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Present Status of the Practice of Swiss-type Claims in China

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In the Chinese pharmaceutical industry, claims written in the form "the use of substance X in preventing or treating Y disease" are not protected under Chinese patent law. Therefore, in order to protect these types of medical use inventions, the strategy of changing the above to Swiss-type claims is used in practice.[1] However, the question remains as to whether drug administration features can be used as technical features when defining a Swiss-type claim. This article outlines the examination criteria and practice and also provides our opinions on what should be noted when drafting a Swiss-type claim.

1. Related provisions

The following provisions regarding Swiss-type claims under Chinese law are covered in the Guidelines for Patent Examination 2010 ("Guidelines"). The substance and its manufacturing method are patentable, and claims regarding medical use inventions of a substance stated in the form of a substance claim or "use for pharmaceuticals" or "use of substance X for the manufacture of medicine for the treatment of Y disease" are not contrary to Chinese Patent Law.

When examining the novelty of medicinal use inventions, the following aspects are taken into consideration: "whether or not the features relating to use, such as the target of administration, dosage forms, route of administration, dosage, administration interval and so on can define the procedure of manufacture of a medicine. Distinguishing features from prior art merely present in the course of administration do not enable novel use"[2]. The Guidelines also prescribe the following regarding the inventive step: "a use invention of a known product is regarded as involving an inventive step if the new use cannot be derived or expected from the structure, composition, molecular weight, known physical and chemical properties and existent use of the product, but utilizes a newly discovered property of the product and produces an unexpected technical effect."[3] Therefore, as indicated by the above Guidelines, Swiss-type claims can be protected in China as pharmaceutical method claims.

2. Case Precedent

In 2013, the Supreme People's Court ("SPC") for the first time stated its opinion concerning the question of using drug administration features to define medical use claims.[4] The claim

[1] A Swiss-type claim is a formerly used claim format intended to cover the second or subsequent medical use of a known substance.

[2] Guidelines for Patent Examination 2010, 5.4 Chapter 10, Part 2

[3] Guidelines for Patent Examination 2010, 6.2, Chapter 10, Part 2

[4] Cubist Pharmaceuticals v. Patent Re-examination Board of the State Intellectual Property Office of the People's Republic of

at issue states, “1. Use of daptomycin for the manufacture of a medicine which treats a bacterial infection in a patient in need thereof without generating skeletal muscle toxicity, where the dosage for said treatment is 3 to 75 mg/kg of daptomycin, where said dosages are administrated repeatedly, and where said administration interval is once every 24 hours to once every 48 hours." The Patent Reexamination Board (“PRB”) determined that for those skilled in the art, it is well known that technical features such as dosage, repeated administration and administration interval are information on how to use the medicine selected by doctors for patients in the process of treatment, and have no bearing on the manufacture of the medicine. Drug administration features cannot define a medicine itself, and the Swiss-type claim 1 defined by such administration features cannot be distinguished from the known medical use as disclosed in the prior art. Both the Beijing No. 1 Intermediate People’s Court and the Beijing Higher People’s Court maintained the trial decision of the PRB in the above opinion.

However, the SPC overturned the Intermediate People’s Court and Higher People’s Court decisions and held that administration features described in claim 1 do not define the method for manufacturing the medicine, and therefore, claim 1 has no novelty. The SPC determined that medical use claims regarding substances should be analyzed from the viewpoint of method claims restricting the manufacturing acts of manufacturers that produce medicines for certain uses. The SPC’s reasoning was that the pharmaceutical process in the patent law generally refers to an act for manufacturing a specific medicine with specific steps, processes, conditions, raw materials, etc., without including the steps of drafting the medicine’s instructions, labels, packaging, and so forth. Further, the dosage (3 to 75 mg / kg) described in claim 1 is a single dosage or daily usage which is determined by the physicians. Obtaining the optimum therapeutic effect of a medicine through selection of an appropriate dosage based on individual differences among patients constitutes treatment of a disease. Likewise, the method of administering medicines at fixed intervals also demonstrates how to use the medicines, which indicates a treatment action without affecting the manufacturing process of the medicine.

3. Recommendations

Based on the SPC’s decision, Chinese patent practice, and other case precedent, the following are our recommendations for drafting certain portions of Swiss-type claims.

(1) Dosage

As a technical feature, we recommend using not the dosage, but a unit dosage – i.e., the amount of active ingredient contained in one unit of medicine. In general, dosage = unit

dosage X times of administration. Since the number of administrations is an act carried out by a doctor, it will not be taken into consideration. Unit dosage, on the other hand, can be reflected in the pharmaceutical process, and should be taken into consideration. However, if the unit dosage is not significantly changed from that of the prior art, and the applicant cannot prove that the unit dosage exerts an unexpected technical effect on the medical use claim, it is possible that the Swiss-type claim defined by unit dosage may not be adequate for the recognition of an inventive step.

(2) Targets of administration
If the targets of administration objectively influence the selection of the manufacturing of the medicine, such as in the case of the raw materials, manufacturing processes, composition components, and contents, these technical features should be taken into account. For example, since the metabolism of adult patients and child patients differ, the manufacturing processes of medicine should also differ accordingly. In the above case precedent, the PRB, the Beijing First Intermediate People's Court, the Beijing Higher People's Court and the SPC stated their opinion that adult patients should be considered when evaluating an inventive step.

(3) Mechanism
It is possible to use disease mechanisms in lieu of disease names to define the range of diseases which can be treated by the medicine to be protected by the Swiss-type claim. If the disease to be treated is the same even when the disease mechanism is different, such a medical use claim has no novelty. For example, the use of pinolenic acid in the manufacture of a medicine for treating obesity by lowering the feeling of hunger or increasing satiety in humans, and where medicines containing pinolenic acid are already used to treat obesity in the prior art. Regarding such claims, the difference with the prior art lies in reducing the feeling of hunger in humans or increasing the feeling of satiety. Such an invention is merely a discovery of the mechanism of therapeutic action and cannot be distinguished from the prior art, so it has no novelty.

In order to comply with the practicality of Article 22, Paragraph 4 and Article 26, Paragraph 3 of the Chinese Patent Law regarding the full disclosure of the specification which concerns a new medical use invention, experimental data (Including animal experimental data) or clinical trial data sufficient to demonstrate that the expected technological effect can be achieved or the technical problem can be solved for those skilled in the art, must be described in the application. Further, if there are many types of diseases related to the mechanisms discovered, but the applicant can only verify the pharmacological activity of

one or a few of the diseases related to the discovered mechanisms, it is necessary to limit the number of specific diseases in order to comply with the provision concerning support requirements of Article 26, Paragraph 4 of the Chinese Patent Law.

4. Summary

The criteria for examination and judgment of the Swiss-type claims is not simply a matter of patent examination, but also an important issue concerning national interests. The majority of the pharmaceutical patents owned by Chinese companies are improved patents of known medicines such as the improvement of dosage forms, improvement of manufacturing methods and second medical uses. It is a chief aim of the Chinese government to develop domestic enterprises in China to narrow the gap with global overseas enterprises. As the R&D capacity of China develops, criteria for the examination and determination of Swiss-type claims may change in the future.

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