Survey on Actual States in Foreign Countries Related to Intellectual Property System or the like over Biopharmaceuticals (Summary)

1. Purpose

In the prescription pharmaceutical market, while biopharmaceuticals are the mainstream of sales and new products are successively placed on the market, there is a present state that patent disputes between original biopharmaceutical companies are being observed. In order to encourage the planning of the pharmaceutical industry promotion policy and the international development of pharmaceutical companies, it is important to know well the actual state of patent disputes in respective countries and the system to prevent patent disputes beforehand.

Therefore, in the survey, it is aimed to gather information that could be future basic materials for the promotion of the pharmaceutical industry developing globally.

2. Overview

In the survey, literature and field survey or the like were carried out with regard to patent disputes on biopharmaceuticals, outline and operation of patent linkage system, and system to prevent disputes beforehand, etc., and the information obtained in the survey was organized and compiled into a survey report.

3. Countries surveyed

The countries surveyed are Japan, the United States, China, South Korea, European Union member states.

4. Survey method

The information was gathered through literature and website survey, inquiries for respective countries, and field survey. The field survey was carried out in South Korea as the target in such a manner that the question items were selected mainly from the items that were found insufficient as a result of analyzing the information in the literature or the like gathered in advance, and questionnaire was prepared.

The 12 entities in total surveyed in South Korea were 4 public institutions, 1 industry organization, 4 companies, 1 local Japanese organization, 1 academic expert, and 1 law firm. Further, additional survey was carried out for 2 industries organizations through written correspondences.

5 . Structure of the report

The report was complied basic information, mainly on the following items for respective

countries surveyed.

Besides, specific collateral measures of international treaties such as economic partnership agreements or the like were described separately as they relate to respective countries surveyed.

(1) Industrial policy concerning pharmaceuticals

(2) Outline of the overall system concerning the intellectual property over pharmaceutical products

"doctrine of experimental or research use exception", "setting of compulsory license (arbitrary license)", "data protection of pharmaceuticals (re-examination system)", "patent term extension system", "patent linkage system", etc.

(3) Patent disputes on pharmaceuticals

"Cases of lawsuits concerning pharmaceuticals", "setting administrative compulsory license (arbitrary license)", "number of disputes", etc.

(4) System or the like concerning adjustment of the pharmaceutical affairs system and patent system

The system operated in respective countryies and provisions related thereto, etc.

(5) Field survey (South Korea only)

The survey was carried out mainly on items judged insufficient as a result of analysis of information from literature or the like gathered in advance, 1) national policy on biopharmaceuticals, 2) patent linkage system, 3) measures to avoide patent disputes in advance, 4) measures to avoid discountinuing the sales of drugs due to patent disputes, 5) actual state of patent disputes, 6) system specific to biopharmaceutical, and the situation, or the like, 7) situation of discussions, and 8) treaty, etc.

6 . National system of respective countries

Outline of the intellectual property systems relating to pharmaceutical in respective countries, which were surveyed and organized in the survey are as follows.

| Items | Japan | U.S.A. | China | South Korea | Europe (EU member countries) |
|---|---|---|---|---|---|
| 1) Experimental or research exception | - Experimental or research use is non-infringement (Art. 69, Para. 1 of Patent Act) | - No general clause<br>- Experiment for application for approval is non-infringement (35 USC § 271 (e) (1))<br>- Submission of an application for approval is infringement (35 USC § 271 (e) (2)) | - The use for the purpose of scientific research and experimentation, or production for the purpose of approval or the like is non-infringement (Art. 69 (4) and (5) of Patent Law) | - Research or testing (including clinical trial of pharmaceuticals) is non-infringement (Art. 96, para. 1 of Patent Act) | - clinical trial for approval applications is non-infringement (Art. 10, para. 6 of Directive 2004/27/EC)<br>- act done for experimental purpose is non-infringement ( Art. 27 (b) of the Community Patent Convention (CPC)) (Not in effect) |
| 2) Setting compulsory license | [Arbitrary license]<br>- where not worked (Art. 83 of Patent Act)<br>- Relationship to work own patented invention (Art. 92 of Patent Act)<br>· Public interest (Art. 93 of Patent Act) | - No general clause<br>- Government use (28 USC §1498)<br>- March-in rights (35 USC § 203) | - Use of State-owned enterprise (Art. 14 of Patent Law)<br>- Non-exploitation or monopoly (Art. 48 of Patent Law)<br>- National emergency or public interest (Art. 49 of Patent Law)<br>- Public health (Ar. 50 of Patent Law)<br>- Relationship to work own patented invention (Art. 51 of Patent Law) | [Arbitrary license]<br>- Government use (Art.106 and Art. 106-2 of Patent Act)<br>- No execution of patent (Art. 107, Nos. 1 and 2 of Patent Act)<br>- Public interest (Art. 107, No. 3 of Patent Act)<br>- rectifying unfair trade practice (Art. 107, No. 4 of Patent Act)<br>- export of medicine (Art. 107, No. 5 of Patent Act) | - No provision in European Patent Convention (EPC) therefore, according to the national law of the respective Member States<br>- Setting compulsory license (Art. 45 of CPC (Not in effect))<br>- lack or insufficiency of exploitation (Art. 46 of CPC (Not in effect))<br>- depending patents (Art. 47 of CPC (Not Ain effect)) |
| 3) Data protection of pharmaceuticals | [Re-examination System]<br>- New active ingredient drugs: principle 8 years<br>- Orphan drung: muximum 10 years<br>- Pediatric indication: maximum 10 years | - New active ingredient drugs: 5 years<br>- Biopharmaceuticals: 12 years<br>- Medicines for rare diseases: 7 years<br>- Pediatric indication: 0.5 years addition | - New substance: 6 years<br>- Orphan drug: No special case<br>- Pediatric indication: no special case | [Re-examination System]<br>- New drugs, etc.: 6 years<br>- Orphan drug: 10 years Orphan drug and pediatric indication: 11 years<br>- Pediatric indication: no special case | - New active ingredient drugs: 10 years<br>8 years for ban on application for generic medicines<br>2 years for ban on application for generic drug sales<br>+ 1 year for additional breakthrough efficacy<br>- Orphan drug: 10 years Orphan drug and pediatric indication: 12 years<br>- Pediatric indication: 6 months addition |

| Items | Japan | U.S.A. | China | South Korea | Europe<br>(EU member countries) |
|---|---|---|---|---|---|
| 4) Patent term Extension | - Maximum 5 years (Art. 67, para. 2 of Patent Act) | - Maximum 5 years. However, it does not exceed 14 years from the approval date (35 USC § 156) | —<br>(No institution) | - only once up to 5 years (Art. 89 of Patent Act) | [Supplementary Protection Certificate System]<br>- maximum 5 years |
| 5) Patent linkage system | (No written rule under the law, but directed by the notice [1])<br>- In principle, "generic drungs should not be approved, if the active ingredient itself cannot be manufactured due to the presence of the patent for the active ingredient of the original drug product"<br>- Submission of the "pharmaceutical patent information report sheet" by new pharmaceutical companies (optional)<br>- Pre-adjustment procedure before drug price listing<br>- provision of patent information by generic medicines applicant<br>- Submission of "patentee's (of original drug manufacturers or the like) consent or the like" by generic drug applicant | [Abbreviated New Drug Application: ANDA] (Federal Food, Drug, and Cosmetic Act (FDCA)<br>- The first applicant that meets certain requirements (Paragraph IV drug application) is given the exclusive right for 180 days.<br>[abbreviated Biologics License Application: aBLA] ("Biologic Price Competition and Innovation Act" (BPCIA))<br>- Patent dance | - Applicant for medicinal products (regardless of new drugs or generic drugs) shall provide the documents explaining the patent situation in China concerning his own patent. The regulatory authority (CFDA) shall publish the patent situation on the website.<br>- Where another party owns the patent in China, the applicant for the medical product shall provide a statement of non-infringement. (Art. 18 of Provisions for Drug Registration (enforcement of 2007)) | - Arts. 50-2 through 50-10 of Pharmaceutical Affairs Act<br>- In order to file an application for registration of the patent information of a drug in the patent list relating to approval of the drug (revised approval of the drug), the applicant shall file an application for registration within 30 days from the date of marketing approval or revised approval or file an application for registration within 30 days from the date of registration of the patent, if there is no patent for registration at the time of approval and the patent was subsequently registered. (Art.50-2, para. 2 of Pharmaceutical Affairs Act) | —<br>(No institution) |