Current Intelligence

Patentability of dosage regime invention in the form of Swiss-type claim under Chinese patent law

Merck & Co Inc. v Patent Reexamination Board of State Intellectual Property Office of People's Republic of China (PRC) (2008) Gaoxing-zhongzi No. 378

Whether a dosage regime invention is patentable under Chinese law is uncertain. In September 2008 the Beijing Higher People's Court held in *Merck v Patent Reexamination Board of State Intellectual Property Office of PRC* that a dosage regime invention in the form of Swiss-type claim was patentable, and that the dosage may serve as a technical feature—which limited the claim—to be taken into account in assessing novelty and inventiveness. However, the revised Guideline for Examination promulgated by State Intellectual Property Office of PRC, effective from 1 February 2010, takes the opposite approach. It is unknown which of the positions the Chinese courts will take.

Legal context

Chinese Patent Law (as revised in 2000, effective from 1 July 2010), Art. 25 (1), provides that 'The following shall not be granted a patent: . . . (3) Method for the diagnosis or for the treatment of diseases . . ..' The law as revised in 2008 and effective from 1 October 2009 has this same provision.

The Guideline for Examination (2006) promulgated by the State Intellectual Property Office (SIPO), Part II, Chapter 10, Sec. 4.5.2, which dealt with medical use of a substance, states:

> An application relating to the medical use of a substance shall not be granted if its claim is drafted in the wording "use of substance X for the treatment of diseases", "use of substance X for diagnosis of diseases" or "use of substance X as a medicament", because such claim is one for "method for the diagnosis or for the treatment of diseases" as referred to in Art. 25.1(3). However, since a medicament and a method for the manufacture thereof are patentable according to the Patent Law, it shall not be contrary to Art. 25.1(3) if an application for the medical use of a substance adopts a pharmaceutical claim or use claim in the form of method for preparing a pharmaceutical, such as "use of substance X for the manufacturing of a medicament", "use of substance X for the manufacturing of a medicament for the treatment of a disease" and so on.
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> The above-mentioned use claim in the form of method for manufacturing a medicament may be drafted as "use of compound X for manufacturing a medicament for the treatment of disease Y" or the like.

The Guideline for Examination (2006) Part II, Chapter 10, Sec. 5.4, which dealt with novelty of a new use of a known product, adds:

> A known product is not rendered novel merely because a new application thereof has been put forward . . . a known product does not destroy the novelty of its new use if the new use per se is an invention. This is because such use invention is an invention of method of application, and the substance of the invention lies in how to apply the product rather than the product per se.
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> . . ..
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> As for a medical-use invention relating to a chemical product, the following aspects shall be taken into consideration when the examination of novelty is carried out: . . . (4) Whether or not the features relating to use, such as the object, mode, route, usage amount, interval of administration can define the procedure of manufacture of a pharmaceutical? *The distinguishing features merely present in the course of administration do not enable the use to possess novelty* [emphasis added].

The corresponding parts of the revised Guideline for Examination (effective from 1 February 2010) remain the same as its predecessor.

Facts

The patent in suit was named 'Method of Treating Androgenic Alopecia With 5-Alpha Reductase Inhibitors' (no. ZL941944 71.9). It was filed by Merck with the former Patent Office of PRC on 11 October 1994. The patent was granted on 25 December 2002.

In June 2004 Henan Topfond Pharmaceutical Co. Ltd filed a request with the Patent Reexamination Board (PRB) of the State Intellectual Property Office of PRC, claiming that the patent should be declared invalid, in particular for lack of novelty and inventiveness. The claim 1 of the patent in suit, the focal point of the dispute, states:

> The use of 17β-(N-tert-butylcarbamoy1-)-4-aza-5α-androst-1-ene-3-one for the preparation of a medicament adapted for oral administration useful for the treatment of androgenic alopecia in a person and wherein said medicament comprises about 0.05-3.0 mg dosage amount of 17β-(N-tert-butylcarbamoy1-)-4-aza-5α-androst-1-ene-3-one.

PRB made no decision until February 2007, when the Guideline for Examination (2006) took effect. In Decision

No. 9508, PRB found that the two features claimed—'0.05–3.0 mg dosage amount' and 'oral administration'—were comprised in the prior art. PRB, however, did not consider that both of them 'limit' the preparation of the medicament, constituting technical features to be considered in assessing novelty and inventiveness: preparation of a medicament is a distinct process from its administration and only such features as the starting materials, manufacturing steps and conditions, and ingredients limited the preparation for a given medicament. However, where particular features of administering a drug require a particular method of preparation, the features can be technical features limiting the preparation of the drug. In this case, PRB recognized that oral administration was a technical feature limiting the preparation for the drug, but denied that the dosage feature could do the same. The board upheld the novelty of the patent in respect of only one feature—'oral administration'—considering the prior art document cited. The patent, however, was declared invalid because this very distinguishing feature was obvious to a person of ordinary skill in the art.

Merck appealed to the Beijing No. 1 Intermediate People's Court, which upheld the decision, but on different grounds. The court reasoned that the claimed dosage feature, the limitation of which was not completely reflected in the preparation of the drug, covered treating measures by physicians. As required by public policy and the legislative purpose behind Art. 25.1(3), the protection scope for a Swiss-type claim should not cover a physician's practice treating a patient with a medicament in a certain dosage. Otherwise, the grant of this kind of patent would restrict a physician's freedom in treating patients. Therefore the dosage feature claimed was not a part of the preparation of the medicament, but a technical feature of treatment for the disease, forbidden by patent law. The court thus affirmed the PRB decision, holding that dosage feature in a Swiss-type claim should be deemed as non-existent in assessing novelty and non-obviousness.

Merck appealed further to the Beijing Higher People's Court, which reversed the decision. In doing this, the court first pointed out that the claim was drafted in Swiss form, which is adopted to take out of the exception to patentability—method for treating disease unpatentable—claims of 'use of compound X for the treatment of disease Y'. What is protected by a Swiss-type claim is essentially the medical use of a compound. An invention of a medical use is an invention of a process. The features of administering a drug, ie dosage form and amount, are technical features for using the compound and should thus be considered as elements comprising the claim. These 'administration features' can often produce unexpected technical results. The court added that the preparation of a medicament is not merely the preparation of the active ingredients or raw medicament, but should include all the steps before packaging of the medicament, including the administration features such as specification of dosage form and amount. The court commented that taking no consideration of administration features in a Swiss-type claim would be detrimental to the development of medical industry and the needs of public health, contrary to the legislative purpose of the Chinese Patent Law.

In refuting the reasoning taken by the court below, the Higher Court commented that the concern was unnecessary, recognizing 'administration features' in a Swiss-type claim might restrict a physician's freedom to cure diseases. First, a physician's treatment of a disease is not for business purposes, and thus never infringes. Secondly, a claim for a medical use comprises features of the compound, of its preparation and of indications to be applied. A physician's treatment never touches upon features of the preparation of a drug, and thus can never infringe a Swiss-type claim.

Analysis

This case is outstanding because the reviewing courts for PRB—Beijing No. 1 Intermediate People's Court for the first instance and Beijing Higher People's Court for the second instance—normally rubber-stamp PRB decisions. Further, the Higher Court in this case even disregarded the provisions in the Guideline for Examination (2006): It did not say a single word about Part II, Chapter 10, Sec. 5.4, as cited above. This is indeed quite rare under the Chinese patent system.

Sadly, the legal grounds for the final judgment are not solid. It can be said that the final judgment of this case is comparable to the Decision of the Enlarged Board of Appeal dated 19 February 2010 (G 2/08). But unlike the European Patent Convention (EPC), Chinese Patent Law (CPL) does not lend such strong support for the final judgment as the EPC does to the decision cited above, even though CPL borrowed much from the EPC. Unlike the EPC, the exceptions to patentability in CPL were—and are—provided in such general terms that there is absolutely no legal foundation for recognizing Swiss-type claims. It is the practice—established mainly by the Guideline for Examination—that gives life to Swiss-type claims under the Chinese legal system. The Higher Court, in rendering the decision, while recognizing a Swiss-type claim provided in the guideline, refused to apply Part II, Chapter 10, Sec. 5.4 of the same legal document, which denies patents to dosage regimes. Aware of this lethal weakness, the court invoked in vain the public policy and the legislative purpose of the patent law, which is not defined clearly, only to draw more criticisms.

Further, the ruling of the Higher Court was unnecessarily broad in commenting that a physician's treatment is

not for 'business purposes' and thus never infringes. It appeared to interpret CPL Art. 11, which provides that 'After the grant of the patent right for an invention or utility model, except as otherwise provided for in this law, without the authorization of the patentee, no entity or individual may, for production or business purposes, exploit the patent . . .' The unintended effect of these comments is that hospitals and health institutions might claim exceptions to patent infringement in general on grounds of non-business purposes as interpreted by the Higher Court in this case.

Practical significance

The significance of the case discussed here remains uncertain. Although decided in 2008, this case is of current interest. First, its counterpart in Europe was only decided in 2010. The two cases take similar positions, though on different legal grounds. According to G 2/08, 'where it is already known to use a medicament to treat an illness, Article 54(5) EPC does not exclude that this medicament be patented for use in a different treatment by therapy of the same illness'. The Chinese case basically said the same. But G 2/08 added: 'where the subject-matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so-called Swiss-type claim as instituted by decision G 5/83'. In the Chinese case, however, the Higher Court held essentially that dosage features should be drafted as Swiss-type claims for them to be taken out of the exception to patentability as provided by CPL Art. 25 (3) and to be considered in assessing novelty and inventiveness. In sum, by this case, the Chinese judicial system shows its willingness to support dosage regime patents and strong patent protection.

Second, the case is current in view of the recently promulgated Guideline for Examination (2010) published by SIPO, in which the Part II, Chapter 10, Sec. 5.4 remained unchanged, in the face of the final judgment. To make matters more complicated, Sec. 5.4 was adopted consciously to solve conflicting approaches to dosage features in Swiss-type claim of patent applications. Before the Guideline for Examination (2006), some were granted, for instance, patents ZL98805686.0 and ZL95193441.4; some were denied, for example, patent ZL 97122526.5. Because the Guideline for Examination (2010) takes the same approach as its predecessor in the face of the judgment on this case and Chinese courts are not bound by precedent, legal clouds remain to be cleared.

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