

## Patent Prosecution in China - an Overview



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## Some figures

- Population of 1.3 billion
- China is predicted to become the fifth largest pharmaceutical market by 2010 and the largest by 2015 (Boston Consulting Group)
- PCT filings in China have increased by 38% from 2006 to 2007, China is now ranking 7th, just after the UK
- In the period of 1999 to 2003, the number of Chinese pharma patent applications filed per year more than doubled

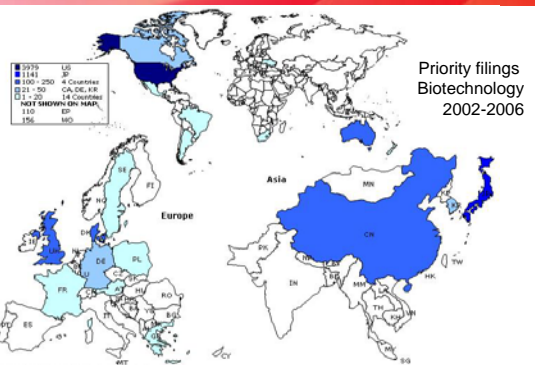
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## Some figures

## 2006 Filing figures

SIPO –	210,000 patent applications, 161,000 UM applications 58,000 patent grants, 108,000 UM grants
EPO –	135,000 patent applications 63,000 patent grants
USPTO –	426,000 patent applications 174,000 patent grants

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## The political climate

- "In IPR cases involving foreign parties, we insist on fair trials and equal protection for all involved." Cao Jianming, Vice President of the Supreme People's Court
- "Competition in the future is competition in IP." Prime Minister Wen Jiabao
- "We must be crystal clear that our country still has far to go in protecting IP rights." Vice Premier Wu Yi
- The Chinese government is promoting IP and encouraging domestic filings by Chinese companies, there are many initiatives to improve the IP system and raise awareness
- But there are still shortcomings, in particular relating to enforcement and policy issues which affect the pharmaceutical industry

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## Geographical Extent of Patents and Trade Marks

People's Republic of China – mainland China  
(not including Hong Kong, nor Macau)

- HK Patents – register CN or GB application [UK or EP(UK)]
- HK Trade Marks - independent
- Macau Patents – register CN
- Macau Trade Marks - independent

Taiwan (Republic of China)

- Taiwan has independent Patent and Trade Mark systems

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## Patents in China

Registration of patents is relatively new – law came into force in 1985  
 Invention Patents, Utility Model Patents and Design Patents all governed by the same law (and implementing regulations)  
 System set up with help from Germany - many aspects reflect the EPC (e.g. patentability requirements and exclusions from patentability) and/or German practice (e.g. separation of validity and infringement)  
 Patent Cooperation Treaty (PCT) joined in 1994  
 World Trade Organisation (WTO) joined in 2001

## Patents in China

Chinese patent law is undergoing substantive revision, the third amendment is expected to come into force in 2009

Key points of the amendments affect

- Security provisions
- Novelty
- Provisions relating to infringement, including introduction of "Bolar-type" provisions

## Application Timeline

Application Filed	- National filing or national phase from PCT
Request Examination	- within 3 years of priority
Publication	- nominally around 18 months from priority or 6 months from CN/PCT
Voluntary Amendments	- within 3 months of entering substantive examination
Actual Examination	- usually begins within 6 months to 2 years of request
Decision to Grant	- when every last "i" is dotted and "t" is crossed
Pay Grant Fees	- within 2 months of decision to grant
File Divisionals	- within 2 months of decision to grant
Annuities	- annually

## Application Timeline

Total time: about 1 to 4 years from national phase entry

There is no official procedure for accelerating examination upon request by the Applicant

## How much will it cost me?

- Filing an application: £2000 to £4000 - largely depends on translation costs
- Requesting examination: £400
- Prosecution: £1000 to £4000
- Grant: £200 plus maintenance (due from 3<sup>rd</sup> year, but accumulated fees can be paid at grant)
- Annuities £180 for 4<sup>th</sup> to 6<sup>th</sup> year then increasing successively, in year 20 to £700

• Please note that the exact costs depend on many factors, such as number of claims, word count, number of priority claims, exchange rates...

## National Security Provisions

Art. 20

*Where any Chinese entity or individual intends to file an application in a foreign country for a patent for an invention made in China, it or he shall file first an application for a patent with the patent administration department under the State Council.*

First filing can be a PCT filing in English with the SIPO

Proposed controversial law changes:

- "any entity or individual"
- Approval procedure: "the Patent Office shall make a decision on the request within 6 months from receipt"

### Formalities

Chinese translation of specification needed at filing date (2 months grace period available to CN/PCT) (Chinese translations for mainland China and Taiwan are different)

Excess claims fees for > 10 claims (number determined by original PCT filing and cannot be reduced [or increased] at national phase entry)

SIPO requires original documents, certified copies from government bodies (e.g. priority documents, name changes) or documents that have been notarised and legalised by the Chinese embassy

### Patentability

#### Art 22 Novelty

- global publication (including Internet), local use

#### Third amendment of the Patents Act

- Proposed amendment to include use anywhere

#### Non prejudicial disclosures

- No US style grace period
- Six months from display at international exhibition or disclosure at academic meeting organized by State Council
- Breach of confidence

### Patentability

#### Art 22 Inventive step

*Inventiveness means that, as compared with the technology existing before the date of filing, the invention has prominent substantive features and represents a notable progress and that the utility model has substantive features and represents progress.*

Similar to the European assessment of inventive step, the "problem solution approach" favoured by the EPO works well

### Patentability Exclusions

#### Patent Law

*Art. 5 - Inventions contrary to the laws of the State or social morality or that is detrimental to public interest.*

#### Art. 25

- *scientific discoveries;*
- *rules and methods for mental activities (includes computer programs and business methods);*
- *methods for the diagnosis or for the treatment of diseases;*
- *animal and plant varieties;*
- *substances obtained by means of nuclear transformation.*

### Patentability Exclusions

#### *Methods for the diagnosis or for the treatment of diseases*

- Second medical use claims are accepted
- Includes surgery (whether for diseases or otherwise) and diagnosis
- What constitutes diagnosis is assessed differently than under EP law
- In contrast to current EPO practice, second medical use claims defining dosage/administration schedules are unlikely to succeed

### Patentability Exclusions

#### *Animal and plant varieties*

Animal and plant varieties or a part thereof are not patentable

Transgenic animals or plants obtained by biological methods are not patentable- note biological methods include recombinant DNA technology (Guidelines for Examination)

A process for the production of a animal or plant variety (including transgenic animal or plant) is patentable

Plant varieties can be protected separately

Microorganisms are patentable if isolated from their natural environment

## Patentability Exclusions- Stem cells

### Exclusions under Art. 5

- Process for modifying the germ line or genetic identity of a human being or a human being this modified
- Process for cloning human being or a cloned human being
- Use of human embryos for industrial or commercial purposes
- Human embryonic stem cells and a method for preparing human embryonic stem cells
- The human body at the various stages of development

## Genetic resources and traditional knowledge

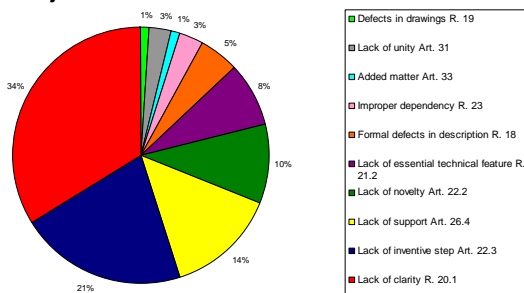
### Proposed Amendment to the Patents Act

#### Art 27

*“For an invention the completion of which depends on acquisition and exploitation of genetic resources or traditional knowledge, the applicant shall indicate the direct source of said genetic resource or traditional knowledge in the description.”*

Could be problematic, interpretation of terms “depends on”, “genetic resources”, “traditional knowledge”?

## Type of objections



Source: DeqI Intellectual Property, 2006

## Support & Sufficiency Art 26

SIPO's favourite objection against pharmaceutical subject matter

- *“based on the disclosure the skilled person could not anticipate that the invention would work across the entire scope as claimed”*

For chemical products, experimental data is **essential**, and it must support the entire range

Examples, examples, examples ... (post-filing examples cannot be added or used as evidence)

## Amendments

Amendments must not go beyond the content of the application as filed

Limited opportunities for voluntary amendments

- filing
- with examination request
- within 3 months of entering substantive examination

Otherwise, amendments limited to responses to examiner's objections or at examiner's discretion

## Patent Term Extensions

No possibility for extending the term of a patent to compensate for a delay in regulatory approval under current provisions

### Appeal : Patent Re-Examination

Re-examination available if application refused by (primary) examiner, file request within three months form date of rejection

Re-examination is conducted by the Patent Re-examination Board (PRB) of the SIPO

Separate, more senior board of examiners, not including primary examiner

Generally takes a more pragmatic view

No voluntary amendments allowed – only amendments that address the primary examiner's objections

Appeal decision by Board at People's Court

### A recent case

#### Pfizer's Viagra Patent Reaffirmed

Patent Reexamination Board invalidated the patent in July 2004 because of insufficient disclosure, Pfizer appealed

In November 2007, The Beijing People's High Court upheld a decision by a first instance court finding Pfizer's Viagra patent valid

The Viagra patent is being remanded to the Patent Reexamination Board due to a third party challenge

### Attacking third party rights

Third Party Observations can be filed – but you do not become party in any way (and you cannot see the examination portion of the file until after grant- there is currently no online file inspection to monitor third party rights)

No Opposition procedure

The only way to invalidate a patent is through invalidation proceedings before the Patent Re-examination Board

First Appeal can be made to 1<sup>st</sup> Intermediate Court of Beijing, further Appeal can be made to High Court of Beijing.

### Patent Invalidation – Grounds (1)

1. The patent lacks novelty, inventive step or practical applicability (Art. 22 of the Chinese patent law)
2. The description is insufficiently clear and complete to enable a skilled person to carry out the invention (Art. 26.3)
3. The claims are not supported by the description (Art. 26.4)
4. An amendment made to the patent specification extends beyond the original disclosure of the application as filed (Art. 33)
5. For an invention patent, the claimed invention is not a technical solution relating to a product, process or improvement thereof; for a utility model, the claimed invention is not a new technical solution relating to the shape and/or structure of a product, which is fit for practical use (Rule 2)

### Patent Invalidation – Grounds (2)

6. More than one patent right has been granted for the same invention (Rule 13)
7. The claims are not clear and concise or do not define the invention in terms of its technical features (Rule 20.1)
8. An independent claim lacks essential technical features (Rule 21.2)
9. The invention is contrary to laws of the State, social morality or detrimental to public interest (Art. 5)
10. The invention relates to unpatentable subject matter (Art. 25)
11. The patent was not granted to the first person to file an application for protection for the invention (Art. 9)

### Other forms of IP

- Utility Models
- Design and Copyright
- Trade Marks

### Utility Models

Must have novelty, inventiveness & usefulness  
 Only shape & structure of products protected (not methods)  
 Only one independent claim  
 Only formalities examination (although includes whether patentable subject matter, added matter, unity, clarity – most aspects except novelty, inventiveness, support & sufficiency)  
 Duration: Ten years from filing date

### Some practical points

Despite the problems that exist (counterfeiting, corruption, stability of the economy), China is a market that is too important to ignore

China should be part of your IP strategy:

- Without any rights in China there is nothing to enforce
- Patent protection lasts for a long time- what will the situation be in 10 or 15 years?
- Plant your flag now!

### Further information

Marks & Clerk Report on IP in China 2006  
 Marks & Clerk Biotechnology Report 2007

"China, an enforcement roadmap" <http://www.ipo.gov.uk/chinaroadmap.pdf>

WIPO Patent Report: Statistics on Worldwide Patent Activity (2007 Edition)  
[http://www.wipo.int/ipstats/en/statistics/patents/patent\\_report\\_2007.html#P392\\_24412](http://www.wipo.int/ipstats/en/statistics/patents/patent_report_2007.html#P392_24412)

SIPO  
[http://www.sipo.gov.cn/sipo\\_English/](http://www.sipo.gov.cn/sipo_English/)

Thank you!

感谢聆听!

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