JPO response to the letter C.8687

In Japan, any law has not been established that any acts conducted solely for the purpose of obtaining approval from the authorities are acknowledged to be exceptions to "experiments or research."

Therefore, Japan does not have any valuable information on (ii) its objectives and goals; (iii) national/regional implementation; and (iv) challenges faced by Member States in its implementation. That is because (ii), (iii), and (iv) are questions under the premise that the exceptions are stipulated under domestic laws.

Meanwhile, the Supreme Court of Japan determined that any clinical investigations of generic drugs (which are needed for filing applications seeking approval from the authorities) would be regarded to be the "working of patented inventions for the purpose of experiments or research." The outline of the Court's decision is as described in paragraph 17 of document SCP/23/3.

And, after this Supreme Court's decision, the problem as to whether or not clinical investigations of generic drugs (which are needed for filing applications seeking approval from the authorities) fall under the "working of patented inventions for the purpose of experiments or research" is regarded to be concluded.

Also, with regard to matters related to (ii), in the original decision of the Supreme Court decision, the original instance court stated that, if it takes certain time for original drug manufactures to seek approval for manufacturing and selling their drugs, this time, which is included in the duration of their patent rights will be supplemented by the system enabling duration of their patent rights to be extended. And this decision was also supported by the Supreme Court.

Modification to the document SCP/23/3

17. In Japan, Article 69 (1) of the Patent Act stipulates that “the effects of patent rights shall not be extended to the working of patented inventions for the purposes of experiment or research.” Opinions were 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 had been divided on this issue.
In the Supreme Court decision on a case concerning generic drugs, the Court recognized the following: (i) 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 patented inventions for a considerable length of time, even after the patent rights have expired; and (ii) patent right holders can ensure their economic benefits based on the exclusive licensing of their patented inventions.

Consequently, 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 or research” under Article 69(1).

Since the Supreme Court based its decision on the regulations under the Pharmaceutical Affairs Act, the scope of the decision may be extended to patented inventions for cosmetics, medical equipment, and agricultural chemicals.