

Dispute Resolution in Life Sciences in China

WIPO Conference on Dispute Resolution in Life Sciences

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1. Enforcement of Patent Rights in China
2. IP & Patent Litigation Statistics
3. Challenges in Patent Litigation
4. Cases in Patent Litigations in China

Agenda

Patent Enforcement in China

- Courts:
 - Supreme People's Court (SPC): highest court, in Beijing
 - 3 levels of local courts:
 - High People's Court
 - Intermediate People's Court
 - District Court

*Only Intermediate level Court can try patent cases

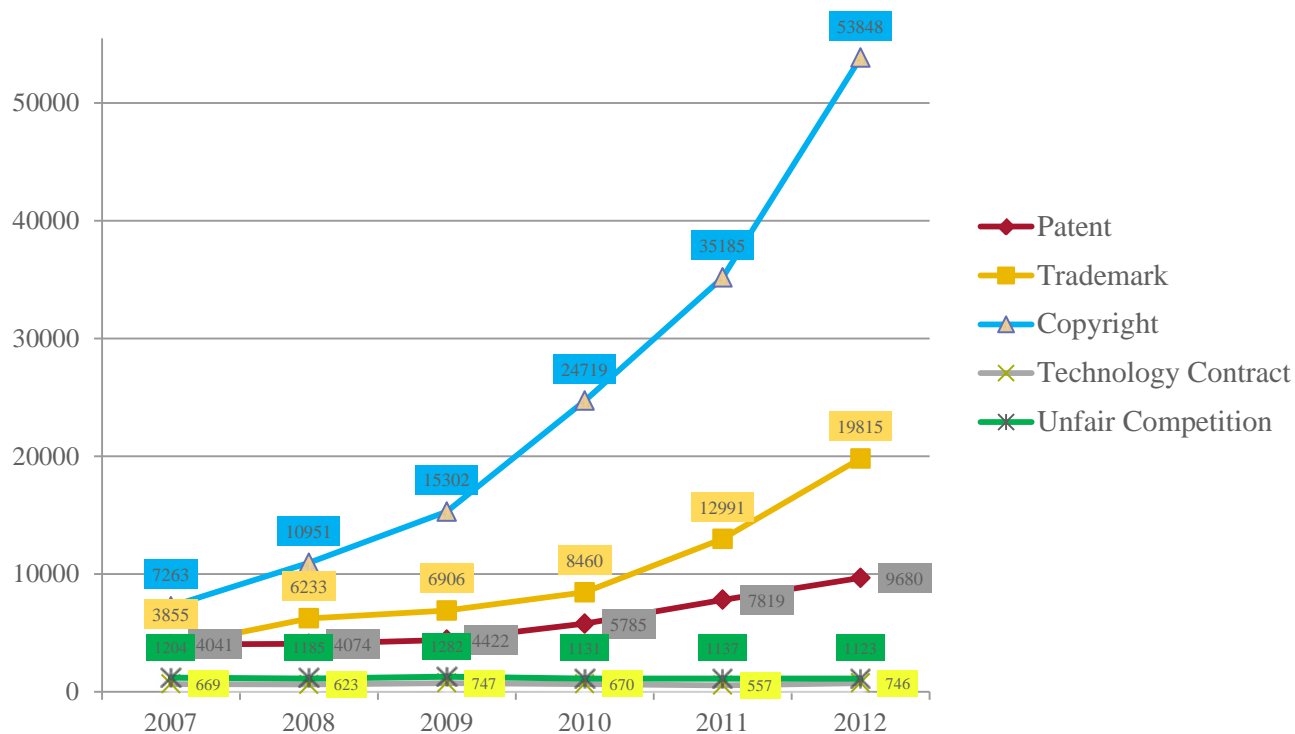
- Administrative authorities (SIPO)
- Customs

Infringement vs Invalidation

- Two tracks system: infringement handled by court (or administrative authority); invalidation handled by Patent Re-examination Board (within SIPO)
- Invalidation can be initiated by any third party as many times within the life of patent
- Usually it is cheaper to fight infringement lawsuit by filing invalidation with PRB
- PRB timeline for resolving invalidation is 6-12 months (faster than court proceeding)

IP Litigations in China

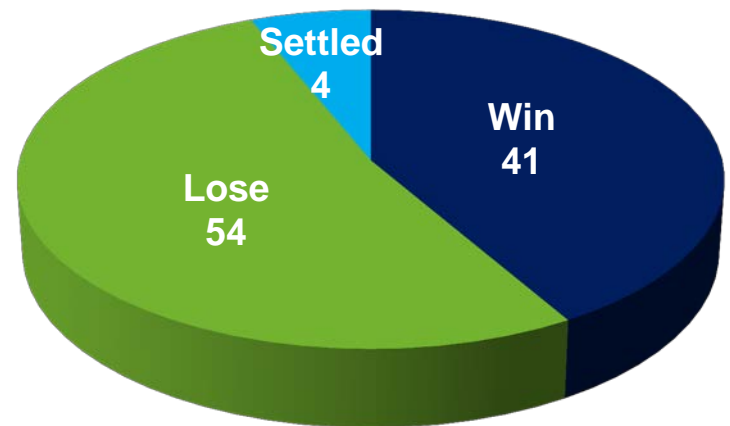
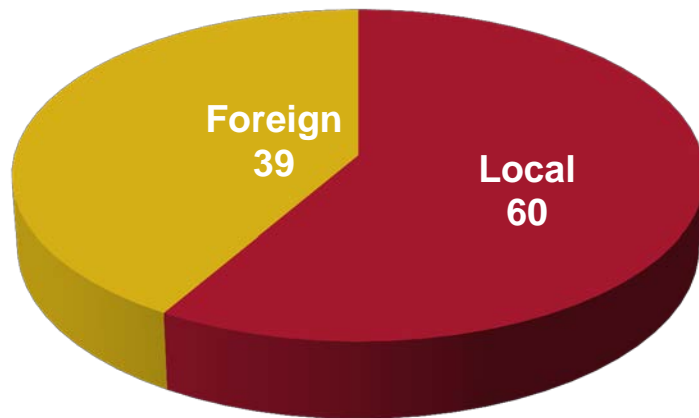
IP Civil Actions Accepted by Court from 2007 to 2012



Pharma patent infringement cases in China: 2000-2015

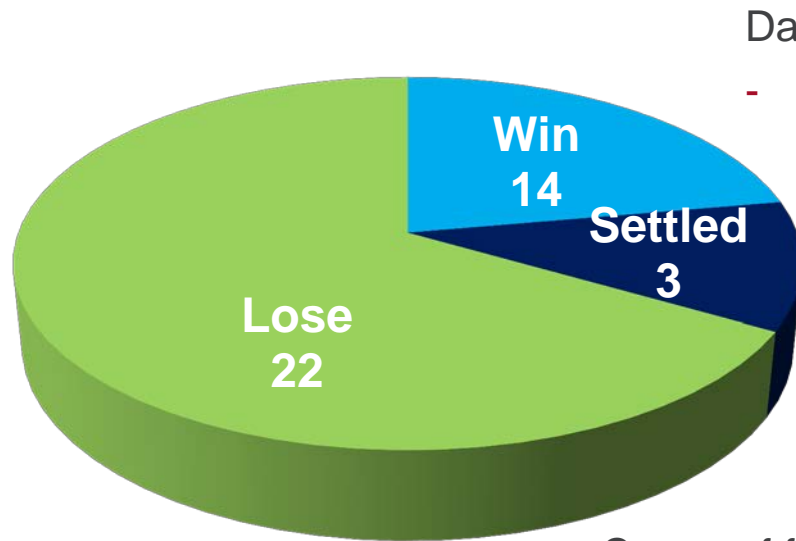
- Plaintiffs lost more cases than winning
- Cases involving foreign companies ~40%
- Damages: highest - RMB5,000,000; average – RMB509,827
- Preliminary injunction very difficult to get
- Evidence preservation orders quite common
- Very few case involving process patents won by foreign plaintiff

Statistics of patent infringement cases in Pharma Industry



Total number of cases involving invention patents = 99

39 out of 99 cases involve foreign parties



Damages of winning cases:

- RMB6,320 – 1,294,635

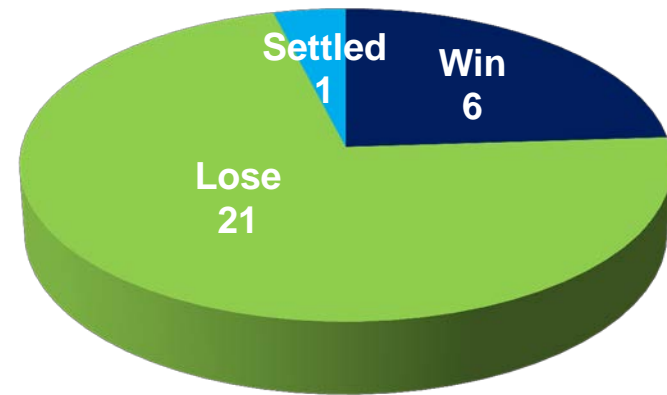
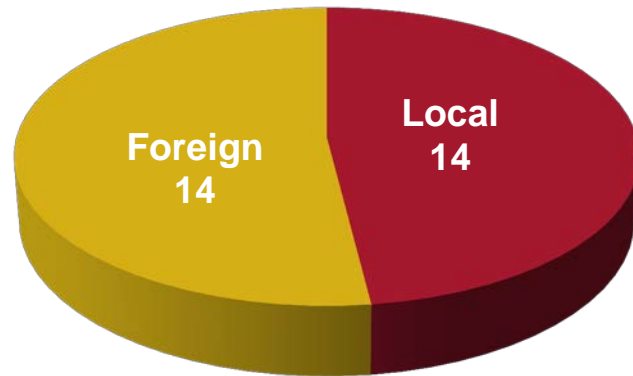
Damages of settled cases:

- RMB10,000 – 200,000

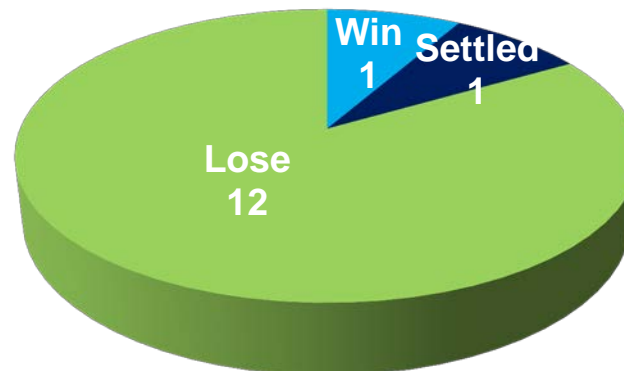
Cause of failure:

- Patent invalidated (6)
- No patent exploiting by the defendant (9)
- Not indential/equivalent to patented inventions (8)

28 out of 99 cases involve process patents



Of 28, 14 cases involve foreign parties



Challenges in patent enforcement

- No discovery – difficulty in evidence collection
- Preliminary injunction – difficult to obtain
- Low damages award
- Recovery of costs: negligible
- Invalidation challenge (separately handled by SIPO)
- Certain local courts may not be impartial
- Problems with quality of patents
 - Translation
 - Insufficient data support (higher requirement in China)
 - No patent filed in China

Certain defendant tactics as seen in China

1. Jurisdiction Challenge – delay tactic
2. Invalidation Request in PRB & applying for stay of proceeding
3. Exploiting the weaknesses of patent
e.g. Ambiguity in claim language (some as result of [poor] translation)
 - A is greater in weight than 6% of B
 - A is greater in weight than B by 6%
4. Twisting the meaning of terms in the statutes
“new product” vs. “new molecule” relevant to a synthesis method patent
5. Reading extraneous limitations into the claim
6. Defendant claiming to be practicing its own patented invention

Some specific pharma patent cases

- Eli Lilly: pre-2007 cases involving insulin analogue
 - Both formulation and method patents asserted
 - Defendant's product and method within scope of patents
 - No infringement because no commercial exploitation (Bolar)
- So cannot sue until after biosimilar/generic is marketed

Some specific pharma patent cases

- Eli Lilly v Huasheng Co.: 2016 SPC retrial case involving process patent for Olanzapin (a schizophrenia drug)
 - Case filed in 2003
 - No infringement found in 2008 by Nanjing Intermediate Court
 - Infringement found in 2011 by Jiangsu Higher Court – damages of RMB500,000 awarded
 - Lilly refiled in 2011 for continued infringement in the period from case filing (2003) to patent expiration (2011) and claimed RMB151,060,000 – damages of RMB3,500,000 awarded by Jiangsu Higher Court
 - Jiangsu Higher Court ruled Huasheng was not able to prove difference between its process with the patent (burden of proof reversed due to new product)
 - **The Supreme Court overturned the case in 2016, finding the process used by Huasheng was neither identical nor equivalent to the patented process**

Some specific pharma patent cases

- Eli Lilly v Huasheng Co.: 2016 SPC retrial case involving process patent for Olanzapin (a schizophrenia drug)
 - The SPC found that:-
 - In terms of technical means, the reaction routes and intermediates in the two processes are different;
 - In terms of technical effects, due to the difference in reaction routes, the productivity of Huasheng's process was a lot lower;
 - Although the difference between the two routes (benzyl protection used to reduce side reaction) is a known technology, the difference is material to the nature of technical means and technical effects
 - The processes are therefore not equivalent

Considerations for potential litigation in China

1. Evidence Collection

- Notarized purchase

2. Choice of court

(minimize delays due to jurisdiction challenge & stay request)

3. Judicial Appraisal

(most important evidence of infringement)

4. Preliminary order – evidence preservation, preliminary injunction, asset preservation

5. Prepare for invalidation actions