The challenge of patent related practitioners from the rapid development of biotechnology

—a comparison of the practice of the United States, the European Community, Japan and China for the protection of biotechnology inventions

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The protection practice of biotechnology inventions

Purpose of the research

The effect way to protect bio inventions-China
Why there is a challenge from the rapid development of biotechnology for patent related practitioners

A review to the development of modern biotechnology
DNA recombinating technology and cell fusion technology

- gene engineering
- enzyme engineering
- cell engineering
- fermentation engineering
- Protein engineering
DNA recombining technology

cell fusion technology

More easy to develop new plant and animal varieties

Large amount of gene related patent applications
challenge

- A. The IPR protection of plant and animal variety - possibility of protection under patent law

- B. The ethic issues in the protection of animal variety

- C. How to protect gene related inventions under patent law
I. Plant protection

- Traditional rule of patent system:
  - Plant varieties are not patentable
    - Not satisfy the requirement of repeatability

The call for protection of Plant varieties from the breeder–establishment of UPOV Convention
I. Plant protection

UPOV Convention:
- 1978 version—protection for limited varieties, prohibition of double protection
- 1991 version—all varieties should be protected, no prohibition of double protection
I. Plant protection

• After 1980s, the repeatability of plant varieties is gradually recognized with the development of biotechnology

• Three ways for protection of plant varieties formed:
  – Protection under the UPOV Convention
  – Protection under patent law
  – Double protection both under the UPOV Convention and patent law
# I. Plant protection

<table>
<thead>
<tr>
<th>UPOV Convention</th>
<th>Patent law</th>
</tr>
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<tbody>
<tr>
<td>US yes 1991 version yes General and specific variety</td>
<td></td>
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<tr>
<td>EU yes 1991 version yes Only General variety</td>
<td></td>
</tr>
<tr>
<td>JP yes 1991 version yes General and specific variety</td>
<td></td>
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<tr>
<td>CN yes 1987 version no The method patentable</td>
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</tbody>
</table>
II. Protection for animal variety

• The only way—protection under patent law—before 1988, no patent issued—lack of repeatability

• Dispute began from the invention of Harvard oncomouse of 1988
  - US issued patent
  - EPO dispute—opposition—morality
## II. Protection for animal variety

<table>
<thead>
<tr>
<th></th>
<th>Protection for animal variety under patent law</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>USPTO</strong></td>
<td>yes</td>
</tr>
<tr>
<td></td>
<td>General and specific animal variety</td>
</tr>
<tr>
<td><strong>EPO</strong></td>
<td>yes</td>
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<tr>
<td></td>
<td>Only specific animal variety</td>
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<tr>
<td><strong>JPO</strong></td>
<td>yes</td>
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<td></td>
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<tr>
<td><strong>SIPO</strong></td>
<td>no</td>
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</table>
III. Discussion about the possible ways to protect plant and animal varieties under patent law in China

• The importance of protect plant and animal varieties under patent law in China
  – big population of more than 1.3 billion and 0.9 billion of the population are engaged in farming and farm-related industry
  – Superior resources of plant and animal varieties
  – The amount of inventions of plant and animal varieties is increasing
III. Discussion about the possible ways to protect plant and animal varieties under patent law in China

- The necessity of protection for the plant and animal varieties per se under the patent law
  - Article 11 of the Chinese Patent Law
    - The protection scope of method extends to the product obtained directly from the method
III. Discussion about the possible ways to protect plant and animal varieties under patent law in China

• The block that prohibit the protection of plant and animal varieties under patent law in China

- Prohibition of double protection rule of 1978 version of UPOV Convention
- the article 25(4) of the Chinese Patent Law
III. Discussion about the possible ways to protect plant and animal varieties under patent law in China

- The possibility under current legal system
- Analysis of the prohibition of double protection rule of 1978 version of UPOV Convention—plant grouping within a single botanical taxon of the lowest known rank
- Choice of protection of general plant variety—not offend the rule
III. Discussion about the possible ways to protect plant and animal varieties under patent law in China

- The possibility under current legal system
- Analysis of the article 25(4) of the Chinese Patent Law
- New explanation to the plant and animal varieties in the article 25(4) of the Chinese Patent Law—exclude only specific variety
- So general variety patentable
IV. Patent protection of gene related inventions

• The requirement of novelty, inventive step, utility under patent law
• The examination standard novelty, inventive step of USPTO, EPO, JPO and SIPO
• USPTO revised the utility examination standard in 2001
IV. Patent protection of gene related inventions

- Dispute about the protection scope of the gene sequence claim
IV. Patent protection of gene related inventions

- German patent law - revised - 2005
- Substance protection limited to function
- Not adopted in US, EU, JP, and CN
V. The patentability of medical method

<table>
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<th>Country</th>
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<tbody>
<tr>
<td>US</td>
<td>Patenable for human and animal medical method</td>
</tr>
<tr>
<td>EU</td>
<td>Not patentable</td>
</tr>
<tr>
<td>JP</td>
<td>Patenable for animal medical method, not for human medical method</td>
</tr>
<tr>
<td>CN</td>
<td>Not patentable</td>
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</table>
VI. Conclusions

1. There is no significant difference in the current patent examination practice of the USPTO, EPO, JPO and SIPO.

2. Specific strategies have to be taken to effectively protect the invention and investment in the bio field-based on the balance between the interest of inventors and the public and the balance between the interest of inventors and the morality standard of the public.
VI. Conclusions

3. The protection of plant and animal varieties under patent law in China is very important. The protection of general plant and animal varieties under patent law in China is possible without conflict with the 1978 version UPOV Convention and the article 25 of the Chinese Patent Law.
Thank you very much for your attention!