November 4, 2004

To: Secretariat of Intellectual Property Strategy Headquarters,
Cabinet Secretariat

Regarding the Report "Concerning Protection of Patents of Medical-Related Acts (Summary)(Draft)" *

We would like to express our opinions on the above report (draft) of the "Task Force on the Protection of Patents of Medical-Related Acts" published on October 20, 2004.

1. Concerning the Protection of Patents of a "Method for Controlling the Operation of a Medical Device"

We think of the following opinions discussed by the Task Force as being indispensable: "careful consideration is necessary in making technology relating to doctor's acts into a patentable subject matter, in consideration of the characteristics of medical care" and "sufficient attention should be paid to the adverse effect on patients who get medical care."

A "method for controlling the operation of a medical device" here refers not to "technology relating to doctor's acts," i.e. how a doctor operates the medical device for treatment according to individual patients' symptoms or how the device acts on human bodies, but to the performance and functions of the "medical device" itself, i.e. how the medical device itself operates functionally and systematically to achieve certain aims such as acting on human bodies and collecting data from human bodies.

Technology for "medical device" has recently made rapid progress due to the advance of nanotechnology, medical measurement technology and high-precision processing technology, as well as fusion and synergy effect with electronics, IT (software) technology and others, making great contributions to improve the medical level. In addition, technologies for generating magnetism, electromagnetic wave and proton linear, detecting data or displaying and analyzing images following the diachronic steps of a "medical device" and technologies for real-time operation based on biological signals have their features of the "method for controlling the operation of a medical device," which is distinct from "technology relating to doctor's acts."

Considering "medical device" development environment in Japan, it is necessary to take measures to give good incentive to promote further development of high-function, high-performance medical devices. Hereby, we are possible to contribute to the health and public welfare of not only Japanese citizens but also people around the world with such devices through early detection of diseases and treatment of incurable diseases.

On the other hand, from the viewpoint of globalization of patent protection, adequate protection is granted to "methods for controlling the operation of a medical device" in the United States and granted to "methods for controlling the operation of a medical device" at the "data collection phase" and at the "comparison phase" in Europe.

Therefore, JIPA requests that "methods for controlling the operation of a medical device," i.e. how a medical device operates functionally and systematically, be made a subject of protection (Plan 1), or like Europe, "methods for controlling the operation of a medical device" at the "data collection stage" and "comparison stage" be made a subject of protection (Plan 2).

Incidentally, according to the Japan Patent Office Examination Guidelines for the "Industrially Applicable Inventions" revised in August 2003, an operating method of a medical device does not fall under "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body" (falls under the subject of protection). Specifically, Example 10 "method for giving electric stimulus by pacemaker" does not fall under the subject of patent but Example 11 "method for controlling pacemaker" falls under the subject of protection. Example 12 "method for

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controlling x-ray CT scanner" does not fall under the subject of protection but Example 13 "method for image processing by x-ray CT scanner" does.

For effective acquisition of patents for "methods for controlling the operation of a medical device," we request the review of the JPO Examination Guidelines (introduction of abundant specific examples) in addition to the revisions of the Patent Law when considering (Plan 1) or (Plan 2).

2. Concerning the Protection of Patents of "Methods for Eliciting New Efficacy and Effect of Medicines for Manufacture and Sale"

JIPA and the Task Force have the following common view: close collaboration between medical world and industrial world is necessary to conduct research on "methods for advanced use of medicines" which is subject to this consideration and to put the results of the research into practical use, and the fosterage of various industries supporting medical care is important as well. Considering research in this field requires a large amount of money and human resources, appropriately protect research results and actively promote technological development and efforts for practical application are indispensable. On the other hand, beyond discussion, it is essential from the viewpoint of a nation's health and welfare to provide medical care without any problems. Balance between these above to be the greatest challenge in this consideration.

At present, in terms of medical care, those which belong to the category of "product," for example, substances, medicines (drugs) and dosage forms (formulations), are deemed to be the subject of patent protection. On the other hand, in recent years, it has become possible to bring out unexpected, significant and excellent effects in medicine research through new methods for sufficiently eliciting effects inherent in medicines. In addition, such research has been making it possible to provide medical care in areas without any effective medicines acquired. Such inventions based on new methods of using medicines contain more than a few technologies that can be protected just by obtaining patents in the category of process. In the past, there seems to have been some attempt to aquire patents for such technologies in the category of "product." However, the scope of protection by such patents is far from nature of inventions, and such protection is considered insufficient to be an incentive for medical researchers and the industrial world.

Due to the above viewpoints, we sincerely hope that patents will be granted for medical-related acts in the category of "process." However, another challenge, the avoidance of medical problems, is an issue that needs to be solved at the same time, and it seems necessary to deserve some consideration. Exemption from responsibility for doctor's medical acts and other agenda remain before the Task Force, we also request the Task Force to consider this point based on more specialized considerations in the future.

According to the above, we hope that, out of the plans proposed in the public comment of this time, Plan 1 be chosen.

3. Summary

As mentioned above, appropriate patent protection and support for industrial progress are essential trends in the globalization of intellectual property. Due to such a background, to establish a system that is sufficient enough to protect intellectual property rights for "methods for controlling the operation of a medical device" and "methods for eliciting new efficacy and effect of medicines for manufacture and sale," in the same way as in other fields is critically important. On the other hand, it is no less important that the particularity of medical technology is the issue to which exhaustive consideration should be given from the viewpoint of a nation's health and welfare.

JIPA believes that compatibility between the protection of intellectual property rights and the particularity of medical technology is necessary in terms of this issue. With the aim of technical advance and industrial progress through appropriate use and improvement of various intellectual property-related systems, we hope for system improvements so as to promote appropriate patent protection with attention paid to prevent problems in doctor's medical acts.

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