Patentability of medical use inventions

Jiancheng Jiang of Peksung asks whether a Higher Court judgment in favour of a medical use claim brings new hope for inventors

In the examining practice by the China State Intellectual Property Office (SIPO), the medical use of a substance, including the first medical use and the second medical use, may be protected if the applicant files an application with a "Swiss-type claim". In particular, "The Guidelines for Examination" explicitly stipulate that the above-mentioned use claim may be drafted as "use of compound X for manufacturing a medicament for the treatment of disease Y" or the like.

According to the Guidelines for Examination, when evaluating novelty of the Swiss-type claims, the examiner should take into consideration whether or not the features relating to use, such as the subject, regimen of administration, route of administration, usage amount and interval of administration, can define the procedure of manufacture of a pharmaceutical. In addition, the Guidelines for Examination explicitly stipulate that the distinguishing features merely present in the course of administration do not enable the use to possess novelty.

Case study

As an example where the above-cited stipulation in the Guidelines for Examination applies, the Decision of Invalidation No. 9508, made by the China Patent Reexamination Board on Chinese Patent No. ZL94194471.9, did not attract much attention.

The granted claim 1 in the above patent reads:

> *1. use of 17,-(N-tert-butylcarbamoyl)-4-aza-5·-androst-1-ene-3-one in the manufacture of a medicament suitable for oral administration for treating androgenic alopecia of a person, wherein the medicament comprises 17,-(N-tert-butylcarbamoyl)-4-aza-5·-androst-1-ene-3-one in a dosage amount of about 0.05 to 3.0 mg.*

In the invalidation procedure, the patentee admitted that claim 1 differs from the prior art in that (1) the invention defines the dosage amount of medicament as 0.05 to 3.0 mg; and that (2) the invention defines the route of administration as oral administration. The Reexamination Board held that the above distinguishing feature (1) has no limiting effect, and is deemed as nonexistent in the evaluation of novelty and inventiveness. As to the distinguishing feature (2), the Reexamination Board acknowledged that it has a limiting effect to some extent on the pharmaceutical product, and thus enables claim 1 to have novelty.

The patentee instituted a legal proceeding before court. The court of first instance (the First Intermediate People's Court of Beijing) supported the opinion of the Board, and upheld the decision. However, the court of second instance (the Higher People's Court of Beijing), while also upholding the decision, did not agree with the Board's view on the limiting effect of the above distinguishing feature (1). The Higher Court held that an invention of medical use is in nature an invention of method for using a medicament; the technical features relating to how to use a medicament, i.e. so-called "administration-related features" including dosage form, dosage amount, etc., shall be considered as features relating to method for using a compound and thus be allowed to be incorporated into claims. In addition, the manufacture of a medicament should comprise all procedures before packing the medicament and delivering it from a factory, thus including of course the so-called "administration-related features", such as dosage form and dosage amount. Where a patentee made an improvement in respect of dosage form and dosage amount, taking no account of the "administration-related features" will impede the development of pharmaceutical industries and furthermore, contravenes the purpose of the Patent Law.

The judgment made by the Higher Court attracted common attention. It is very uncommon that the stipulation of the Guidelines for Examination is not applied by the court. In this case, the Higher Court seemed to hold that, in spite of the fact that the dosage amount of a medicament is a distinguishing feature "merely present in the course of administration", it has a limiting effect on the medical use claims, and thus should be considered in the evaluation of novelty and inventiveness.

In practice, some medical use inventions make contribution over the prior art by proposing new dosage amounts for administrating a medicament, but not new indications. Since the method for treatment of diseases cannot be allowed in China, the inventors will have to draft Swiss-type claims if they want to get their invention protected. According to the Guidelines for Examination, however, if the distinguishing feature of a claim is only present in the dosage amount administered, the claim will have no novelty; even if the claim includes other distinguishing features which make the claim novel, the feature relating to the dosage amount administered will be considered nonexistent in the evaluation of inventiveness.

Hope for inventors?

The above judgment made by the Higher Court seemed to raise a gleam of hope to the inventors in this field. They may assume that this judgment has cleared the way for patenting such inventions in China.

However, things are not so simple. As we all know, China is not a case law jurisdiction, so that the court judgment is legally binding only on the particular case to which the judgment is directed, and has no general binding force. In addition, in Chinese jurisprudence, although courts are entitled not to apply (this is very uncommon as described above) the administrative rules (such as the Guidelines for Examination) made by administrative authorities (in this case, SIPO), courts are not entitled to order the administrative authorities to revise the administrative rules. Whether or not to revise the Guidelines for Examination in consideration of the court judgment will be decided by SIPO itself. In fact, SIPO is now in the process of revising the Guidelines for Examination so as to make it consistent with the new Patent Law, which will come into force on October 1, 2009. As far as the author knows, at least at present, SIPO has no intention to revise the portion of the Guidelines for Examination which was denied by the Higher Court. Thus, if a similar patent application is examined by the SIPO, the current examining standards will be applied, but not the opinion given in the Higher Court's judgment.

On the other hand, the judgment does bring hope to the inventors in this field. Since the court explicitly expressed its opinion on this issue in the form of a judicial judgment, people can reasonably expect that the court will most likely make the same judgment to similar cases which they take. From the perspective of practice, if an invention is so important that it is worth taking the time and cost to get a patent right, the applicant may proceed with filing a patent application. If the application fails to pass the examination by the SIPO because of the above stipulation of the Guidelines for Examination, the applicant may try to get the court's support through judicial procedure. ■

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