Summary of the Report "What Kind of Patent Protection Should There Be for Medical Practices (Conclusion)" and Our Proposals for the Future*

Biotechnology Committee

(Abstract)

We reviewed the deliberation process at the Task Force on Patent Protection for Medical Practices under the Intellectual Property Strategy Headquarters, and discussed specific problems to be solved for future intellectual property systems and a desirable direction of solution, based on the Report titled "What Kind of Patent Protection Should There Be for Medical Practices (Conclusion)," which was developed and disclosed by the task force. Having considered whether or not patent protection should be afforded for advanced methods of using medical devices and medicinal substances, the task force concluded that a "*method of operating a medical device*" as a whole should be regarded as a patentable subject matter and a "*method of bringing about new efficacy or effects of medicinal substances for the purpose of manufacturing and selling the substances*" should be protected by a patent for an *invention of a product*, while excluding a method of using medicinal substances from the scope of patentable *inventions of methods*. The task force stressed the necessity of revising the Examination Guidelines so as to expand the scope of patent protection as widely as possible, taking one step forward which was still insufficient to solve all problems in this field. In the future, it is hoped that improvements will be made to the patent system in accordance with the conclusion of the task force's report, aiming to afford sufficient protection for technologies relating to *methods* in this field without causing an adverse effect on medical services.

(Contents)

1. Introduction

The Task Force on Patent Protection for Medical Practices under the Intellectual Property Strategy Headquarters (hereinafter referred to as the "Task Force") developed and published the Report entitled "What Kind of Patent Protection Should There Be for Medical Practices (Conclusion)" (hereinafter referred to as the "Conclusion")[1]. The Conclusion was the outcome of efforts for more than one year, through eleven sessions, since the Task Force was established in July 2003 and was called for the first meeting in October (See Table 1). The medical field is not only important for Japan's recent policy for development of advanced technology but also has a considerable impact on people's lives. We, those engaging in intellectual property affairs in the biotechnology field, strongly feel the necessity and responsibility to fully understand the Conclusion that the Task Force had drawn through deliberate discussion, and reflect it in the future intellectual property systems of Japan.

This report reviews the deliberation process and examines specific problems to be solved for future intellectual property systems and a

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desirable direction of solution based on the Conclusion.

The committee members prepared this report by hearing the sessions of the Task Force and making reference to the agenda, materials, and minutes available on the Task Force website[2].

Table 1 Deliberation Process of the Task Force on Patent Protection for Medical Practices

Session		Issues and conclusion
1st	Oct. 31, 2003	Discussed patent protection in the medical field
2nd	Dec. 5, 2003	
3rd	Dec. 18, 2003	
4th	Feb. 5, 2004	
5th	Mar. 17, 2004	
6th	May 20, 2004	Excluded *medical methods* from patent protection Decided to discuss the patentabilty of *methods of using medical devices and medicinal substances*
7th	June 3, 2004	Discussed patent protection for *methods of using a medical device and medicinal substances* Discussed the impact and concern of the expansion of the scope of patent protection
8th	June 30, 2004	
9th	Sept. 9, 2004	
10th	Oct. 13, 2004	
	Oct. 20, 2004	(Invited comments from the public for 16 days)
11th	Nov. 22, 2004	Prepared the Conclusion

Table 2 Scope of Patent Protection in Japan, the United States, and Europe

	Surgical methods Therapeutic methods Others	Diagnostic methods			Medicinal substances Medical devices
		Inspection methods to directly obtain the result of diagnosis	Methods to only obtain the interim result of diagnosis	Methods of examining tissues taken from the human body	
	Therapeutic methods Surgical methods Gene therapy methods Regenerative therapy methods Cardiac stimulation methods Radiotherapy methods Dialysis treatment methods Medication methods Drug delivery systems Contraception methods Childbirth methods	Gene diagnosis Endoscopy	MNR inspection X-ray inspection Blood pressure measuring methods	Blood sampling methods	Medicinal substances per se Methods of manufacturing medicinal substances Medical devices per se Methods of manufacturing medical devices Methods of controlling medical devices Methods of manufacturing biologic products (e.g. cultured skin)
Japan	×	×	×	○	○
Europe	×	×	○	○	○
US	○	○	○	○	○

○: Patentable; ×: Non-patentable

2. Deliberation Process and Summary of Conclusion

2.1 What Kind of Patent Protection Should There Be for Medical Practices

The Task Force was established to discuss the issues addressed in the "Strategic Program for the Creation, Protection and Exploitation of Intellectual Property" (hereinafter referred to as the "Strategic Program"), Chapter 2-3(1) "Researching the desirable way of providing patent protection of medical practices," based on the decision entitled "Establishment of Task Forces Concerning Important Policy Issues under the Strategic Program for the Creation, Protection and Exploitation of Intellectual Property" made by the Intellectual Property Strategy Headquarters. Prior to the establishment of the Task Force, the Intellectual Property Strategy Task Force of the Council for Science and Technology Policy (hereinafter referred to as the "IP Policy Task Force") recommended, in its "Interim Report on Intellectual Property Strategy"[3], that patenting of advanced medical technologies should be encouraged and improvements should be made to the patent system to this end, which indicates that there was a strong request for a solution to this issue as a background factor for the establishment of the Task Force. Furthermore, in the initial discussion at the Task Force, the results of the deliberations at the Medical Practice Working Group, Patent System Subcommittee, Intellectual Property Strategy Committee, Industrial Structure Council (hereinafter referred to as the "Medical Practice Working Group") were taken into account with regard to patent protection for medical technologies mainly relating to regenerative medicine and gene therapy[4),5)].

The Strategic Program stated as follows. "While giving sufficient consideration so as not to cause an adverse impact on medical practices that should be equally performed under trustful relationships between patients and medical practitioners, the GOJ will set up a forum for extensively discussing the treatment of medical practices under the Patent Law, from the viewpoint of driving the progress of useful and safe medical technologies that will contribute to raising the level of citizens' health care, such as enabling patients to receive more advanced medical treatment. The GOJ will draw a conclusion early in FY 2004." The Task Force discussed whether or not to include medical methods, which were fundamental technologies for medical services, in the scope of patent protection. While some members advocated that patent protection for medical methods was indispensable for promoting further development and commercialization of advanced medical technologies, providing incentives for medical practitioners and medical researchers, or supporting efforts of related businesses in commercialization, other members argued that it was unacceptable from the perspective of preserving medical ethics or ensuring safety in medical services. Thus, the Task Force saw a major conflict in terms of the necessity of patent protection and flexibility in medical services. The Task Force also discussed issues regarding health economics as well as a comparison with the United States, the leading country in patent protection in this field (See Table 2), but did not reach a consensus. Consequently, at the sixth session, the Task Force decided to exclude medical practices that should be performed exclusively by medical practitioners (hereinafter referred to as "exclusive medical practices" in order to distinguish them from medical practices involving people other than medical practitioners)[4] from the scope of patent protection, and focused the discussion on whether or not to afford patent protection for *methods of using medical devices and medicinal substances*.

2.2 Patent Protection for "Methods of Operating Medical Devices"

According to the policy mentioned above, the Task Force discussed patent protection, dividing issues into those relating to medical devices and those relating to medicinal substances, and focusing on *methods of operating medical devices* and *methods of bringing about new efficacy or effects of medicinal substances for the purpose of manufacturing and selling the substances* in the respective categories.

With respect to a method of using a medical device, the Task Force saw a continued consensus that patent protection should be afforded for the structure and functions that were provided in the medical device for the purpose of controlling the operation of the device in itself, rather than how medical practitioners used the

device in the course of performing medical practices. The question was whether or not it was possible to clearly separate, in terms of patentability, acts of controlling the operation of the medical device from exclusive medical practices. The Task Force members supported the proposal that patent protection should be afforded for a *method of operating a medical device*, limiting the object of protection to the part of the method that was performed just before the medical practitioner applied the device to the patient and therefore dependent only on the devise itself. However, there was concern that the impact of regarding the whole part of a *method of operating a medical device* as a patentable subject matter was still uncertain. For this reason, another proposal was presented that the scope of patent protection should be limited, as in Europe, to part of a diagnosis method or method to obtain the interim result for diagnosis (see Table 2). Upon the invitation of comments from the public, the third proposal was also presented (see Table 3). Twenty-four comments were submitted from associations and individuals, most of which supported Proposal 1.

Through the deliberation process reviewed above, the Task Force drew a conclusion that the whole part of a *method of operating a medical device* should be regarded as a patentable subject matter, excluding technologies involved in acts performed by medical practitioners from the method.

2.3 Patent Protection for "Methods of Bringing about New Efficacy or Effects of Medicinal Substances for the Purpose of Manufacturing and Selling the Substances"

In recent pharmaceutical R&D projects, new inventions have been made by using several medical agents simultaneously or making an innovative change to the dose or dosing interval, and the amount of investments in such projects has been increasing. Under such circumstances, at the Task Force, patent protection was sought for technologies relating to *methods of using medicinal substances*, whereas deliberate and multilateral consideration was also required regarding the impact of and concern for the expansion of the scope of patent protection. Various other issues were discussed, such as the impact on exclusive medical practices or trustful relationships between patients and medical practitioners, medical safety, medical costs, technology monopoly, and influence on generic drugs. The Task Force finally reached a consensus that exclusive medical practices involved in methods of using medicinal substances should be excluded from the scope of patent protection, and focused on the difference between dosing methods employed as *methods of using medicinal substances*, and prescription and dosing instructions given in the course of performing exclusive medical practices.

A majority in the Task Force advocated the following proposal. "*Methods of using medicinal substances* to be separated from exclusive medical practices and afforded patent protection, should be limited to *methods of bringing about new efficacy or effects of medicinal substances for the purpose of manufacturing and selling the substances*, which must be characteristic in the combination of medicinal substances or the dose or dosing interval." However, this proposal could not eliminate the concern of a minority, who argued that this proposal failed to clearly separate methods of using medicinal substances from exclusive medical practices, so the scope of patent protection should be limited to inventions of *products* at the present stage. For this reason, Proposal 3 (see Table 3) was also presented to invite comments from the public.

Most of the 24 comments submitted by associations and individuals supported Proposal 1, which also gained support from a majority in the Task Force. However, at the 11th session, the Task Force drew the following conclusion, while giving consideration to the strong concern about the impact on medical services. "It should be aimed to the greatest possible extent to explore the possibility of protecting technologies relating to *methods of bringing about new efficacy or effects of medicinal substances for the purpose of manufacturing and selling the substances* by *product patents*, by making reference to cases in other technical fields and existing patents granted for medicinal substances and giving consideration to the effect of right, and clearly provide such treatment in the Examination Guidelines."

The Task Force also stated as follows. "Even in this case, inventions of products differ

from inventions of methods in terms of the scope of the subject matter and the effect of the patent, and it is impossible to fully protect technologies relating to medical practices only as *inventions of products*; therefore, the authorities concerned should continue efforts to explore the possibility of protecting such technologies as *invention of methods* in accordance with the purport of individual inventions." The Task Force also recognized the necessity to "take various specific measures…so as to make assurance to avoid an adverse effect on medical services" and "continue deliberate consideration…, assuming that an unpredictable impact or concern might occur."

Table 3 Proposals presented to the public for comments

Method of operating a medical device		Method of bringing about new efficacy or effects of medicinal substances for the purpose of manufacturing and selling the substances by product patents	
Proposal 1	A *method of operating a medical device*, which relates to the functions and system of the device, should be regarded as a patentable subject matter.	Proposal 1	A *method of bringing about new efficacy or effects of medicinal substances for the purpose of manufacturing and selling the substances by patents for inventions of products*, which is characteristic in the combination of medicinal substances or the dose or dosing interval, should be regarded as a patentable subject matter.*
Proposal 2	It is a hasty attempt to expand the scope of protection beyond the scope in Europe; patent protection should be afforded only for part of an inspection method (among three phases that comprise a diagnostic method, i.e. (1) data collection, (2) comparison, and (3) choice of medical practices, the part of the method in (1) and (2)).	Proposal 2	Whatever expressions we may use to describe a medical method, it is difficult to separate it from acts performed by the medical practitioner; therefore, technology relating to such a method should be protected as an *invention of a product*.
Proposal 3	Consideration is still needed in respect of an adverse impact of the expansion of the scope of patent protection on medical services.	Proposal 3	Consideration is still needed in respect of an adverse impact of the expansion of the scope of patent protection on medical services.

* Footnotes are omitted.

3. Examination

There are two major issues in the deliberation at the Task Force. One issue is whether or not there are any medical practices that should be regarded as patentable subject matters but not yet fully protected as such, and the other issue is whether or not it is possible to separate such practices, in terms of patentability, from those exclusively performed by medical practitioners. More specifically, the first issue focuses on the view that a medical device and medicinal substances per se are regarded as a patentable subject matter and treated as an *invention of a product* but a method of using them is not regarded as a patentable subject matter, pointing out inadequacy in patent protection for inventions relating to medical devices and medicinal substances. The second issue focuses on whether or not it is possible, in the case where a method of using a medical device or medicinal substances is regarded as a patentable subject matter, to separate a method of using a medical device and medicinal substances from exclusive medical practices or separate patentable technologies from medical practices.

Under the existing patent system, an invention of technology relating to a medical device or medicinal substances used for medical practices is patentable by *product* claims and it is not patentable by *method* claims. This treatment is based on the provisions of the Examination Guidelines that methods of treating the human body by surgery or therapy and diagnostic methods practiced on the human body are not considered as industrially applicable (Examination Guidelines for Patent and Utility Model[6], Part II, Chapter 1), and in accordance with the provision of the Patent Law that an industrially inapplicable invention shall not be patented (the

principal sentence of Section 29(1) of the Patent Law[7]). In other words, the authorities seem to consider that medical methods are not industrial and therefore inventions of technologies relating to medical methods cannot be regarded as patentable. However, it has become obvious that some medical technologies can be described only by method claims and they may be needed industrially aside from exclusive medical practices. Such technologies closely relate to recent advanced medical practices, e.g. regenerative therapy, gene therapy, advanced use of medical devices and medicinal substances. The Task Force recognized the necessity to review the patent system, with the aim of protecting these medical practice-related technologies appropriately. As mentioned above, the IP Policy Task Force and the Medical Practice Working Group pointed out inadequacy in patent protection for inventions of medical practices-related technologies[3),5)]. Furthermore, problems arising from the patenting of use inventions relating to advanced methods of using pharmaceutical products (problems of modified agent claims) were also closely analyzed in research projects of the Institute of Intellectual Property, leading to the conclusion that acceptability of method claims should be considered in this field[8)].

The Task Force, in light of the difficulty in separating inventions relating to advanced medical methods from exclusive medical practices, initially considered including all medical practices in the scope of patent protection without restrictions, and then treating exclusive medical practices as non-patentable subject matters. As a result of the consideration, the Task Force concluded that the impact of the patenting of medical methods on medical services was not yet fully examined and concern about possible problems could not be completely eliminated, so ruled out the idea of including all medical methods in the scope of patent protection.

Following this policy, from the seventh session, the Task Force focused on patent protection for advanced methods of using medical devices and medicinal substances. Although a debate took place again regarding the impact of the patenting of medical methods on medical services, the Task Force arrived at a conclusion that the safety measures under the patent system functioned properly, and examined the necessity to protect medical methods not only by *product* patents, as under the existing patent system, but also by *method* patents. Through the comparison among Japan, the United States, and Europe in terms of the existing scope of patent protection, the Task Force, from the perspective of industrial competitiveness, also confirmed the necessity to afford patent protection for medical methods to the level available in the Untied States. Having reviewed all these issues, the Task Force went back to the initial issue and discussed whether it was possible to separate patentable medical practices from exclusive medical practices.

With respect to a method of using a medical device, the Task Force concluded that the act of applying a medical device to the human body (the patient) was deemed to be included in exclusive medical practices whereas other acts performed before the application of the device to the human body in order to operate the device were excluded, and therefore patent protection should be afforded for a *method of operating a medical device*. This conclusion was based on the idea that the operation of a medical device that would take place to fulfill its intended purposes was a matter of the device itself and it could be separated from exclusive medical practices. According to this conclusion, for instance, an existing mechanical device would be protected by patent if it were able to provide innovative and advanced medical techniques through arrangements in its operational method. Thus, the path appeared to have been opened for affording patent protection for a *method of operating a medical device*. The Task Force's conclusion in this respect is consistent with the view expressed in the comments submitted by the committee[9)] and other entities. It is hoped that specific measures in this direction will be taken in the future.

Compared with a *method of using a medical device*, a *method of using medicinal substances* seems to be more difficult to separate from exclusive medical practices. The Task Force closely examined the necessity to afford patent protection for technologies that were not protected by *product* patents under the existing patent system. In particular, opinions were divided as to the current patent protection for inventions relating to (1) the simultaneous use of several medical agents and (2) the dose or dosing interval, which were raised as typical tech-

nologies needing patent protection; some members pointed out that inventions mentioned in (1) had already regarded as patentable inventions of *products*. However, some inventions in which existing pharmaceutical products are used can be characterized by the dosing schedule (temporal factor) or the combination with other pharmaceutical products that are usually not supplied at the same time (geographical or spatial factor). These two factors that form the gist of inventions are not *products* and therefore not protected by *product* patents. The Task Force clearly recognized that the solution to this problem was a challenge in affording patent protection for a *method of using medicinal substances*. Based on this recognition, the Task Force considered including *methods of bringing about new efficacy or effects of medicinal substances for the purpose of manufacturing and selling the substances* in the scope of patent protection. A majority in the Task Force supported patent protection for methods for using medicinal substances, whereas there was also a minority view that such methods should be protected only by *product* patents. The Task Force concluded that technologies relating to *methods of bringing about new efficacy or effects of medicinal substances for the purpose of manufacturing and selling the substances* should be protected by *product* patents, and further efforts should be made to explore the possibility of expanding the scope of patent protection to the greatest possible extent. Thus, the Task Force shelved the idea of recognizing *methods of using medicinal substances* per se as patentable subject matters and led to a conclusion that was different from the comments submitted by the committee[9]. However, it was confirmed that sufficient discussion would be needed toward protecting technologies relating to *methods* by *product patents*, so we should also fully examine this point.

As mentioned above, the Task Force discussed (1) the *simultaneous use of several medical agents* and (2) the *dose or dosing interval* as typical examples of *methods of using medicinal substances*. Currently, technologies relating to (1) may be deemed to be protected by patents for *compounds*. However, *compounds* do not involve a time factor or geographical factor[10]. In the future, we should discuss (1) and (2) together in considering the possibility of protecting methods of using medicinal substances by *product* patents, because the *simultaneous use of several medical agents* can be regarded as an invention not only for the mere combination of several agents but also for the choice of the dose or dosing interval for the medical agents to be combined together. In this respect, (1) and (2) involve problems that should be solved at the same time. Since technologies relating to *methods of using medicinal substances* involve temporal factors and geographical factors, the problems cannot be solved merely by improving the stability of patent protection for *compounds*, which have been patented based on *product* claims, so more specific discussion is desired. This is also important for determining novelty and inventive step, because it is often the case that where a patent is sought for a method of using a pharmaceutical product, the *method of use* is novel but the *product* is publicly known.

One reason that the Task Force discussed patent protection for *methods of using medical devices and medicinal substances* is inadequacy in protection by *product* patents under the existing patent system. Patents that have already established based on *product* claims do not fully reflect the gist of the patented inventions[8] and they lack legal stability. In future discussion on institutional improvement, patent protection that will contribute to the development of industry, which is the principal purpose of the patent system (Section 1 of the Patent Law[7]), will be desired. To achieve this, we should design a patent system while taking into consideration the phase of exercising a patent right, and consider a system in which patentability will be determined by giving due consideration to the technical matters of *methods* and granting legally stable *product* patents.

The point that was controversial throughout the discussion in the Task Force was the impact of the patenting on medical services. On this point, the Task Force examined various issues individually, and drew the Conclusion detailed above, holding that problems would not occur with respect to these individual issues but consideration should be given to unexpected circumstances because the filed of medicine would directly affect people's health. The necessity of sufficient consideration to medical services gained unanimous support in the Task Force and also mentioned in our comments[9]. In the Conclusion, taking this point into account,

the Task Force recommended that measures should be taken to make assurance and deliberate consideration should be continued in future discussion on institutional improvement. Specific measures are also desired on this point as suggested in many comments from the public.

4. Committee's Conclusion

With respect to *methods of operating medical devices*, the Task Force's conclusion that the whole part of the method should be regarded as a patentable subject matter, has opened the path for affording patent protection for inventions of methods described by *method* claims, which had been a pending issue until then. On the other hand, with respect to *methods of bringing about new efficacy or effects of medicinal substances for the purpose of manufacturing and selling the substances*, the Task Force only concluded that they should be protected as patentable subject matters and this treatment should be clearly provided in the Examination Guidelines, leaving various problems unsolved that would occur due to the unavailability of *method* claims, which had been criticized until then. We cannot deny that this is a regrettable outcome from the perspective of the development of medical industries, progress in the application of advanced technologies to medical purposes in the life science field, and advancement of international competitiveness in these fields. However, considering that the field of medicine directly affects public welfare, the Task Force's Conclusion could be evaluated as one step forward toward solving longstanding problems, by exploring the possibility of protecting technologies relating to *methods of bringing about new efficacy or effects of medicinal substances for the purpose of manufacturing and selling the substances* by *product* patents. As recommended in the Conclusion, it is hoped in the future that discussion will be held to revise the Examination Guidelines so as to expand the scope of patent protection as widely as possible and improvements will be made to the patent system while giving consideration to taking measures to increase the consistency and transparency in the implementation of the Examination Guidelines or clearly stipulate the scope of protection.

Notes:

1) Task Force on Patent Protection for Medical Practices, Intellectual Property Strategy Headquarters, *What Kind of Patent Protection Should There Be for Medical Practices (Conclusion)* (Cabinet Secretariat, 2004): http://www.kantei.go.jp/jp/singi/titeki2/tyousakai/iryou/torimatome.pdf
2) For agenda, materials, and minutes of the first to eleventh sessions of the Task Force on Patent Protection for Medical Practices, see the Task Force page on the Cabinet Secretariat website: http://www.kantei.go.jp/jp/singi/titeki2/tyousakai/iryou
3) Intellectual Property Strategy Task Force, Council for Science and Technology Policy, *Interim Report on Intellectual Property Strategy* (Cabinet Office, 2002): http://www8.cao.go.jp/cstp/output/iken 020619_2.pdf
4) For agenda, materials, and minutes of the first to forth sessions, see the website of the Medical Practice Working Group, Patent System Subcommittee, Intellectual Property Strategy Committee, Industrial Structure Council: http://www.jpo.go.jp/shiryou/toushin/shingikai/strategy_wg_menu.htm
5) Medical Practice Working Group, Patent System Subcommittee, Intellectual Property Strategy Committee, Industrial Structure Council, *Treatment of Medical Practice-Related Inventions under the Patent Law* (Ministry of Economy, Trade and Industry, 2003): http://www.jpo.go.jp/shiryou/toushin/toushintou/pdf /iryou_report.pdf
6) Examination Guidelines for Patent and Utility Model (Japan Patent Office, 2004): http://www.jpo.go.jp/shiryou/kijun/kijun2/tukujitu_kijun.htm
7) Patent Law (2004; including the part put into force on June 4, 2004): http://www.houko.com/00/01/ S34/121. htm
8) Institute of Intellectual Property, *Study on the Examination and Implementation of Use Inventions in Major Countries, V. Problems and Solutions Relating to Use-Related Inventions in Each Technical Field, A. Problem in the Pharmaceutical Field (I)* (responsible authors: Hitoshi Inaba and Ikuko Okubo) (Institute of Intellectual Property, 2004), 105-127
9) Chairman Yasuo Sakuta of the Institute of Intellectual Property, "Draft Report What Kind of Patent Protection Should There Be for Medical Practices (Conclusion)," *Chizaikanri* Vol. 54, No. 13 (2004), 2007-2009
10) Hitoshi Inaba, *Study on Combination in Major Countries* (2004; unpublished)

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