

# Impact of Drug Dosage Feature on Novelty of Swiss-type Use Claim

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In September 2008, the Beijing Higher People's Court, upon reviewing a patent validity decision made by the Patent Reexamination Board (PRB), overruled the PRB's view that drug administration features, overruled, did not limit or restrict the novelty of a Swiss-type use claim. However, the PRB's view conformed to the specific provisions of the State Intellectual Property Office's (SIPO) Guidelines for Examination as of 2006. The Beijing Higher People's Court's view was very much different from the provisions of the Guidelines for Examination, which was rare in the history of the courts' review of administrative decisions on patent validity<sup>1</sup>.

By way of probing into the origin of the Swiss-type use claim and outlining the historical debates on the matter involved in novelty assessment, this article is meant to explore the requirements concerning examination of the novelty of the Swiss-type use claim and the possible changes along the line in the future in China.

## I. Origin of Swiss-type use claim

Ever since the Chinese Patent Law entered into force on 1 April 1985, no patent has ever been granted to methods for diagnosis and treatment of diseases under the law in China. When "the method of use of compound X for diagnosis or treatment of disease Y" is invented, a patent applicant's claims for the invention, such as "a method for diagnosis or treatment of disease Y, characterised in that compound X is made available to patients", are not patentable under the law. Not patenting methods for diagnosis and treatment of diseases is "to make it possible for doctors to freely choose methods to diagnose or treat diseases out of humanitarian considerations and for the socio-ethical reasons. Besides, these methods are applied to living human or animal body, and are not industrially applicable; hence, they are not the

invention-creations in the meaning of the Patent Law."<sup>2</sup>

After a chemical compound becomes a patentable subject matter as of 1 January 1993, for the above inventions, if compound X is new, patent protection may be applied for the compound *per se*. For example, the claim may be drafted as "a compound X, having a structural formula of ...", with the performance for diagnosis or treatment of a disease being a proof of the effect that said claim possesses inventiveness. But if compound X is known and its new use for diagnosis or treatment is found, say for diagnosis or treatment of disease Y, then one should consider seeking the patent protection therefor in some other ways.

To avert the obstacle to the patentability of methods for diagnosis or treatment of diseases, the Swiss Federal Intellectual Property Office created what is now known as the Swiss-type use claim, which is typically drafted as "use of a compound X in manufacture of a medicament for diagnosis or treatment of disease Y" according to the Office's Statement of Practice [1984] OJ EPO 581 concerning the "use claim". The patentability of claims of the type has been accepted by the EPO, and affirmed by the Enlarged Board of Appeal in the form of Decision G05/83, which is known as the "second or further medical use".

In Decision G05/83, the Enlarged Board of Appeal held that "A European Patent with claims directed to the use may not be granted for the use of a substance or composition for the treatment of the human or animal body by therapy. Claims directed to the use of a substance or composition for the preparation of a pharmaceutical product are equally clearly directed to inventions which are susceptible of industrial application within the meaning of Article 57 EPC", which serves as the basis on which a Swiss-type use claim possesses industrial applicability. Accordingly, if a particular medical use is new and possesses inventive step, the corre-

sponding Swiss-type use claim is patentable.

In China, a known substance whose new use of disease diagnosis or treatment is found, if being presented in a prescribed format, viz, the claim that “use of a compound X in making the medicament for diagnosis or treatment of disease Y”, would be granted the patent protection. The Guidelines for Examination as of 1993 provided for the “claim for the medical use of a substance” as follows:

“The medical use of a substance, presented as ‘for treatment of a disease’ or ‘for diagnosis of a disease’ in the claims of an application filed for patent, is the method for ‘for diagnosis or treatment of diseases’ under Article 25 (3) of the Patent Law, so it is not permissible; but since a medicament and a method for making it are patentable under the Law, inventions relating to medical use of substance presented in medicament claims or use claims in the form of ‘use in making a medicament’ or ‘use in making a medicament for treatment of diseases’ in patent applications relating to the types of methods for making medicament, are not prohibited under Article 25 (3) of the Patent Law

Said use claims for methods for making medicament may be drafted as ‘use of compound X for making medicament for treatment of disease Y’ or in a similar form<sup>3</sup>”.

Similar provisions have also been set forth in the Guidelines for Examination as of 2006<sup>4</sup>. Thus, the way to draft the Swiss-type use claim is permissible in China, and it is believed to have rectified the flaws resulting from not patenting claims for diagnosis or treatment methods.

In the patent practice in China, the above Swiss-type use claims are extensively patented. So far, there has not arisen any case where a Swiss-type use claim with the distinctive feature lying in that compound X is applicable to diagnosis or treatment of a disease is cancelled or invalidated for lack of novelty.

## II. Debates on novelty of Swiss-type use claim with its distinctive feature lying in dosage

A typical Swiss-type use claim is drafted in the form of “an use of compound X for making medicament for diagnosis or treatment of disease Y”. The claim has these essential features: (i) compound X; (ii) for manufacture of a medicament; and (iii) said medicament being used for diagnosis or treatment of disease Y, of which features (i) and (ii) are usu-

ally known, with the distinctive feature only lying in the applicability of compound X to diagnosis or treatment of disease Y. In other words, this method for making the medicament in the claim is not different from an existing preparation method using the same active agent,<sup>5</sup> and its novelty is merely inflected in the new indications of the disease to which compound X is applied. For that matter, the novelty of a Swiss-type use claim is not necessarily reflected in the steps and conditions of the method for preparing a medicament. Rather, the new diagnosis or treatment use of the known substance renders a Swiss-type use claim novel. This is by no means controversial in the patent practice in China.

However, when the inventive point lies in the definition of the use of diagnosis or treatment, e.g. defining the dosage, does the distinctive feature of dosage contribute to the novelty of a Swiss-type use claim? The Guidelines for Examination before 2006 did not set forth any provisions concerning the matter. In practice, Swiss-type use claims having the feature of applying a medicament with dosage lower than the known one were granted the patent by the SIPO, as are the case with the Chinese patents ZL94194471.9, ZL98805686.0, and ZL95193441.4.

### (1) Novelty of Swiss-type use claim with dosage as the distinctive feature affirmed by SIPO and PRB

Upon substantive examination, the SIPO granted, in August 2002, the Chinese patent ZL94194471.9, claim 1 of which went like this:

“1. The use of 17 $\beta$ -(N-tert-butylcarbamoyl)-4-aza-5 $\alpha$ -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 17 $\beta$ -(N-tert-butylcarbamoyl)-4-aza-5 $\alpha$ -androst-1-ene-3-one.)”

The claim differed from the prior art in that it used a lower dosage and defined oral administration of the medicament, that was, the distinctive features rendering said claim novel lay in the lower dosage and mode of administration of the medicament.

Upon substantive examination, the SIPO granted, in July 2003, the Chinese patent ZL98805686.0, claim 11 of which read:

“Use of a pharmaceutical composition comprising 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2, 4-dione (hereinafter ‘Compound (I)’), characterised in that the composition comprises 2 to 8 mg of Compound (I) in a pharmaceutically acceptable form and optionally a pharma-

ceutically acceptable carrier therefore, in the manufacture of a medicament for the treatment of diabetes mellitus and conditions associated with diabetes mellitus.”

The claim differed from the prior art in that it used a lower dosage of the medicament, that was, the distinctive feature rendering said claim novel lay in the lower dosage of the medicament.

The Chinese patent ZL 95193441.4 underwent the substantive examination and the patent reexamination proceedings. In May 2002, the SIPO rejected the patent application in its substantive examination. Then, the applicant requested the PRB for re-examination, and amended the claims. The PRB made its decision upon examination on accepting the applicant's amended claims, and cancelled the SIPO's rejection decision<sup>6</sup>. After that, the SIPO examined said application again, and granted it the patent and published the grant in August 2005, with the patented claim 17 going like this:

“Use of a composition comprising an Sn-117 m (Sn4+) chelate complex in the manufacture of a medicament for alleviating bone pain associated with human cancer or a medicament for treating primary or metastatic cancer in skeletal bone of a human, wherein the medicament has a specific activity of Sn-117m of greater than 6 mCi/mg to 80 Ci/mg and a dosage of Sn-117m of a 6 mCi to 50 mCi per 70kg body weight, and said pharmaceutical composition does not result in bone marrow toxicity.”

The claim differed from the prior art in that it used a lower dosage of the medicament, that was, the distinctive feature rendering said claim novel was that “the dosage of Sn-117m was 6mCi-50mCi/70kg body weight”.

## (2) Novelty of Swiss-type use claim with dosage as distinctive feature denied by SIPO and PRB

However, the above cases of patent grant do not indicate that the SIPO and PRB consistently accept that all Swiss-type use claims with dosage as the distinctive feature possess novelty.

In April 2003, the SIPO rejected patent application 97122526.5, and its rejection decision was directed to claim 1, which went like this:

“The use of a compound of the formula (I) or a pharmaceutically acceptable salt or solvate thereof, in the preparation of a medicament for preventing breast cancer in a human, said medicament to be administered to said human for a sufficient term and at an effective dose of from 60mg to 120mg/day.”



The claim differed from the prior art in that the former's dosage was 60-120mg/day and the latter's 200-600mg/day. For the SIPO, this “dosage” did not limit the said claim, so it rejected the patent application for lack of novelty.

Regarding the SIPO's rejection decision, the applicant requested the PRB for re-examination; the PRB made the re-examination decision in December 2005, upholding the SIPO's rejection decision. The PRB took the view that while in the claim 1 was used the expression “to be administered to said human for a sufficient term and at an effective dose of from 60mg to 120mg/day”, it substantially limited the “dosage” and “duration of administration of the medicament”, and it did not limit the medicament *per se* used in making the drug. Besides, said feature failed to clearly distinguish the technical solution of the application in suit from that of the prior art, nor could a person skilled in the art find that, relative to the prior art, whether said feature was limited or not had any impact on the extent of protection of the technical solution of claim 1 of the application in suit. For example, it was specifically mentioned in the prior art that the dosage was 200-600mg/day, whereas though the application in suit specified the dosage of 60-120mg/day, when said dosage was embodied in the content of the prepared active agent, it was impossible to determine whether said dosage of 60-120mg/day stated in the application in suit had any requirements different from the prior art with regard to the prepared active agent and the content and whether it was different from the active agent of the corresponding medicament in the prior art in the range of content: for said medicament, with different dosage and the duration thereof, the medicament *per se* might not change, nor the medical use of said product. In case like this, claim 1 did not possess novelty<sup>7</sup>.

In February 2004, the proceedings were initiated for the invalidation of the above-mentioned patent ZL98805686.0. During the invalidation proceedings, the patentee disclaimed said patent himself, and the PRB did not officially comment on the patentability of the patent in suit.

In August 2004, the proceedings were initiated for the invalidation of the above-mentioned patent ZL94194471.9. During the invalidation proceedings, the interested parties both agreed that the patent in suit was different from the prior

art in that “(1) the dosage of said medicament as defined in the patent in suit was 0.05-3.0mg while the minimum dosage as defined in the prior art was 5mg; and (2) the way of administration of the medicament as defined in the patent in suit was oral”. However, whether such features as dosage constituted the distinctive character of a Swiss-type use claim became one of the issues in the case. The PRB did not make its decision until February 2007 when the Guidelines for Examination as of 2006 took effect, which will be further elaborated in the follow section.

### III. The administrative examination authority’s views incorporated in the Guidelines for Examination and the background of the formation thereof

Directed to this practical inconsistencies in the patent grant practice, the SIPO made, when amending the Guidelines for Examination in 2006, the provision as follows<sup>8</sup>:

“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 made.

...

(4) whether or not the features relating to use, such as the object, mode, route, usage amount, interval of administration can define the process of manufacture of a pharmaceutical. The distinguishing features merely present in the course of administration do not render the use to possess novelty.”

In the Amendment to the Guidelines for Examination issued for comments, the SIPO explained the preceding amendment as the following:

“Here is an addition of the principle for the examination of inventions relating to the second medical use of a medicament for the reasons that there are relatively more applications in the area with relatively complicated circumstances, and inconsistency could arise in applying the current standards. This amendment has been made on the basis both of our own examination experience and the benchmark for the examination of inventions relating to use of chemical products, with reference made of the experience of some foreign nations along the line.”<sup>9</sup>

Stating that “this amendment has been made on the basis both of our own examination experience”, it seems that the SIPO drew on the precedents (e.g. the case of rejection

of the patent application 97122526.5), in which the novelty of a Swiss-type use claim with lower dosage was not permitted, and it obviously did not take the affirmative view on the matter as in more such cases (involving the substantive examination and reexamination of applications for the patents ZL 94194471.9, ZL98805686.0 and ZL95193441.4).

As for what the SIPO explained “with reference made of the experience of some foreign nations along the line”, quite likely it had referred to the Decision T0056/97-3.3.2 the EPO Board of Appeals made on 30 August 2001. In said Decision, the Board took the view that Modification of drug dosage regimens used for administering a particular medicament calls first and foremost for the exercise by a medical practitioner of his professional skill in curing, preventing or alleviating the symptoms of suffering and illness. Such activities are typical of the non-commercial and non-industrial medical activities which Article 52(4) EPC intends should remain free from restraint. Against that background, the Board has difficulty in seeing claim 1 as more than an unsuccessful attempt to obtain protection for a method of therapeutic treatment of the human or animal body by couching it in the form of a “Swiss type claim”.

But the SIPO obviously did not refer to the more recent EPO precedents. The EPO Board of Appeals, in the subsequent precedents, did not agree to the view presented in Decision T0056/97. For example, the Board was not for the view as presented in Decision T0056/97 in its Decision T1020/03-3.3.4 made on 29 October 2004 because the Board held that Decision T0056/97 conflicted with Decision G 0005/83. In the Headnote the Decision T1020/03, the Board pointed out that “Any use to which Article 52 (4) EPC first sentence applies in circumstances where the composition has already been suggested for some therapeutic use, allows a second medical use claim to the preparation of the composition for that second medical use, irrespective of in what detail that use was specified, subject to the use being novel and inventive.”

Like in the Decision T1020/03, the Board made it clear in Decision T0230/01-3.3.2 that a Swiss-type use claim with the feature of dosage and mode of administration was patentable.

In New Zealand Swiss-type use claims are held to be novel and different from claims for mode of administration, and the novelty thereof lies in the new method of treatment by virtue of different dosage and mode of administration.

This is also the position taken by the UK Supreme Court

of Appeal, which held in its rulings in cases A3/2007/1625 and A3/2007/1650, in respect of what was stated in the claim that “the application of finasteride in making oral pharmaceutical preparation for treating trichomadesis caused by androgenic hormone, with the dosage of 0.05-1.0mg”, that said claim possessed novelty and inventive step, and the court affirmed that the Swiss-type use claim whose novelty came from the new dosage or mode of administration was patentable.<sup>10</sup>

Making a selective reference to the existing examination experience and that to other nations, the SIPO provided in the Guidelines for Examination as of 2006 that “... the object, mode, route, usage amount, interval of administration ... . The distinguishing features merely present in the course of administration do not render the use novel” as the benchmark for the SIPO and the PRB to examine the novelty of Swiss-type use claim with the feature of dosage. Referring to this benchmark, the PRB declared patent ZL94194471.9 invalid in February 2007. In its invalidation decision, the PRB held that the technical features of claim 1 of the patent in suit (namely (1) the dosage of 0.05-3.0mg; and (2) the oral administration of the medicament) “were both features of administration, which, *per se*, did not define the technical solution of a process for making a medicament, ... If a particular medicament administration process objectively making some requirement on making the drug, ... that is, the feature of medicament administration implied, to an extent, the medicament-making feature, it might be held to indirectly define the medicament-making process, and it might be deemed to be a medicament-making technical feature”<sup>11</sup>. Accordingly, the PRB decided that the technical feature of claim 1 “the dosage of 0.05-3.0mg” did not define and limit, and contribute nothing to the novelty of, said claim.

Directed to the PRB’s invalidation decision, the patentee brought a lawsuit in the Beijing No.1 Intermediate People’s Court, and later appealed to the Beijing Higher People’s Court.

## IV. Beijing courts’ view

### (1) The first-instance court’s view

Before the Beijing court reviewed the validity of the patent ZL94194471.9, the PRB’s Reexamination Decision that patent application No. 97122526.5 lacked novelty was submitted to the Beijing No.1 Intermediate People’s Court for judicial review; the court supported the PRB’s conclusion

and reasoning, and made the first-instance ruling in December 2006 after the Guidelines for Examination as of 2006 took effect, holding that “[it] was administered on human at the dosage of 60-120mg/day for a sufficient period of time” as stated in claim 1 still substantially defined the “dosage” and “duration of medicament administration”, but did not define the process for making said medicament, so it was right for the PRB to have held that claim 1 did not possess novelty<sup>11</sup>. The interested party did not appeal the first-instance ruling.

After the patent ZL94194471.9 was invalidated by the PRB, the patentee brought an administrative suit in the Beijing No. 1 Intermediate People’s Court for judicial review of the PRB’s decision. Regarding the matter of whether medicament administration features, such as “dosage”, would render a Swiss-type use claim novel, the first-instance court agreed on the PRB’s decision, without repeating its reasoning (this often indicates that the court is doubtful about the PRB’s reasoning). The first-instance court’s grounds were as follows:

“In a Swiss-type claim, which is one of method, the dosage amount of administration is the amount of the active ingredient used during the treatment of a disease, i.e. a method of using the medicament, and is not directly relevant to the content of the active ingredient of the prepared pharmaceutical product. It is a dosage amount of a specific medicament selected by a doctor for an individual patient in order to meet the patient’s special needs and produce the desired therapeutic effects on the individual patient. The dosage amount depends not only on the selection of the unit dosage amount of the medicament during the preparation of the medicament, but also on the selection made by a doctor according to the special needs of an individual patient in the course of treatment. Thus it can be seen that the definition of the dosage amount of administration is not completely reflected during the preparation of the medicament, and it also covers what the doctor does in the treatment. However, the protection scope of a Swiss-type use claim does not cover a doctor’s act of treating a patient with the medicament in a certain dosage amount; otherwise, it would restrict the doctor’s condition and freedom for selecting various methods in the course of treatment, which is prejudicial to the public interests and contrary to the legislative aim of the Chinese Patent Law. Thus it can be seen that the dosage amount feature is not reflected in the preparation of a medicament, and it could be nothing but a technical feature of treatment of the disease. The defendant’s (PRB) view is a right one that the



dosage amount feature does not define and limit claim 1 and is deemed absent during the examination of novelty and inventiveness”<sup>12</sup>.

## (2) The second-instance court's view

The interested party appealed the first-instance court's decision to the Beijing Higher People's Court. During the second-instance judicial review, on the matter of whether medicament administration features, such as “dosage”, would render a Swiss-type use claim novel, the Higher People's Court made a conclusion different from those drawn by the PRB and the first-instance court. The Beijing Higher People's Court explicitly noted that it did not agree with the PRB and the first-instance court's reasoning, but without directly commenting on the administrative view presented in the Guidelines for Examination as of 2006 that “the distinctive feature merely embodied in the administration does not render said use novel”.

Regarding the PRB's practice of taking no account of the feature of dosage when examining novelty (namely, the dosage of 0.05-3.0mg), the Higher People's Court decided in its judgment that<sup>13</sup>:

“This patent is for an invention relating to medical use of a compound. The claims are drafted in the form of a typical Swiss-type claim ‘use of a compound X in the manufacture of a medicament for the treatment of disease Y’. Drafting the claim this way is to avoid the unpatentable subject matter of ‘use of compound X for the treatment of disease Y’ under the Chinese Patent Law, and what is claimed in the claim is virtually the medical use of compound X. If the medical use of compound X is characterised by the preparation of a medicament, it can be considered a process for preparing the medicament and is equivalent to ‘a process for manufacturing a medicament for the treatment of disease Y, characterized in the use of a compound X’.

A medical use invention is essentially an invention of a method of using a medicament, with technical features of how to use the medicament, i.e. the so-called ‘administration features,’ such as dosage form and dosage amount. They are technical features of method of using a compound and should be allowed in the claims. In practice, there also exists a need for achieving unexpected technical effects by improving the ‘administration features’, such as those of dosage form and dosage amount. In addition, the preparation of a medicament is not the preparation of the active ingredients or raw medicament, and it should comprise all the steps before packaging of the medicament, and should, of

course, include the ‘administration features’, such as specification of dosage form and dosage amount. This patent is one for which application is filed for a medical use invention relating to improvement of the dosage amount. Since the patentee has improved the dosage form and dosage amount, ignoring these ‘administration features’ would be detrimental to the development of medical industry and to the satisfaction of the public health needs, and contrary to the legislative aim of the Patent Law.”

Additionally, unlike the first-instance court, the Beijing Higher People's Court expressly held that taking account of the medicament administration feature, such as dosage form and dosage amount, in the medical-use invention claim would not make a doctor less free to provide his treatment. On this, the Higher People's Court decided in its judgment that:

“The court of the first instance holds that what is claimed in a Swiss-type use claim does not cover how much medication a doctor prescribed for a patient to treat his disease, otherwise it would restrict the doctor's condition and freedom to select various methods in his diagnosis and treatment and impair the public interests, and run counter to the legislative aim of the Chinese Patent Law. For the Court, this concern is not necessary. First, a doctor's act of treatment is not for business purposes, nor does it constitute an infringement of the patent right. Second, a Swiss-type use claim of a medical use invention generally includes the feature of substance of the medicament, the feature of its preparation, and the feature of the indications. However, a doctor's act of treatment is only associated with the technical features concerning how to use the medicament (which may involve the feature of indications), but with the features concerning the preparation of the medicament, so it does not infringe the patent right. Therefore, the incorporation of the technical features, such as those of dosage form and dosage amount, in the claims of a medical use invention does not restrict a doctor's freedom to treat diseases.”

Accordingly, the Beijing Higher People's Court, in determining the novelty of claim 1 of the patent in suit, decided that the technical features of “the dosage of 0.05-3.0mg” and “oral administration of the medicament” were both distinguishing technical features different from the prior art. Based on said two distinctive technical features, claim 1 possessed novelty.

## V. Conclusion

In deciding on the novelty of Swiss-type use claim with the distinguishing features such as dosage, the Beijing Higher People's Court did not support the PRB's administrative view that the technical features of "the dosage of 0.05-3.0mg" and "oral administration of the medicament" did not define claim 1.

Since China is not a case law country, the Beijing Higher People's Court's *ad hoc* judicial view is not binding on the PRB's examination of other cases. However, it is the second instance court that has the exclusive jurisdiction over the PRB's decisions made on patent validity. Faced with the Beijing Higher People's Court's judicial view different from the administrative benchmark set forth in the Guidelines for Examination, the PRB can make one of the following three choices in its course of action:

1) Revising correspondingly the Guidelines for Examination in such a way as to harmonise the administrative view presented therein with the judicial view;

2) Requesting the Beijing Higher People's Court or the Supreme People's Court for retrial to harmonise the judicial view with the administrative view presented in the Guidelines for Examination; or

3) Communicating with the Beijing Higher People's Court, so that the latter change its judicial view in the future to make it consistent with the administrative view presented in the Guidelines for Examination.

Otherwise, allowing the conflict between the administrative and judicial views to go unchecked, the PRB will be faced with the risk of its decision on the novelty of Swiss-type use claims to be corrected or cancelled by the Beijing Higher People's Court.

Considering the practice and developments of the law on examination of novelty of Swiss-type use claims in various countries, including China, it is believed that the Beijing Higher People's Court's judicial view is of far-reaching significance to the harmonisation of the standards on the examination of the novelty of Swiss-type use claims. ■

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sions set forth in the Guidelines for Examination: one, on the issue of whether one applicant's several similar design patents constituted double patenting, the Court presented a view different from the provisions of the Guidelines for Examination (see the Beijing Higher People's Court's Administrative Judgments Nos. Gaoxingzhongzi 464, 465, 467, 469 and 470/2006), which resulted in the PRB's later accepting the judicial views and changing its relevant examination benchmark in practice, and, meanwhile, led to the permission for filing one application relating to two or more similar designs incorporated in one product (see Article 32 of the Patent Law as of 2009), although the aforesaid administrative judgements were eventually supervised and reversed by the Supreme Court in December 2008; two, on the issue of whether the utility model patent and invention patent for which applications were filed by one applicant on the same day constituted double patenting, the court presented a view different from the provisions of the Guidelines for Examination, resulting in the PRB's appealing to the Supreme People's Court; the latter reviewed the Beijing Higher People's Court's effective judgment and supported the PRB's view (see the Supreme People's Court's Administrative Judgment No. Xingtizi 4/2007), resulting in the formulation of the express provision on the issue (see Article 9 of the Patent Law as of 2009).

<sup>2</sup> Paragraph two of Section 4.3 of the Guidelines for Examination as of 2006.

<sup>3</sup> Section 3.4.2, Chapter 10 of Part 2 of the Guidelines for Examination as of 1993.

<sup>4</sup> Section 4.5.2, Chapter 10 of Part 2 of the Guidelines for Examination as of 2006.

<sup>5</sup> The EPO Board of Appeal's Decision G5/83 [1985] OJ EPO 64, Section 23.

<sup>6</sup> See the PRB's Decision No. 4567.

<sup>7</sup> See the PRB's Decision No. 7610.

<sup>8</sup> Section 5.4, Chapter 10 of Part 2 of the Guidelines for Examination as of 2006.

<sup>9</sup> A Guide to the Amendments to the Guidelines for Examination as of 2006 (2nd edition), P.217.

<sup>10</sup> <http://www.ipeg.eu/blog/wp-content/uploads/actavis-uk-vs-merck-may-2008.pdf>

<sup>11</sup> See the PRB's Decision No.9508.

<sup>12</sup> The Beijing No.1 Intermediate People's Court's Administrative Judgment No. Yizhongxingchuzi 683/2006.

<sup>13</sup> The Beijing No.1 Intermediate People's Court's Administrative Judgment No. Yizhongxingchuzi 854/2007.

<sup>14</sup> The Beijing Higher People's Court's Administrative Judgment No. Gaoxing zhongzi 378/2008.

<sup>1</sup> In the court's judicial review of the PRB's decisions on the validity of patent in the past, the Beijing Higher People's Court presented, on two different occasions, its judicial views different from the relevant provi-