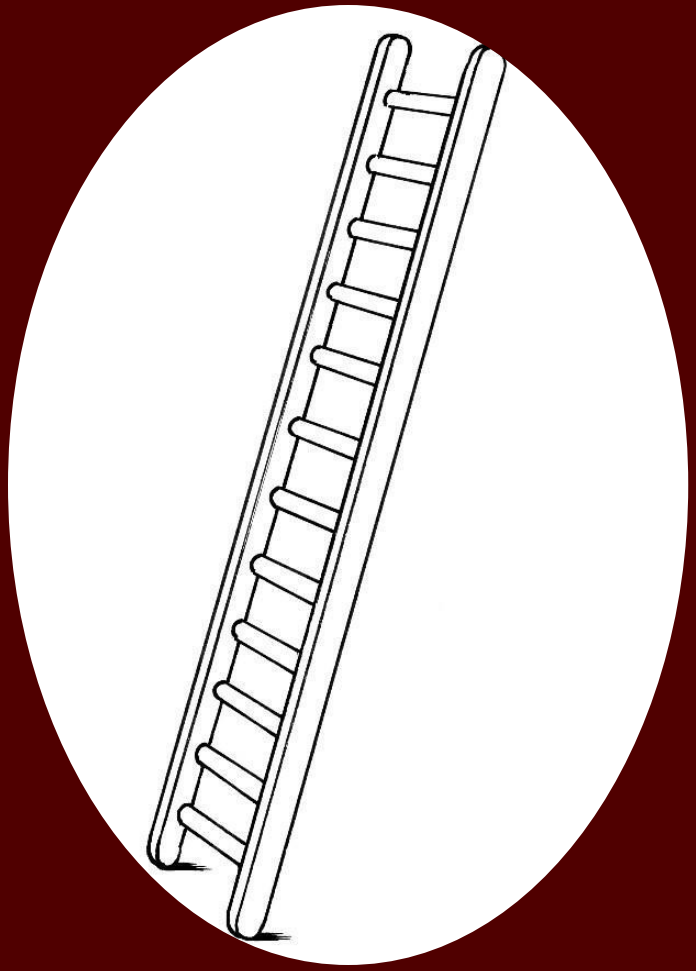
Prof. Peter K. Yu (余家明)
Director, Center for Law and Intellectual Property
Texas A&M University School of Law
http://www.peteryu.com

China's Innovative Turn and the Changing Pharmaceutical Landscape

Patent Reform



1984 – Patent Law

1985 – Paris Convention

1992 – 1st Amend. to Patent Law

1994 – PCT

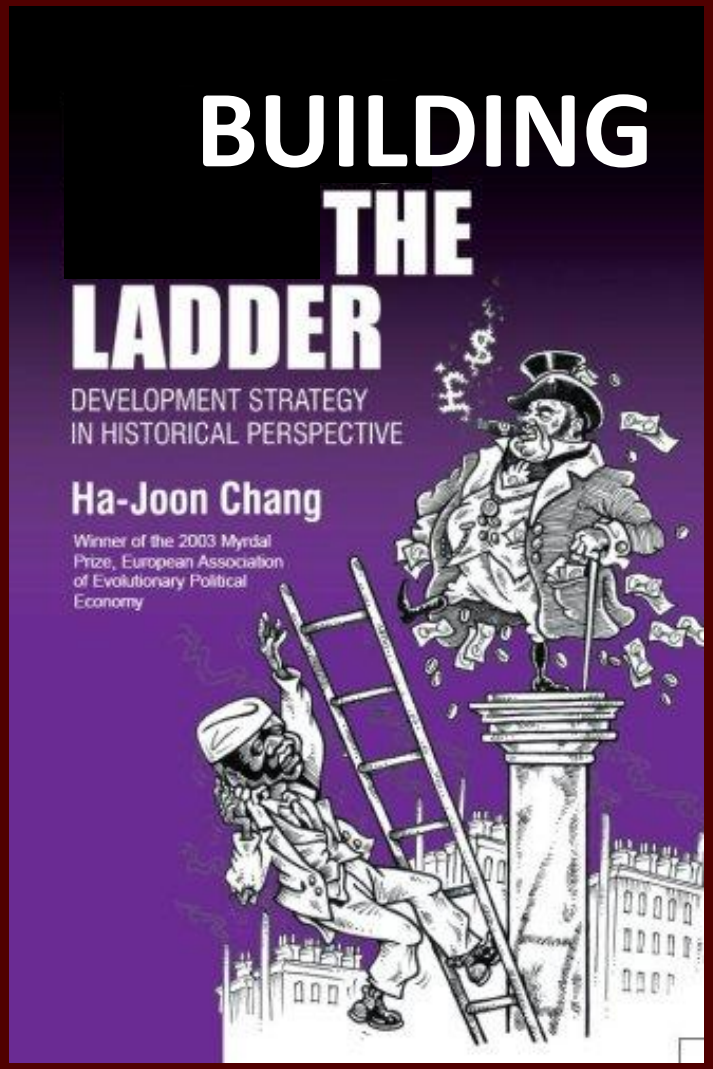
1999 – UPOV Convention

2000 – 2d Amend. to Patent Law

2001 – WTO TRIPS Agreement

2008 – 3rd Amend. to Patent Law

Soon – 4th Amend. to Patent Law


BUILDING
THE
LADDER
DEVELOPMENT STRATEGY
IN HISTORICAL PERSPECTIVE
Ha-Joon Chang
Winner of the 2003 Myrdal
Prize, European Association
of Evolutionary Political
Economy

Imitation and Transplantation

Standardization and Customization

Integration and Assimilation

Indigenization and Transformation

National IP Strategy (June 2008)
国家知识产权战略

Independent Innovation
自主知识产权

Frontier Technologies

National Medium- and Long-Term Plan for Science and Technology Development (2006–2020)

- biotech
- information technology
- advanced materials
- advanced manufacturing
- advanced energy technology
- marine technology
- laser technology
- aerospace technology

Frontier Technologies

National Medium- and Long-Term Plan for Science and Technology Development (2006–2020)

- biotech
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- advanced energy technology
- marine technology
- laser technology
- aerospace technology

Made in China 2025

- next-generation information technology
- high-end numerical control machinery and robotics
- aerospace and aviation equipment
- maritime engineering equipment and high-tech maritime vessel manufacturing
- advanced rail equipment
- energy-saving and new energy vehicles
- electrical equipment
- agricultural machinery and equipment
- new materials
- biomedicine and high-performance medical devices

Made in China 2025

- next-generation information technology
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- advanced rail equipment
- energy-saving and new energy vehicles
- electrical equipment
- agricultural machinery and equipment
- new materials
- biomedicine and high-performance medical devices

Patent Cooperation Treaty

2018	Country	Estimate	Share
1	USA	56,142	−0.9%
2	China	53,345	9.1%
3	Japan	49,702	3.1%
4	Germany	19,883	4.9%
5	S. Korea	17,014	8%
6	France	7,914	−1.2%
7	U.K.	5,641	1.3%
8	Switzerland	4,568	1.8%
9	Sweden	4,162	4.7%
10	Netherlands	4,138	−6.6%

2018	Applicant's Name	Country	PCT Apps.
1	Huawei Technologies	China	5,405
2	Mitsubishi Electric	Japan	2,812
3	Intel Corp.	USA	2,499
4	Qualcomm Inc.	USA	2,404
5	ZTE Corp.	China	2,080
6	Samsung Electronics	S. Korea	1,997
7	BOE Technology Group	China	1,813
8	LG Electronics	S. Korea	1,697
9	LM Ericsson	Japan	1,645
10	Robert Bosch	Germany	1,524

GLOBAL INNOVATION INDEX 2019

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WIPO
WORLD INTELLECTUAL PROPERTY ORGANIZATION

GII 2019

Rankings

2019 Rank	Economy	2018 Rank	Change
1	Switzerland	1	0
2	Sweden	3	1
3	United States of America (the)	6	3
4	Netherlands (the)	2	-2
5	United Kingdom (the)	4	-1
6	Finland	7	1
7	Denmark	8	1
8	Singapore	5	-3
9	Germany	9	0
10	Israel	11	1
11	Republic of Korea (the)	12	1
12	Ireland	10	-2
13	Hong Kong, China	14	1
14	China	17	3
15	Japan	13	-2
17	Canada	18	1
19	Norway	19	0
20	Iceland	23	3

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WORLD INTELLECTUAL PROPERTY ORGANIZATION

GII 2019

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1	Switzerland	1	0
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5	United Kingdom (the)	4	-1
6	Finland	7	1
7	Denmark	8	1
8	Singapore	5	-3
9	Germany	9	0
10	Israel	11	1
11	Republic of Korea (the)	12	1
12	Ireland	10	-2
13	Hong Kong, China	14	1
14	China	17	3
15	Japan	13	-2
17	Canada	18	1
19	Norway	19	0
20	Iceland	23	3


CNIPA
NATIONAL INTELLECTUAL PROPERTY ADMINISTRATION,PRC

2018	Total No.	Percentage
Resident Invention Patent Applications	1,393,815	90.4
Nonresident Invention Patent Applications	148,187	9.6
Resident Utility Model Applications	2,063,860	99.6
Nonresident Utility Model Applications	8,451	0.4
Resident Design Patent Applications	689,097	97.2
Nonresident Design Patent Applications	19,702	2.8
Total Patent Applications	4,323,112	

2018	Total No.	Percentage
Resident Invention Patent Applications	1,393,815	90.4
Nonresident Invention Patent Applications	148,187	9.6
Resident Utility Model Applications	2,063,860	99.6
Nonresident Utility Model Applications	8,451	0.4
Resident Design Patent Applications	689,097	97.2
Nonresident Design Patent Applications	19,702	2.8
Total Patent Applications	4,323,112	

2017		
Resident Patent Applications	1,245,709	190, 559
Nonresident Patent Applications	135,885	332,522
Nonresident Apps. Percent Share	9.8	63.6
Total Patent Applications	1,381,594	523,081
Resident Patent Grants	326,970	167,367
Nonresident Patent Grants	93,174	180,275
Nonresident Grants Percent Share	22.2	51.9
Total Patent Grants	420,114	347,642


INTELLECTUAL
PATENTED
PROPERTY


QUALITY
QUALITY
QUALITY

Behind only
Japan,
South Korea
and Germany

16% – Behind
Only the
United States
and Japan

2018 Supreme People's Court Report

16,010 new patent cases (+29.56%)

37,946 new trademark cases (+39.58%)

137,267 new copyright cases (+57.80%)


What about Pharmaceuticals?

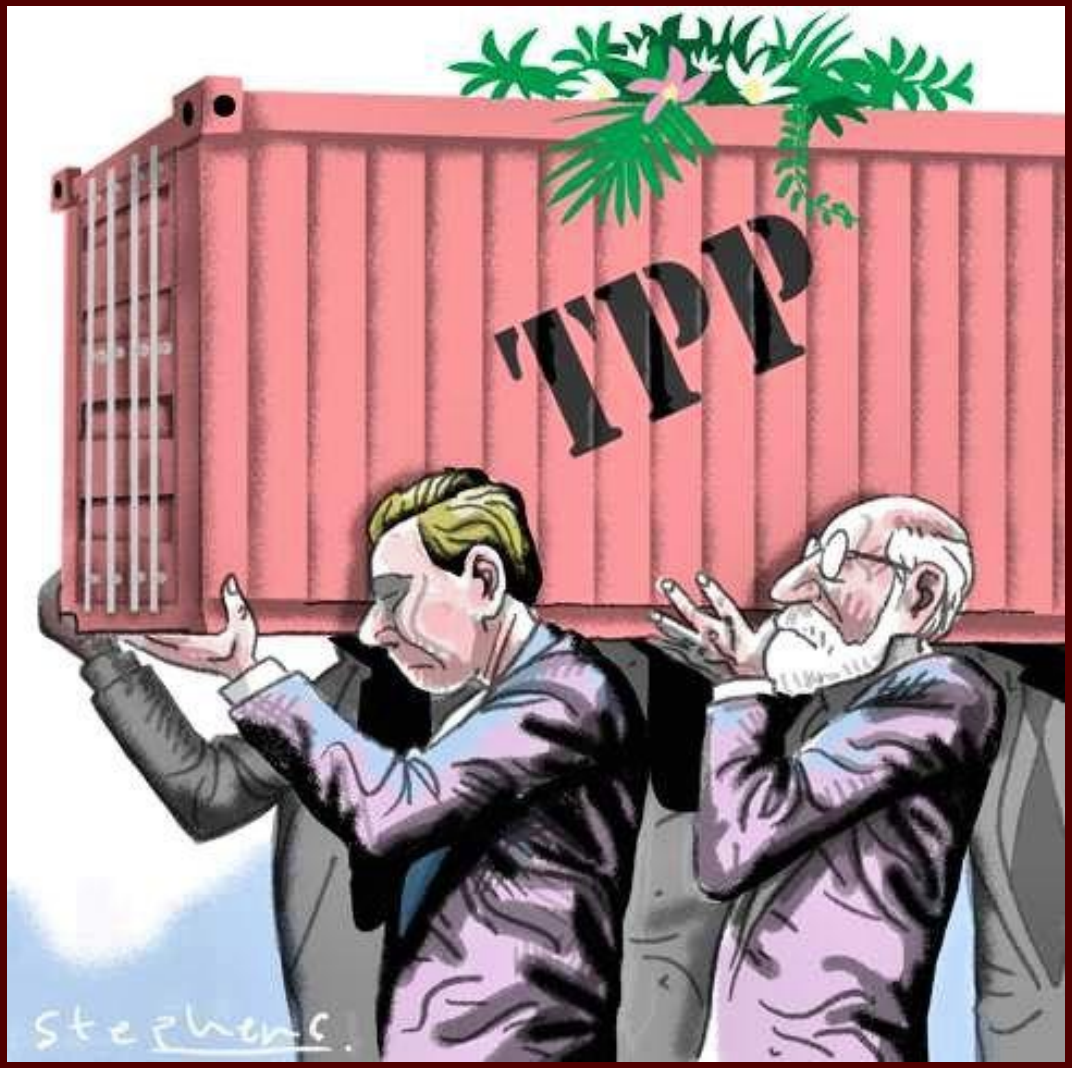
Proposed Provisional Measures for the Implementation of Test Data Protection for Pharmaceutical Products

Article 5

innovative drugs (创新药) – 6 years

innovative therapeutic biologics (创新治疗用生物制品) – 12 years

Patent Term Extension
(Due to Regulatory Delay)


'TPP'
Stephens.

Article 18.50: Protection of Undisclosed Test or Other Data

1. (a) If a Party requires, as a condition for granting marketing approval for a new pharmaceutical product, the submission of undisclosed test or other data concerning the safety and efficacy of the product, that Party shall not permit third persons, without the consent of the person that previously submitted such information, to market the same or a similar product on the basis of:

(i) that information;

or (ii) the marketing approval granted to the person that submitted such information,

for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party.

Article 18.50: Protection of Undisclosed Test or Other Data

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(i) that information;

or (ii) the marketing approval granted to the person that submitted such information,

for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party.

Article 18.51: Biologics

1. With regard to protecting new biologics, a Party shall either:

(a) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic provide effective market protection through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, mutatis mutandis, for a period of at least eight years from the date of first marketing approval of that product in that Party; or, alternatively,

Article 18.51: Biologics

1. With regard to protecting new biologics, a Party shall either:

(a) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic provide effective market protection through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, mutatis mutandis, for a period of at least eight years from the date of first marketing approval of that product in that Party; or, alternatively,

(b) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection:

(i) through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, mutatis mutandis, for a period of at least five years from the date of first marketing approval of that product in that Party,

(ii) through other measures, and

(iii) recognising that market circumstances also contribute to effective market protection to deliver a comparable outcome in the market.

(b) with [illegible] to the first marketing approv[illegible] Party of a new ph[illegible]tical product that is or c[illegible] biologic, provide effe[illegible]rket protection:

(i) through the [illegible]ntation o[illegible]18.50.1 (Protection of [illegible]ed T[illegible]ner Data) and Article 18.50.3, m[illegible], for a period of at least five years from [illegible]r first marketing approval of that pr[illegible]Party,

(ii) through other [illegible]s, an[illegible]

(iii) recognisin[illegible]arket circumst[illegible]o contribute to effe[illegible]ket protection to de[illegible]mparable outc[illegible]he market.

USMCA Chapter 20

Article 20.48: Protection of Undisclosed Test or Other Data

1. (a) If a Party requires, as a condition for granting marketing approval for a new pharmaceutical product, the submission of undisclosed test or other data concerning the safety and efficacy of the product, that Party shall not permit third persons, without the consent of the person that previously submitted that information, to market the same or a similar product on the basis of:

(i) that information, or

(ii) the marketing approval granted to the person that submitted that information,

for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party;

(b) If a Party permits, as a condition of granting marketing approval for a new pharmaceutical product, the submission of evidence of prior marketing approval of the product in another territory, that Party shall not permit third persons, without the consent of a person that previously submitted the information concerning …

Article 20.48: Protection of Undisclosed Test or Other Data

1. (a) If a Party requires, as a condition for granting marketing approval for a new pharmaceutical product, the submission of undisclosed test or other data concerning the safety and efficacy of the product, that Party shall not permit third persons, without the consent of the person that previously submitted that information, to market the same or a similar product on the basis of:

(i) that information, or

(ii) the marketing approval granted to the person that submitted that information,

for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party;

(b) If a Party permits, as a condition of granting marketing approval for a new pharmaceutical product, the submission of evidence of prior marketing approval of the product in another territory, that Party shall not permit third persons, without the consent of a person that previously submitted the information concerning …

Article 20.49: Biologics

1. With regard to protecting new biologics, a Party shall, with respect to the first marketing approval in a Party of a new pharmaceutical product that is, or contains, a biologic provide effective market protection through the implementation of Article 20.48.1 (Protection of Undisclosed Test or Other Data) and Article 20.48.3 (Protection of Undisclosed Test or Other Data), mutatis mutandis, for a period of at least ten years from the date of first marketing approval of that product in that Party.

2. Each Party shall apply this Article to, at a minimum, a product that is produced using biotechnology processes and that is, or contains, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, for use in human beings for the prevention, treatment, or cure of a disease or condition.

Article 20.49: Biologics

1. With regard to protecting new biologics, a Party shall, with respect to the first marketing approval in a Party of a new pharmaceutical product that is, or contains, a biologic provide effective market protection through the implementation of Article 20.48.1 (Protection of Undisclosed Test or Other Data) and Article 20.48.3 (Protection of Undisclosed Test or Other Data), mutatis mutandis, for a period of at least ten years from the date of first marketing approval of that product in that Party.

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IP
Standards

USMCA

TPP

CPTPP

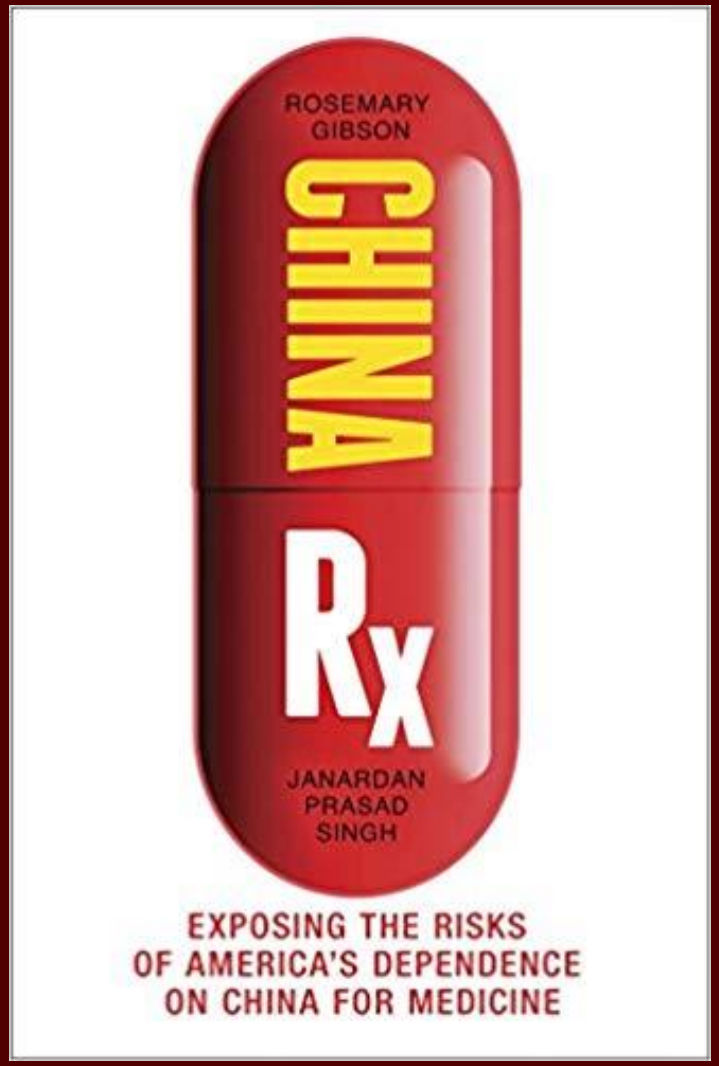
TRIPS

NAFTA


Ramifications

Changing Discourse

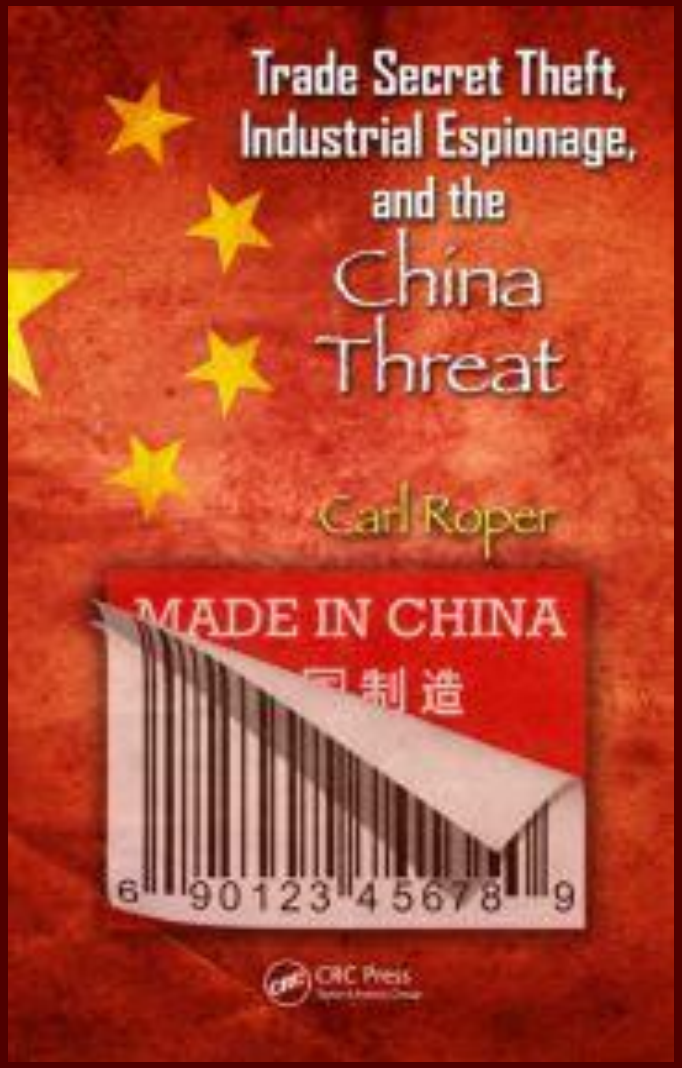

VIAGRA
100mg
VIAGRA
100mg
VIAGRA
100mg
CHINA CUSTO


ROSEMARY
GIBSON
CHINA
Rx
JANARDAN
PRASAD
SINGH
EXPOSING THE RISKS
OF AMERICA'S DEPENDENCE
ON CHINA FOR MEDICINE

OFFICE *of the* UNITED STATES TRADE REPRESENTATIVE
EXECUTIVE OFFICE OF THE PRESIDENT

FINDINGS OF THE INVESTIGATION INTO CHINA'S ACTS, POLICIES, AND PRACTICES RELATED TO TECHNOLOGY TRANSFER, INTELLECTUAL PROPERTY, AND INNOVATION UNDER SECTION 301 OF THE TRADE ACT OF 1974

March 22, 2018


Trade Secret Theft,
Industrial Espionage,
and the
China
Threat
Carl Roper
MADE IN CHINA
制造
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CRC Press

AS AN IP POWER


WIPO
WORLD INTELLECTUAL PROPERTY ORGANIZATION
IP Services
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Cooperation
Knowledge
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Search WIPO
Home › WIPO Media Center › Press Releases › 2018
China Drives International Patent Applications to Record Heights; Demand Rising for Trademark and Industrial Design Protection
Geneva, March 21, 2018
PR/2018/816


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EXECUTIVE OFFICE OF THE PRESIDENT
TRADE AGREEMENTS
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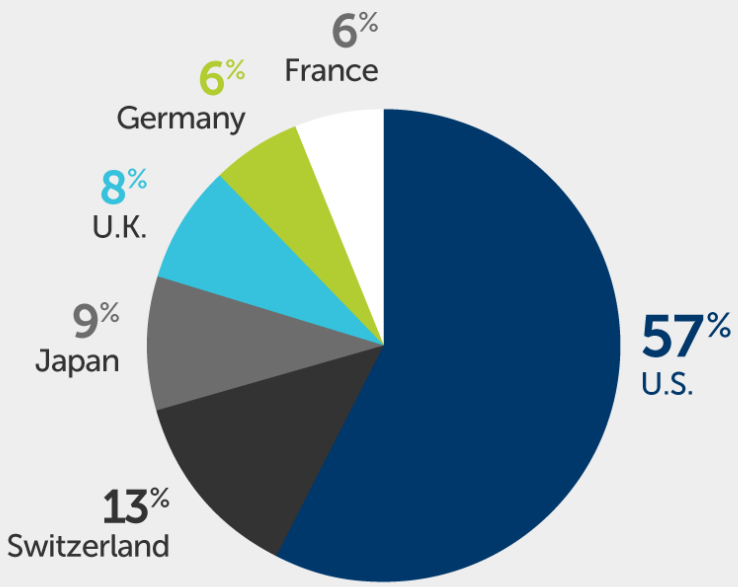
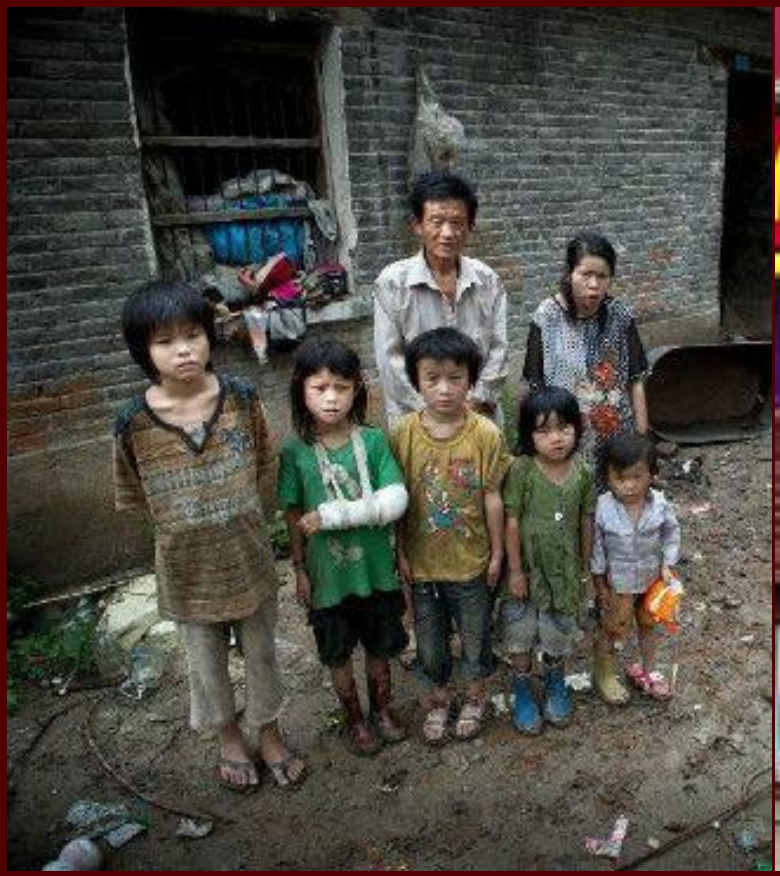
March
Following President Trump's Section 301 Decisions, USTR Launches New WTO Challenge Against China
Joint Readout from Meeting of the United States, European
Following President Trump's Section 301 Decisions, USTR Launches New WTO Challenge Against China
03/23/2018

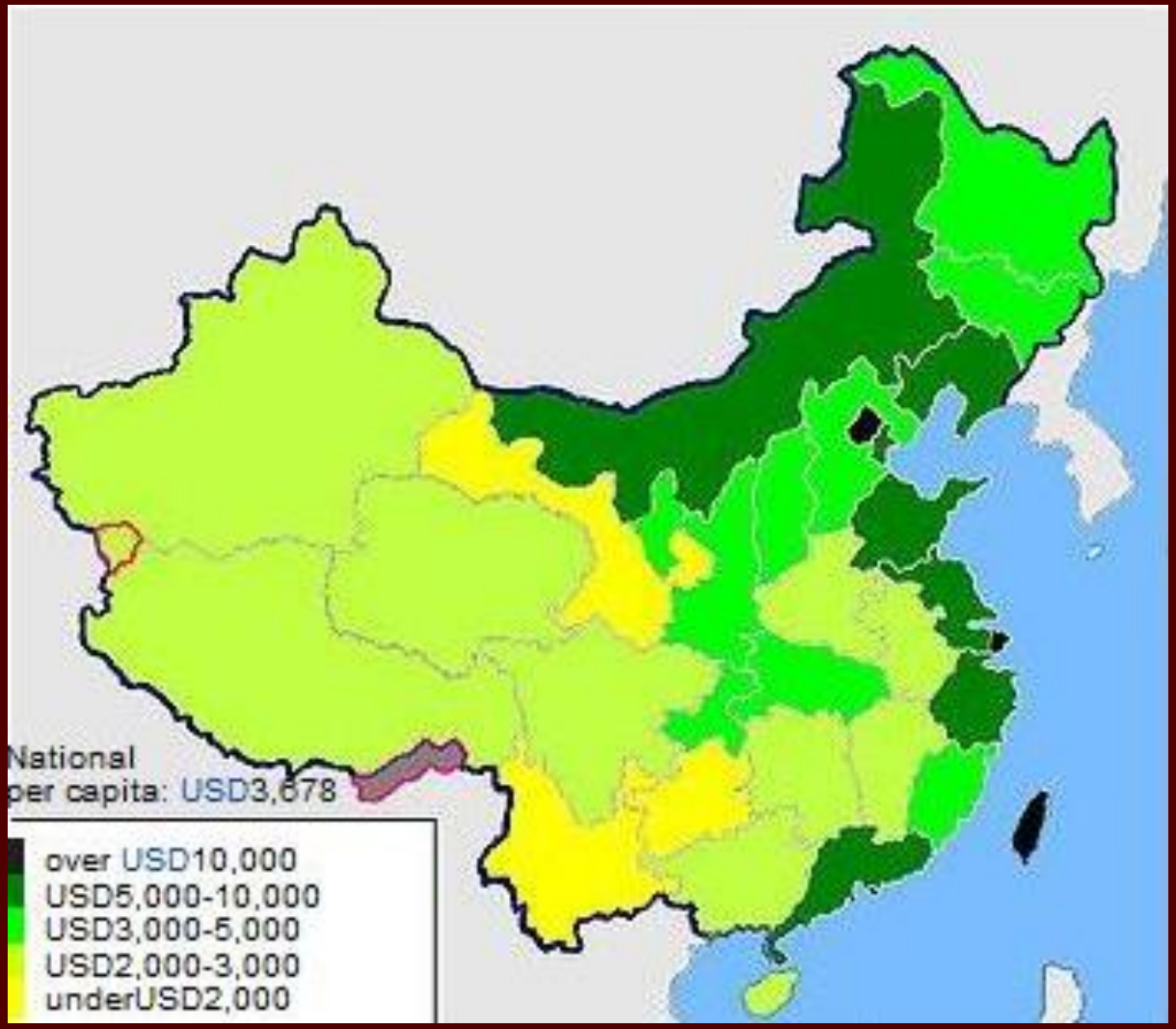
Where are new drugs coming from?



Source:
Milken Institute. 2011 (September). *The Global Biomedical Industry: Preserving U.S. Leadership,* Table 2, available at: http://assets1c.milkeninstitute.org/assets/Publication/ResearchReport/PDF/CASMIFullReport.pdf (last accessed October 13, 2016).

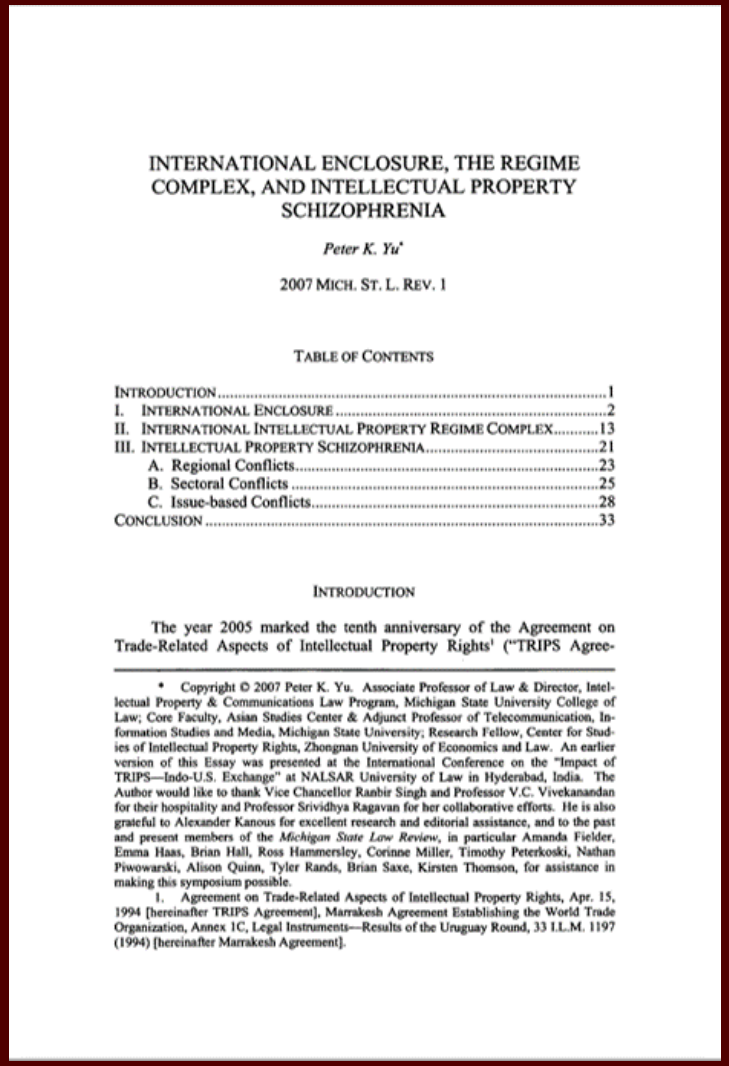


Internal Challenges


National
per capita: USD3,678
over USD10,000
USD5,000-10,000
USD3,000-5,000
USD2,000-3,000
underUSD2,000

2018	Province	Inv. Pat. Apps	Inv. Pat. Grants
1	Guangdong	216,469	53,259
2	Jiangsu	198,801	42,019
3	Zhejiang	143,081	32,550
4	Anhui	108,782	14,846
5	Shandong	72,764	20,338
6	…	…	
7	…	…	
18	Jilin	10,530	2,868
19	Yunnan	9,606	2,297
20	Shanxi	9,395	2,284

Gansu, Inner Mongolia, Xinjiang, Ningxia, Hainan, Qinghai, and Tibet



INTERNATIONAL ENCLOSURE, THE REGIME COMPLEX, AND INTELLECTUAL PROPERTY SCHIZOPHRENIA

Peter K. Yu[*]

2007 MICH. ST. L. REV. 1

TABLE OF CONTENTS

INTRODUCTION

The year 2005 marked the tenth anniversary of the Agreement on Trade-Related Aspects of Intellectual Property Rights[1] ("TRIPS Agree-

Associate Professor of Law & Director, Intellectual Property & Communications Law Program, Michigan State University College of Law; Core Faculty, Asian Studies Center & Adjunct Professor of Telecommunication, Information Studies and Media, Michigan State University; Research Fellow, Center for Studies of Intellectual Property Rights, Zhongnan University of Economics and Law.

An earlier version of this Essay was presented at the International Conference on the "Impact of TRIPS—Indo-U.S. Exchange" at NALSAR University of Law in Hyderabad, India. The Author would like to thank Vice Chancellor Ranbir Singh and Professor V.C. Vivekanandan for their hospitality and Professor Srividhya Ragavan for her collaborative efforts. He is also grateful to Alexander Kanous for excellent research and editorial assistance, and to the past and present members of the *Michigan State Law Review*, in particular Amanda Fielder, Emma Haas, Brian Hall, Ross Hammersley, Corinne Miller, Timothy Peterkoski, Nathan Piwowarski, Alison Quinn, Tyler Rands, Brian Saxe, Kirsten Thomson, for assistance in making this symposium possible.

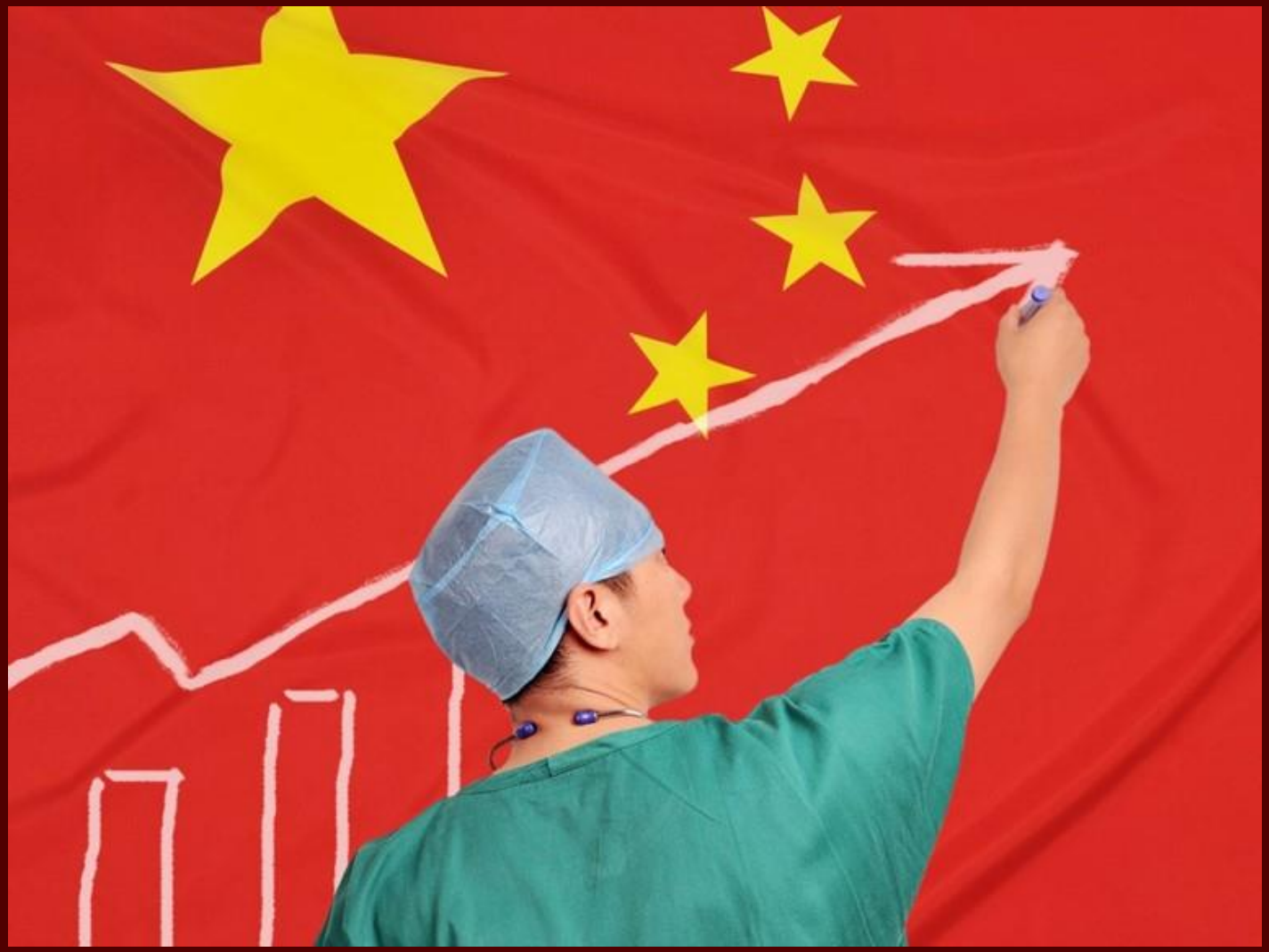
1. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994 [hereinafter TRIPS Agreement], Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1197 (1994) [hereinafter Marrakesh Agreement].

China is likely to prefer stronger protection of intellectual property rights in entertainment, software, semiconductors, and selected areas of biotechnology to increased protection in areas concerning pharmaceuticals, chemicals, fertilizers, seeds, and foodstuffs.

Proposed Provisional Measures for the Implementation of Test Data Protection for Pharmaceutical Products

Proposed 4th Amendment to the Patent Law


我不是藥神
DYING TO SURVIVE



State Council approves centralized medicine procurement

Updated: Jan 17,2019 4:57 PM english.gov.cn

The State Council approved State-run centralized medicine procurement and 11 pilot cities for the program in a circular issued on Jan 17. It is an effort to deepen reform of the medical and health sector and optimize the pricing system of drugs.

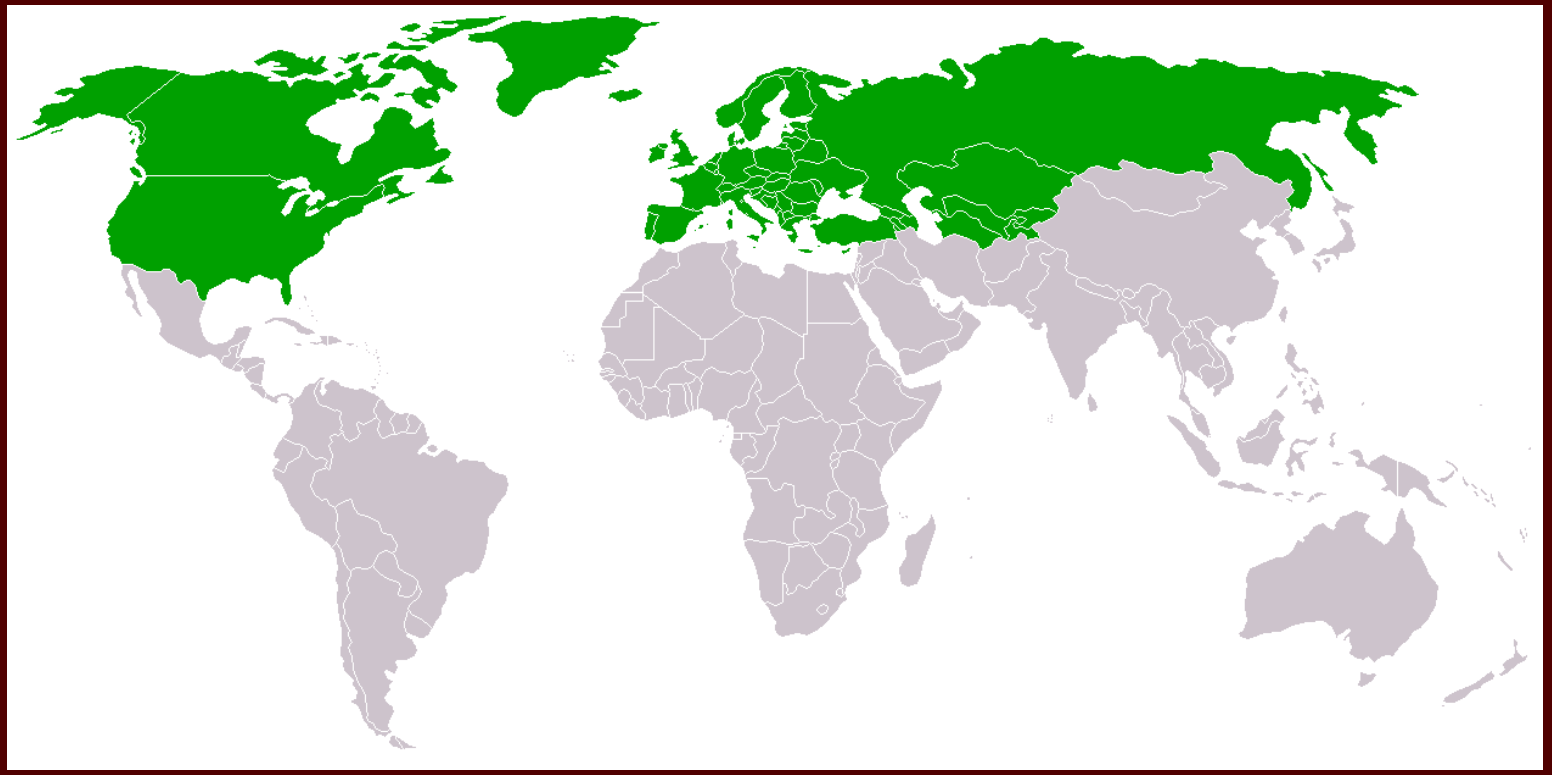
According to the circular, in the 11 pilot cities — Beijing, Tianjin, Shanghai, Chongqing, Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu, and Xi'an — drugs will be selected from generic brands for centralized medicine procurement. The selected drugs must pass the consistency evaluation on quality and effectiveness.

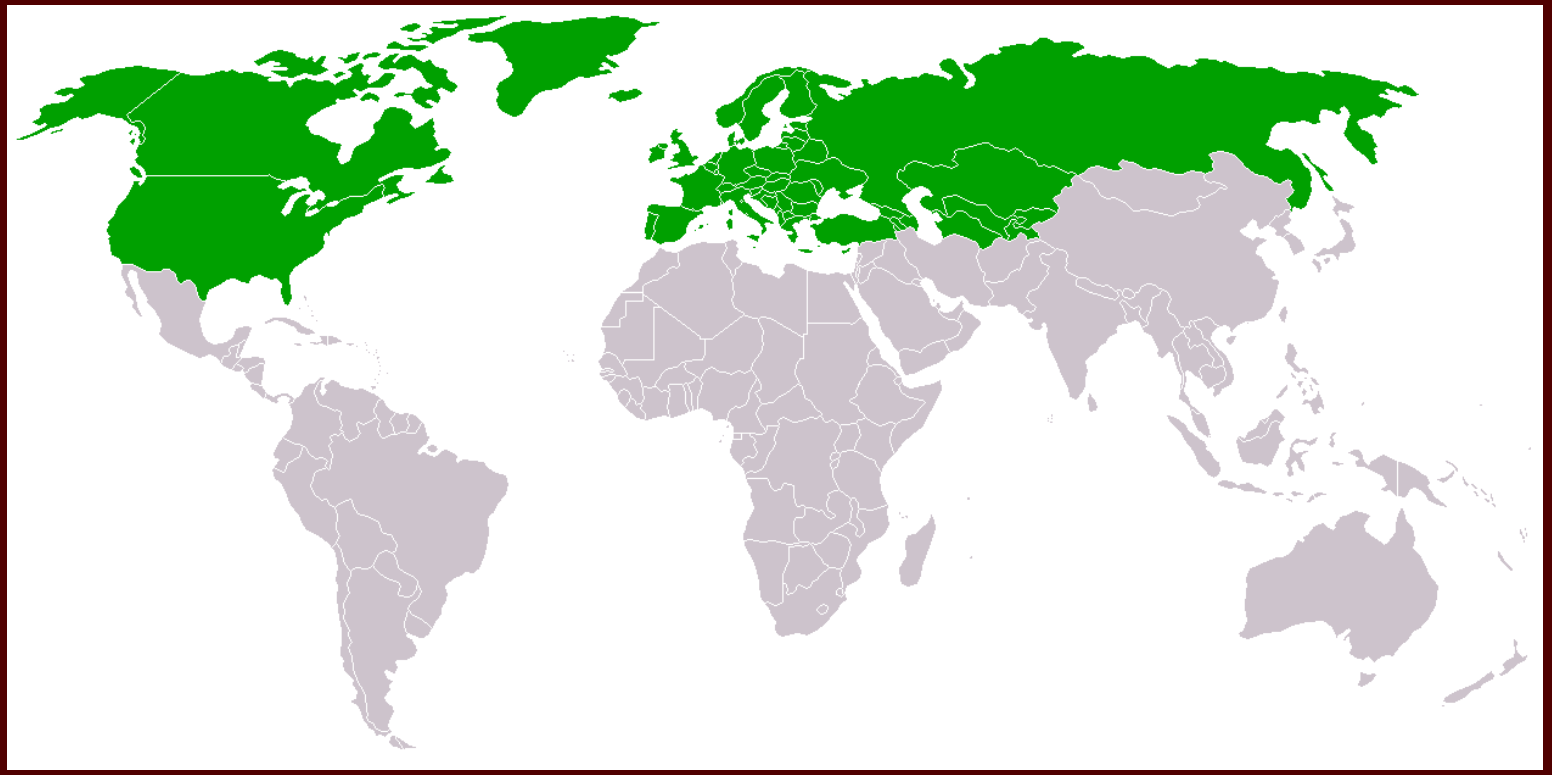
Global Complications


4 Years
12 Years


SUN
PHARMA
RANBAXY
LABORATORIES LIMITED


Dr. Reddy's






WTO


WIPO


COMPREHENSIVE
AND PROGRESSIVE
AGREEMENT FOR
TRANS-PACIFIC
PARTNERSHIP
(CPTPP)


Regional Comprehensive
Economic Partnership
R C E P


Going
Forward


HEALTH
INSURANCE
DATA
ANALYTICS
Ai

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GLOBAL INNOVATION INDEX 2019

Creating Healthy Lives—The Future of Medical Innovation

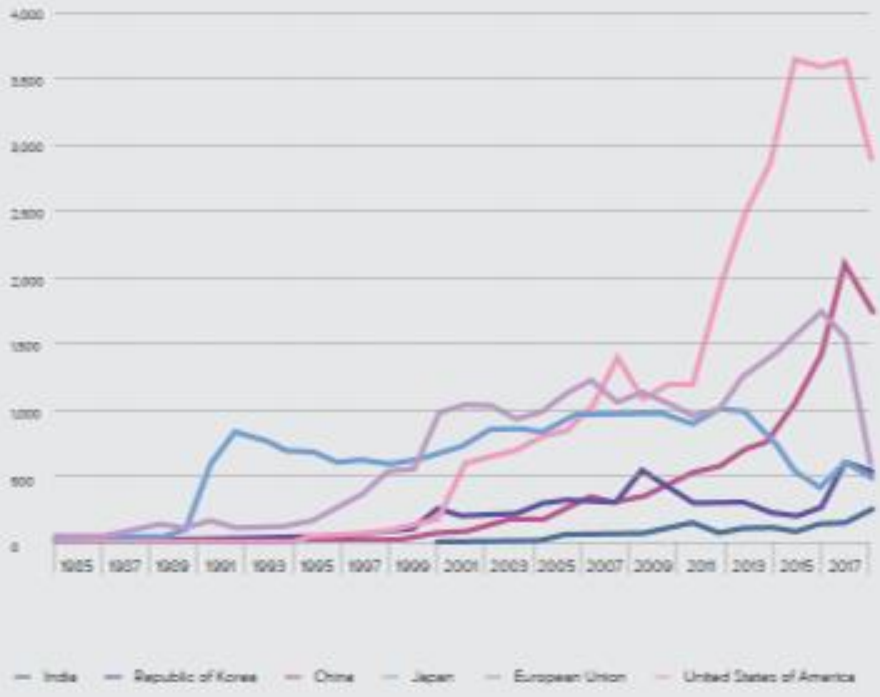
CII Confederation of Indian Industry

DASSAULT SYSTEMES

SESI SENAI CNI

FIGURE 5.2

Healthcare AI patent applications in major countries and regions, 1985 to 2017



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GLOBAL INNOVATION INDEX 2019

Creating Healthy Lives—The Future of Medical Innovation

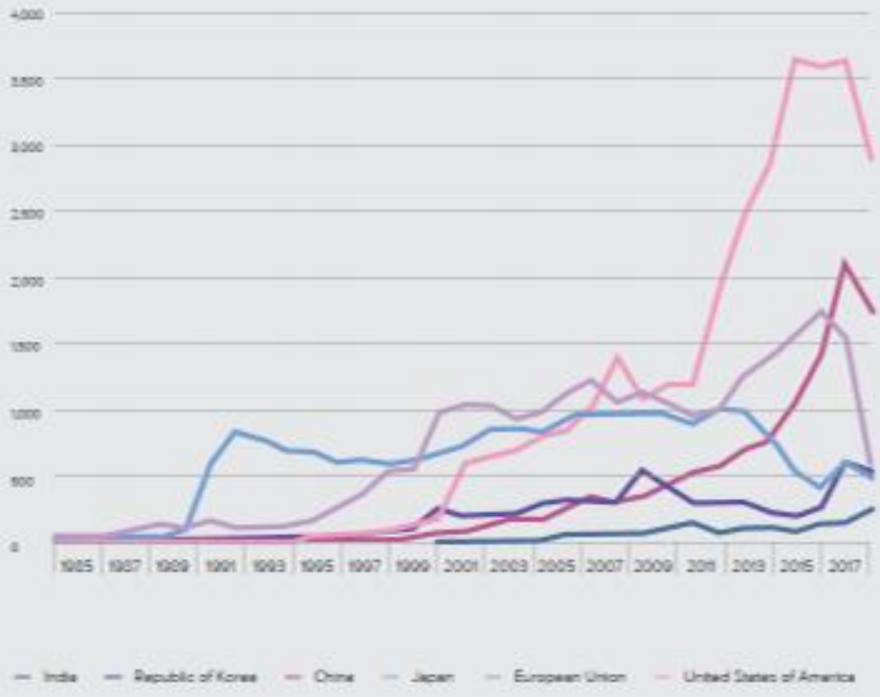
CII Confederation of Indian Industry

DASSAULT SYSTEMES

SESI SENAI CNI

FIGURE 5.2

Healthcare AI patent applications in major countries and regions, 1985 to 2017



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GLOBAL INNOVATION INDEX 2019

Creating Healthy Lives—The Future of Medical Innovation

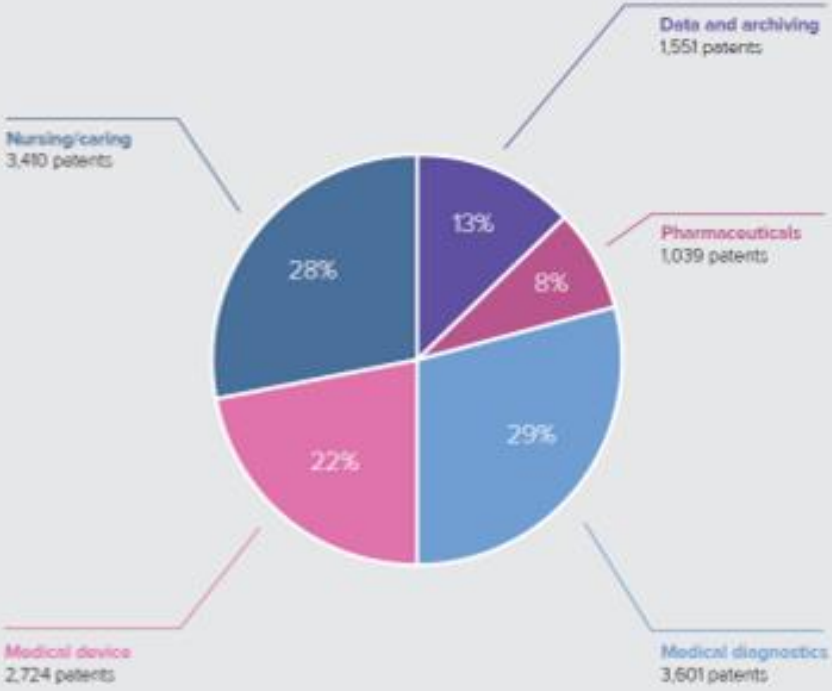
CII

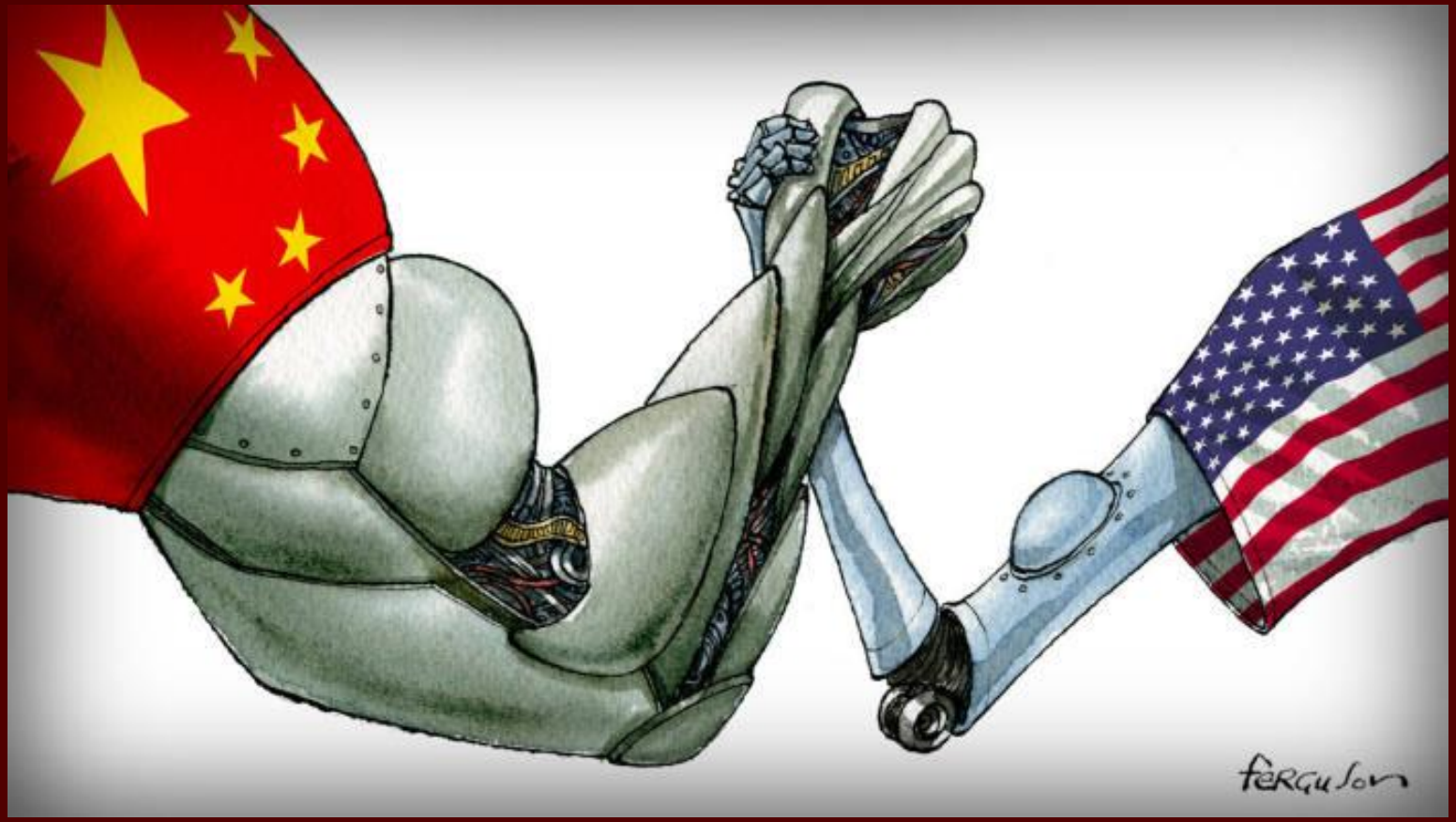
DASSAULT SYSTEMES

CNI

FIGURE 5.3

Healthcare AI patent categories in China




FERGUSON


5G

Prof. Peter K. Yu (余家明)
Director, Center for Law and Intellectual Property
Texas A&M University School of Law
http://www.peteryu.com

China's Innovative Turn and the Changing Pharmaceutical Landscape