Response to C.8481 (Japan)

## 1. "Experiment and Research"

### (i) Interpretation of "Experiment or Research"

In Japan, Article 69 (1) of the Patent Act of Japan stipulates exceptions to patent rights, stating that the effects of patent rights are not extended to the working of patented inventions for "experimental or research" purposes.

The first case in which the scope of "experimental or research purposes" was defined under Article 69 (1) was a court case on an herbicide in 1987.[1] In that case, the point in dispute was whether experiments, which were conducted on the effects of the herbicide for registering and selling it as an agricultural chemical, fell under the exceptions stipulated under Article 69 (1). In the case, the court determined that the experiments did not fall under the exceptions stipulated in the Article because they were conducted exclusively for the purpose of selling the herbicide, not for the purpose of advancing technologies on it. However, when discussing the general interpretation of "experiments and research" under Article 69 (1), we find that as of yet, few judicial precedents have been set, as most of the interpretations are based largely on academic theories. Among the theories, one generally accepted theory is that the scope of "experiments or research" to which the effects of patent rights are not extended should be limited to those conducted for the purpose of "technological advancement," i.e. patentability searches, function searches, and experiments for the purpose of technological improvements and development.

### (ii) Clinical Investigations of Generic Drugs and "Experiments and Researches"

Opinions are divided on whether clinical investigations needed for filing applications seeking approval for manufacturing generic drugs fall under "experiments or research," to which the effects of patent rights are not extended. Both academic theories and court decisions are divided on this issue. In the Supreme Court decision on a case concerning generic drugs,[2] the Court recognized the following: (1) if any clinical investigations needed for getting approval of manufacturing generic drugs were not able to be conducted during the time when the patent rights are effective, this would substantially result in third parties' not being freely able to use the subject patented inventions for a considerable length of time, even after the subject patent rights have expired; and (2) patent rights holders can ensure their economic benefits based on the exclusive licensing of their patented

[1] Tokyo District Court, July 10, 1987 (Case No. 7463(wa) of 1985)
[2] Second Petty Bench of the Supreme Court, April 16, 1999 (Case No.153(ju) of 1998) (Minshu 53 (4) 627).

inventions. Based on the above, the Court ruled that any working of patented inventions for the purpose of clinical investigations that are needed for getting approval for manufacturing drugs would be regarded to be “experiments and research” under Article 69 (1) .

Also, this Supreme Court decision is based on regulations under the Pharmaceutical Affairs Act. Consequently, the scope of the decision can be regarded to extend to patented inventions for cosmetics, medical equipment, and agricultural chemicals, in addition to those for drugs and quasi-drugs.

## 2. Compulsory License

Until now, 23 rewards were requested for the rights of patents, utility models, and designs. Among them, nine were based on the claim that the inventions had not been worked, and 14 involved the interests of use. However, all of them were withdrawn before any award was granted. As a result, there is no case in which a non-exclusive license has been granted.