Invention</th>
<th>Medical Treatment Process Invention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Substances</td>
<td>Strongly Patentable</td>
<td>Patentable</td>
<td>Patentable (if applicable)</td>
<td>Not Patentable</td>
</tr>
<tr>
<td>Medical Devices</td>
<td></td>
<td>New (2nd) Medical Use</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-Surgical</td>
<td>-Therapeutic</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-Diagnostic</td>
<td>-Gene Therapy</td>
<td></td>
</tr>
</tbody>
</table>

As shown in Table 25, the patentability is still controversial in medical use invention and medical treatment process invention. Therefore, in this study, the first two inventions will be briefly discussed and the more focus will be on the last two inventions, medical use invention and medical treatment process invention.

25 See Yoon, supra note 15.
3. New Medicament Invention

3.1 International Intellectual Property Laws

The medicament inventions can be categorized into mainly four types: new medicament invention, new manufacturing method invention, new drug form invention, and medical use invention. The new medicament invention refers to an invention which introduces a matter with a new efficacy, and the new manufacturing method invention is about the new manufacturing technology for existing medicament whose patent term is expired. In addition, the new drug form invention is considered when a new drug form was invented in order to improve its efficacy and convenience of internal use. Also, the medical use invention is accepted when the new efficacy or use of the existing medicament is found.

Especially, new medicaments made with new materials or new drug forms are called “original drug”, but this is not a formal term. It is rather called “brand name drug”.26 In this section, new medicament invention will be discussed and in the later section, medical use invention will be further introduced.

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26 Recent Developments Chemical and Biochemical Practice at the EPO: Medical and Therapeutic Treatments. http://www.ladas.com
3.2 Examination Trend of New Medicament Inventions

Recently, in terms of the examination trend of the Patent Office, it can be satisfied with only describing the new use of active compounds and requires the concrete trial data on its pharmaceutical efficacy. However, when the active compound containing composites is claimed as new medicament invention and when only its utility as a medicament is written and the definite trial data on pharmaceutical efficacy are missing, it establishment of invention is not accepted. Therefore, the fill-out or attachment of trial data or trial result on pharmaceutical efficacy as well as application methods and delivery system is a requirement for writing specifications, the effectiveness of new medicament can be approved only if the detailed description of invention was supported on its patent application.

3.3 Cases of Medicament-Related Patents Granted to the Korean University Hospitals

Although new medicament invention was mainly led by the pharmaceutical industry, many studies and research are undergoing in medical schools and hospitals these days, which indicates that this type of medical invention is not only related to the pharmaceutical industry but also to the medical industry where the actual medical procedures take place. The actual
cases of medicament-related patents granted to the university hospitals in Korea are illustrated below.\textsuperscript{27}

a. Samsung Medical Center

\textit{Antidiabetics containing anti tumor necrosis factor antibody}

This invention is related to antidiabetics, which contains anti tumor necrosis factor antibody as an efficient element. In this invention, tumor necrosis factor (TNF) is identified to be a primary factor causing diabetes and it would prevent the combining activity of tumor necrosis factor and tumor necrosis factor receptor on the cell surface through the complement combination between anti tumor necrosis factor antibody and tumor necrosis factor, which further provide the antidiabetics that can cure or prevent diabetes.

\textit{Arsenic Hexoxide}

This invention is about the use of a natural chemical, arsenic hexoxide, as a new anti-tumor therapeutics. A natural chemical separated and purified while removing the toxic material from a natural stone, arsenic hexoxide, and

\textsuperscript{27} Lee, Se Jin. The Medical Industry and Intellectual Property Rights. "Medicine and
its pharmaceutical composites show a strong anti-tumor activity with direct cell
toxicity and also have a special effect as a anti-tumor drug by inhibiting the new
production of blood vessels around tumors.

**Retrovirus Vector Applicable for Hunter Syndrome Gene Therapy**

This invention concerns on retrovirus vector that can be used for the
treatment of Hunter Syndrome. More specifically, this invention deals with
retrovirus vector which includes normal IDS (iduronate 2-sulfatase) gene that
can be used for gene therapy of Hunter Syndrome caused by gene abnormality.
Therefore, Hunter Syndrome can be effectively cured by transplanting it to the
certain site of patient in order to make physically infected the above vector into
their cells.

b. Severance Hospital

**Pharmaceutical Compound for Sex Hypersensitivity**

This invention is concerning the medical compounds for the prevention
and treatment of sex hypersensitivity. It provides the biocompounds to
prevent and treat the male patients with the lack of controlling power to
ejaculate due to hypersensitivity.
Diagnostic Reagent and Vaccine for Korean-type Hepatitis C

RNA is extracted by separating a virus particle within the blood of the Korean patients with Hepatitis C, and cDNA clone synthesized from this and its nucleotide sequences are manifested in a stem cell. By using proteins produced through the above process, it would provide the diagnostic reagent and vaccine for diagnosing Korean Type Hepatitis C.

4. Medical Instrument Invention

4.1 Introduction

Medical instruments refers to the various types of medical supplies such as therapeutic devices in internal medicine or external medicine, diagnostic devices, dental instruments, orthopedic supplies, and radiotherapy and its diagnostic instruments.

The medical instrument invention is accepted as an invention that can be industrially usable since it is an invention on goods. Originally, since the industry deals with the products, i.e. goods, the invention of goods such as medical instruments can be patented based on the fact that in terms of the invention of goods, their production itself can be industrially usable.
4.2 Relation between Medical Instrument Technology and Medical Treatment Process

Although the medical instrument inventions are patented by approving them as technology inventions, if the invention is related to the medical treatment process, which will be discussed later, it is not considered to be inventions with industrial applicability. Especially, its industrial applicability may be determined according to whether the human body is the requirement for the invention.

For example28, the manufacturing method of denture, artificial leg, cast, etc. is the method to apply such instruments to apply exactly to the injured or affected part. Therefore, since the manufacturing process such as the process to make a shape to the injured or affected part needs the human body as a required for the invention, it is not approved as an invention with industrial applicability contrary to the order of public. However, the invention without such a process does not involve the human body may be considered as a industrially usable invention.

28 See Yoon, supra note 15.
4.3 Conflicts

Since the ultimate goal of medical instrument technology, like medicaments, is the treatment of human diseases, it can be included into the treatment process in a comprehensive sense. Also, the inventors often apply for the patents by converting the medical treatment process invention or mixing with the medical instrument invention. Therefore, more detailed discussions is required to establish the boundary of medical treatment process and medical instrument.

5. Medical Use Invention

5.1 Requirement in the Examination Guideline

As shown in the Examination Guideline, if the treatment invention for humans lacks the industrial applicability, some may raise the question whether the medical use inventions are not patentable since they falls under the category of human treatment. The invention that the disease can be cured if the invention known matters is given to human naturally belongs to the human’s treatment process. Therefore, according to the Examination Guideline of the
Korea Intellectual Property Office\textsuperscript{29}, the expression of medical treatment process is not yet allowed.\textsuperscript{30}

\textbf{5.2 Arising Problems Regarding the Office’s Position}

First, the medical use invention can be either the medical treatment invention or material invention depending on the claim types. In other words, in the presentation type of claims, the success or failure of industrial applicability of specific invention can be different. The fact that although the contents of inventions are the same, they can be industrially applicable or not applicable is a ridiculous argument. The root cause of such a weird interpretation comes from that the medical treatment process is stipulated to be industrially non-applicable.

Second, even though the property of medical use invention is method invention, stating the claim as a material type unjustly expands the protection range of invention. The Article 94 of the Korea Patent Act states that “a patentee shall have the exclusive right to work a patented invention both

\textsuperscript{29} Medical Examination Guideline 3.41. Ba


The method to treat diabetes by injecting Compound (1) in the mammals cannot be patented since it is medical treatment method. However, if the presentation type of claims are changed, the medical use inventions do not belong to the treatment method. It means that its patentability can be accepted if the claim type is presented as a ‘-medicament’ or ‘mixture’. 
commercially and industrially” and also the Article 2.3 defines the term “working” by separating it into the product and process patent. To sum up, the product patent has the wider range of patent rights and is easier to receive relief for the infringement litigation than process invention.

Therefore, the problems of overprotecting the product invention whose nature is actually the process invention occurred since the Office tried to grant the patent right for the medical use invention, avoiding the Examination Guideline that clearly states the lack of industrial applicability. Thus, unlike Europe which as a clearly stated provision in the European Patent Act, the thorough review on these problems are strongly required since the Examination Guideline of the Korea Intellectual Property Office and the judicial cases of the Supreme Court establishes such a regulation although it is not clearly stated on the Act.

31 Chapter I, Article 2.3 [Definitions], Korea Patent Act. “Working” means any one of following acts:

(a) in the case of an invention of a product, acts of manufacturing, using, assigning, leasing, importing, or offering for assigning or leasing (including displaying for the purpose of assignment or lease) the product;
(b) in the case of an invention of a process, acts of using the process; and
(c) in the case of an invention, of a process of manufacturing a product, acts of using, assigning, leasing, importing, or offering for assigning or leasing the product manufactured by the process, in addition to the acts mentioned in subparagraph (b).

32 If the product claim, ‘a diabetics containing Form (1)’, and the process claim, ‘the treatment process of diabetes by administering the Form (1) Compound’ can be compared. The former can be included in the range of rights, but the latter one establishes the infringement only if the patient take the medicine to cure diabetes, i.e. only if it concerns ‘the part of use’.
6. Medical Treatment Process Inventions

6.1 Patentability of Medical Treatment Process Invention

Currently in Korea, the patentability of medical treatment process is denied considering its lack of industrial utility, but the treatment process for animals are applicable for patent after the case of Supreme Court 90 do 250. Also, medical procedure or practice is not considered as an industry.

As I mentioned above, in case of Korea, the medical treatment process such as surgical method, diagnostic method, and therapeutic method is not recognized as an invention due to its lack of industrial utility because the requirement of such an invention includes the human body itself. Thus, the industrially unusable inventions, i.e. inventions that violate the Article 29.1 of Korea Patent Act, include all kinds of medical practices directed to the humans because it cannot be approved morally due to its direct influence on the life.

6.2 Surgical, Therapeutic and Diagnostic Methods

The surgical, therapeutic or diagnostic method for the human is generally called the practice performed by medical doctors (including oriental doctor) or the person with doctor’s commission. The treatment process invention that may harm or restraint doctors’ medical practice is considered to
be not industrially applicable, but medical instruments or medicaments themselves are not included in the treatment process. In addition, the treatment process of procurement from one’s body to restore for his treatment is included in the surgical, therapeutic, and diagnostic methods of the human, such as hemodialysis.\textsuperscript{33}

On the other side, the treatment process of the extracts from the human such as blood, urine, skin and hair, or the method to collect various kinds of data through its analysis is not patentable. Nevertheless, the invention in this case should be the examination or measurement invention that can be measured right before its use to the diagnosis, not the direct diagnostic method. It means that such an invention did not utilize the human body directly as a subject. On the other hand, if the results of such a measurement method or an examination method are substantially directly connected to diagnosis, they belong to the diagnostic method not industrially applicable.

\textsuperscript{33} See Yoon, supra note 15.
CHAPTER IV
MEDICAL PATENTS IN FOREIGN COUNTRIES

1. Introduction

The term, “medical patents” are interpreted very differently around the world and the patentability of medical inventions are also diverse depending on the countries. The subjects for patent protection of foreign countries are compared in Table 4.

The patentability of each subject is very similar in terms of most of materials, but very different in methods. Currently, only the United States approves the patentability for treatment process in medicine while other countries including Europe, Japan, and Korea, still restricts the patentability of such methods.

Therefore, the main focus of the discussions in this chapter is the comparative study on the patentability of medical use invention and medical treatment invention in each foreign country.
Table 4. Comparison of Patent Protection Subjects\textsuperscript{34}

<table>
<thead>
<tr>
<th>Classification</th>
<th>Subject</th>
<th>Korea</th>
<th>US</th>
<th>EPO</th>
<th>JAPAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material</td>
<td>Gene</td>
<td>Patentable</td>
<td>Patentable</td>
<td>Patentable</td>
<td>Patentable</td>
</tr>
<tr>
<td>(Product)</td>
<td>DNA</td>
<td>Patentable only if its applicability is specifically proved</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Proteins</td>
<td>Patentable</td>
<td>Patentable</td>
<td>Patentable</td>
<td>Patentable</td>
</tr>
<tr>
<td></td>
<td>Microbes</td>
<td>Patentable</td>
<td>Patentable</td>
<td>Patentable</td>
<td>Patentable</td>
</tr>
<tr>
<td></td>
<td>Animals</td>
<td>Patentable</td>
<td>Patentable</td>
<td>Patentable, but not their varieties</td>
<td>Patentable</td>
</tr>
<tr>
<td></td>
<td>Plants</td>
<td>Only asexual reproductive varieties</td>
<td>Patentable</td>
<td>Patentable, but not their varieties</td>
<td>Patentable</td>
</tr>
<tr>
<td></td>
<td>Human Body Parts</td>
<td>Not Patentable</td>
<td>Not Patentable</td>
<td>Not Patentable</td>
<td>Not Patentable</td>
</tr>
<tr>
<td></td>
<td>Embryonic Stem Cells</td>
<td>No Patentable</td>
<td>Patentable</td>
<td>Not Patentable</td>
<td>Not Patentable</td>
</tr>
<tr>
<td>Method</td>
<td>Surgical</td>
<td>No Humans Only Animals</td>
<td>Patentable</td>
<td>Not Patentable</td>
<td>No Humans Only Animals</td>
</tr>
<tr>
<td>(Process)</td>
<td>Diagnostic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Therapeutic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. International Regulations

2.1 WTO/TRIPs

According to Article 27 of WTO/TRIPs Agreements, all kinds of inventions in the field of technology, which satisfy industrial utility, novelty, and non-obviousness, can be patented without discrimination. However, some exceptions still exist and the patenting of medical treatment process inventions depends on each member country.

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents 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. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is
necessary to protect public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.
2.2 WIPO

WIPO also proposed that the regulation on the patentability of medical inventions in their recent proposal by the Standing Committee on the Law of Patents. WIPO’s point of view on the medical patents is very much similar to the point of view of the previous international agreements including the above. WIPO emphasized the public health throughout its proposal in 2000.

Article 10 Fields of Technology

Alternative A

(i) Patent protection shall be available for inventions in all fields of technology which are new, which involve an inventive step and which are industrially usable, except for:

(ii) inventions whose use would be contrary to public order, law, or morality or injurious to public health;

(iii) plant or animal varieties or essentially biological processes for the production of plants or animals;

(iv) discoveries and materials or substances already existing in nature;
(v) methods of medical treatment for humans or animals;;
(vi) nuclear and fissionable material.
(vii) Contracting States may, on ground of public interest, national security, public health, nutrition, national development and social security, exclude from patent protection, either in respect of products processes for the manufacture of those products, certain fields of technology, by national law.

3. United States

3.1 Definition of Medical Process Patent

To avoid any potential confusion, the American Medical Association’s (AMA’s) Council on Ethical and Judicial Affairs clarified that “medical process patents” refer to those patents taken out on medical procedures and techniques.\(^{35}\) In the language of the United States Code, a patent on medical procedure is legally characterized as a patent on a medical process.\(^{36}\)

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3.2 Historical Background

The U.S. Constitution grants Congress the power to make laws to promote the Progress of Science and useful Arts by securing for limited times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries. Accordingly, beginning with the Patent Act of 1790, Congress established a system whereby, in return for full disclosure of a novel, nonobvious, and useful invention, an inventor is given broad exclusive right to the invention for a period of seventeen years from the date of patent. As a result of a provision in the General Agreement on Tariffs and Trades, effective June 1995, the period of patent protection increased to twenty years from the date that an application is first filed. Patentees may use the invention themselves or license the invention in exchange for royalties. An unauthorized person, even one without knowledge of the patent, who makes, uses or sells any patented invention, within the United States during the term of the patent infringes the patent.

Currently, under legislation passed in 1952, patents are applicable to any new or useful process, machine, manufacture or composition of matter, where “process” means “process, art or method and includes a new use of a
known process, machine, manufacture, composition of matter or material.” This definition, while not directly addressing the question of medical procedures, leaves open the possibility of the legitimacy of medical process patents.

Furthermore, in 1980 decision, the Supreme Court granted patent protection to the inventor of an artificial life form on the grounds that “man-made” bacterial plasmids qualify as a new manufacture or composition of matter.39 This broad interpretation of the statutory scope of patentable inventions40 makes it unlikely that medical procedures can be excluded from the legal definition of process without additional legislative action.41 While such a statutory exception previously has been utilized only for nuclear warfare technologies, legislation recently was proposed to prohibit patents for any invention or discover of technique, method, process for performing a surgical or medical therapy, administrating a surgical or medical therapy, or making a medical diagnosis independent of an otherwise patentable instrument or pharmaceutical.

40 The US Patent and Trademark Office established the classes and subclasses for the medical treatment such as Surgery. For more detailed information, see Appendix 1 & 2.
The Patent and Trademark Office (PTO) has approved a number of patents for pure process claims as well as the more common claims in which method is combined with some form of novel instrumentation. Throughout the 1980s, these patents tended to be granted to procedures that were used rarely or constituted extraordinary health care. The patenting of medical procedures recently has expanded; however, both in terms of volume of patents issued and the subject matter of the approved process patents. One estimate places the rate of approval of medical process patents at fifteen per week although this figure does not distinguish between pure process claims and patent claims that involve both a instrument and a method.

In addition, the trend appears to be moving toward the patenting of common and widely-used medical procedures, as evidenced by PTO’s decision to grant a patent to a stitch-free incision for cataract removal that is used by an estimated forty percent of ophthalmologist. Equally disturbing is the fact that the patentee on this procedure commenced the first infringement litigation involving a physician as codefendant; in 1994 defense costs already had reached

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42 A method for making an incision of a particular shape in surgery using an ordinary scalpel would constitute a “pure” medical method. By contrast, a method using a new type of instrument or a method using a new drug would not be a “pure” medical method. It is the “pure” medical method patents that have caused great concern in the medical community.


44 For more detailed examples, see Appendix 3.
125,000 and, if the suit is successful, up to 200 surgeons could be subject to similar prosecution.

3.3 Enforcement of Medical Process Patents

Judge William Sessions of the US district court in Burlington, Vermont, ruled against Dr Samuel Palin of Sun City, Arizona, who claimed that he had invented "no stitch" cataract surgery in 1990 by making a frown shaped cut on the patient's eyeball and had obtained a patent on the procedure. He later sued some Vermont eye surgeons who performed the operation and said that he planned to seek royalties for millions of no stitch cataract operations.

Ophthalmologists countered his claim by pointing to articles in medical journals that showed that other doctors had used slightly different techniques to remove cataracts without stitches being needed to close the incision before Dr Palin's development.


46 Although the US Patent Office has been permitted to issue medical process patents since 1952, only recently has the issue captured the attention of the medical community and policymakers in Washington.
Judge Sessions declared Dr Palin's claims invalid and forbade him to enforce any patent claim against any doctor or medical center. The defendant in the suit, Dr Jack Singer of Hanover, New Hampshire, said, "Physicians need to be able to practice medicine without the fear of a patent infringement suit hanging over their heads."\textsuperscript{47}

US doctors have begun to seek patents on medical and surgical methods and several patents are issued every week. Dr Palin's lawsuit was the first effort to collect royalties. Medical organizations, including the American Medical Association\textsuperscript{48}, have pointed out that these patents drive up the cost of health care and are unethical. About 80 countries, including Britain and France, prohibit them.

\textbf{3.4 Law Reform}

The spending bill passed by the U.S. Senate in 1995 and signed into law by President Clinton provides relief for health care practitioners from the threat of legal action for performing patented medical procedures. The law includes a provision prohibiting enforcement against physicians of all medical procedure


patents issued after the effective date of the legislation. Medical procedure patents confer ownership over medical procedures such as surgical incisions or other treatments not associated with a novel drug or instrument.

The new law would likely have prevented the enforcement of the Pallin patent, as well as other questionable patents that have been issued in recent years, including a patent for determining the gender of a fetus by reading an ultrasound and patented treatments for male impotence.

3.5 Florida’s Medical Technology Patent Activities 49

1,114 medical technology patents were issued to Florida inventors and Florida assignees between 1998 and 2000. This includes medical, surgical, instrument, dental, pharmaceutical, biotech and other biomedical utility patents. This represents 12% of Florida’s entire patent activity in these years (1,114 of 9,260). The top producing regions match the presence of Florida’s current medical schools (University of Miami, University of Southern Florida, University of Florida, and Nova Southeastern).

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According to the general statistics, 1,307 medical technology patents were issued to Florida inventors and Florida assignees between 1998 and 2000. This number appears to be stable in the short term, with 434 issued in 2000 alone. This represents 14.2% of Florida’s entire patent activity in these years (1,307 of 9,221). A breakdown of medical patents issued by year and technology classification is listed in Table 5.
Table 5. Florida Medical Patents by Year and Class

<table>
<thead>
<tr>
<th>CLASS NO.</th>
<th>CLASS</th>
<th>1998</th>
<th>1999</th>
<th>2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>800</td>
<td>Multicellular Living Organisms &amp; Unmodified Parts Thereof &amp; Related Processes</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>601</td>
<td>Surgery: Kinesitherapy</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>430</td>
<td>Radiation Imagery Chemistry: Process, Composition, or Product Thereof</td>
<td>7</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>607</td>
<td>Surgery: Light, Thermal, and Electrical Application</td>
<td>13</td>
<td>20</td>
<td>17</td>
</tr>
<tr>
<td>351</td>
<td>Optics: Eye Examining, Vision Testing &amp; Correcting</td>
<td>17</td>
<td>2</td>
<td>15</td>
</tr>
<tr>
<td>433</td>
<td>Dentistry</td>
<td>21</td>
<td>24</td>
<td>23</td>
</tr>
<tr>
<td>602</td>
<td>Surgery: Splint, Brace, or Bandage</td>
<td>26</td>
<td>22</td>
<td>28</td>
</tr>
<tr>
<td>D24</td>
<td>Medical and Laboratory Equipment</td>
<td>28</td>
<td>22</td>
<td>27</td>
</tr>
<tr>
<td>623</td>
<td>Prosthesis (i.e. Artificial Body Member), Parts Thereof, or Aids and Accessories Therefor</td>
<td>28</td>
<td>25</td>
<td>27</td>
</tr>
<tr>
<td>604</td>
<td>Surgery</td>
<td>33</td>
<td>44</td>
<td>53</td>
</tr>
<tr>
<td>514</td>
<td>Drug, Bio-Affecting and Body Treating Compositions</td>
<td>45</td>
<td>34</td>
<td>39</td>
</tr>
<tr>
<td>600</td>
<td>Surgery</td>
<td>59</td>
<td>57</td>
<td>49</td>
</tr>
<tr>
<td>424</td>
<td>Drug, Bio-Affecting and Body Treating Compositions</td>
<td>65</td>
<td>96</td>
<td>54</td>
</tr>
<tr>
<td>606</td>
<td>Surgery</td>
<td>85</td>
<td>78</td>
<td>93</td>
</tr>
</tbody>
</table>
4. Europe

4.1 Medical Process Patent

There are two ways to obtain the patent right of European countries; one is obtaining in each country and the other is being issued in several countries at the same time through the European Patent Office.\textsuperscript{50} As such, each country’s own patent act and the European Patent Act enacted by European Patent Convention coexist in Europe. As the European Patent Act has been enforced since 1997, the member countries of this European Patent Convention unified their own patent acts in substantial side. However, although the European patents can be granted by the European Patent Act, the court decisions and patent office decisions afterwards can be made independently to each other.

a. Regulation

The European Patent Convention states in Article 52 (Patentable inventions) that:

(3) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

(4) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

1. discoveries, scientific theories and mathematical methods;
2. aesthetic creations;
3. schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
4. presentations of information.

(5) The provisions of paragraph 2 shall exclude patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent application of European patent relates to such subject-matter or activities as such.

(6) Methods or treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal
body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1.

b. Historical Background

The reason that it is hard to understand the European Patent Act regarding medical inventions lies in its rejection of patentability for inventions of medical treatment. Therefore, understanding the background of this provision may help to discuss its validity and furthermore the root of our court decisions or patent office decisions can be found here as well.51

UK had not clearly excluded the treatment procedure from the subject of patent protection before the Patent Act of 1977, which was influenced by the European Patent Convention, but the court and the patent office rejected it. According to the judicial case in 1914, the patent was not granted to the method to influence on the human body since it did not belong to the traditional definition of invention, that is, ‘manner of new manufacture’.52

In Austria and Swiss, the patent for medical procedure was abated in their case law mainly based on the ethical reasons. In Belgium, France, Italia,

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and Germany, the industrial utility was the most significant obstacle and therefore this was reflected to the European Patent Act and has influenced till now.\textsuperscript{53}

In Germany, the patent office granted a few patents to the treatment process for a number of years at the beginning, but the patent was rejected due to the requirement of industrial utility later on. At that time, the Imperial Patent Office interpreted this very strictly, but in 1904, the court of appeal decided that the treatment process did not belong to the industrial invention based on the fact that only the areas acting or treating the raw materials mechanically or chemically can be industrially usable.\textsuperscript{54} This trend lasted until 1967 when the Federal Supreme Court rejected the examination of patent deciding that the invention of surgical method for fleck removal on face was not industrially usable and this decision had a definitive influence on the later European Patent Act.\textsuperscript{55} In this decision, although the ethical aspect such as public good was thoroughly reviewed, quoting the lack of industrial utility as a reason for form’s sake provided the source for disputes.

\textsuperscript{52} See Moufang, supra note 42.
\textsuperscript{53} See Moufang, supra note 42.
\textsuperscript{54} Decision of the Board of Appeal II of the Imperial Patent Office of December 30, 1904, 1905 Bl.f. PM Z 4-Badewasser.
\textsuperscript{55} Decision of the Federal Supreme Court of September 26, 1967, 48 BGHZ 313.
This German-style approach was accepted in the process of enacting the European Patent Act and the provision that the process of medical treatment is not the industrially usable invention was established. Therefore, many countries in Europe included this provision in their own patent acts, and Germany, France, and UK stipulated as described in EPC. On the other hand, Demark, Italy, and Sweden prescribed that the medical process invention was not even the invention.

c. Treatment Process

The European Patent Act regarding medical inventions and treatment process seems very complicated since countries with different cultures and traditions were gathered and had to compromise to establish the consolidated agreement.

According to Article 52 (1) of the European Patent Act, “European patent shall be granted for any inventions with are susceptible of industrial application, which are new and which involve an inventive step.” On the other hand, according to the first sentence of Article 52 (4), “Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph
1.” Thus, unlike the Korea Patent Act, the European Patent Act clearly denies the industrial utility of medical treatment process and even the treatment process for animals are not included in the subject for patent protection.

On the other hand, since the second sentence of Article 52 (4) clearly states that “this provision shall not apply to products, in particular substances or compositions, for use in any of these methods”, the new drug itself or medical instruments are surely patentable.

### 4.2 Second Medical Use Patent

The position is complicated by a provision in Article 54(5) that states that this prohibition shall not exclude patentability for any substance or composition for use in [such] a method even if previously known for some other purpose as long as that purpose was not a method of treatment or diagnosis practiced on a human or animal body. The use of compound-limited use claims and the so-called “Swiss Form” second medical use claim to provide some means of alleviating the problems caused by this wording in seeking to protect inventions relating to new medical uses of known compounds are by now well known.
However, such “Swiss Form” claims are only acceptable in the case of new uses of a medicament. Thus, in Second Surgical Use/ Codman they were not allowed for other types of medical treatment such as a new use of a known laser surgery system.\(^{56}\) The board insisted that “a surgical use of an instrument is not analogous to a therapeutic use… since the former is not consumed in the application and could be used repeatedly for the same or even other purposes as well… Medicaments, on the other hand, are expended in the process of use and have only a once for all utility. Any new use is exactly correlated with a corresponding expansion of the manufacture of the entity for the purpose.

In order to avoid the prohibition on claims to methods of medical treatment, it was necessary that if the claim contained a method step, it was essential that none of the method steps should be a method for treatment of a human or animal body by way of therapy surgery or diagnosis. In the present


The prohibitions on medical treatment claims have been narrowly construed in other cases. In the earlier case of Flow measurement/ Summers [1090] OJ EPO 171, the Appeal Board allowed a claim for a process whereby an electrically conductive liquid containing a medicament is introduced into a patient by means of a pump attached to an implanted dosing apparatus. The Board reasoned that the purpose of Article 52(4) is to ensure that a physician or veterinarian can practice his profession freely without being restricted by fears of patent infringement. Since the claim in question did not restrict the physician in selecting appropriate administration of medicaments it did not fall within the patentability bar. In this case, the claim was to a method of measuring liquid flow that was particularly applicable to determining whether drugs such as insulin were flowing freely from an implanted reservoir. The Board concluded, “The steps [claimed] even in an implanted device – represent no more than a method of measuring the efficiency of a pump fitted in the device”. Therefore, the method was patentable.
case, certain signals interpreted by the instrument controlled the output of the pacer which was applied to the human body to obtain a therapeutic effect. The fact that acts of contributory infringement would clearly be of industrial utility was felt to be irrelevant; some act of direct infringement had to be industrially applicable for patentability.

5. Japan

Japan is in the same position as Korea in granting the patent for medical treatment process. In other words, the treatment process (examination method through X-ray, early diagnosis method for cancer, etc.) is included in the medical business and practice, and this medical business or practice is not the subject for patents since there is no industrial utility in this business. However, there is no clear provision in the Japanese Law.
According to the judicial case of a court of appeal related to this, the court ruled that the invention of application method for ion toothbrush has no industrial utility since it requires the existence of human body.\textsuperscript{57} In addition, in the Examination Guideline, the manufacturing method and treatment process among the methods which essentially require the human body is considered to be the inventions without industrial utility, and the inventions that restrain the freedom of human body inhumanely on their application violate the good public order and customs. Moreover, since the inventions whose requirement is the extracts from dead body or discharges from the human body may fall under the group that would harm or violate the good public order or customs, it would require special concern and care in the aspects such as universally accepted ideas in society and human dignity or integrity.

However, the Japanese government recently decided that Japan would grant the patent for medical practice or technology including diagnostic, surgical, and treatment process from next year.\textsuperscript{58} The Japan Patent Office announced it would expand the range of subjects of medical patents, which only allowed the medical products, manufacturing method, and medical

\textsuperscript{57} Japanese Judicial Case, Court of Appeal, 1971. 12. 22
\textsuperscript{58} It took 1009 for the Japanese corporations have the English Trademark, Joonang Ilbo, May 1, 2002.
instruments or equipments. As a result, Japan would be the second country, which formally grants the medical process patents in the world beside the U.S.
CHAPTER V

PATENTABILITY OF MEDICAL INVENTIONS

1. Ethical Considerations on Medical Patents

In determining whether there is an ethical basis for the patent system, the issues that require ethical study include justice, patient and physician autonomy (self-rule) and professionalism.

1.1 Justice

There are several theories that related to distributive justice. The most prevalent is utilitarianism and the basic premise is to do the greatest good for the greater number. This is most often applied to explain the benefits of patents. Justifying patents on utilitarian grounds should be seen as a problem of allocation of resources - a policy decision, like any other.\textsuperscript{59} Many arguments that speak against patents as being utilitarian, such as inefficient allocation of resources, incurrence of substantial legal and administrative cost,

\textsuperscript{59} Packer, Packer. Ethics and Medical Patents. ARCHIVES OF OPHTHALMOLOGY. Vol. 117 (6), 1999, p. 824-826.
and adverse effect on research funding. Stavo\textsuperscript{60} believed that the patent system encouraged the blind promotion of technological innovation in general, with the mere hope that the outcome will maximize utility. He also points out that choosing in favor of the patent system, rather than other ways of encouraging research (or other, non-research allocation of resource), constitutes a choice to allocate very considerable resources to the legal system. It would be good news for lawyers, but certainly a utilitarian cost of the patent system that cannot be ignored.

A related issue to patents is licensing. Brody\textsuperscript{61} comments that licensing encourages social well-being as long as it is not too restrictive or too costly. He addresses the important concern that the government often has not benefited from research that it has paid for. Thus, laws are necessary that gave the government "march in" rights to not allow abuses and to protect the public. The question to ask is whether we want or need price controls and more government intrusion into health care.

\textsuperscript{60} Stavos, M. Biotechnology and the utilitarian argument for patents, SOC PHILOSOPHY POLICY. 1996:13:113-144.
\textsuperscript{61} Brody, B. Public goods and fair prices: balancing technological innovation with social well-being, HASTINGS CENT REP. 1998;26:5-11.
Finally, patents are not created to benefit the least advantaged (although one could argue that without patents the advances would not have been made). Also, patents do not result in any egalitarian distribution of resources. Therefore, patents have little ethical support when considering the elements of justice. One must recognize that patents may be used by big businesses to gain control of markets and to prevent small businesses from succeeding.

1.2 Autonomy

Physicians and patients may have restricted choice and decreased access to medical advances owing to patents. This may be because licensing is either too restrictive or too costly. From a utilitarian perspective, giving people what they want and the satisfaction of their desires is what morality is ultimately all about. However, more importantly, while markets may be the most efficient mechanism for ensuring that people get what they want, they may not be the most efficient mechanism for ensuring that people get what they need or what they desire. Thus, the economic merits of markets will be a moral virtue only if you rank desires above needs and merits.62

Patents fail to adhere to principles of a free market since they represent government interference. External interference, in the form of government legislation, will distort the market, and ensure that it no longer delivers goods in the most efficient manner. Closure, in the form of price-fixing cartels, will mean that the market no longer provides the best possible product at the best possible price.

This supports the government not allowing patents or at least minimizing their untoward social effects (increased price, decreased access), and at the same time preventing big business from controlling markets and having the same adverse effects. Thus, patents represent a form of reducing consumer autonomy, as does the government interference with a free market. The balancing act for a democratic government is obviously a difficult one.

1.3 Professionalism

The profession of medicine is under attack, in part for its guild-like behavior. Patenting medical procedures reduces physicians to salesmen in the eyes of the public. Remuneration through these restrictive and costly business methods cannot engender trust; it can only reduce it; also, the relationship fostered in many of the PRK networks is suspect. The commercial
relationships of physicians with corporations create ethical dilemmas for the physicians.\textsuperscript{63}

The American Medical Association Code of Ethics states: the intentional withholding of new medical knowledge, skills, and techniques from colleagues for reasons of personal gain is detrimental to the medical profession and to society and is to be condemned.\textsuperscript{64}

When physicians enter the marketplace, as they do when they provide patient care under the mantle of economic benefit owing to patent protection, society will think of them in economic terms. Pellegrino has pointed out that the patient is vulnerable and thus needs an agent who first will act in the patient's best interest.\textsuperscript{65} Thus, the physician-patient relationship may be adversely affected when care is being rendered in circumstances that have legal patent protection.

\textsuperscript{63} Packer, S. Ethics and the excimer laser, ARCH OPHTHALMOL. 1997;15:666-667.
\textsuperscript{65} Pellegrino, E, Thomasma, DC. A Philosophical Basis of Medical Practice Toward a Philosophy and Ethic of the Healing Professions. New York: Oxford University Press, 1981.
2. Patentability

An invention is considered to be patentable pursuant to the Korea Patent Act if it possesses novelty, inventive step, and industrial applicability.66

2.1 Novelty

An invention falling under any one of the following is deemed to have lost novelty.

- An invention which was publicly known or worked in the Republic of Korea prior to the filing of the patent application.

- An invention which was described in a publication or on the Internet distributed in the Republic of Korea or in a foreign country prior to the filing of the patent application.

2.2 Non-obviousness

A patent cannot be obtained in the event that the invention could easily have been made, prior to the filing of the patent application, by a person having ordinary skill in the art to which the invention pertains.
2.3 Industrial applicability

Even if it is a highly advanced invention utilizing rules of nature, a patent may not be granted if it lacks industrial applicability. The "industry" referred here is to be interpreted in its broadest sense (as is the case with the Paris Convention) and industrial applicability means that the invention has the potential to be industrially worked repeatedly.

3. Discussion

3.1 Incentive for Innovation

Although patents provide for individual benefit to inventors, either economically or in terms of recognition and respect for their discoveries, it may be argued that this is not the primary purpose of the patent system. Rather, patent policy is predicated on securing the invention for public benefit by offering a reward as an incentive to innovate and disclose; individual reward by itself is a secondary concern.

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66 See Chun, supra note 11.
Not all procedures or method require extensive research and development; however, some do. These procedures or method may never be made available to the public without the possibility of patent protection. Furthermore, complex medical procedures or methods are developed in an academic world in which government funding is often insufficient and the distinction between for-profit and non-profit academic research is becoming blurred.68 Private companies may be unwilling to provide capital for research and development if they cannot expect to see an economic return on their investment.69 Therefore, patenting by offering broad exclusive rights may provide precisely that incentive. In addition, once a method is patented and licensed by an academic institution, it is possible that the royalty fees can be used to support the hospital and its investigators in further research.

The additional argument for the patenting of medical procedures or methods is that the alternative to patenting for innovative physicians who wish to protect their interests is non-disclosure.70 With patenting, the physician is guaranteed some kind of reward for making the procedure or method public knowledge. Without such a guarantee, those physicians who wish to protect

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68 Eisenberg, R. Patenting the Human Genome, 39 EMORY LAW JOURNAL 720:1990.  
their discoveries may keep them secret, thereby hindering the dissemination of knowledge. While uncommon in the medical community, such non-disclosure has occurred and continues in more subtle form today.

Although patents can provide economic benefits to inventors, the medical field over the years has established its own internal system of rewards, including recognition and respect for discoveries through the publication of findings in respected medical journals and other media. This type of appeal to non-financial incentives does not entirely address the issue of incentive for innovation because the internal recognition and respect do not necessarily generate the money to enable the creation of new procedure or methods in the first place. The patent system provides incentive for inventors as well as individuals physician-inventors.

Unlike the development of medicament inventions or medical instrument inventions, the development of medical procedures or methods usually relies on intellectual curiosity and creativity rather than the availability of capital for research and development. Especially, in the case of pure medical treatment process patent, the inventions tend to be novel mental step rather than the creation of a new physical entity.
3.2 Regulation versus Prohibition

As mentioned above, the basis on which to draw a distinction between appropriate and inappropriate patents can be found in the fundamental tenet of the patent system that a patented invention be both “novel” and “non-obvious.” While the novelty condition is too broad to discourage the patenting of procedures or methods such as cataract incision, the requirement that the patented invention be non-obviousness may be significantly more useful. For a procedure or a method to qualify as non-obvious, it must represent a substantial advance over the state of the prior art, one that neither could have been easily deduced from the background of medical knowledge at the time of the generation of the procedure. It seems reasonable to assert generally that non-obvious procedures would be the ones that require additional incentives and economic investment.

Nevertheless, the option of regulation is not tenable. As evidenced by the recent debate over the patenting of medical procedures or methods, there is a significant gap between a strict interpretation of the terms “novel” and “non-obvious”, and the way that these terms currently are applied in assessing patent

applications.\textsuperscript{72} In the United States, as in the case of biotechnology generally, the Patent and Trademark Office (PTO) has applied the statutory rules to broadly, resulting in unduly expansive patenting decisions.\textsuperscript{73} Often PTO relies on subsequent litigation challenging the validity of issued patents to weed out those patents that are not truly novel and non-obvious. Therefore, the patenting of common medical procedures or methods undermines the essential distinction between appropriate and inappropriate medical treatment process patents.


\textsuperscript{73} U.S. Patent No. 5,267,570 (approved Dec. 7, 1993).
CHAPTER VI

CONCLUSION

As reviewed in this thesis, most countries do not accept the patentability of medial treatment process except for new medicament invention, medical device invention, and medical use invention (treatment process using drugs) among medical inventions or limit their effectiveness. Therefore, it seems that there still remain three issues related to this.

The first issue of all is that since the patents for treatment process employs the human body as its subject, they lack the industrial applicability. In most of medical inventions, it is inevitable to take the human body as a subject in terms of the characteristics of medical industry. In this kind of situation, I believe that it is better to review from other points of views rather than to consider the lack of industrial applicability in medical inventions since their subjects are the human bodies.

Secondly, the problem that the exclusion of medical practice from patent subject for the public health is desirable in terms of national economy
still remains. The protection of inventions in the area of public health is required to stimulate the technological, commercial, and social development and to provide incentives of research and development, which would eventually lead to the improvement of public health. Thus, it is hard to justify the denial of patentability of medical treatment process. In other words, the decrease in medical development due to the absence of incentives for medical research and development may rather harm the national health. However, there is the problem that the medical treatment process needs the authority from the patentees at each time of its uses here. Also, as long as there is a clear evidence that the restriction of medical treatment process patents would bring the shrinkage of investment and research in the medical industry, it would be more reasonable to exclude this from the patent subjects due to the public goods or public interest.

Last, if it were rational to exclude the treatment process from the patent subjects, the issue would be how to enforce this rationally and co-purposefully. This irrationality would be found in the following reasons; that both the treatment process by drug and general treatment process were excluded from the patent subject not by distinguishing them and that the reason for such exclusion was drawn, as mentioned above, from the lack of industrial applicability.
More specifically, the provisions in the Examination Guideline is unreasonable: that is, the exclusion of medical treatment due to its lack of industrial applicability and the entry of medical use inventions as a type of material claims.

There would be several alternative plans for this. First of all, the provision that ‘excludes the patent for medical treatment process which does not include the treatment process by drugs due to the ethical reason’ should be stipulated on the Korea Patent Act; moreover, I suggest that the phrase in the Examination Guideline, ‘the medical practice has no industrial applicability’, should be deleted.74

Apart from this, another plan would be that the treatment process inventions should be allowed for the patent subject, but in the process of granting the patent, more thorough and specified principles or criteria should be applied: the principles on the Korea Patent Act such as novelty, non-obviousness, and industrial applicability as well as the ethical considerations or ethical principles as discussed in the previous chapter. In order to enforce this effectively, more rational and reasonable examination of claims would be

74 See Yoon, supra note 15.
possible in granting the patents for not only the medical industry but also other industries such as BT industry, which may need the ethical consideration as well, by establishing the ethics review committee under the Korea Intellectual Property Office.

In addition, the appropriate protection for the true nature of inventions should be given by allowing expressing the medical use inventions as a type of process claims, not material claims.

However, the most important thing to consider in applying or introducing this is not the government-driven policy establishment but the social consensus because the ethical consideration is necessary in granting the patents in medical industry for its unique characteristics unlike the patent in other areas or fields. In order to accomplish both public interest or goods and industrial development harmoniously, the attitude to consider more carefully is strongly required.
APPENDIX 1.

MEDICAL TECHNOLOGIES PATENT CLASSIFICATIONS

The following United States Patent Trademark Office (USPTO) standard classifications were selected to represent medical technology patents. Selected technologies include medical instrument, biotech, pharmaceutical, dental, surgical, research and other health science applicability patents. Only major classifications were used (subclassifications were not considered).

<table>
<thead>
<tr>
<th>CLASS</th>
<th>MAJOR CLASS TITLE/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>128</td>
<td>SURGERY</td>
</tr>
<tr>
<td>351</td>
<td>OPTICS: EYE EXAMINING, VISION TESTING AND CORRECTING</td>
</tr>
<tr>
<td>424</td>
<td>DRUG, BIO-AFFECTING AND BODY TREATING COMPOSITIONS</td>
</tr>
<tr>
<td>430</td>
<td>RADIATION IMAGERY CHEMISTRY: PROCESS, COMPOSITION, OR PRODUCT THEREOF</td>
</tr>
<tr>
<td>433</td>
<td>DENTISTRY</td>
</tr>
</tbody>
</table>
514 DRUG, BIO-AFFECTING AND BODY TREATING COMPOSITIONS

600 SURGERY

601 SURGERY: KINESITHERAPY

602 SURGERY: SPLINT, BRACE, OR BANDAGE

604 SURGERY

606 SURGERY

607 SURGERY: LIGHT, THERMAL, AND ELECTRICAL APPLICATION

623 PROSTHESIS (I.E., ARTIFICIAL BODY MEMBERS), PARTS THEREOF, OR AIDS AND ACCESSORIES THEREFOR

800 MULTICELLULAR LIVING ORGANISMS AND UNMODIFIED PARTS THEREOF AND RELATED PROCESSES

930 PEPTIDE OR PROTEIN SEQUENCE

D24 MEDICAL AND LABORATORY EQUIPMENT
APPENDIX 2.

SUBCLASSES OF SURGERY (CLASS 606)

19. MEANS FOR INTRODUCING OR REMOVING MATERIAL FROM BODY FOR THERAPEUTIC PURPOSES (E.G., MEDICATING, IRRIGATING, ASPIRATING, ETC.):

This subclass is indented under the class definition. Subject matter including means for conducting body treating material into or out of a body or to or from the external membrane tissue surface of a body to treat said body.

(1) Note. It is to be noted that many devices will include conduits for conducting the material into or out of the body, however, some devices may be merely placed over a body opening to place material in or receive material from the body. An example of the latter form would be nose douches, wherein no tube extends into the nasal passages, but where material may be flushed into the nares and the discharge therefrom received in the device.

SEE OR SEARCH THIS CLASS, SUBCLASS:

27+, for devices and methods for material introduction into and removal from the body through passages in the device.

48+, for introduction into or removal from within the body of therapeutic material.

93.01+, for devices for material introduction into or removal from within the body by means of a conduit, holder, or implanted reservoir inserted into the body.
289+, for devices and methods for material application and/or removal from external surface of body.

500+, for methods for material introduction into or removal from within the body.

890.1+, which provides for a device or system comprising a reservoir and control, pump, or controllable valve means for dispensing a drug to a living body which device is implanted in the body.

19. METHOD:

This subclass is indented under subclass 27. Subject matter including processes wherein the body treating material enters and leaves the body through a channel or channels in a device inserted in a body.

(1) Note. To be classifiable in this subclass, a patent must claim the process of both injection and withdrawal of fluent material.
APPENDIX 3.
EXAMPLES OF U.S. PATENTS
IN MEDICAL TREATMENT\textsuperscript{75}

1. NO. 6,329,352 Method and Composition for Treating Sleep Apnea
(Meyer et al.)

\textit{Summary of the Invention}

The relation between snoring and sleep apnea is associated but not necessarily causative. Therefore, therapies focusing on reduction in snoring may not decrease by as significant an extent episodes of hypopnea and apnea. Snoring per se, while bothersome to the sleeper and annoying to companions, is not necessarily pathological or seriously harmful. It is therefore an object of the present invention to develop a therapy for sleep apnea and hypopnea leading to significant reduction in such episodes, whether or not there is a concomitant reduction in snoring. Another object is to provide a convenient method and apparatus of using the therapy which is not invasive or distracting, or which produces serious discomfort. A still further object is to provide an

\textsuperscript{75} United States Patents, US Patent & Trademark Office, \url{http://www.uspto.gov}
effective therapy for alleviating sleep hypopnea and apnea episodes in a single pre-sleep treatment without disturbing the sleeper during a normal 7-9 hour period of rest.

In accordance with the present invention, a pulmonary alveolar surfactant preparation in a physiologically compatible liquid vehicle is applied to the posterior pharyngeal region of a patient in a pharmacologically effective dose prior to a period of sleep. Such pharmacologically effective dose may range from 0.25 to 2.75 mg, generally administered in 0.75 to 1.25 ml, a volume sufficient to coat the affected region without excessive draining to the throat. The method further provides for such application of a surfactant substance containing phospholipid-containing ingredients capable of lowering the surface tension of water to about 15-50 nM*sup.-1. The surfactant preparation of the present method may optionally include apoproteins selected from SP-A, SP-B, SP-C, and SP-D in a pharmacologically effective dose, and further optionally, neutral lipids. A pharmacologically effective dose of the apoproteins will be a level from 10 ug to 150 ug, but functionally in a range to achieve anchoring of the phospholipid moieties contained in the surfactant to the pharyngeal tissue. The phospholipids are typically selected from saturated phosphatidylcholine, unsaturated phosphatidylcholine, phosphatidylglycerol, dipalmitoylphosphatidylcholine, and combinations.
In the apparatus of the present invention, the liquid containing the above ingredients is placed in a dispensing vessel capable of propelling a liquid in an aerosol, having a reservoir portion for holding the liquid, a nozzle means portion capable of being aligned to direct the aerosol towards the posterior pharyngeal region of a subject throat, and a label affixed to the reservoir potion of the vessel giving directions for use. The nozzle or delivery means may be a conventional inhaler tip or a pressurized flow valve aperture.

2. No. 6,329,354 Methods for the Treatment of Osteoporosis
(McOsker)

Summary of the Invention

The present invention provides methods of treatment for osteoporosis in a human or other animal subject, comprising: administering a bone-active phosphonate to said subject, at a level of at least about 0.1 LED per day of said treatment; and administering an estrogen hormone to said subject at a level of from about 0.2 to about 0.8 LED per day of said treatment. The bone-active phosphonate is preferably a bisphosphonate, or a phosphonoalkyl phosphonate.
**Description of the Invention**

The methods of the present invention comprise the administration of bone-active phosphonates and estrogen hormones to a human or other animal subject. Specific compounds and compositions to be used in these processes must, accordingly, be pharmaceutically-acceptable. As used herein, such a "pharmaceutically-acceptable" component is one that is suitable for use with humans and/or animals without undue adverse side effects (such as toxicity, irritation, and allergic response) commensurate with a reasonable benefit/risk ratio. Further, as used herein, the term "safe and effective amount" refers to the quantity of a component which is sufficient to yield a desired therapeutic response without undue adverse side effects (such as toxicity, irritation, or allergic response) commensurate with a reasonable benefit/risk ratio when used in the manner of this invention. The specific "safe and effective amount" will, obviously, vary with such factors as the particular condition being treated, the physical condition of the patient, the duration of the treatment, the nature of concurrent therapy (if any), and the specific formulations employed.
3. No. 6,344,190 Method and Compositions for the Treatment of Fungal Nail Disease (Nair et al.)

Claims

We claim:

1. A method for inhibiting dermatophytes in an infected nail in humans which comprises; multiple separate applications to the nail of an effective amount of the ingredients camphor, menthol, eucalyptus oil, and thymol in a topical carrier, which is a solvent for the ingredients, is absorbed by the nail and skin, and is not a grease or jelly, until the dermatophytes are inhibited, wherein the dermatophytes, which are inhibited by the composition, are Acremonium chrysogenum, A. strictum, Aspergillus flavus, A. terreus, Candida albicans, C. krusei, C. parapsilosis, Epidermophyton floccosum, Fulsarium oxysporum, F. proliferatum, Microsporum canis, Scopulariopsis brevicaulis, Scytalidium dimidiatum, S. hyalinum, Trichophyton mentagrophytes, and T. rubrum.

2. The method of claim 1 wherein the composition contains each of the ingredients in an amount between 0.01 and 25% by weight of the composition.

3. The method of claim 1 wherein the eucalyptus oil is from Eucalyptus citriodora.

4. The method of claim 1 wherein the composition contains 4.8% camphor, 2.6% menthol, 1.2% eucalyptus oil by weight and an amount between 0.01 to
25% by weight of thymol which is effective against the dermatophytes.

5. The method of claim 1 wherein the solvent is an ester of an alcohol.

6. The method of claim 1 wherein the solvent is isoamyl acetate.

7. A method for inhibiting dermatophytes in an infected nail in humans which comprises multiple separate applications of the ingredients camphor, menthol, eucalyptus oil, and thymol in a topical carrier to the nail until the dermatophytes are inhibited, wherein the composition has a minimum inhibitory concentration (MIC_{sub.100}) of at least 750 \mu g/ml of the composition in the topical carrier against Acremonium chrysogenum, A. strictum, Aspergillus flavus, A. terreus, Candida albicans, C. kruseii, C. parapsilosis, Epidermophyton floccosum, Fulsarium oxysporum, F. proliferatum, Microsporum canis, Scopulariopsis brevicaulis, Scytalidium dimidiatum, S. hyalinum, Trichophyton mentagrophytes, and T. rubrum.

Summary of the Invention

The present invention relates to a method for inhibiting a dermatophyte in an infected nail in humans which comprises: multiple separate applications of an effective amount of a composition which consists of an active ingredient selected from the group consisting of camphor, menthol, eucalyptus oil, thymol and mixtures thereof as active ingredients in a topical carrier to the nail until the dermatophyte is inhibited.
Further the present invention relates to a composition for treating a nail infection caused by a dermatophyte which consists essentially of: (a) an effective amount of an active ingredient selected from the group consisting of camphor, menthol, eucalyptus oil, thymol and mixtures thereof; and (b) a topical carrier, wherein the active ingredient is present in an amount between about 0.01 and 25% by weight of the composition.

Further still, the present invention relates to a kit for the treatment of a nail infection caused by a dermatophyte which comprises: (a) a closed openable container containing a composition which consists essentially of an effective amount of an active ingredient selected from the group consisting of camphor, menthol, eucalyptus oil, thymol and mixtures thereof in a topical carrier; and (b) application means for applying the composition on and under the nail which is infected with the dermatophyte. The compositions can contain between 0.01 and 25% by weight of each of the ingredients based upon the weight of the composition. In a mixture of the four (4) ingredients the amount would be 100%. Preferably the amount is between about 1 and 10% by weight of each of the ingredients based upon the weight of the composition.
Summary of the Invention

The present invention relates, first, to the discovery, identification, and characterization of novel nucleic acid molecules that are associated with central nervous system-related disorders and processes, e.g., human neuropsychiatric disorders, such as schizophrenia, attention deficit disorder, schizoaffective disorder, dysthymic disorder, major depressive disorder, and bipolar affective disorder (BAD) including severe bipolar affective (mood) disorder (BP-I), bipolar affective (mood) disorder with hypomania and major depression (BP-II). The invention further relates to the discovery, identification, and characterization of proteins encoded by such nucleic acid molecules, or by degenerate, e.g., allelic or homologous, variants thereof. The invention further relates to the discovery, identification, and characterization of novel nucleic acid molecules that are associated with human myopia or nearsightedness, such as early-onset, autosomal dominant myopia, as well as to the discovery, identification, and characterization of proteins encoded by such nucleic acid molecules or by degenerate variants thereof.
The invention also encompasses the expression products of the nucleic acid molecules listed above; i.e., peptides, proteins, glycoproteins and/or polypeptides that are encoded by the above HKNG1 nucleic acid molecules.

Transgenic non-human animals of the invention include animals engineered to express an HKNG1 transgene at higher or lower levels than normal, wild-type animals. The transgenic animals of the invention also include animals engineered to express a mutant variant or polymorphism of an HKNG1 transgene which is associated with HKNG1-mediated disorder, for example an HKNG1-mediated neuropsychiatric disorders, such as BAD and schizophrenia, or, alternatively, a myopia disorder such as early-onset autosomal dominant myopia. The transgenic animals of the invention further include the progeny of such genetically engineered animals.

The invention further relates to methods for the treatment of HKNG1-mediated disorders in a subject, such as HKNG1-mediated neuropsychiatric disorders and HKNG1-mediated myopia disorders, wherein such methods comprise administering a compound which modulates the expression of a HKNG1 gene and/or the synthesis or activity of a HKNG1 gene product so symptoms of the disorder are ameliorated.

The invention further relates to methods for the treatment of HKNG1-mediated disorders in a subject, such as HKNG1-mediated neuropsychiatric disorders and HKNG1-mediated myopia disorders, resulting from HKNG1
gene mutations or aberrant levels of HKNG1 expression or activity, wherein such methods comprise supplying the subject with a nucleic acid molecule encoding an unimpaired HKNG1 gene product such that an unimpaired HKNG1 gene product is expressed and symptoms of the disorder are ameliorated.

The invention further relates to methods for the treatment of HKNG1-mediated disorders in a subject, such as HKNG1-mediated neuropsychiatric disorders and HKNG1-mediated myopia disorders, resulting from HKNG1 gene mutations or from aberrant levels of expression or activity, wherein such methods comprise supplying the subject with a cell comprising a nucleic acid molecule that encodes an unimpaired HKNG1 gene product such that the cell expresses the unimpaired HKNG1 gene product and symptoms of the disorder are ameliorated.

The invention also encompasses pharmaceutical formulations and methods for treating HKNG1-mediated disorders, including neuropsychiatric disorders, such as BAD and schizophrenia, and myopia disorders, such as early-onset autosomal dominant myopia, involving HKNG1 gene.

In one embodiment, such methods comprise contacting a compound to a cell that expresses a HKNG1 gene, measuring the level of HKNG1 gene expression, gene product expression or gene product activity, and comparing this level to the level of HKNG1 gene expression, gene product expression or
gene product activity produced by the cell in the absence of the compound, such that if the level obtained in the presence of the compound differs from that obtained in its absence, a compound that modulates the expression of the HKNG1 gene and/or the synthesis or activity of the HKNG1 gene products has been identified.

In yet another embodiment, such methods comprise administering a compound to a host, such as a transgenic animal, that expresses an HKNG1 transgene or a mutant HKNG1 transgene associated with an HKNG1-mediated disorder such as a neuropsychiatric disorder (e.g., BAD or schizophrenia), or to an animal, e.g., a knock-out animal, that does not express HKNG1, and measuring the level of HKNG1 gene expression, gene product expression, gene product activity, or symptoms of an HKNG1-mediated disorder such as an HKNG1-mediated neuropsychiatric disorder (e.g., BAD or schizophrenia). The measured level is compared to the level obtained in a host that is not exposed to the compound, such that if the level obtained when the host is exposed to the compound differs from that obtained in a host not exposed to the compound, a compound modulates the expression of the mammalian HKNG1 gene and/or the synthesis or activity of the mammalian HKNG1 gene products, and/or the symptoms of an HKNG1-mediated disorder such as a neuropsychiatric disorder (e.g., BAD or schizophrenia), has been identified.
The present invention still further relates to pharmacogenomic and pharmacogenetic methods for selecting an effective drug to administer to an individual having a HKNG1-mediated disorder. Such methods are based on the detection of genetic polymorphisms in the HKNG1 gene or variations in HKNG1 gene expression due to, e.g., altered methylation, differential splicing, or post-translational modification of the HKNG1 gene product which can affect the safety and efficacy of a therapeutic agent.

5. No. 6,315,720 Methods for Delivering a Drug to a Patient while Avoiding the Occurrence of an Adverse Side Effect Known or Suspected of Being Caused by the Drug (Williams et al.)

Summary of the Invention

The present invention is directed to improved methods for delivering a drug to a patient in need of the drug, while avoiding the occurrence of an adverse side effect known or suspected of being caused by the drug, of the type in which prescriptions for the drug are filled only after a computer readable storage medium has been consulted to assure that the prescriber is registered in the medium and qualified to prescribe the drug, that the pharmacy is registered in the medium and qualified to fill the prescription for the drug, and the patient is registered in the medium and approved to receive the drug. In one
embodiment of the invention, there are provided improved methods comprising the steps of:

a. defining a plurality of patient risk groups based upon a predefined set of risk parameters for the drug;

b. defining a set of information to be obtained from the patient, which information is probative of the risk that such adverse side effect is likely to occur if the drug is taken by the patient;

c. in response to the information set, assigning the patient to at least one of the risk groups; and

d. entering the risk group assignment in the medium before the patient is approved to receive the drug.

The improved methods described herein provide advantageous and effective means for monitoring, controlling and authorizing the distribution to patients of drugs known or suspected of causing adverse side effects. The methods of the present invention include a variety of checks and balances which serve to limit unauthorized and possibly inappropriate distribution of the drug. These methods are particularly applicable to distribution of teratogenic drugs, in which case the checks and balances may be particularly advantageous for preventing distribution of the drug to patients whose use of the drug may pose an unacceptable risk that a foetus carried by the patient or a recipient of the bodily fluids of the patient will be exposed to such drugs. Accordingly, the
present methods may be advantageously used to avoid exposure of foetuses to teratogenic drugs, thereby avoiding the terrible birth defects which may result from such exposure.

The invention is not limited to the distribution of teratogenic drugs; other potentially hazardous drugs may also be distributed in accordance with embodiments of this invention and such drugs may be distributed in such a fashion that persons for whom such drugs are contraindicated will not receive them. These and other aspects of the invention will become more apparent from the present description and claims.
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*It took 1009 for the Japanese corporations have the English Trademark*, Joonang Ilbo, May 1, 2002.


Medical Examination Guideline 3.41. Ba


*Recent Developments Chemical and Biochemical Practice at the EPO: Medical and Therapeutic Treatments*. http://www.ladas.com


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