BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

August 28, 2006

Honorable Lipu Tian
Commissioner
State Intellectual Property Office
of the Peoples' Republic of China
6 Xi Tu Cheng Road, Ji Men Bridge
Hai Dian District
100088 Beijing
Peoples' Republic of China

Via Facsimile to: 86-10-62-01-96-16 and or via email to: sipoffice@sipo.gov.cn

Dear Mr. Tian:

I am writing on behalf of the Biotechnology Industry Organization (BIO) in response to your request for comments on the draft amendments to the Patent Law of the Peoples' Republic of China.

BIO is a trade association representing more than 1,100 companies, research institutions and academic centers in over 33 countries, including those with subsidiaries in the Peoples' Republic of China. Our members are involved in the research and development of cutting-edge biotechnology products and technologies with healthcare, agricultural, industrial and environmental applications. BIO's members have developed and marketed hundreds of medicines and diagnostic applications worldwide. Our companies are involved in the development of novel medicines targeting the most intractable diseases such as heart disease, cancer, Alzheimer's disease, tuberculosis, malaria, and HIV/AIDS. In addition, our members are making strides in the development of renewable and alternative sources of energy, as well as safe, drought- and insect-resistant crops. In short, our members are dedicated to addressing many of the world's challenges through research and innovation.

To obtain capital and to recoup their investments for this formidable task, BIO members depend heavily on effective intellectual property systems throughout the world. Patents provide incentives and security for investors and entrepreneurs to invest the great amount of financial resources over decades of research required to develop a biotechnology product or technology. Biotechnology companies rely on strong and predictable patent protection to assure their partners and potential financiers that their venture is secure and will one day yield a significant return. Investors will not finance innovations where patent rights can be easily challenged; or where there is increased patent uncertainty; or where there is a gap in patent protection. The result would be that novel biotechnology products with the potential to treat diseases or feed the world, or provide energy independence, will not be developed.

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Consequently, we appreciate your request for comments from stakeholders such as our members on these important amendments to the Patent Law of the Peoples' Republic of China.

Many of the proposed amendments represent a significant step forward in the Patent Law. We were particularly pleased to note the following proposed changes that we believe will be beneficial for China:

> The clarification that only one patent should be granted of a single invention, sometimes referred to a statutory prohibition on double patenting (Article 9);
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> The assignment of patents on inventions made during Government-sponsored research in China to those conducting the research, similar to the "Bayh-Dole" Act in the United States (Article 14);
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> The clarification of the novelty and inventiveness standards, and focusing the inquiry on the hypothetical person skilled in the relevant technology (Article 22);
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> The elimination of compulsory licenses merely for failure to obtain a voluntary license (Article 48), and limitations on the use of patented inventions under compulsory licenses (Article 52); and
>
> The clarification of definition of infringement and the inclusion of the "doctrine of equivalents" in infringement, as well as clarification of the types of relief available for infringement (Articles 57 and 60).

There are some provisions, however, that greatly concern our members and there are some opportunities for improving the Patent Law that are not reflected in the proposed amendments. A brief description of our concerns and suggestions follows.

Filing in China

Article 20 currently requires any Chinese entity or individual to file a patent application in China first, if the invention was made in China. The proposed amendment changes it to "any" entity or individual. We believe that international companies who conduct research in China sometimes have legitimate reasons for first filing a patent application in another country, and that Article 20 in its current, unamended form provides a better economic incentive for supporting research in China.

Inventions that Depend on the Acquisition or Exploitation of Genetic Resources

Amended Article 25 would provide a new ground for rejecting claims in a patent application if the completion of the invention depended on the acquisition and exploitation of genetic resources. Amended Article 26 would require patent applicants to indicate the source of genetic resources if the completion of the claimed invention depended on the acquisition of genetic resources.

It would appear that these amendments are intended to promote compliance with the provisions of the Convention on Biological Diversity (CBD) related to access to genetic resources and the equitable sharing of benefits arising from this access. Unfortunately, we believe that these amendments will not significantly enhance fulfillment of the objectives of the Convention while burdening inventors. Also, we believe that these amendments as drafted are ambiguous.

With respect to the fulfillment of the provisions of the CBD, we believe that patent systems are **not** efficient tools for enforcing access and benefit sharing provisions of the CBD. From experience, we know that only a small fraction of the resources accessed will be used in research that results in patentable inventions and, then, only years after accession – regardless of whether the access was authorized or not. Consequently, regulation such as the amendments to Articles 25 and 26 would have no effect on most unauthorized users and would not ensure that equitable benefits would be provided to most providers of resources who authorize access to resources. They will, however, add a significant bureaucratic burden on applicants and the State Intellectual Property Office.

Further, these disclosure requirements provide the opportunity for unscrupulous competitors to use the patent system to harass inventors through unfounded claims in litigation for failure to satisfy the requirements. This problem is compounded by the current lack of specificity in access records and requirements related to access. We know from experience that these significant risks will discourage capital investment in research conducted by biotechnologies companies. Without this capital investment, biotechnology companies cannot undertake vital research on better foods, alternative sources of energy, and medicines.

In short, we believe that the burdens and risks of these amendments far outweigh their very limited contribution to the fulfillment of the goals of the Convention, especially as we still believe that the goals of the CBD are more readily and more effectively fulfilled through contracting between the holders and users of genetic resources. These views are echoed in a number of documents disseminated by the International Chamber of Commerce.[1]

We also believe that the scope of the amendments is unclear as both amendments apply to "genetic resources," yet the term is not defined in your Patent Law. This fact presents some serious problems as the ordinary meaning of the term without a qualification in the Law could include human genetic resources – resources that are not covered by the CBD. A clarification of the relationship that the genetic resource must have to the claimed invention would also be beneficial. For example, the patentability of a synthetic drug or medical device may depend on proof of therapeutic usefulness, typically provided by testing in cell lines or experimental animals. Would evidence of the source of cell lines or test animals be required, or is that sufficiently removed from the invention? What if the genetic resource, or material derived from it, is chemically or genetically modified before the applicant received it, so as to be very different from what is found naturally? With the law as presently proposed, the required relationship between the genetic resource and the invention is not clear.

The amendment to Article 25 requires that acquisition and exploitation not be "contrary to relevant laws and regulations of the State" and raises a number of questions that we cannot answer. Does this amendment mean that the laws of China are to be applied to the patent

[1] These documents are at http://www.iccwbo.org/policy/ip/id2480/index.html

applicant's production/use of a genetic resource anywhere in the world, if related to patenting in China? Does this mean that the laws of China only apply to access and exploitation in China? If the latter, why is indirect enforcement in the patent laws necessary to control acts of acquisition and exploitation within China? Do "relevant laws" include the provincial and local laws? It is also unclear who makes the patentability determination under the amendment to Article 25. Would the State Intellectual Property Office determine what constitutes a "genetic resource" and decide how and with which relevant laws and regulations its acquisition and exploitation must comply?

The amendment to Article 26 requires the disclosure of the "source" of the genetic resource. This requirement raises questions for us. Does the term "source" in this context mean the "country" where the genetic resource was originally found in nature? Does the term "source" in this context mean the person or enterprise from whom the applicant directly obtained the genetic material?

In addition, it is not at all clear to us that the amendments would be consistent with obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights.

Grace Period

Current Article 24 provides for a limited "grace period" or exception to the novelty requirement for three enumerated acts. This grace period, however, only extends for a six-month period before the filing date of the application (presumably the foreign priority date, if applicable). By reformulating the Article as exceptions to the "prior art," the proposed amendment would extend the grace period to prohibit use of the enumerated acts as evidence of lack of inventive step, which we view as a positive step.

We note that the proposed exclusion from prior art is for a six-month period. We believe that many inventors disclose inventions without understanding fully the consequences of such disclosures under the patent law. Often, these inventors do not become aware of the consequences within a six-month period from disclosure or, if they do, they do not have time to prepare a patent application adequately. Thus, they are penalized very harshly for a simple mistake. We believe that a one-year grace period would provide a better balance; it is more likely that inventors will be able to correct their failure to file a patent application but it would set a reasonable limit for the public to determine what acts constitute prior art.

Exhaustion of Rights

The proposed amendment would clarify that importation of a product made or sold by the patent owner abroad does not constitute infringement. In other words, the patent right in China to a product is exhausted if that product is placed into commerce in another country. This approach is often called the "international" exhaustion principle.

In the long term, we believe that the adoption of an international exhaustion principle in China or other countries is not in the best interests of China. For consumers in China, it would encourage the diversion of goods moderately priced for consumption in China to wealthier markets. Chinese manufacturers would not be able to establish differential prices for goods destined for other markets. They could not charge lower prices in poorer markets and higher prices in

wealthier markets because products would likely be diverted from the poorer to wealthier markets. Thus, they would either have to forego trade in the less wealthy markets or set worldwide prices at the price they can reasonably charge in the less wealthy markets.

Bolar-type Exemption

The proposed amendments would add a new paragraph 5 to Article 63, often called a Bolar-type exemption to clarify that certain exploitation for obtaining information for administrative approvals is exempted from the definition of infringement. In our view, this new paragraph standing alone would distort the current balance of rights that exists between patent owners and competitors heavily in favor of competitors, because realistically it has the effect of further eroding the already short period of exclusivity in the Chinese market. If China chooses to adopt a Bolar-type provision, we suggest that China provide for extensions of patent term to compensate for delays in marketing due to these administrative procedures. This approach was adopted in the United States and encourages prompt access to competing products after the expiration of a patent but still provides effective incentives for innovation through the patent system that would be lacking if the proposed amendment were adopted.

Opportunities for Improving the Patent Law or the Amendments

We believe that despite the extensive amendments in the current proposal, there are some additional procedural and substantive amendments that should be considered.

First, our translation of the proposed amendments did not include a provision that clearly states the entry into force of the provisions. We note some provisions that clarify existing law should or could take effect immediately and should apply to all pending applications or patents in force. On the other hand, it may be desirable to apply other amendments, *e.g.,* those related to the criteria for patentability, to patents granted on applications filed after a specific date.

Second, currently plant and animal varieties are excluded from patentable subject matter under Article 25. Moreover, some plant varieties are not eligible for other forms of protection in China, which would appear to be inconsistent with China's obligations under TRIPS Article 27.3. We believe that the recession of this exclusion would encourage research and development related to vastly improved plants and animals for use in China, and we urge you to rescind this exclusion in this group of amendments.

Third, with regard to compulsory licenses under Article 48, BIO seeks clarification that, for regulated inventions, conducting experimental or clinical studies required for regulatory approval would qualify as a "justified reason" for not, or not sufficiently, exploiting the patent.

Finally, we urge you to consider incorporating provisions to restore the term of patents when the period of exclusivity has been reduced due to pre-marketing administrative procedures. We believe that it is not fair for unregulated inventions to benefit from exclusivity for the entire 20-year patent term while inventions in the pharmaceutical and agricultural chemical that could significantly enhance the quality of life receive a significantly lesser period of exclusivity. Again, we appreciate the opportunity to comment on these important changes to the Patent Law

of the Peoples' Republic of China. If you or your staff have questions, we would be pleased to clarify our comments.

Sincerely,

Tom DiLenge
Vice President & General Counsel