

Deals in Medical Device & Diagnostics

SABPA Pacific Forum

November 8, 2008

University of California, San Diego

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Agenda

1. Overview
2. What have we been seeing
3. Specific issues

Overview

1. More and more foreign device, diagnostic, and pharmaceutical companies looking to enter Chinese market
2. Increasing number of local, Chinese start-ups
3. Local, Chinese companies starting to become players on both the local and international levels

Our Experience

1. China Inbound

- a. Setting up more and more manufacturing and sales operations (see also IP, regulatory and compliance)
- b. Starting to see more outbound work:
Companies looking to do business in the U.S. and Europe

Top Issues for Foreign Companies Doing Business in China

1. Recruiting & Retaining Talent

- Competitive compensation
- Job growth opportunities
- Favorable workplace environment and culture
- Special training opportunities
- Flexible project rotations

Top Issues for Foreign Companies Doing Business in China

2. IP Concerns

- Physical and IT security issues
- Ownership
- Trade secret violation
- Non-compete

Specific Issues

1. Regulatory (see also compliance)
2. Reimbursement
3. IP
4. Financing
5. Marketing/sales/distribution (Partnerships)
6. Compliance

Regulatory

1. Inbound
 - a. Registration certificate
 - i. Issued by State Food and Drug Administration (SFDA)
 - ii. Three classes
2. Outbound to U.S.
 - a. FDA approval – also three classes
 - i. 510K
 - ii. PMA
3. Need Global Strategy

Reimbursement

1. Inbound
 - a. No formal reimbursement (No health insurance)
 - b. Two markets
 - i. Premium
 - ii. Rural market – largely untapped
2. Outbound to U.S.
 - a. Complex reimbursement systems
 - b. Huge driver of time to market
3. Need a global strategy

Intellectual Property

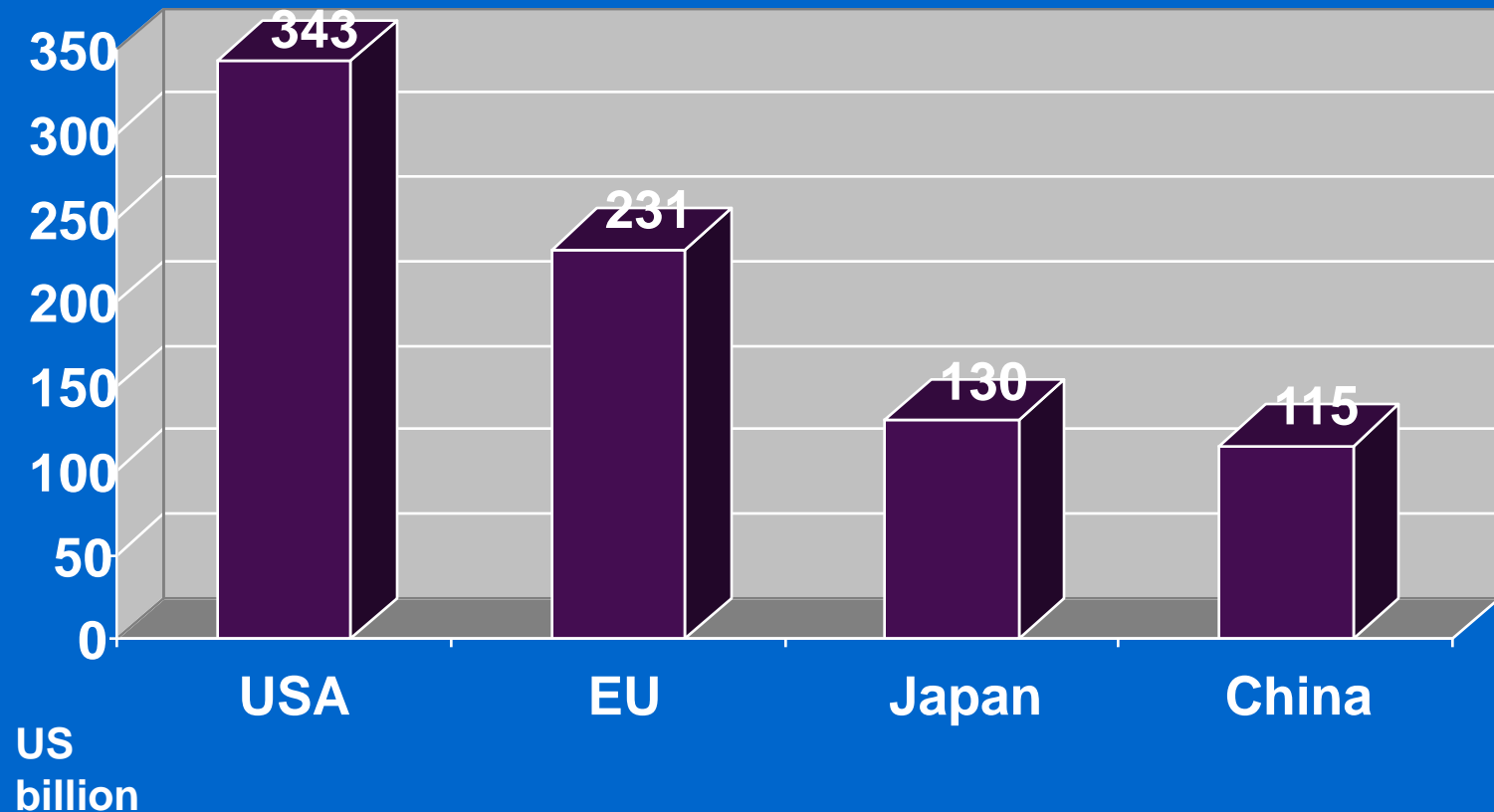
1. Inbound

- a. Filings in China increasing dramatically
- b. 3 types:
 - i. Invention (U.S. Utility)
 - ii. Utility model
 - iii. Design

2. Outbound to U.S.

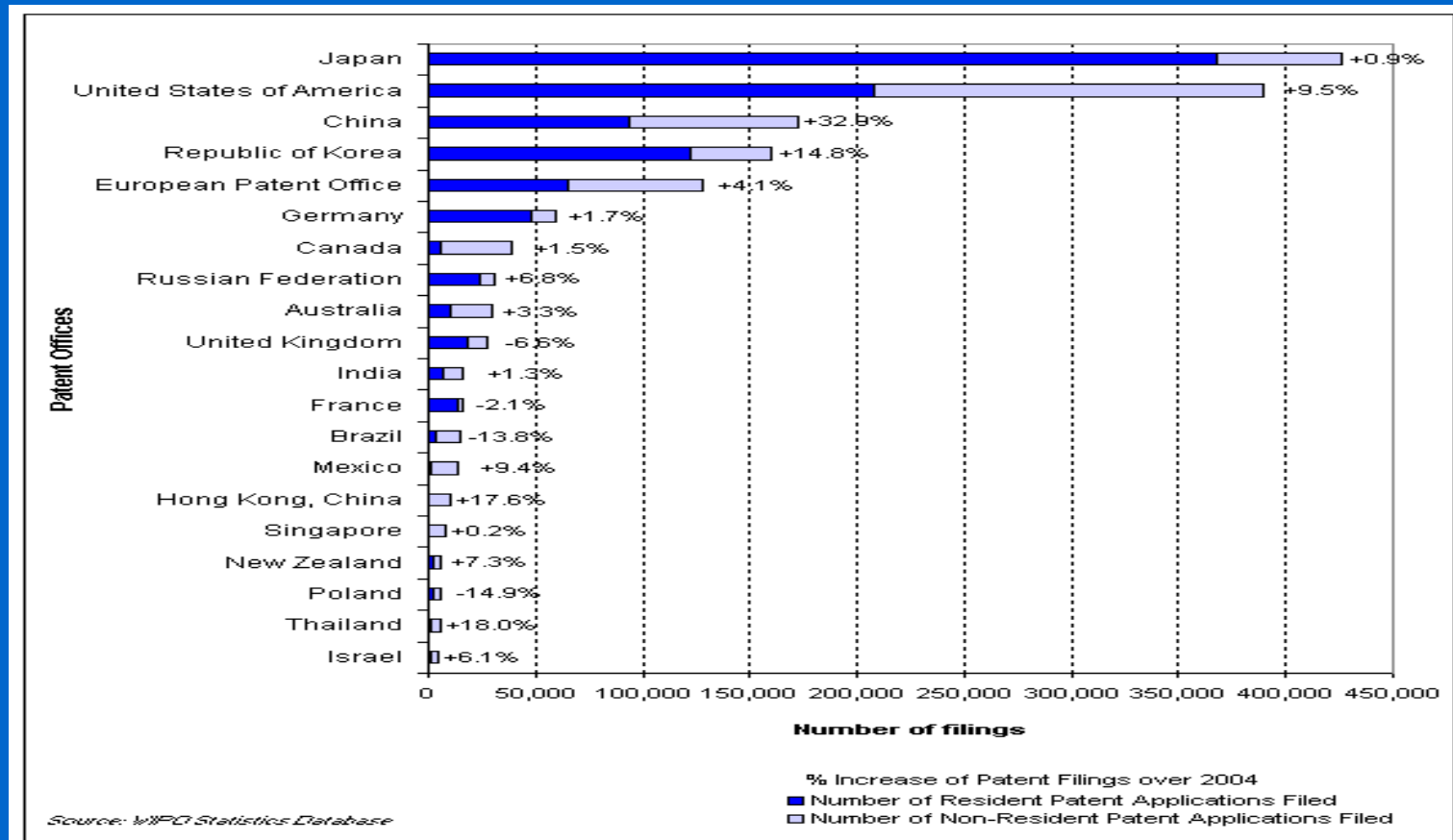
- a. Need a global strategy
 - i. Where to file – and where to file first
 - ii. Using U.S. Attorney to draft the applications

The World's 4 Largest R&D Spenders

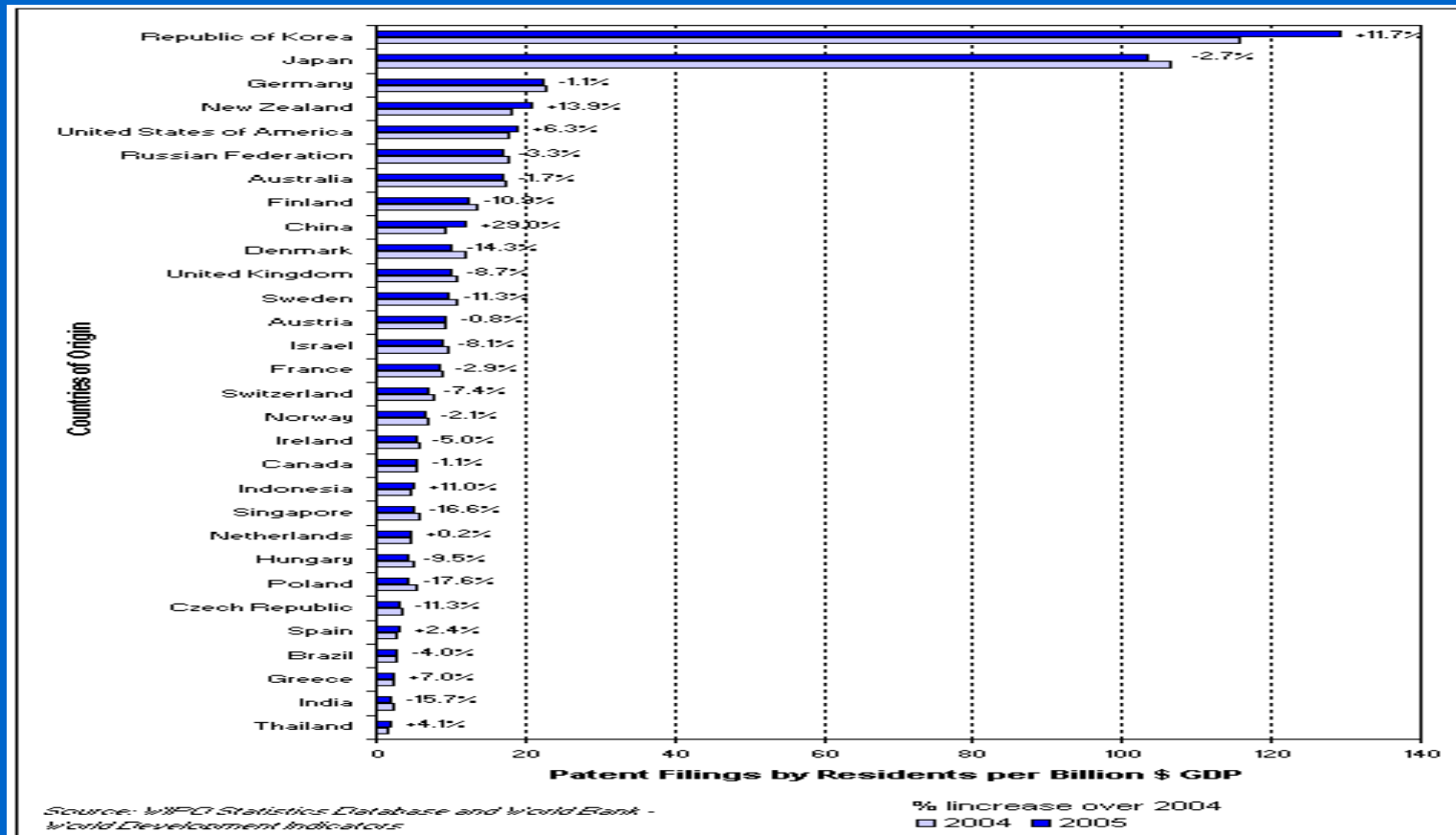


Source: UK R&D Scoreboard 2006

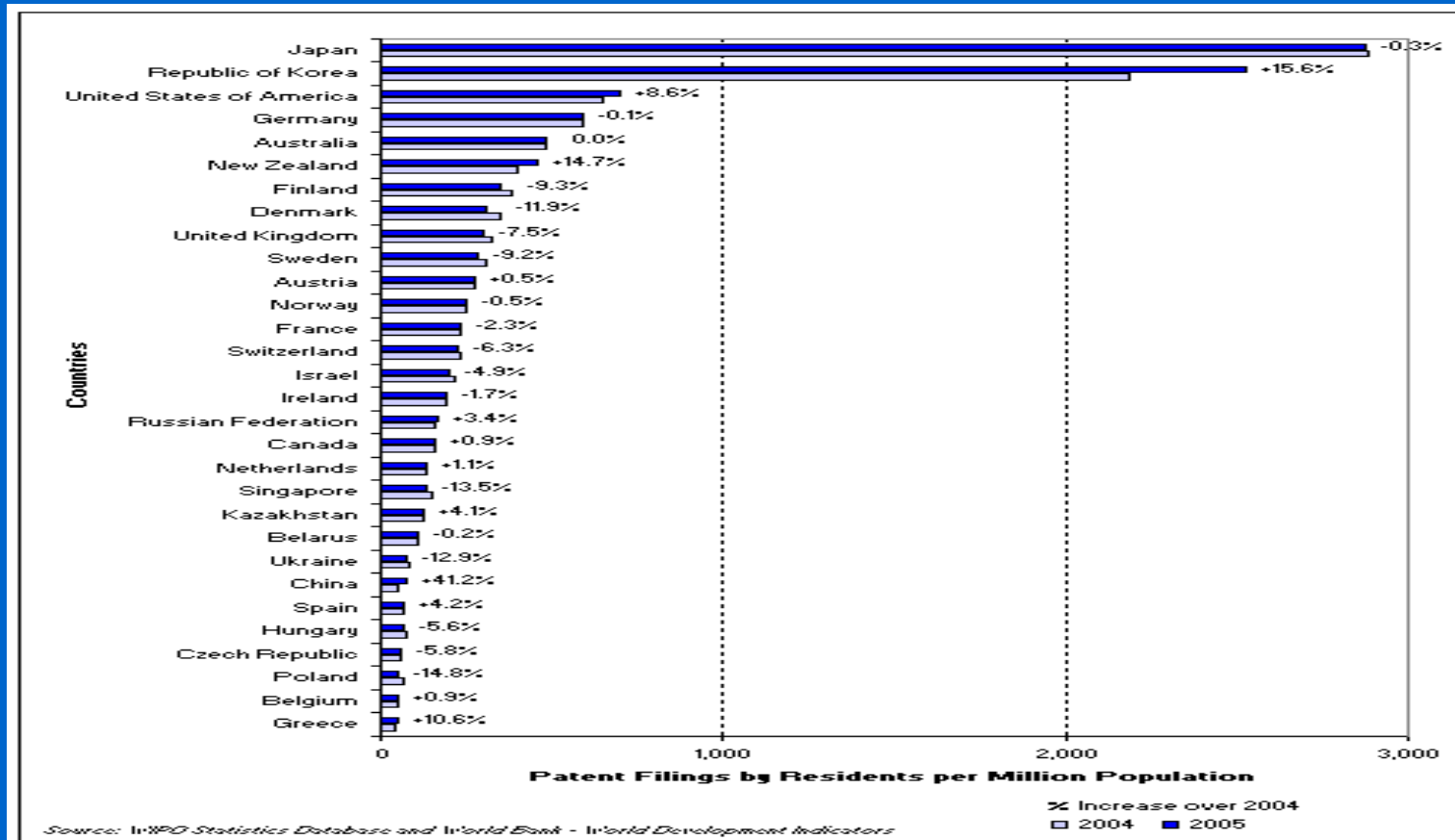
Patent Filing by Country



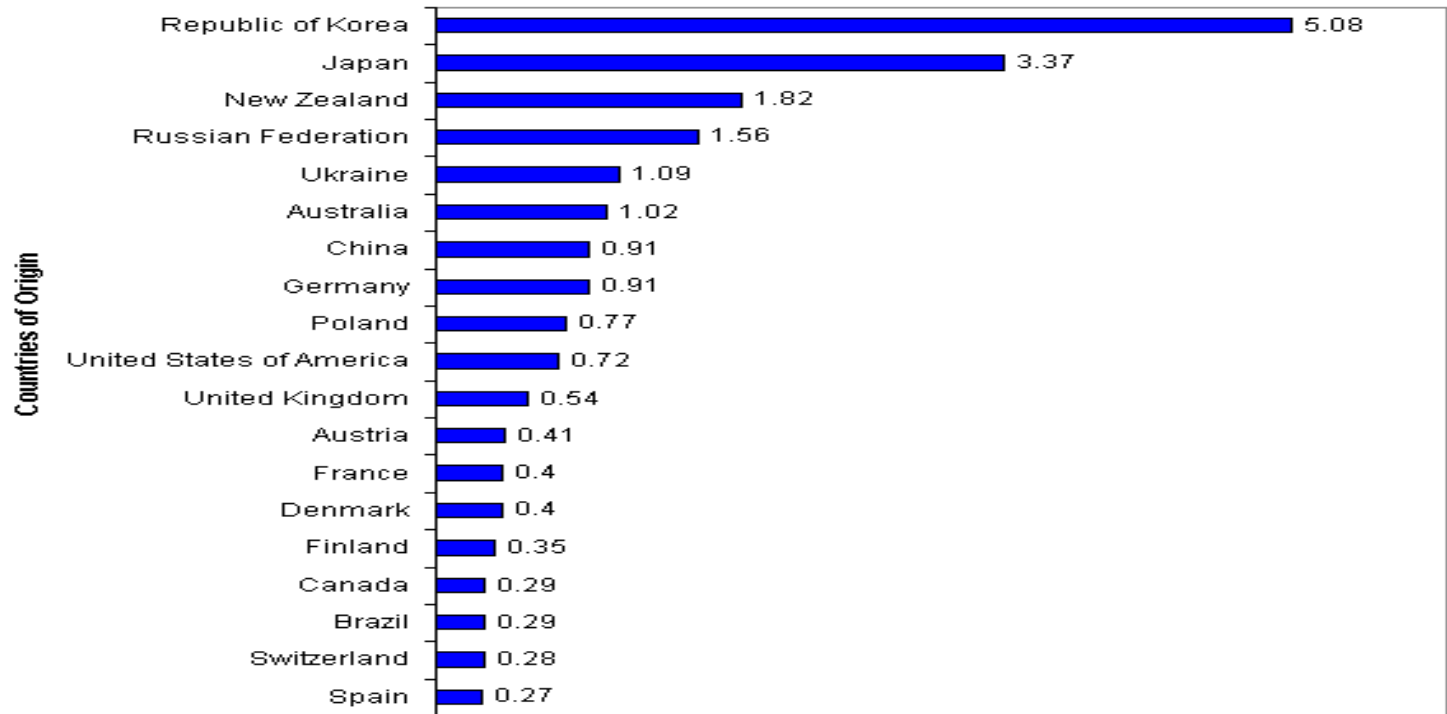
Patent Filing per GDP



Patent Filing per Million Population



Patent Filings per Million R&D Expenditure



Source: WIPO Statistics Database, World Bank - World Development Indicators, UNESCO Institute for Statistics

■ Resident Patent Filings per Million 1\$ R&D Expenditures (constant 2000\$ at PPP)

Facts of R&D in China

- Spending ~1.3% of GDP in 2005 (0.6% in 1995), projected to be 2.5% in 2020
- Domestic spending ~US41.4B in 2006
- 750 R&D centers set up by foreign enterprises
- Most foreign centers in SH, BJ, and Shenzhen
- 400,000 patent applications filed in 2005
- ~1m researchers (75% increase last 10 years)

Top 10 Foreign R&D

- Toyota
- Pfizer
- Ford
- Johnson & Johnson
- DaimlerChrysler
- General Motors
- Microsoft
- GlaxoSmithKline
- Siemens
- IBM

Top 3 Companies with Most Invention Patent Applications

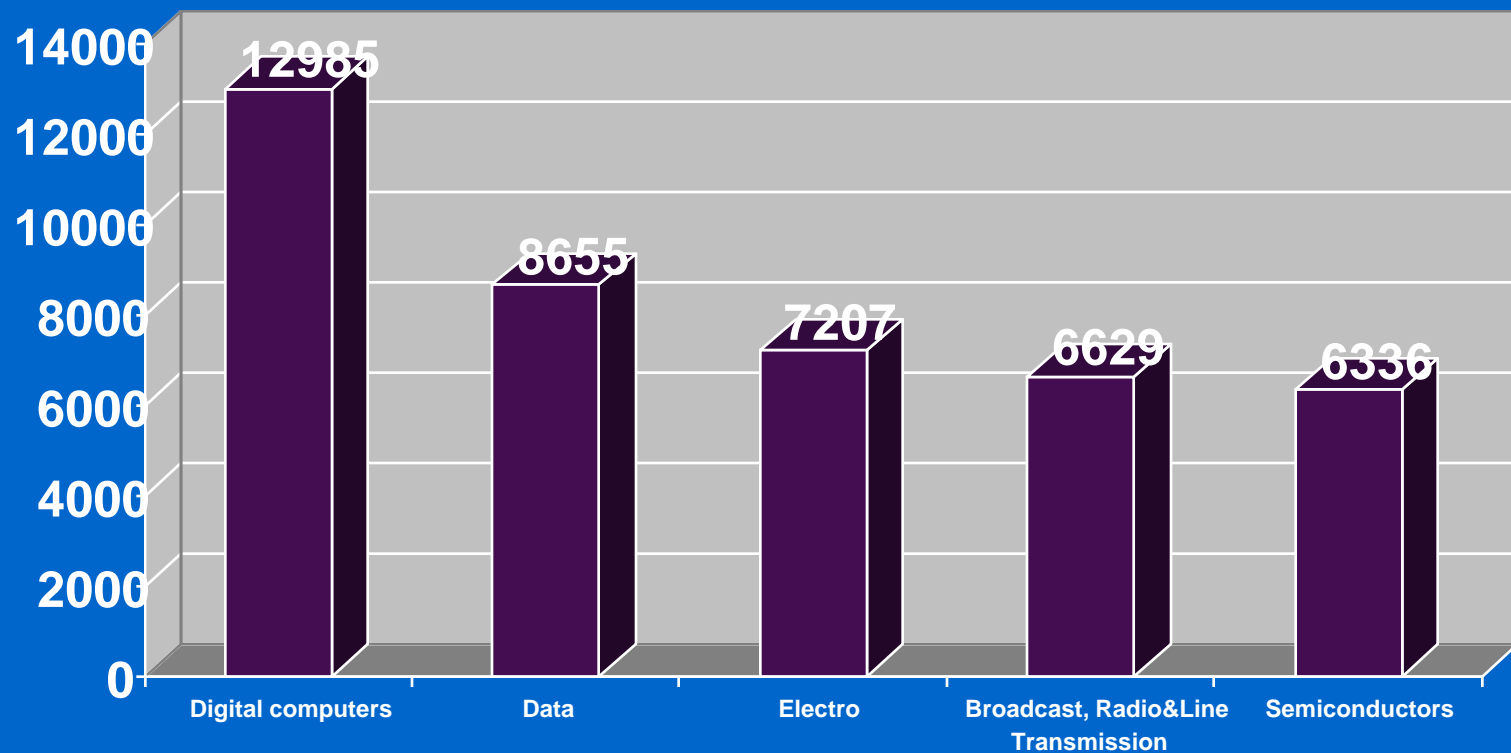
Year	Domestic Enterprises	Foreign Enterprises
2007	1. Huawei Technologies: 5,203	1. Samsung Electronics: 3,315
	2. ZTE Corporation: 4,787	2. Panasonic Electric Industry: 2,329
	3. Hon Hai Precision Industry: 1,630	3. Royal Philips: 2,059
2006	1. Huawei Technologies: 5,593	1. Samsung Electronics: 3,770
	2. ZTE Corporation: 2,322	2. Panasonic Electric Industry: 2,679
2005	1. Huawei Technologies: 3,164	1. Samsung Electronics: 3,508
	2. LG Electronics Tianjin Appliances Co. Ltd. (LGETA): 1,669	2. Panasonic Electric Industry: 3,042
	3. Hon Hai Precision Industry: 1,255	3. Royal Philips: 2,709

Foreign R&D Investment in China

List of the prominent captive R&D Centers

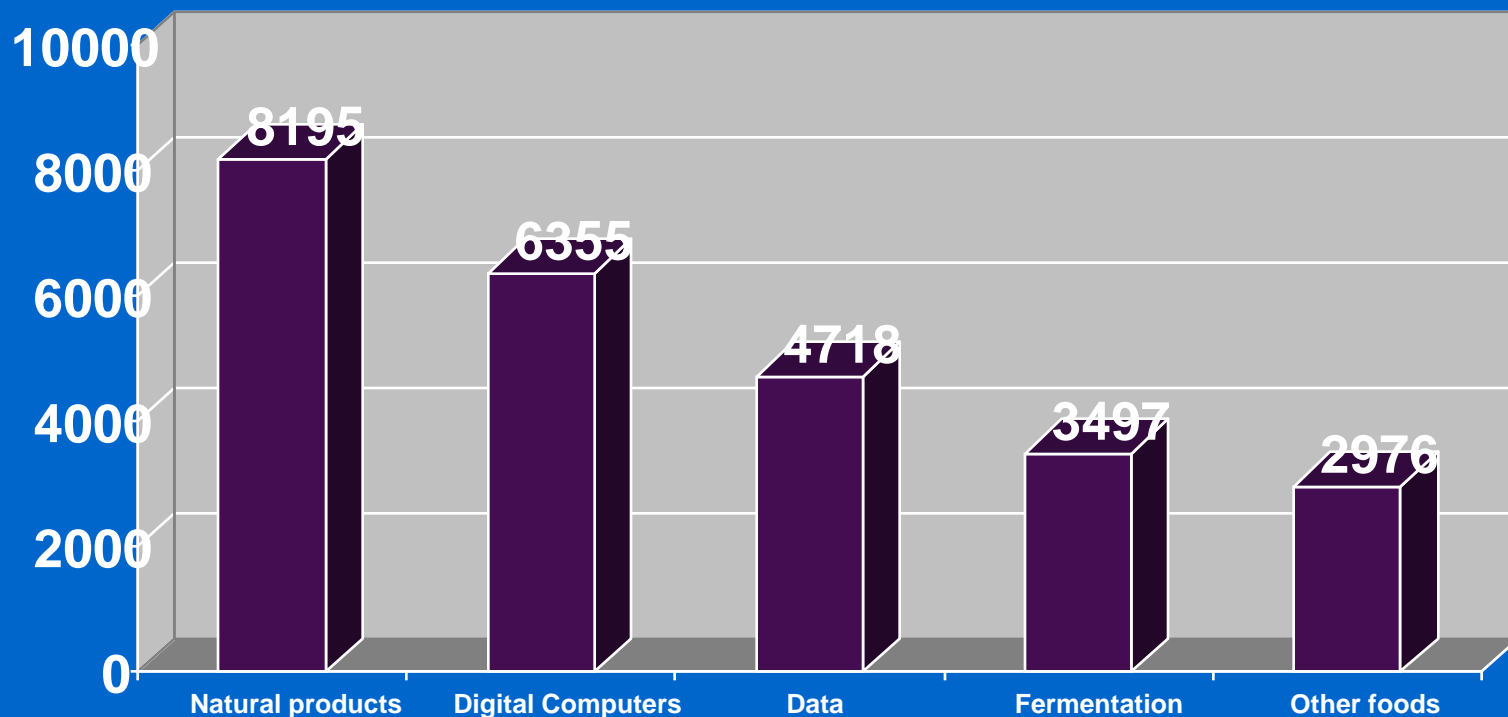
Year	Company	Year	Company
1995	Alcatel	2004	Pfizer, Honeywell,
1997	Ericsson		Roche
2001	Motorola	2005	ABB
2002	Agilent Labs		Cisco
	Novo Nordisk	2007	Google
2003	Siemens		Shell
	Accenture		GlaxoSmithKline

Top Five Patented Technologies 2005 (Foreign Applicants)



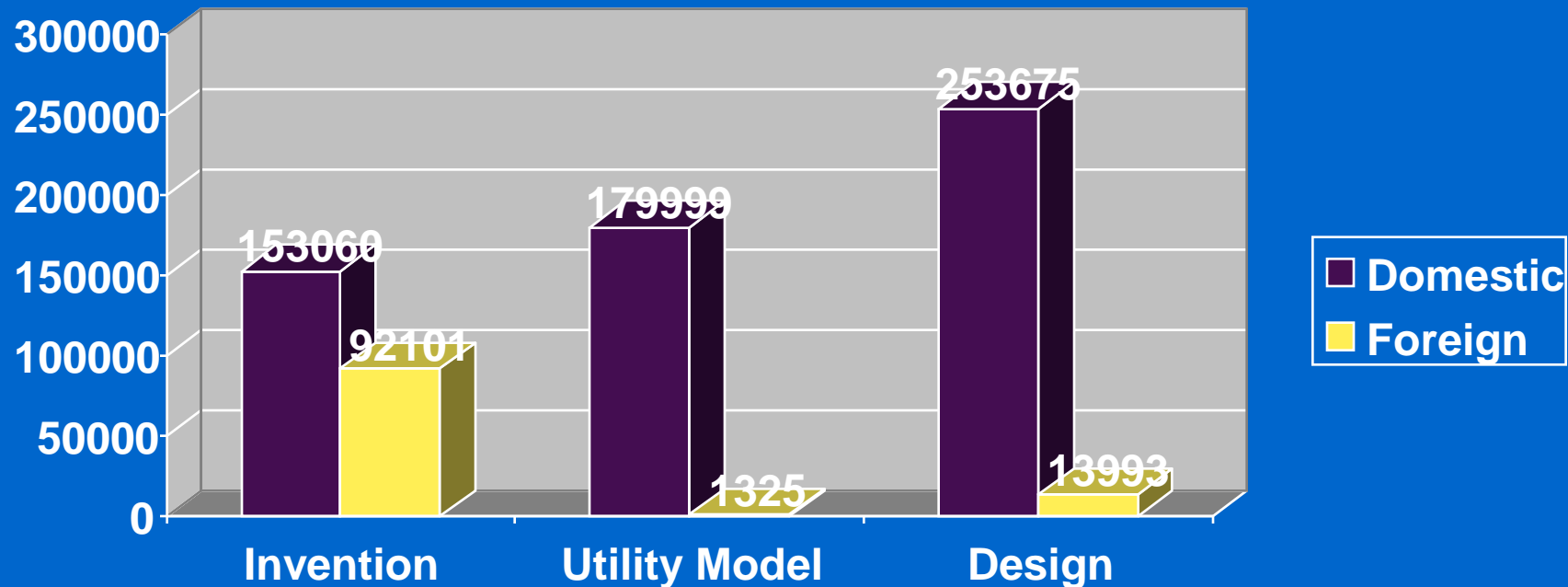
Source: Thomson Scientific

Top Five Patented Technologies 2005 (Chinese Applicants)



Source: Thomson Scientific

Foreign vs. Domestic Patent Filing 2007



Source: SIPO

Financing

1. Outbound to U.S.
 - a. Need to understand potential investors
 - b. What are they looking for?
 - i. Strong IP
 - ii. Strong management team
 - c. May need to have revenue
 - d. Strategic investing

Sales/Distribution/Marketing

1. Inbound

- a. Partnerships and alliances are key

2. Outbound to U.S.

- a. Very different, need to understand these areas to be successful
- b. Who are you selling to? (see compliance)
- c. How do you market to them?
- d. What are distribution chains?

Sourcing from China

3 Stages:

- Pre-sourcing
- Negotiation and Contract
- On-going management of sourcing partners

Pre-sourcing Stage

Due Diligence on prospective partners

1. Visit

- Interview factory and ask questions
- Check references

2. Background check

- Business consultant to conduct open or covert investigation on business info, IP infringement record

Pre-sourcing Stage

List of Questions

- References
- How do they protect IP of other customers?
- Any sub-contractors and how to make sure sub-contractor protect IP
- Where is the factory?
- Other info (e.g. labor situation)

Negotiation & Contract Stage

- Quotation
- Provide specs for accurate quotation
- How much detail to give
- NDA/Confidentiality Agreement
- Electronic communication

Negotiation & Contract Stage

- Supply contracts
- Language – Chinese or English
- Standard International Form (50 pages) or Local Chinese (2 pages)
- Enforceability
- Dispute Resolution

Negotiation & Contract Stage

Essential IP Terms

1. Usual IP ownership and confidentiality
2. Ownership of Tooling – tooling with IP
 - Consider paying for the tooling, either upfront or amortize over the course of the contract
3. Disposal of waste or overruns
 - System to record and account for such waste/overruns
 - IP owner should be given a refusal right to purchase
4. Audit rights
 - Open announced audit or unannounced audit

Managing Sourcing Partners

1. Manage raw materials, labels, packaging
2. Incorporating authentication devices
 - Hologram, watermarks, anti-counterfeiting ink technology, covert marks, RFID
3. Exercising audit rights
 - Exercise the right as often as possible
4. Terminate relationship
 - Similar to exit interview for employee
 - Written confirmation that they return confidential info; destroy overruns; not keeping extra labels

Recent IP Enforcement Statistics

	2006	2007
1. Trademark		
Customs seizure	- 2,473 cases - 196.8m goods - value: RMB200m (~US28.5m)	- 7,467 cases - 334m goods - value: RMB439m (~US62.7m)
AIC Raids	- 33,900 cases (7,439 involve foreign right holders)	- 50,318 cases (10,320 cases involving foreign)
Police Investigation	- 4600 investigations	- 2,283
2. Copyright (Admin actions)	- 150m illegal publications - 106m AV products - 7.6m Software - 20.5m books - 14 DVD production lines	NA
3. Civil Cases	- 14,219 cases (1 st instance) - 2,686 (appeal)	- 17,877 cases (1 st instance) - 2,865 (appeal)

Compliance

1. Inbound
 - a. In 2006, Chinese Government stepped up crack down on bribery of physicians
 - b. Foreign Corrupt Practices Act (FCPA)
2. Outbound to U.S.
 - a. Need to understand regulations here:
 - i. Promotional activities
 - ii. Gifts
 - iii. Meals and entertainment
 - iv. Data privacy
 - v. Hiring physicians as consultants



**Tuesday,
November 18, 2008**

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The U.S. Regulatory Environment: FDA Requirements for Medical Devices

Featuring

Clay Anselmo
*President and CEO,
Reglera, LLC*

Noel Gillespie
*Baker & McKenzie,
San Diego*

Roger Kuan
*Baker & McKenzie,
San Diego*

Moderated By

Babak Nemati, Ph.D.
*President and CEO,
Strategic Intelligence,
Inc.*

The FDA process is often viewed as a formidable challenge for companies in the life sciences. Despite ongoing changes in the regulatory environment, and FDA's changing stance and requirements for securing marketing clearance, a well thought-out regulatory strategy could prove to be a significant competitive advantage for successful medical device companies. Furthermore, proper alignment of overall business strategy, intellectual property strategy, and FDA strategy could significantly enhance the chances of the success of an emerging medical device company.

Join us for a one-and-a-half hour briefing to discuss combining utility and design patent, trademark, and copyright protection with FDA strategy to protect your medical device product to obtain optimal business outcomes.

Please register by November 11.

China M&A Webinar Series

Buying into the China Story

A 360 Degree Look at
China M&A Transactions

Baker & McKenzie invites you to a series of eight bi-weekly webinars in which specialist partners from our award-winning China team will examine China M&A transactions from multiple angles, taking deep dives into Regulatory, Antitrust, Tax, Employment, IP, Real Estate, Environmental, Finance, Compliance, Dispute Resolution and Risk Management issues.

China's Ever-changing M&A Regulations Thursday, November 20, 2008	Real Estate and Environmental Hazards Thursday, January 22, 2009
Effective Tax Structuring Strategies Thursday, December 4, 2008	Dealing with Compliance and Anti-corruption Issues Thursday, February 5, 2009
Impact of the New Labor Contract Law Thursday, December 18, 2008	Clearing Creditor, Payment and Financing Hurdles Thursday, February 19, 2009
Technology and IP Challenges Thursday, January 8, 2009	Post-closing Risk Management Thursday, March 5, 2009



China Update 2009

Palo Alto – Spring 2009

In keeping with tradition, Partners from our Beijing, Shanghai, and Hong Kong offices will be joining their US colleagues in Santa Clara, California to provide practical and insightful sessions on issues pertinent to US companies doing business in China. Our speakers will start the day with a round-up of all the latest legal developments, and then break into specialized and interactive workshops that will dive deeper into a host of major operational issues.