Chinese Patent Protection on the Living Matters

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I. History

A. Intellectual Property Protection and Developing Countries

There is historical precedent for developing countries to “borrow” from other countries’ technologies,¹ and there are several concerns rendering them reluctant to give intellectual property (IP) to its full protection. One of which is that the expensive technology transfer fee to the technology-exporting countries will ultimately result in a lack of funds to develop its own domestic technological infrastructure.² Rigid IP protection also has a tendency to create monopolies in developing economies where the market is commonly less competitive, thus undermining the effective development of domestic innovations.³ More importantly, the cost of implementing protective IP regimes is extremely burdensome on less developed countries as it requires extensive legislation, institutional development, training and enforcement.⁴ As a result, many developing countries find it more desirable to copy certain types of technology rather than impose a strict regime of IP protection.⁵

On the other hand, there is consensus that strong IP protections will encourage economic development by 1) promoting domestic innovation by protecting the development of nascent technology; (2) preventing brain drain by ensuring innovators are rewarded for their effort; and (3) fostering technology transfers, such as foreign direct

² Id.
³ Id.
⁴ Id. at 169.
⁵ Id. at 168.
investments, licensing, and imports. In addition, more and more developing countries have realized that although piracy may be desirable in the short term, it does not support absorption of technology. Piracy could potentially result in long-term losses through decreased transfers of advanced technology and the inability of the technology transfer recipient to innovate further on the basis of technology obtained through piracy.

B. Development of Chinese Intellectual Property Protection

China’s début on the international arena of the intellectual property (IP) protection dates back to 1980, when it joined the World Intellectual Property Organization (WIPO), and demonstrated its intention to meet international standards of IP protection. Since then, China has acceded one after the other to the major international conventions and agreements for the protection of IPR, the Paris Convention of Industrial Property (Paris Convention) in 1984, the Patent Cooperation Treaty (PCT) in 1993, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Budapest Treaty) in 1995, the International Convention for the Protection of New Varieties of Plants (UPOV Convention) in 1999. On November 10, 2001, China became a member of the WTO, agreeing to abide the

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6 Schiappacasse, Supra, n.1 at 167.
7 Id.
entire WTO regime, including Trade Related Aspects of Intellectual Property Rights (TRIPs).  

As to its domestic legal system, four years after joining WIPO, China enacted its first patent law to facilitate trade and establish a legal framework for foreign exchange. The 1984 Patent Law provided for the granting of patents in the areas of inventions, utility models, and designs. However, Article 25 of it explicitly prohibited granting of patents to pharmaceutical and chemical inventions or animal and plant varieties. It was not until the 1992 amendment to the Patent Law that the ban on granting of the patent to new pharmaceutical and chemical inventions was lifted. By 2000, a second amendment to the Patent Law was adopted, which strengthened the protection on the patent rights and simplified patent review procedures, and harmonized the statute with TRIPs standards.

In order to provide the law enforcement agencies a clear guideline, in 2001, the State

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18 The Patent Law was amended in accordance with the Decision of the Standing Committee of the Seventh National People's Congress on Amending the Patent Law of the People's Republic of China at its 27th Meeting on September 4, 1992. After the amendment, Article 25 provides

“For any of the following, no patent right shall be granted:

(1) scientific discoveries;
(2) rules and methods for mental activities;
(3) methods for the diagnosis or for the treatment of diseases;
(4) animal and plant varieties;
(5) substances obtained by means of nuclear transformation.

For processes used in producing products referred to in items (4) of the preceding paragraph, patent right may be granted in accordance with the provisions of this Law.”


II. Current Status of the Chinese Patent Protection on Biotechnology

A. General Applications

Generally, application should be made in Chinese to State Intellectual Property Office (SIPO). If any foreigner, foreign enterprise or other foreign organization having no habitual residence or business office in China applies for a patent, or has other patent matters to attend to, in China, it or he shall appoint a patent agency designated by the Patent Administration Department Under the State Council to act as his or its agent.

Applicant must submit documents on prescribed forms containing detailed information of the applicant and setting forth the name, a clear and complete description of the item sufficient for a person skilled in the relevant field of technology to carry it out, a diagram or picture should be included when necessary, and a requested scope for protection.

22 The Chinese version of the Guidelines is available online at http://www.acpaa.cn/lawreg/reg/guide/0-0.htm.
23 The Patent Law, Article 20.
24 A list of the designated agencies and their addresses is available online at http://www.sipo.gov.cn/sipo_English/zlsq/rhsqzl/t20020418_34053.htm.
26 Id. Article 26.
The object to be protected by the patent law must possess novelty, inventiveness, and practical applicability.\(^{27}\) The whole process of examination may take up to three years.\(^{28}\) If all the requirements are satisfied, a certificate of patent will be granted, registered and published.\(^{29}\) The protection for new inventions will be valid for twenty years,\(^ {30}\) and annual fees must be paid to maintain patent protection.\(^ {31}\)

If the application fails the examination, it will be rejected.\(^ {32}\) However, the applicant may request a re-examination to the Patent Re-examination Board within three months of reception of the rejection notice.\(^ {33}\) If the applicant does not agree with the decision made by the Re-examination Board, within three months of reception of the notice, the applicant may file a complaint to the People Courts.\(^ {34}\)

B. Animal and Plant

Article 25 paragraph 4 of the Chinese Patent Law prohibits the granting of patent to “animal and plant varieties.”\(^ {35}\)

The reason for denying the patentability of the animal and plant varieties is due to the particularity borne within the varieties themselves, namely, the complicated phenomena of life.\(^ {36}\) Because of this particularity, it is difficult to reduce the description of the varieties clearly and precisely into the written form as required by the Patent Law.\(^ {37}\) Because of the particularity, it is also difficult to publish the varieties by presevering

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27 Id. Article 22.
28 Id. Article 35.
29 The Patent Law, Article 39.
30 Id. Article 42.
31 Id. Articles 43, 44.
32 Id. Articles 37, 38.
33 Id. Articles 41.
34 Id.
35 Id. Article 25. See Supra n. 19.
them like biological materials.\textsuperscript{38} In addition, because of the varieties are very susceptible to the environment, they have a high variability.\textsuperscript{39} Finally, because the animal and plant varieties are closely related to our daily life and economy, it is very difficult, in terms of patent protection, to clarify the scope of protection and to regulate their production and commercialization.\textsuperscript{40} Therefore, although Patent Law requires inventiveness, novelty and practical applicability,\textsuperscript{41} a new set of requirements is necessary to determine whether an animal or plant variety should be protected: novelty, distinctness, uniformity, and distinctness.\textsuperscript{42}

As a result, although not protected by the Patent Law, the intellectual property of the new varieties of plants is protected by the Regulations of the People’s Republic of China on the Protection of New Varieties of Plants (“Regulations”).\textsuperscript{43} According to the Regulations, the entity which or the person who has accomplished the breeding has an exclusive right in their protected variety\textsuperscript{44} for 20 years, in cases of vines, forest trees, fruit trees and ornamental plants, or 15 years, in cases of other plants.\textsuperscript{45} The right extends to the “[production or sale] for commercial purposes the propagating material of the protected variety,”\textsuperscript{46} and the commercial use of which “in a repeated manner in production of the propagating material of another variety,”\textsuperscript{47} and the right to assign in

\begin{itemize}
\item Implementing Regulations, Article 25.
\item WANG, \textit{Supra} note 34.
\item \textit{Id.}
\item Id.
\item the Regulations of the People’s Republic of China on the Protection of New Varieties of Plants, Article 2.
\item This Regulation was promulgated by the State Council on March 20, 1997. English version is available online at \url{http://www.upov.int/en/publications/nplaws/china/china.pdf}. The Regulations are the statutory authority. For detailed information concerning intellectual property protection on the new plant varieties, please see X. Zhang, \textit{Statutory Protection of New Varieties of Plants in China}, __ Okla. J.L. & Tech. __ (2005)
\item Regulations, Art. 6.
\item \textit{Id.} at Art. 34.
\item \textit{Id.} at Art. 6
\item Regulations, Art.6.
\end{itemize}
accordance with the law.\textsuperscript{48} However, the Regulations only protect the varieties that are on the Lists of Protected Plant Varieties, \textsuperscript{49} which is published by the Ministry of Agriculture and the State Forestry Administration. Although, so far the Ministry of Agriculture has published five sets of such lists, and the State Forestry Administration has published four sets of the lists, inevitably, a large number of plant varieties are still not protected by the Regulations.

Nevertheless, the recent Canadian Supreme Court opinion in \textit{Monsanto Canada Inc. v. Schmeiser} may indicate another approach for the owners of those plant varieties that are not on the Lists. The court in \textit{Schmeiser} held that although living higher life forms were not patentable, the modified or isolated genes and cells were patentable\textsuperscript{50}. In addition, the court held that if these genes and cells were patented, the Patent Act of Canada will in effect not only protect the actual plants themselves, but the act of growing and harvesting the transgenic plants as well\textsuperscript{51}, because the majority decided that the saving and planting of seed, then harvesting and selling plants, containing the patented chimeric gene, was in fact use of the patented invention.\textsuperscript{52} In China, although the plant itself is not patentable, genes, plasmids, microorganisms and cell lines are patentable\textsuperscript{53}. Therefore, if the Chinese courts are willing to take the Canadian approach, the breeders will in fact enjoy the same protection on their plant varieties even if the varieties are not on the published Lists.

\textsuperscript{48} \textit{Id.} at Art 9.
\textsuperscript{49} Regulations, Art. 2
\textsuperscript{50} \textit{Monsanto Canada Inc. v. Schmeiser}, 2004 SCC 34 at para 22.
\textsuperscript{51} \textit{Id.} at para. 69.
\textsuperscript{53} Guidelines, Part II, Chapter 10, § 7.1.1.
On the other hand, Chinese legislatures have not drafted any legislation that protects the intellectual property of the animal varieties. However, because the Patent Law allows the protection to the biological materials, such as genes, plasmids, microorganisms, and cell lines, scholars have argued that it is possible as a practical matter to protect the intellectual property rights in an animal variety by obtaining patent protection for its genes, plasmids, and cell lines, etc. The Supreme Court of Canada took this approach in its historic decision Harvard College v. Canada, [2002] 4 S.C.R. 45. The Court denied the patentability of the Harvard mouse, and held that “the mouse is a higher life form, and is not patentable because it is not a ‘manufacture’ or ‘composition of matter’ within the meaning of ‘invention’ in [the Patent Act of Canada]. But both the majority and minority opinions have held that a gene or a cell is patentable.

C. Biological Materials

Although Chinese Patent Law does not expressly address the biological materials, according to the Implementing Regulation and the Patent Examination Guidelines, some biological materials can be granted a patent and be protected by the Patent Law. According to the Examination Guideline, the “biological materials” include genes, plasmids, microorganisms, and cell lines of animals or plants.

The microorganisms include bacteria, actinomyces, fungus, virus, protozoan, and algae. Because according to the modern biological theory, the microorganism belongs to neither animal nor plant, the prohibition of Article 25 Paragraph 4 of the Chinese

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55 Guidelines, Part II, Chapter 10, § 7.1.2
56 Id. at § 7.1.1
57 Id. at § 7.1.2.1
Patent Law does not apply. However, for those microorganisms that exist in their natural status and without any process by human technology, they will be categorized as scientific discovery and, therefore, as ineligible for patent protection as prohibited by Article 25 Paragraph 1 of the Patent Law for granting of the patent. Only when these microorganisms become pure culture by separation, and possess some industrial value, will they become the object protected by the Patent Law.

The genes are defined by the Guidelines as “DNA sequences with specific physiological functions.” Similar to microorganisms, genes and DNA fragments separated and obtained from living matters are natural substances. Therefore, these are excluded from patent protection according to Article 25 Paragraph 1 of the Patent Law. However, if the gene or the DNA fragment is separated or obtained from the nature for the first time, and its base sequence has never been recorded under the contemporary technology, and if the base sequence can be formulated precisely, then both the gene or the DNA fragment itself and its method of obtaining will become the object protected by the Patent Law as long as it can be used industrially.

Another restriction on the granting of a patent is that it must be possible for the biological material to be obtained repeatedly by the same process described in the application documents. Otherwise, it will not satisfy the practical applicability criteria.

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58 Id.
59 Id.
60 Id.
61 Id.
62 Id. at § 7.1.2.2
63 Id.
64 Guidelines, Part II, Chapter 10, § 7.1.2.2
65 Id. at § 7.2.1
required by Article 22 of the Patent Law.\textsuperscript{66} For example, a specific microorganism separated and screened from a soil sample from a specific location will not be able to obtain patent protection. Because of the uncertainty of the natural condition and human activities, it is very unlikely that within twenty years of the protection period, a microorganism of the exact same species and transmissibility will be obtained by the same process. Therefore, unless otherwise adequately proved by the applicant, this process is not practically applicable under the standard of the Patent Law.\textsuperscript{67} Another example is a microorganism created by chemical or physical mutagenesis. Due to the random and unforeseeable result of the mutagenesis, unless the applicant proves otherwise, neither the microorganism nor the process of obtaining it is practically applicable.\textsuperscript{68}

When applying for a patent for a biological material which is not accessible to the public, and the description of which is not sufficient enough to enable a skilled person to carry out the invention, the applicant, in addition to fulfilling the ordinary application requirement, should also deposit a sample of the material in application to one of the two designated depository institution\textsuperscript{69} -- China General Microbiological Culture Collection Center (CGMCC) in Beijing, and China Center for Type Culture Collection (CCTCC) in Wuhan\textsuperscript{70}. In the application forms, the applicant should indicate the name and address of

\begin{itemize}
  \item Article 22 of the Patent Law provides that “[a]ny invention or utility model for which patent right may be granted must possess novelty, inventiveness and practical applicability….Practical applicability means that the invention or utility model can be made or used and can produce effective results.”
  \item Guidelines, Part II, Chapter 10, § 7.2.1
  \item Id. at § 7.2.2
  \item Implementing Regulations, Article 25.
  \item The detailed information about the two depository institution is available online at http://www.sipo.gov.cn/sipo_English/zlsq/rhsqpc/t20040924_34163.htm.
\end{itemize}
the depository institution of the biological material, the date, and accession number of the deposit.  

A biological material is deemed not accessible to public when it was obtained through a process that is not replicable, and the material itself is possessed by an individual or institution not open to public.  

After it is deposited to the designated depository institution, it is publicly accessible so long as the accession does not infringe on the rights protected by the Patent Law; and is pursuant to the administrative procedures provided by Article 26 of the Implementing Regulations.

D. Agrochemical Products and Pharmaceuticals

According to the Memorandum of Understanding Between the Government of the United States of America and the Government of the People’s Republic of China on the Protection of Intellectual Property of January 17, 1992 (the “MOU”), the Chinese government agreed to extend patent protection to all chemical inventions including pharmaceuticals.

For patent applicant for pharmaceuticals, the application documents should contain details of the applicant and setting forth the name, chemical formula, prescription, forms, indications, method of production and processing, dosage, usage, effects and a summary of the technological preparation method for the pharmaceutical product.

For patent applicant for non-pharmaceutical chemical substances, the application documents should contain details of the applicant and setting forth the name, and the

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71 Implementing Regulations, Article 25.
72 Guidelines, Part II, Chapter 10, § 7.3
73 Article 26 of the Implementing Regulations provides the procedure for application to access the biological material deposited in the designated depository institutions.
74 The English version of the MOU is available online at http://www.mac.doc.gov/tcc/data/commerce_html/tcc_2/PRCIntellectual_ (3).html.
75 MOU, Article 1- 1(a).
76 See Guidelines, Part II, Chapter 10.
substance must be identified by its chemical formula, DNA sequence, physical or chemical specifications or its producing method. In addition, the documents should contain details for its usage and at least one method of production.  

Under the MOU, the Chinese government also agreed to extend administrative protection to some of the US pharmaceuticals that were not otherwise protected by the patent law. By a series of bilateral and multilateral agreements, the scheme has been extended to other countries and is now applicable to pharmaceutical products which are owned by individuals or enterprises from the U.S., Japan, Switzerland and member countries for the European Union.  


Administrative protection grants quasi-patent protection which is enforceable primarily through the SDA. Protection is available for active ingredients as well as

77 Id.
78 MOU, Article 2.
80 Chinese version of the Regulations is available online at http://www.people.com.cn/zixun/flfgk/item/dwjff/falv/7/7-5-01.html.
81 Chinese version of the Rules is available online at http://www.people.com.cn/zixun/flfgk/item/dwjff/falv/7/7-5-07.html.
82 For more information, please see http://www.sda.gov.cn.
specific dosage forms. Administrative protection is available in respect of pharmaceutical product inventions:  

- for which an exclusive rights were not available under the Patent law of the People’s Republic of China prior to January 1, 1993;
- for which an exclusive right prohibiting the manufacture, use or sale by others in the country where the applicant is located was obtained between January 1, 1986 and January 1, 1993; and
- which have not been sold in the PRC prior to the filing of an application for administrative protection.

Administrative protection is obtained through applying to the OAPP. The following documents must be submitted in the official language of the applicant’s country and in Chinese:

- an application in prescribed form containing details of the applicant and setting forth the name, chemical formula, prescription, forms, indications, method of application, dosage and a summary of the technological preparation method for the pharmaceutical product;
- a notarized copy of the certificate of incorporation or equivalent document of the applicant;
- a notarized and legalized copy of the Patent Certificate issued in the applicant’s country evidencing the grant of a product patent to the applicant between January 1, 1986 and January 1, 1993;

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83 Pharmaceutical Product Regulations, Article 5.
84 Id. Article 8.
• a notarized and legalized copy of a Maintenance Fee Status Report, a Certificate of Payment of Renewal Fee or other certificate showing that the annual patent maintenance fees have been paid in respect of the patent;

• a notarized and legalized copy of a Certificate or Authorization of Manufacture or Sale issued to the applicant in respect of the pharmaceutical product by the relevant regulatory body in the applicant’s country;

• a notarized and legalized Agreement between the Applicant and a PRC enterprise legal person granting the PRC enterprise the right to manufacture or sell the pharmaceutical product in the PRC;

• copies of the Enterprise Legal Person Business License and the Pharmaceutical Manufacturing / Business Enterprise License of the PRC enterprise legal person referred to above; and

• a power of Attorney in favor of the official agent.

In addition, product approval must be requested from the PRC Ministry of Public Health for the manufacture or sale of the pharmaceutical product in the PRC either before or after the application for administrative protection is filed.85

Examination of the application documents should normally be completed by the OAPP within 6 months.86

Upon approval by the OAPP, administrative protection will be granted for a single term of seven and a half years from the date of issuance of a Certificate of Administrative Protection.87

85 Pharmaceutical Product Regulations, Article 9.
86 Id. Article 11.
Protection for the pharmaceutical product. The approval of the OAPP will be published. Annual fees must be paid to maintain administrative protection.

A party that believes that issuance of a certificate of administrative protection does not comply with the provision of the regulations may submit a written request to the OAPP for cancellation of the administrative protection. The administrative protection holder may appeal a cancellation decision to court.

E. Medical Diagnosis and Therapy

Most countries have refused to grant patent protections to methods for the diagnosis or for the treatment of diseases. These countries share two concerns, in terms of humanitarianism, medical service is commonly regarded as a sacred profession, rather than a profit-oriented industry. Therefore, patent regulations should not restrict medical practitioners from using methods for diagnosis to serve their patients. In addition, the method for diagnoses or treatment is usually implemented on individual human bodies, therefore, is not likely to be practiced repeatedly with same results, and cannot satisfy the “practicability” requirement.

Consequently, Article 25 Paragraph 3 of the Patent law prohibits patent protection to “methods for the diagnosis or for the treatment of diseases.”

However, the Examination Guidelines enumerated several exceptions to the “methods for the diagnosis or for the treatment of diseases.” For example, medicine or medical

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88 Id. Article 12.
89 Id. Article 16.
91 Id.
92 See Supra n.18.
93 Guidelines, Part II, Chapter 10, § 2.4.
tools used for the diagnosis or for the treatment of diseases may be protected by the Patent Law.\textsuperscript{94}

F. Other non-protected biotechnology

Article 5 of the Patent Law prohibits granting of patent right for “any invention-creation that is contrary to the laws of the State or social morality or that is detrimental to public Interest.”\textsuperscript{95}

The Examination Guidelines construe this provision in terms of biotechnology invention applications as prohibiting the granting of a patent right for invention of the followings:\textsuperscript{96}

- The process and production of human cloning;
- The process of altering inherited identity of human reproductive system;
- The process of industrial or commercial use of human embryos;
- The process of altering inherited identity of animals that may result suffering of the animals and does not substantially benefit human or animal medical treatment, and the animals produced by such process.

III. Conclusion

China's patent work has been developing continuously over 25 years, and has established a relatively complete and independent patent examination system in a short period of time. However, there are still many subject matters, especially in the living matter area, that are not patentable under the Chinese Patent Law. Among which, the most discussed about are the animals and plants and their varieties.

\textsuperscript{94} Id.
\textsuperscript{95} Patent Law, Article 5.
\textsuperscript{96} Guidelines, Part II, Chapter 10, § 7.1.2.4
It is true that so far the only legislations that expressly protect the breeders’ rights are the Regulations on Protection of New Variety of Plants and its Implementing Rules, and they only protect varieties that are on the published List of Protected Plant Varieties. Nevertheless, the Patent Law does recognize the patentability of the genes, plasmids, cell lines and other biological materials. Therefore, it seems that although the Patent Law explicitly prohibits granting patent to plant and animal varieties, the breeders may still enjoy the same protection by applying patent on those biological materials.

In the past two decades, the Chinese government has exerted arduous efforts to protect IPR. However, in a large developing country with a population of 1.3 billion, relatively backward economy, and low level of science and technology, a complete IPR protection system cannot be established overnight. China has come a long way but has a long way to go in this regard. China still is faced with heavy tasks in IPR protection.