American Intellectual Property Law Association

AIPLA 2011 Spring Meeting

“Patent Protection of Biotechnological Inventions in China”

By Gesheng Huang
Zhongzi Law Office

May 12-14, 2011
San Francisco, CA
Table of Contents

I. Introduction

II. Patentability of Typical Biotechnological Subject Matter
   A. Method of Treatment and Diagnosis
   B. Animal and Plant Variety
   C. Stem Cell
   D. Gene and Protein
   E. Antibody

III. Disclosure Requirements for Biotechnological Invention
    A. Written Description of Biotechnological Invention
    B. Deposit of Biological Material
    C. Disclosure of Genetic Resources

IV. Patent Linkage and Data Exclusivity

V. Enforcement of Patent Rights for Biotechnological Invention
   A. Bolar Exemption
   B. Collection of Evidence

VI. Conclusion
Patent Protection of Biotechnological Inventions in China

I. Introduction

This paper is mainly focused on patent prosecution of biotechnological inventions in China. It begins with patentability discussion of different subject matter in the biotechnology field, including methods of treatment and diagnosis, animal and plant varieties, stem cell, gene/protein, and antibody. The paper also introduces the information that may need to be disclosed in a patent application for biotechnological inventions. The paper ends with addressing two specific issues on patent enforcement for biotechnological inventions in China, i.e., the so-called Bolar exemption and collection of evidences during litigation.

II. Patentability of Typical Biotechnological Subject Matter

A. Method of Treatment & Diagnosis

Methods of treatment or diagnosis of diseases per se are explicitly excluded from patent protection under Article 25 (3) of the Chinese Patent Law. For most of patent application directed to this subject matter, patent rights may still be granted after a suitable amendment of claims.

1. Methods of Diagnosis for Diseases

According to the Patent Examination Guidelines, a method is regarded as a method of diagnosis for diseases if the following two conditions are met:
  a. it is practiced on a living human or animal body, and
  b. its immediate purpose is to obtain the diagnostic result of a disease or health condition. (cf. Section 4.3.1.1, Chapter 1, Part II of the Guidelines).

As a special case in this regard, however, it is further interpreted under the Guidelines that if an invention is practiced on samples in vitro, but its immediate purpose is to obtain the diagnostic result of a disease or health condition for the same subject, said invention shall still be regarded as a method for diagnosis of diseases.

The followings are examples of claims that are rejectable under Article 25 (3) for being method of diagnosis of diseases:
  a. method of measuring blood pressure;
  b. method of evaluating the risk of suffering diseases;
  c. method of predicting the therapeutic efficacy;
  d. method of detection of blood sample in vitro for a substance which can be used as an indication of diseases.

The following examples show how claims originally directed to methods of diagnosis be amended into patentable subject matter and finally be granted (searched from SIPO website: www.sipo.gov.cn):

a. ZL03823342.8

Original claim 1: A method to determine the degree of serum cholesterol elevation which will occur in a patient during treatment with an immunosuppressant medication comprising:
a) determining for the two copies of the IL-1\(\beta\) gene present in the patient the identity of the nucleotide pair at the polymorphic site -511 C\(\beta\)T (at position 1423 of sequence X04500) of the IL-1\(\beta\) gene; and

b) assigning the patient to a high cholesterol elevation group if both pairs are AT, assigning the patient to an intermediate cholesterol elevation group if one pair is AT and one pair is GC and assigning the patient to a low cholesterol elevation group if both pairs are GC.

Granted Claim 1: A pharmaceutical composition comprising an immunosuppressant and a cholesterol-lowering medication.

b. ZL02808648.1

Original claim 1: The use of the direct correlation between the overexpression or the functional molecular modification of human horologes of the sgk family and hypertension for quantitative diagnosis of a particular form of genetically determined hypertension.

Granted claim 1: The Use of the hypertension-relevant SNP C\(\rightarrow\)T in exon 8 of the hsgk1 gene as shown in Fig. 1, the hypertension-relevant SNP T\(\rightarrow\)C in intron 6 of the hsgk1 gene 551bp upstream from the SNP in exon 8 as shown in Fig1, or of both the SNPs for producing a diagnosticum for the in vitro diagnosis of a genetically determined form of hypertension.

2. Method of Treatment for Diseases

According to the Patent Examination Guidelines, method of treatment for diseases refers to “the processes of intercepting, relieving, or eliminating the cause or focus of diseases so that the living human or animal bodies may recover or gain health or relieve pain.....Prophylactic methods and methods of immunization are regarded as methods of treatment for diseases” (cf. Section 4.3.2, Chapter 1, Part II of the Patent Examination Guidelines).

To overcome a rejection under Article 25 (3) for claiming an unpatentable method of treatment, a feasible way is to draft it in the form of so-called Swiss-style medical use claim, i.e., “Use of compound A for the manufacture of a medicament for treatment of disease X”.

As to a special and questionable issue in this regard, i.e., whether features of administrative regimen or dosage shall be taken into account when considering the novelty or inventive step of a Swiss-style use claim, obviously there is a discrepancy between the court and the PRB (Patent Re-examination Board of SIPO).

In the case Merck vs. PRB (Beijing High Court Case No.: (2008) Gao Xin Zhong Zi No. 378), the Beijing High Court held that “A medical use invention is essentially an invention of the method of using a medicament. The technical features concerning how to use the medicament, i.e., the so-called “dosing features” such as dosage form and dosage amount, belong to the technical features of the method of using the compound and should thus be allowed to be incorporated into the claims to define the medical use invention. In practice, there is also a need of achieving unexpected technical effects by improving the so-called “dosing features” such as dosage form and dosage amount. In addition, the preparation of a medicament is not the preparation of the active ingredient or raw material drug, and it should comprise all the steps until packaging of the medicament, and should, of course, include the so-called “dosing features” such as specification of dosage form and dosage amount.”

1 Available at http://bjgy.chinacourt.org/public/paperview.php?id=27312
Based on this understanding, the court reversed the decision made by the lower court as well as the decision made by the PRB, both of the latter held that the feature of dosing regimen normally do not have limitations to a Swiss-style use claim, thus should not be taken into account when examining the novelty and inventive step of the invention.

In practice, however, as China is not a common law country, the opinion held by the Beijing High Court in the above case has not been commonly accepted by the CPO and the PRB, and the Patent Examination Guidelines has not been amended accordingly to reflect the opinion of the court.

B. Animal/Plant Variety

Animal and plant varieties are explicitly excluded from patent protection under Article 25 (4) of the Chinese Patent Law.

Different from the practice at EPO, there is no discrimination between animal/plant variety and specific animal/plant under the Chinese patent practice. According to the Patent Examination Guidelines, “Animal” referred to in the Patent Law is defined as “the life form which cannot synthesize carbohydrate and protein by itself but maintains its life only by absorbing natural carbohydrate and protein”, and “plant” is defined as “the life form which maintains its life by synthesizing carbohydrate and protein from the inorganics, such as water, carbon dioxide and inorganic salts, through photosynthesis, and usually is immovable” (cf. Section 4.4, Chapter 1, Part II of the Patent Examination Guidelines).

It is further interpreted under the Patent Examination Guidelines that “animal variety” also includes “an embryonic stem cell of an animal, an animal at the various stages of its formation and development, such as a germ cell, an oosperm, an embryo and so on”, and “plant variety” includes “a single plant and its reproductive material (such as seed, etc.)” (cf. Section 9.1.2.3, Chapter 10, Part II of the Patent Examination Guidelines).

Therefore, a claim directed to any of subject matter as mentioned above, regardless how it is defined, shall be rejected by the Chinese Examiner.

For an invention in the related field, patent protection can be procured by the following two possible ways:

a. changing the subject matter of a claim originally directed to an animal/animal variety to a somatic cell of an animal, a tissue or an organ of an animal (except an embryo), and similarly, the subject matter of plant/plant variety can be changed to a plant cell, tissue or organ which does not possess the property of photosynthesis, since these latter subject matters are excluded from the unpatentable subject matter of animal/plant variety stipulated by Article 25 (4) of the Law.

In order to make such amendment of the claims, it should be aware that the specification as filed should comprise the relevant content of the subject matter of said cell, tissue or organ, preferably provide examples of said content. Otherwise, such a change of subject matter may possibly result in a new matter rejection during prosecution.

b. changing the subject matter of a claim originally directed to an animal/animal variety to a method for the production of said animal/plant variety, since said method is a patentable subject matter under Article 25, paragraph 2 of the Law.
Furthermore, according to Article 11 of the Patent Law, the protection of a patented method can be extended to a product directly obtained by the patented method. That is to say, with the grant of a method for the production of an animal/plant variety, said animal/plant per se can also be protected to some extent.

In addition, for patent varieties, please note that the so-called breeder’s right protection is also available in China, which, however, is a kind of administrative protection based on the Regulations for Protection of New Plant Varieties.

C. Stem Cell

Stem cells include those obtained from an embryo and those from somatic cells. For these two kinds of stem cells, the CPO takes a different policy for their patentability.

1. Embryonic Stem Cell

Even for embryonic stem cells, they are still treated differently according to the origin of the stem cell.

a. Embryonic Stem Cell from Human Beings

According to Article 5 of the Law, “No patent shall be granted for any invention-creation that is contrary to the laws or social morality or that is detrimental to public interest.

Section 9.1.1.1, Chapter 10, Part II of the Guidelines further stipulates that “Both an embryonic stem cell of human beings and a preparing method thereof shall not be granted the patent right in accordance with the provisions of Article 5.1”.

From the above provisions, it can be clearly aware that any use of human embryos for industrial or commercial purposes shall be regarded as against social morality and thus no patent right shall be granted for any invention thereon, neither an embryonic stem cell of an animal, its preparation nor its uses.

b. Embryonic Stem Cell from Animal

As discussed in the Item of “animal and plant variety” above, embryonic stem cell of an animal is regarded as belonging to animal variety. Therefore, according to Article 25 of the Law, embryonic stem cell of an animal itself is excluded from patent protection, but a process for the manufacture of an embryonic stem cell of an animal can be protected by a patent in China.

2. Non-embryonic Stem Cell

Non-embryonic stem cell, i.e., stem cell from a somatic cell, is usually not of biological potentiality, and cannot develop into an animal. Thus, non-embryonic stem cell is usually not belonging to an animal variety and is a patentable subject matter under the Chinese Patent Law.

However, if said stem cell from a somatic cell is subject to treatment and of biological potentiality, it shall be excluded from patent protection under Article 25 (3) as being regarded as animal variety.
D. Gene and Protein

Gene and protein are both patentable subject matters under the Chinese Patent Law. According to the Guidelines for Examination and the current practice in China, a gene or protein can be defined in one or more of the following ways:

1. by the specific nucleic acid/amino acid sequence of said gene/protein;
2. by a combination of the phrase “substitution, deletion, or addition of one or several amino acids” and the functions of said gene/protein;
3. by a combination of the phrase “hybridize under stringent conditions” and the functions of said gene/protein;
4. by a combination of the phrase “having a percent homology” and the functions of said gene/protein;
5. by possible other features, such as functions, physiochemical properties, origin of said gene/protein, or a process for producing said gene/protein, if it is hard to be defined by any of the above ways.

To have variants of a gene/protein as defined in the above items 2-4 been accepted by the Chinese Examiners, it is usually required that:

1. said variants are of the same functions of the original gene/protein;
2. specific example of a variant was illustrated in the original specification, including its sequence, manufacture process and biological data; and
3. the number of examples of variants should be sufficient to support the definition of said variants in the claims, for example, the range of percent identity of exemplified variants need to be consistent with the identity percentage as claimed.

Patent applicants sometimes complain about Chinese Examiners for their high standards in examining biotech inventions, and some even have the impression that under the Chinese patent practice, the claims of a gene/protein can only be limited to that specifically exemplified in the specification.

In this regard, on one hand, it has to be admitted that the Chinese Examiners usually take a conservative attitude towards the sufficient disclosure issue and support issue for biotech inventions. On the other hand, it also has to be admitted that most rejections of patent applications for biotech inventions were mainly caused by the fact that the patent applicants failed to provide suitable and sufficient examples as required above in the original specification.

E. Antibody

As a kind of proteins of specific functions, antibody is of course a patentable subject matter and is also subject to the same general guides for the examination of protein inventions as discussed in the paragraph under “Gene/protein” above.

However, as a special protein, antibody is of some special characteristics as compared with other proteins, especially in terms of its structure and biological properties. Due to lack of specific guides for the examination of such kind of invention, different Examiners may take a different standard on how to define an antibody in the claims.

The followings are some of definitions of antibody that have been accepted by SIPO:

1. By the Specific Sequence of Light Chain Variable Region (VL) + the Specific Sequence of Heavy Chain Variable Region (VH)
Example: Claim 1 of Chinese Patent No. ZL01808430.3
Claim 1. A humanized antibody having a light chain variable region of the sequence given by SEQ ID NO : 9 and a heavy chain variable region given by SEQ ID NO : 10.

2. By the Specific Sequences of CDR1-3 of VL and CDR 1-3 of VH + Antigen

Example: Claim 1 of Chinese Patent No. ZL200380101543.2
Claim 1. An isolated antibody comprising a light chain CDR1, a light chain CDR2, a light chain CDR3, a heavy chain CDR1, a heavy chain CDR2, and a heavy chain CDR3, wherein
the heavy chain CDR1 consists of the amino acid sequence of SEQ ID NO: 34;
the heavy chain CDR2 consists of the amino acid sequence of SEQ ID NO: 35;
the heavy chain CDR3 consists of the amino acid sequence of SEQ ID NO: 36 or SEQ ID NO: 37;
the light chain CDR1 consists of the amino acid sequence of SEQ ID NO: 38, SEQ ID NO: 39, or SEQ ID NO: 40;
the light chain CDR2 consists of the amino acid sequence of SEQ ID NO: 41 or SEQ ID NO: 42;
the light chain CDR3 consists of the amino acid sequence of SEQ ID NO: 43 or SEQ ID NO: 44;
and the antibody can bind specifically to IFN-γ.

3. By the Deposited Hybridoma Cell with the Specific Deposition Number

Example: Claim 1 of Chinese Patent No. ZL200480015677.7
Claim 1. An isolated monoclonal antibody prepared by the hybridoma cell line deposited with the ATCC as Accession Number PTA-5065.

4. By the Specific Antigen

Example: Claim 14 of Chinese Patent No. ZL200510121733.1
Claim 14. Antibody reactive with a bacterium according to claims 1 to 6.

III. Disclosure Requirements for Biotechnological Inventions

A. Written Description of Biotech Inventions

Article 26 (3) of the Law requires that the description shall set forth the invention in a manner sufficiently clear and complete so as to enable a person skilled in the art to carry it out.

Compared with the practice with the USPTO or EPO, it seems that SIPO usually takes a higher standard on enablement requirement, especially for biotechnological inventions and pharmaceutical inventions. In fact, it can be felt that more and more patent applications for biotech inventions have been rejected by the CPO in recent years mainly based on enablement ground.

In order to meet the enablement requirement and to avoid a rejection in this regard, the following points may be addressed:
1. As for an invention relating to a biotech product, such as a gene, a recombinant vector, a transformant, a polypeptide, or a monoclonal antibody, the description needs to disclose the identification, preparation, and use and/or technical effect of the product.

2. A general description of the biological effect of the claimed product cannot meet the enablement requirement. Instead, specific example with biological data needs to be disclosed.

3. The biological data should be directed to specific product, a general conclusion such as “the compounds of the instant invention have an IC 50 value in the range of…” normally will not be regarded as meeting the enablement requirement.

4. The number of examples should be sufficient in order to support the scope as claimed.

5. Biological data should be disclosed in the original description. An enablement rejection usually cannot be overcome by submission of biological data after filing of the application.

B. Deposit of Biological Material

Besides the requirement of written description as mentioned above, as a special requirement for patent applications for inventions that involve the use of new biological material, it is stipulated under Rule 24 of the Regulations that the applicant needs to make a deposit of said new biological material if said biological material is not available to the public and cannot be described in the application in such a manner as to enable the invention to be carried out by a person skilled in the art.

Specifically, the applicant needs to go through the following formalities:

1. to deposit a sample of the biological material with a depository authority under the Budapest Treaty on or before the filing date/priority date of the application;

2. to submit deposit proof (Receipt of Deposit and Viability Statement) issued by the depository authority, on the Chinese filing date/date of entry in China, or at the latest, within four months from the Chinese filing date/date of entry;

3. to indicate in the Description the necessary information of the deposit, including the scientific name of the biological material, name and address of the depository authority, date of deposit and the accession number of the deposit (or to supplementing said deposit information into the Description within four months from the Chinese filing date or the entry date of the application.

C. Disclosure of Genetic Resources

Provisions on “genetic resource” are completely new content introduced when the Chinese Patent Law was revised for the third time in 2008. Under the amended Law, two new paragraphs are added with respect to “genetic resources”, Article 5.2 stipulates that no patent right shall be granted to inventions which were made by illegal acquisition and utilization of genetic resources, while Article 26.5 requires the applicant to disclose the direct and original source of genetic resources in a patent application.

1. What Is Meant by “Genetic Resources”?

The term “Genetic resources” is explicitly defined as “a material of actual or potential value that is taken from human bodies, animals, plants or microorganisms and contains functional units of heredity” in Rule 26 of the Implementing Regulations of the Law.
Furthermore, according to the Guidelines, the term “Functional units of heredity” refers to genes of an organism or DNA or RNA fragments with genetic function, and “genetic function” refers to the ability of an organism to pass the characteristic or feature from generation to generation or the ability to replicate the entire organism by propagation (cf. Section 3.2, Chapter 1, Part II of the Guidelines).

2. For Which Applications the Applicant Needs to Disclose “Genetic Resources”?

The requirement for disclosure of genetic resources shall apply to all patent applications that are directed to invention-creations that are completed relying on a genetic resource. Here, “an invention-creation completed relying on a genetic resource” means “an invention-creation that is completed by utilizing the genetic function of the genetic resource, which comprises separation, analysis, treatment and the like of the functional units of heredity, for the purpose of realizing the value of said genetic resources” (cf. Section 3.2, Chapter 1, Part II of the Guidelines).

3. Which Specific Information Needs to Be Disclosed?

As required by Article 26.5 of the Law, the applicant needs to indicate the direct source and original source of genetic resources.

The Guidelines further defines that “the direct source of a genetic resource refers to the direct channel for obtaining said genetic resource, including the time, place, way and provider for obtaining said genetic resource.”, and

“The original source of a genetic resource” refers to “the site of collecting the organism to which the genetic resource belongs in primary environment. The primary environment can be either an environment for natural growth of said organism or an environment of forming a specific characteristic or feature for said organism if the genetic resource is cultured or acclimatized. In order to indicate the original source of the genetic resource, the applicant is required to provide such information as the time, place, and collector for obtaining said genetic resource.” (cf. Section 9.5.1, Chapter 10, Part II of the Guidelines).

In addition, Rule 26 of the Implementing Regulations further requires that if the applicant is not able to disclose the original source of genetic resources, he needs to give corresponding reason(s).

4. How to Disclose the “Genetic Resources”?

As a new requirement under the amended Law, the applicant is asked to disclose the direct and original source of the genetic resources. However, the applicant is not asked to disclose said information in the patent specification.

Instead, SIPO has prepared and published a specific form to be used by applicants for this purpose. The form is titled as Registration Form for Disclosure of Origin of Genetic Resource, as shown below:
Fill in the following columns by reference to the attached “NOTICES”

<table>
<thead>
<tr>
<th>Column</th>
<th>Description</th>
<th>Reference</th>
<th>Patent Office, if unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Title of invention</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Application number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Applicant(s)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Filing date</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Name of genetic resource</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Channels of acquiring genetic resource</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>Source: □ animal □ plant □ microorganism □ human</td>
<td></td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>Channels: □ purchase □ donation or exchange □ depository authority □ seed bank (germplasm bank) □ gene library □ collection by self □ collection by entrustment □ others</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Direct source</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Time of acquisition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Name of provider</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Country or region of provider</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Contact of provider</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Collection site</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Collection site (country, province (city))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Name of collector</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Contact of collector</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Original source</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Name of collector</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Contact of collector</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>Time of acquisition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Place of acquisition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Specify reasons if the original source of the genetic resource cannot be declared:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>Signature or seal by all applicants or patent agency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>Opinion of Patent Office</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. “When to Disclose the “Genetic Resources”?”

The amended Law and the Regulations do not set a specific time limit for the applicant to disclose the information of “genetic resources”. The disclosure can either be made at patent filing
in China by applicants on their own initiative, or at the time when responding to an Office Action wherein the Examiner raises such a request.

6. What Are Consequences for Violation of the Requirements?

For violation of Article 5.2 of the Law, the patent application can be rejected by the Examiner during substantive examination. Furthermore, even it has been granted by mistake, it can also be invalidated during invalidation proceeding.

For violation of Article 26.5 of the Law, however, it is merely a ground for rejection, but not a ground for invalidation.

IV. Patent Linkage and Data Exclusivity

The so-called patent linkage usually refers to the connection of the marketing approval of a generic drug with the expiration of patent term of an innovative drug, so as to avoid possible patent infringement.2

According to the practice in the States, the drug patent linkage system mainly comprises the following constitutional parts:2

a. Patent declaration system
b. Orange book system
c. Simplified applications system for generic drug
d. Data exclusivity system
e. FDA and USPTO linkage system

Under the Provisions for Drug Registration in China (SFDA Order No.28), some similar systems are formally established for patent linkage, which comprise:

1. Declaration for Patents.

According to Article 18 of said Provision, an applicant for drug registration shall provide the information on patent and its ownership of the applicant or other parties in China, in respect of the drug applied for registration. If another party owns the patent in China, the applicant shall provide a statement of non-infringement.

2. Information Disclosure System

Although Article 8 of said Provisions requires that the SFDA shall disclose on its website some relevant information of the approved drug, only very limited information is available from the SFDA website, especially the information concerning patent as required by Article 18 of said Provisions above, due to the fact that this patent information is completely obtained from drug applicant and there is no penalty for failing to disclose said information.

---

3. Data Exclusivity System

According to Article 20 of said Provisions, a protection period of six years is provided for undisclosed experimental data, i.e., the SFDA shall reject any application made by any other applicants by using said undisclosed data, unless the data is independently acquired by the applicants other than the original one.

However, as a necessary and most effective part of patent linkage, the functional linkage between the competent authorities, SIPO and SFDA, has not been established under the current Provisions for Drug Registration. SIPO is merely responsible for examination of patent application, and SFDA responsible for drug approval, there is in fact no exchange of patent information between SIPO and SFDA.

In view of the above facts, therefore, it has to be admitted that there is no substantial and effective patent linkage system in China nowadays.

V. Enforcement of Patent Rights for Biotech Inventions

A. Bolar Exemption

The so-called Bolar exemption is a new content introduced into the amended Patent Law. The following is a citation of Article 69(5) of the Law:

“Article 69. None of the following shall be deemed an infringement of the patent right:

……

(5) Where any person manufactures, uses or imports patented drug or patented medical device for the purpose of providing information that is necessary for regulatory approval, or any other person manufactures or imports patented drug or patented medical device solely for him to provide such information.”

From the provision above, it can be noted that under the Chinese Patent Law, Bolar exemption applies not only to patented drug, but also to patented medical device.

Although Bolar exemption was formally and explicitly stipulated under the amended Law, it have accepted and applied by Chinese courts for many years. For example, in Eli Lilly vs. Ganli (Beijing High Court Case No.: (2007) Gao Min Zhong Zi No.1844), the Beijing High Court held that:

“It has been investigated that the insulin analog involved in claim 2 of the subject patent is insulin lispro, which is just the basic ingredients of “Su Xiu Lin.” The fact has been ascertained by the court. “Recombinant Insulin Lispro Injection” applied by Ganli to SFDA has obtained drug registration permit, and is ready to be launched onto market. However, the direct purpose of Ganli’s above act is to get ratification of SFDA regarding registration and production of the accused infringing product as a drug, rather than using the subject patented method of Eli Lilly and Company for a business purpose. Therefore, Ganli’s act of applying “Recombinant Insulin Lispro Injection” to SFDA and obtaining the registration permit does not constitute exploration of the subject patent. The appellate allegation of Eli Lilly and Company lacks legal grounds,
and thus this court does not support it.”  

B. Collection of Evidences

As a general principal under the Civil Procedure Law in China, the party who claims usually shall take an initial burden of proof, therefore, the success of a patent infringement suit largely depends on the evidences possessed by each party.

Unlike in the States, discovery procedure is not available in China. How to collect enough evidences in order to prove exist of patent infringement becomes a big challenge for patent holders.

The Civil Procedure Law empowers the court the rights to investigate and collect evidences, as stipulated by Article 64 of Civil Procedure Law:

“Where a party and its agent ad litem are unable to collect the evidence on their own for reasons beyond their control, or where the people’s court deems it necessary for the trial of the case, the people’s court shall investigate and collect the evidence.”

In practice, however, this power is seldom be used by courts due to the reason that the evidences that can prove patent infringement are usually only in possession of the alleged infringer and may involve the commercial secret of the alleged infringer. However, in a patent infringement suit for a biotech or pharmaceutical invention, the court is likely willing to collect said evidence ex officio, should a party make such a request to the court, because the information concerning the accused product or process is usually present in the regulatory document submitted to the SFDA by the accused infringer and it is comparatively easier for the court to collect said regulatory documents from the SFDA. In practice, this resource is frequently used by parties in patent infringement cases involving drugs and biologics.

VII. Conclusion

In view of the specialty and complexity of biotechnological inventions, SIPO accordingly sets forth some special provisions for examination of biotechnological inventions. Furthermore, the Chinese Examiners sometimes consciously or unconsciously raised the standard of patentability of biotech inventions and even shift undue burden on patent applicants. To success procure a patent for a biotech invention or to enforce a biotech patent in China, the practitioners need to be aware and familiar with those special requirements and practice at SIPO as well as at the courts.

Mr. Huang is a partner of the law firm Zhongzi Law Office. The views expressed here are personal to him, and are not necessarily those of the firm or any client of the firm.
