

Balancing Innovation and Competition Through Intellectual Property Policies in the Pharmaceutical Sector

China Pharmaceutical University
Nanjing, China
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Acting Under Secretary for Intellectual Property,
United States Department of Commerce



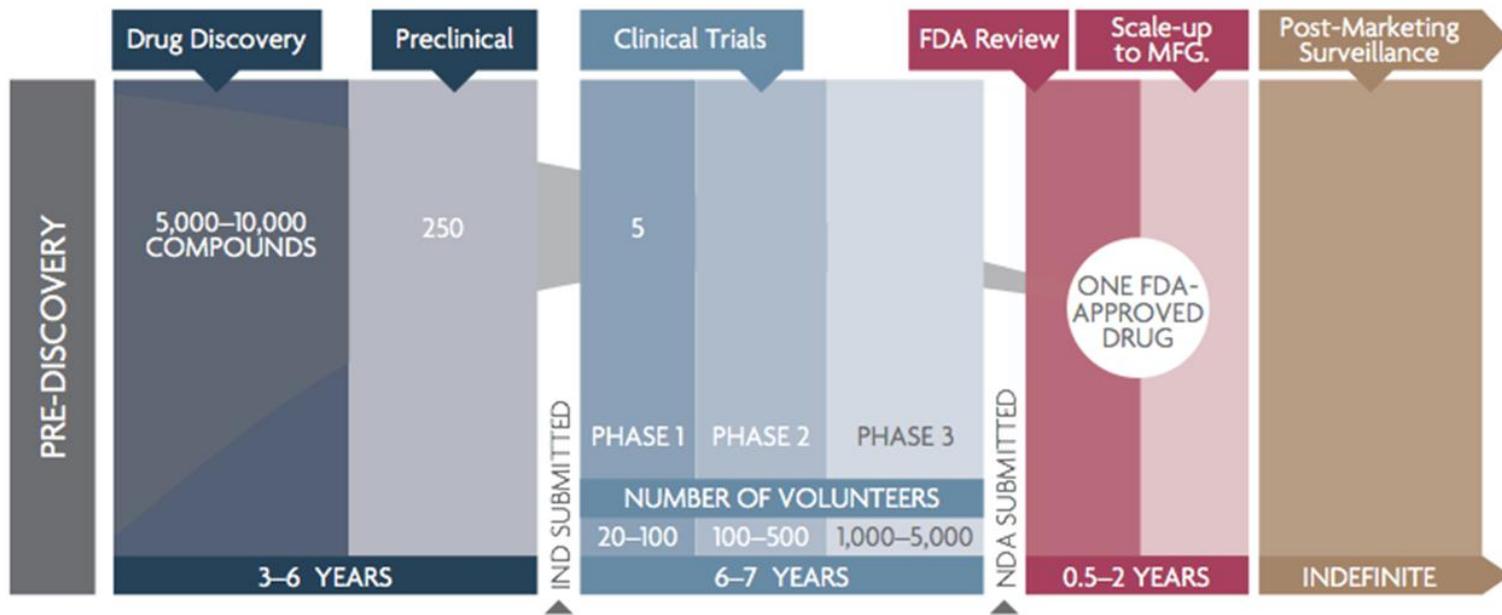
Pharmaceutical Patents Granted by U.S. PTO

(Recorded by Origin of Priority Document 8/23/2013)

FY	U.S. All	EPC	Japan	S. Korea	China
2013	6,338	783	477	76	65
2002	5,244	1,287	456	29	6
% Increase	+21%	-39%	+4.6%	+162%	+983%



Drug Discovery and Commercialization





China Pharmaceutical University

- CPU owns 507 Patents for Technology Transfer
- CPU has Filed 11 Patent Applications with the U.S. PTO since 1990, with 5 granted, 5 pending, and one abandoned.



Senator Birch Bayh





Medicine Patent Filings in China

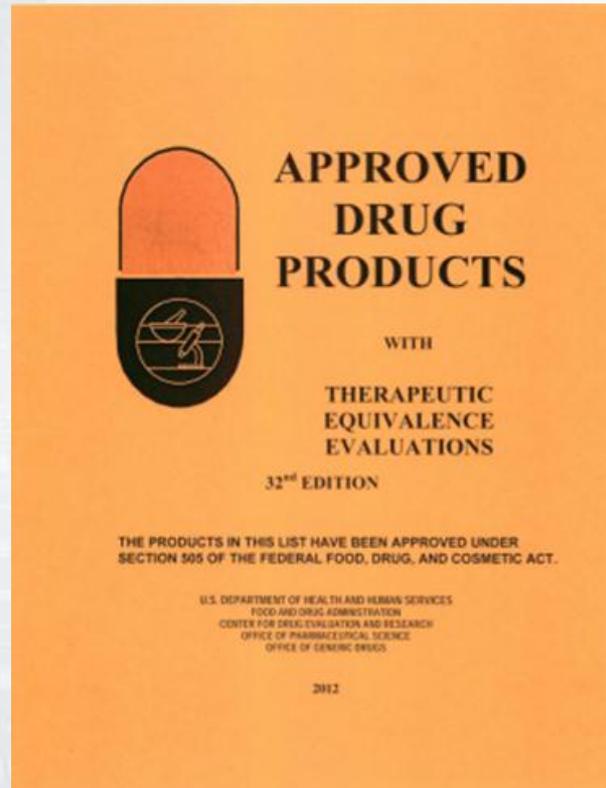
	2009-2010 Medicine Patent Applications (N)	% of Total Applications
Chemical Medicine	6206	43.2%
Biological and Biochemical Medicine	1456	10.1%
Traditional Chinese Medicine	5623	34.3%
Total	14368	

Source: 2010 and 2011 China Statistics Yearbook on High Technology Industry



“Orange Book”

<http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>





Example from the Orange Book

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
N021880	001	5635517	Oct 4, 2019	Y		U - 1211	
N021880	001	6045501	Aug 28, 2018			U - 1210	
N021880	001	6281230	Jul 24, 2016			U - 1212	
N021880	001	6281230	Jul 24, 2016			U - 1414	
N021880	001	6315720	Oct 23, 2020			U - 1210	
N021880	001	6555554	Jul 24, 2016		Y	U - 1211	
N021880	001	6561976	Aug 28, 2018			U - 1210	
N021880	001	6561977	Oct 23, 2020			U - 1210	
N021880	001	6755784	Oct 23, 2020			U - 1210	
N021880	001	6908432	Aug 28, 2018			U - 1210	
N021880	001	7119106	Jul 24, 2016		Y		
N021880	001	7189740	Apr 11, 2023			U - 1215	
N021880	001	7465800	Apr 27, 2027	V	V		

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
<u>N021880</u>	001	I - 672	Jun 5, 2016
<u>N021880</u>	001	ODE	Dec 27, 2012
<u>N021880</u>	001	ODE	Jun 29, 2013
<u>N021880</u>	001	ODE	Jun 5, 2020

http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021880&Product_No=001&table1=OB_Rx



Article 26(3) of China's Patent Law

- “The written description shall contain a clear and comprehensive description of the invention or utility model so that a technician in the field of the relevant technology can carry it out; ...”
- “说明书应当对发明或者实用新型作出清楚、完整的说明，以所属技术领域的技术人员能够实现为准； ...”



Comparisons with Chinese Practice

- SIPO 1993/2001 Examination Guidelines – 4.1, Chapter 10 of Part 2 (“Sufficiency of Disclosure”)
 - For an application for a chemical product invention, the use and technical effect of the product shall be sufficiently disclosed.
- SIPO 2006/2010
 - For an application for a chemical product invention, the use and/or technical effect of the product shall be completely disclosed.
- US (1991)
 - “there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed.” (In Re Vaeck, 947 F.2d 488 (Fed. Cir. 1991))
- US (1995) (MPEP)
 - “The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention.”

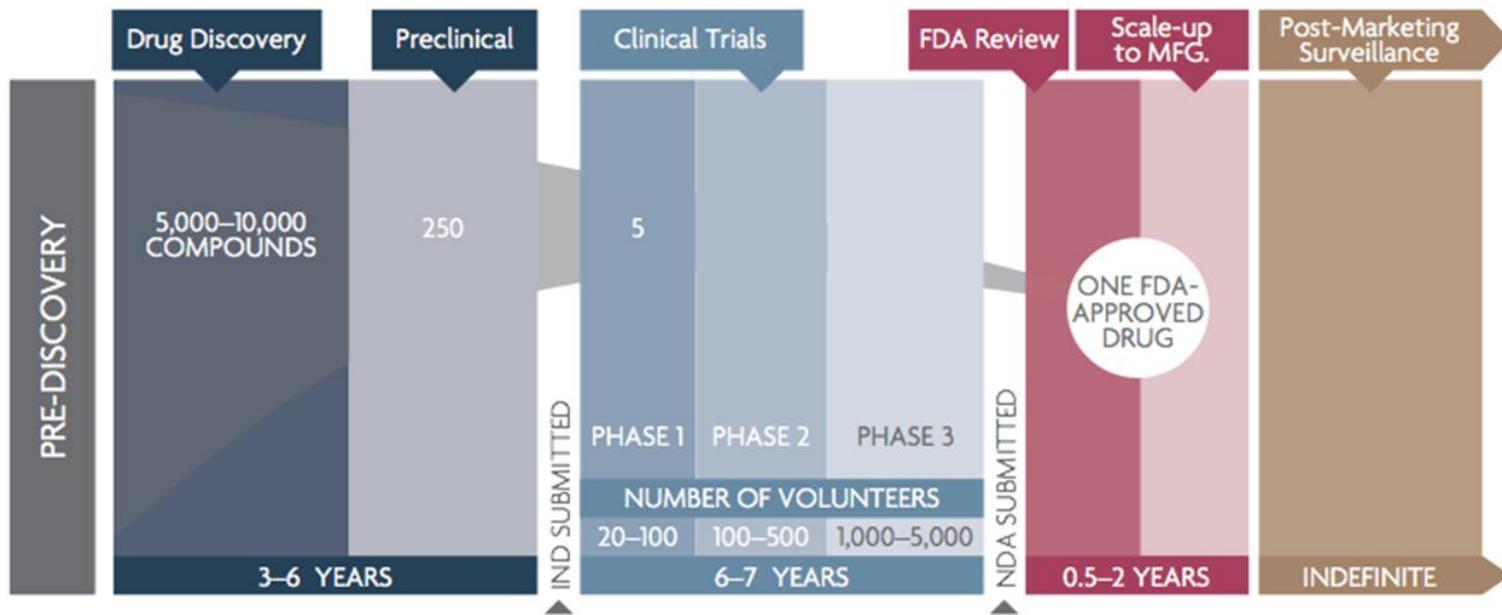


Comparisons with Chinese Practice

- For a new pharmaceutical compound...
 - SIPO
 - 1993 - The effective amount, method of application or method of formulation shall be described to such an extent that a person skilled in the art can carry it out.
 - 2001/2006/2010: There should be qualitative or quantitative laboratory test data (including animal test) or clinical test sufficient to prove that the technical solution can achieve the forecasted technical solution or effect.
 - US/1991: There must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. In *Re Vaeck* (1991).



Drug Discovery and Commercialization



Source: PhRMA⁶



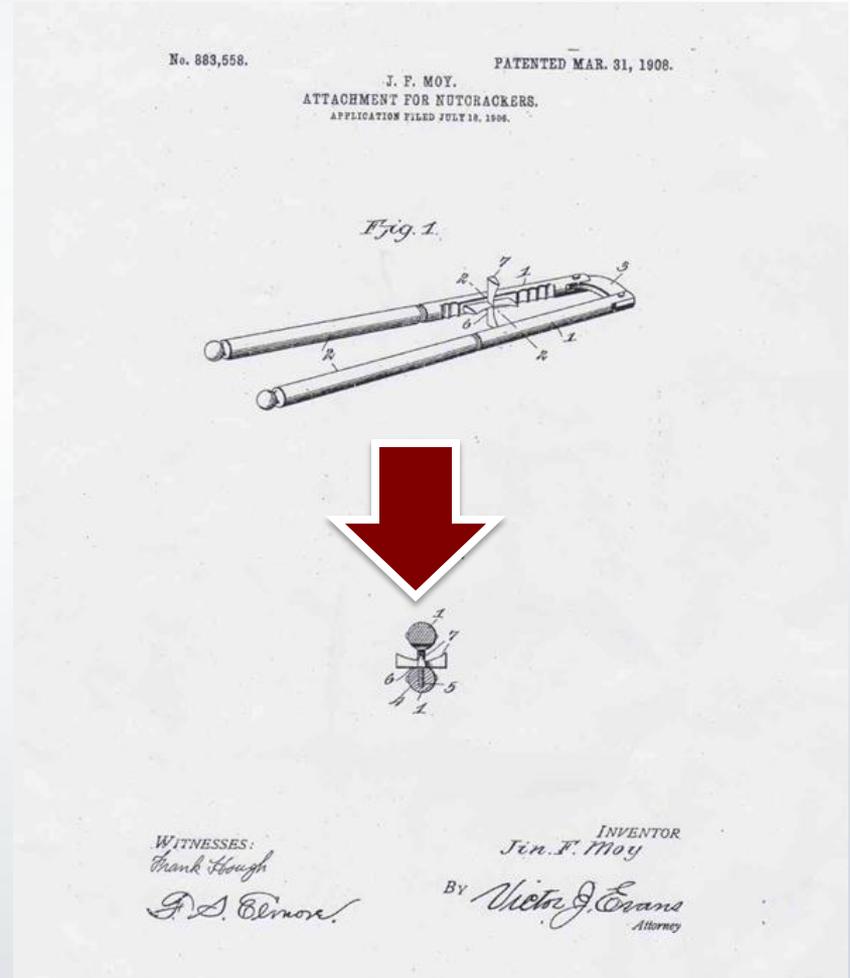
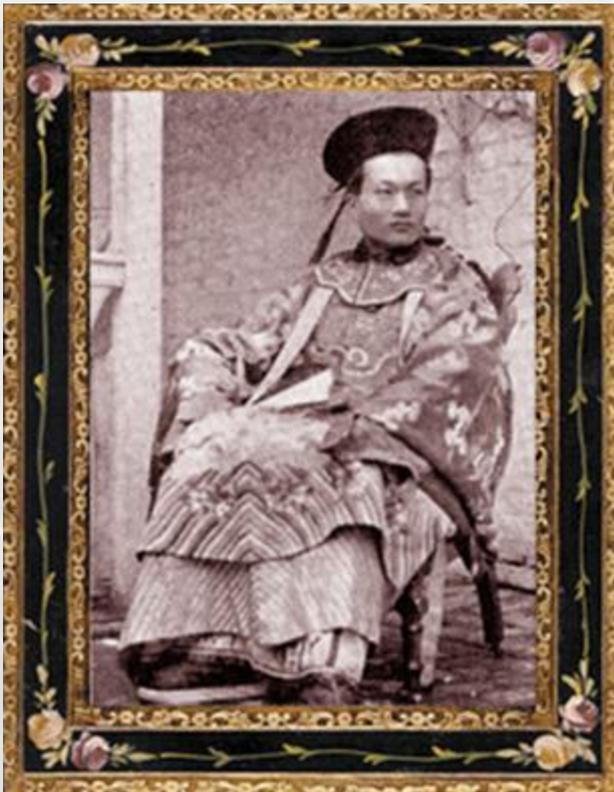
Comparisons with Chinese Practice

- SIPO
 - 1993: Prerequisite for supplementing use and effect after the filing date [is]...it must be a use or effect that has been implied in the original specification so that a person skilled in the art is able to deduce directly; or it is use that can be deduced directly from the prior art.
 - 2001: ~~Prerequisite for supplementing use and effect after the filing date [is]...it must be a use or effect that has been implied in the original specification so that a person skilled in the art is able to deduce directly; or it is use that can be deduced directly from the prior art.~~
 - 1993& 2001: Any embodiment submitted after the filing date can only be used as a reference by the examiner for assessing novelty, inventiveness, and practical applicability.
 - 2006/2010: Embodiment and experimental data submitted after the filing date shall not be taken into consideration.
- US (1971) Post-filing evidence "can be used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification." In re Marzocchi (439 F.2d 220 1971)



First Chinese Patent Applicant in the United States

Dr. Jin Fuey Moy (梅振魁; Mei Zhenkui, 1862-1924)



谢谢!



THANK YOU