Secretariat of Intellectual Property Strategy Headquarters, Cabinet Secretariat

## Opinion on Formulation of Intellectual Property Strategy by Sector

Dear Sir/Madam,

On behalf of the Japan Intellectual Property Association (JIPA), I would like to express my great admiration for the activities thus far carried out by the Secretariat and the Intellectual Property Strategy Headquarters. At the same time, we ask for your continued effort and guidance from the viewpoint of strengthening the international competitiveness of the Japanese industry.

In response to your solicitation of opinions on "formulation of intellectual property strategy by sector," we hereby state the JIPA's opinion on this topic. We ask that you discuss and examine our opinion at the Expert Committee for Strengthening Competitiveness Based on Intellectual Property and other relevant meetings.

The JIPA intends to actively support discussions and examinations at the Expert Committee for Strengthening Competitiveness Based on Intellectual Property and other relevant meetings. Therefore, we would very much appreciate it if you could provide us with opportunities for elaboration and exchange of opinions in a timely manner.

Yours sincerely,

Taisuke Kato, President Japan Intellectual Property Association

Views of the JIPA:

(1) Life science

1. As a measure to promote R&D incentives in the biotechnology field, we request that the conventional narrow interpretation of "the working of patented inventions for experimental or research purposes against which patent rights shall not be effective" based on academic

theory be reviewed, and that a basic interpretation of "experiment or research" that fits actual circumstances surrounding R&D be presented. In addition, we request that case examples of the modes of working against which a patent right shall not be effective be compiled as guidelines.

In November 2004, the Working Group on Patent Strategic Plan Related Issues established under the Patent System Subcommittee of the Intellectual Property Policy Committee, Industrial Structure Council, compiled a report entitled "Issues Related to Smooth Use of Patented Inventions." The report indicated that "there is no sufficient accumulation of court decisions regarding how 'experiments or research' should generally be interpreted," and explained that "a conventionally prevalent academic theory distinguishes the scope of the exempted 'experiments or research' as to its subjects and purpose, and states that subjects should be limited to patent inventions per se and the purpose should be limited to acts intended for "technological progress" (patentability searches, function searches, and experiments aimed at improvement/development)."

However, the academic theory in question was proposed prior to the development of such technology as genetic engineering, and does not quite fit actual current conditions surrounding R&D. For example, in the case of R&D on a protein antibody for the development of a therapeutic agent for a new disease, it is necessary to produce the actual antibody. In order to do so, the protein must be produced first by using genes, and then the antibody is produced using said protein. According to the above-mentioned academic theory, such R&D would satisfy the subject and purpose of "research or experiment" with regard to a patented invention relating to "antibodies" (improvement and development of antibodies), but it is not necessarily clear whether it corresponds to said purpose with regard to patented inventions related to "genes" or "proteins." In addition, there is no system in place for facilitating such use of patented inventions. This current situation is hindering R&D in the biotechnology field, particularly the type of R&D mentioned above, which focuses on industrial application, and is making the continuance of R&D unstable due to uncertainty regarding the accessibility to licenses.

Therefore, as a measure to promote R&D incentives in the biotechnology field, we request that the conventional narrow interpretation of "the working of patented inventions for experimental or research purposes against which patent rights shall not be effective" based on academic theory be reviewed, and a basic interpretation of "experiments or research" that fits the actual circumstances surrounding R&D be presented. In addition, we request that case examples of the modes of working against which patent rights shall not be effective be compiled as guidelines.

2. We request that extensive patent protection be extended to cutting-edge technological inventions in the biotechnology field.

In November 2004, the Expert Committee on Patent Protection for Medical Acts established in the Intellectual Property Strategy Headquarters compiled a report entitled "Patent Protection for Medical Acts (Summary)." The report stated that "opinions have been voiced indicating the need for examination in future of how the patent system should respond to ongoing technological progress, particularly given the remarkable technological breakthroughs observed in the fields of gene therapy and regenerative medicine in recent years." The Intellectual Property Strategic Program 2007 also advocates "paying attention to patent protection in the medical field" as a target, but the situation pertaining to subsequent follow-ups is unknown. Since the fields of gene therapy and regenerative medicine are technical fields in which Japan excels, we request that concrete efforts be made.

Many inventions in the fields of gene therapy and regenerative medicine are essentially characterized by their methods. R&D pertaining to new methods of use of known substances is also increasing in the fields of pharmaceuticals, quasi-drugs, health food and cosmetics. Under the current system, such R&D results must be filed as "product" inventions. However, it is often difficult to express inventions that are essentially characterized by their methods as "product" inventions, resulting in insufficient patent protection.

We request that extensive patent protection be extended to cutting-edge technological inventions in the biotechnology field by allowing for the filing of inventions that are essentially characterized by their methods as "method (process)" inventions, which is the mode that can most appropriately express these inventions, or by interpreting use inventions not only as "product" inventions, but also as inventions that contain "method-like elements."

At the same time, it is important to take "measures to prevent adverse effects on medical practice resultant from patent protection," as pointed out by the document "Patent Protection for Medical Acts (Summary)" mentioned above. Therefore, we request that legal measures be taken so as to exempt medical acts by doctors from liability.

## (2) Information and communications

## 1. We request that measures against patent trolling be examined upon formulating an intellectual property strategy for the information and communications field.

Patent trolling, as observed in the United States, has been a long-standing social issue, and cases wherein Japanese companies are being sued in the United States have been on the increase. The distinctive aspect of patent trolling is that, while patent trollers own patents for elements of technology used in semiconductor chips or software, they attack manufacturers or dealers of end products, at which stage their patents acquire added value. The malicious aspect of the cases observed recently is that the patent trollers do not enforce their rights against suppliers of elemental components, which are directly infringing their patents, but rather they file actions against the manufacturers or dealers of end products that use these elemental components. In the case of an elemental component, the appropriate license fee is an amount that corresponds to the sales of the elemental component. However, in the case of an end product, the license fee is high, since the amount is calculated based on the value of the end product. This increases litigation risks considerably and threatens to ravage the industrial sector.

For manufacturers and dealers of end products, the components and software included in the products they purchase from suppliers are unknown, and as such it is difficult for them to keep track of the details of such components or software. Since they do not have enough technical knowledge and information to determine whether or not their products infringe on- or conflict with other people's patents, it is impossible for them to identify patents of potential infringers beyond the scope of suppliers or determine potential conflicts with such patents in advance.

It is extremely difficult for companies to carry out business activities in a stable manner when facing the risk of being sued and claimed damages for using another company's products in their own product in a manner previously believed to be safe.

Patent law was originally established for the purpose of achieving industrial development. However, if companies are constantly exposed to excessive risk of exposure to claims for damages (being sued), business activities could be hindered and the industrial sector could find itself ravaged.

Accordingly, we request that measures against patent trolling be examined promptly by all means necessary upon the formulation of an intellectual property strategy for the information and communications field.