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Medical Technology Innovation Scorecard: The race for global leadership

January 2011

Today's presenters

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Today's discussion

1. What is innovation?
2. Five Pillars of Innovation in Medical Devices & Technology
 - Financial incentives
 - Innovation resources
 - Regulatory framework
 - Demanding patients
 - Investment community
3. The future of innovation

Basis for today's discussion

PwC Medical Device Innovation Scorecard

- 9 key countries in the developed and emerging markets
- Survey/interview data from Med Device companies
- Will be released in January 18
- Context and “sneak preview” in September *In Vivo* feature article

MEDICAL DEVICES

THE CHANGING FACE OF MEDICAL TECHNOLOGY INNOVATION

The dynamics of the US focused, are shifted, are introduced, are unveiled later this fall in nine countries, all countries track global shifts in

- Medical device technology in the US has long benefited from an “innovation ecosystem” that has supported R&D and the commercialization of technology breakthroughs.
- The dynamics of the innovation ecosystem are changing, driven by health reform, uncertain levels of future R&D funding, a slower and more risk-averse regulatory process and constrained venture capital funding and being supplemented by new factors that are driving the globalization of innovation.
- PwC is developing a Medical Technology Innovation Scorecard to understand how technology innovation is changing and which nations have the strongest capacity for innovation.

Executive Summary >> T

2 | September 2010 | IN VIVO THE BUSINESS

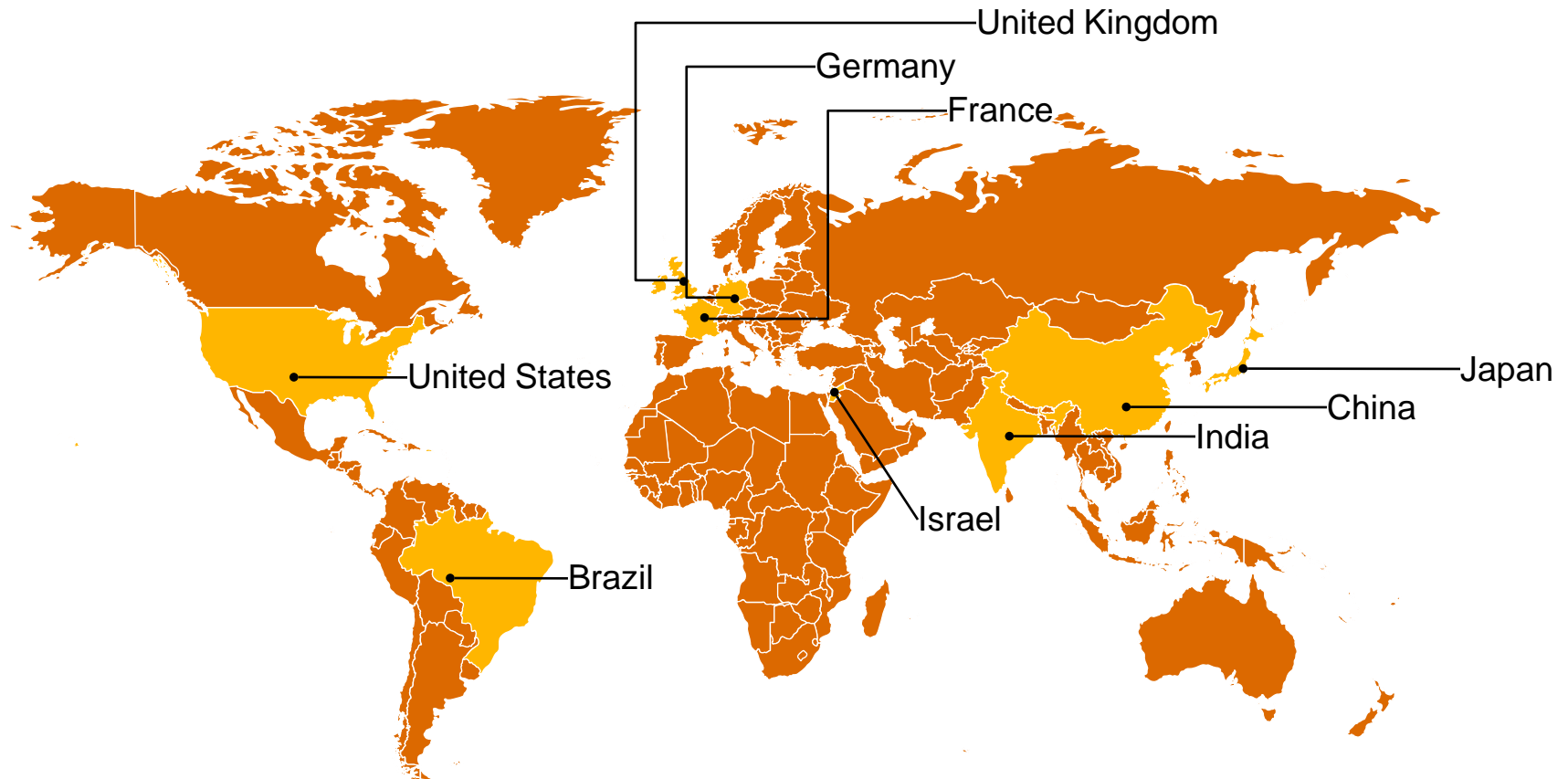
Medical Technology Innovation Scorecard

The race for global leadership

January 2011
The PwC Medical Technology Innovation Scorecard explores the changing nature of healthcare innovation. The results show that the gap between innovation leaders and emerging economies is rapidly narrowing.

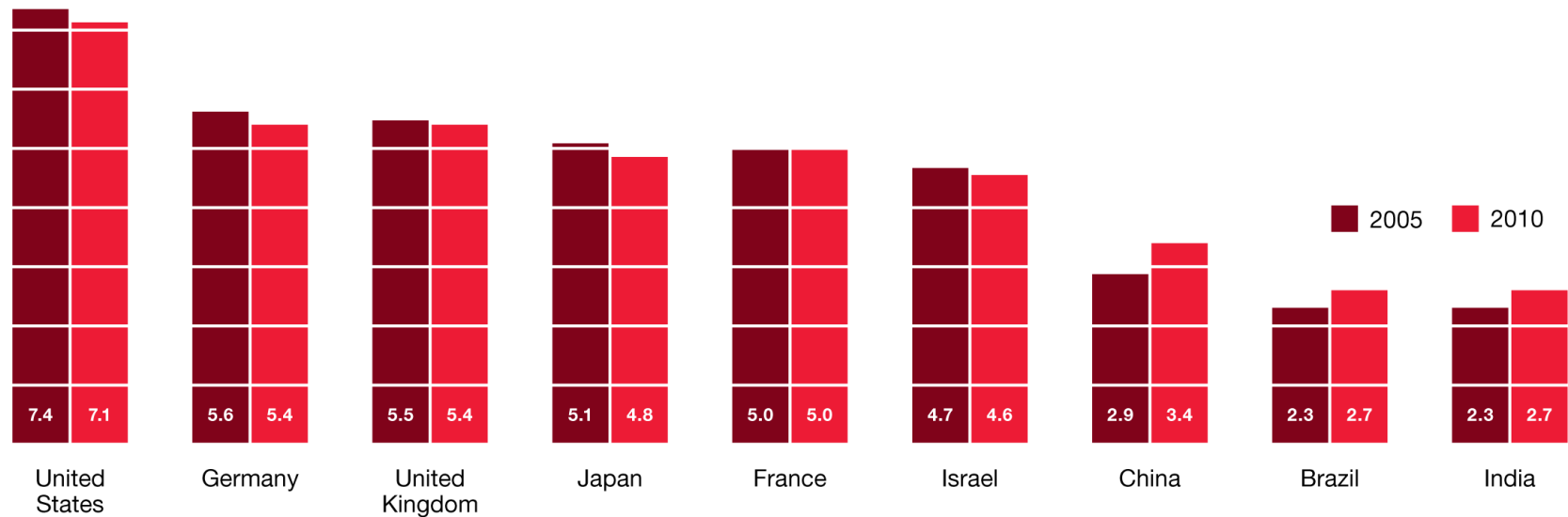
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We selected 9 countries for our study – each with major economies and innovative markets



The US is experiencing the most rapid relative decline, while China accelerates the fastest followed by Brazil and India

Scorecard



Historically, 5 pillars of Medical Device Innovation in the US

Powerful financial incentives	Leading resources for innovation	Supportive regulatory system	Demanding and price-insensitive patients	Supportive investment community
<p>The US spent more per capita on healthcare than all other countries.</p> <p>Generous coverage + high procedure reimbursement fueled physician adoption of new innovations</p>	<p>The US established itself as a world leader in AMCs</p> <p>Annual NIH grant funding exceeding \$30 billion per year supported the advancement of medicine.</p>	<p>FDA led in setting standards for safety and efficacy of medical technologies.</p> <p>Other countries would wait to see FDA's position before acting upon medical technology applications.</p>	<p>Americans' high demand for healthcare services as measured by MD visit frequency.</p> <p>Declining share of payments made OOP – from 68% to 14% over 50 years</p>	<p>Med-Tech ranked 2nd or 3rd largest category among VC and angel investors.</p> <p>VC funding averaged ~\$2.5 Billion p.a. over the last decade, enabling commercialization of innovations</p>

HC Reform and evolving industry structures are creating powerful tensions that are transforming innovation

Yesterday...

Tension 1: Feature vs. solutions	Tension 2: Silos vs. systems	Tension 3: Volume vs. value
<ul style="list-style-type: none">• Novelty rewarded as much as innovation• New features = price premium.• Payers reimburse procedures regardless of value	<ul style="list-style-type: none">• Med Tech operated in silos, focused on a small part of a disease or healthcare problem.• Providers used innovative technology to drive procedure volume	<ul style="list-style-type: none">• FDA approval based on safety and efficacy in large populations studies based on statistical measures

Today ...

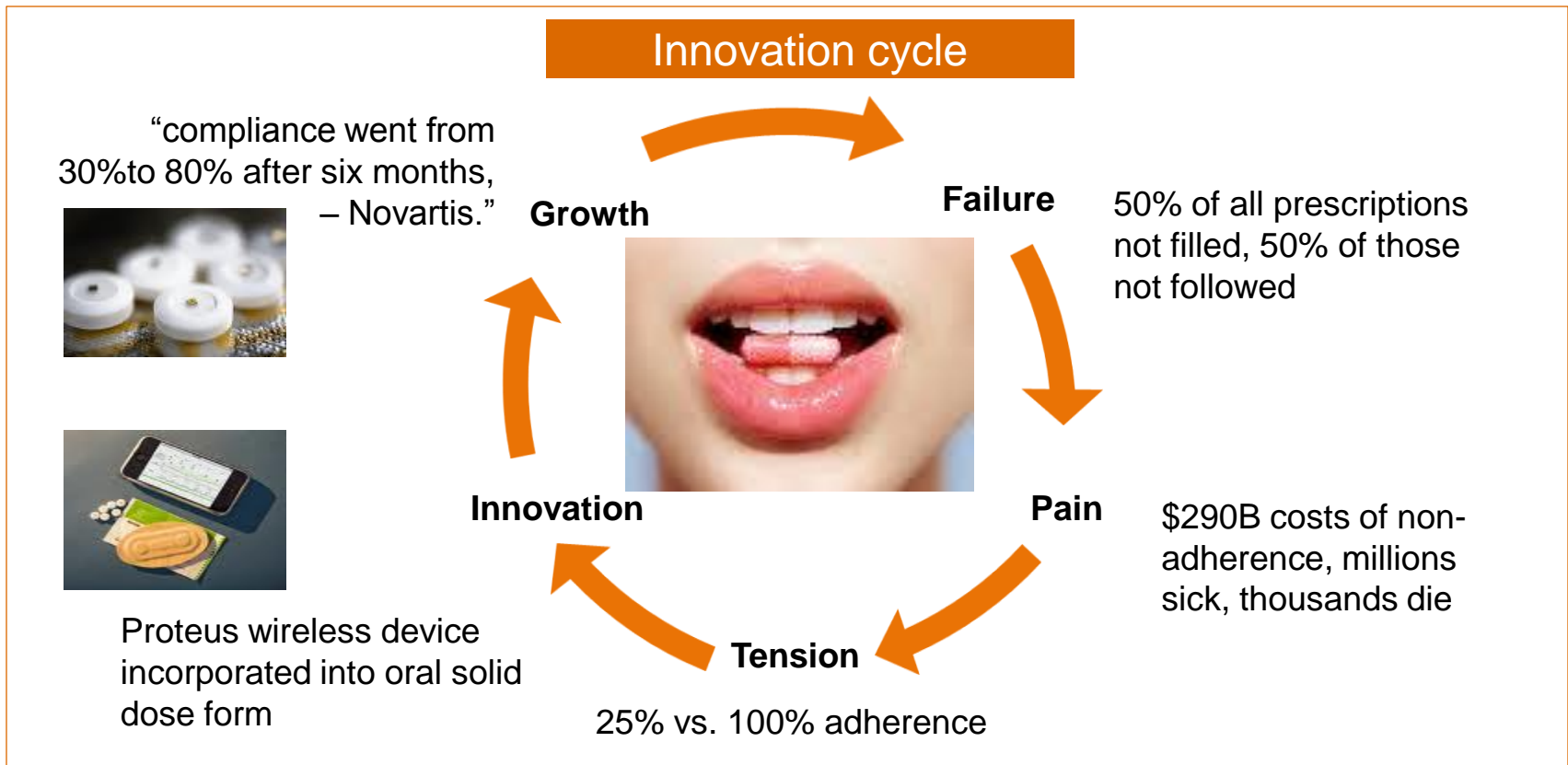
<ul style="list-style-type: none">• Companies must innovate to remain relevant and maintain revenue.• Incremental innovation doesn't lead to equal incremental revenue.• Reimbursement focus shifts toward solutions.	<ul style="list-style-type: none">• Shortage of medical talent strains the system, requiring systems perspective.• Shortage of money requires innovations in care delivery.• Ubiquitous connectivity enables coordinated care.	<ul style="list-style-type: none">• Genomics enables personalized healthcare.• Med Tech companies must consider genomic differences• Value occurs by personalizing solutions within the system.
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What is innovation

1

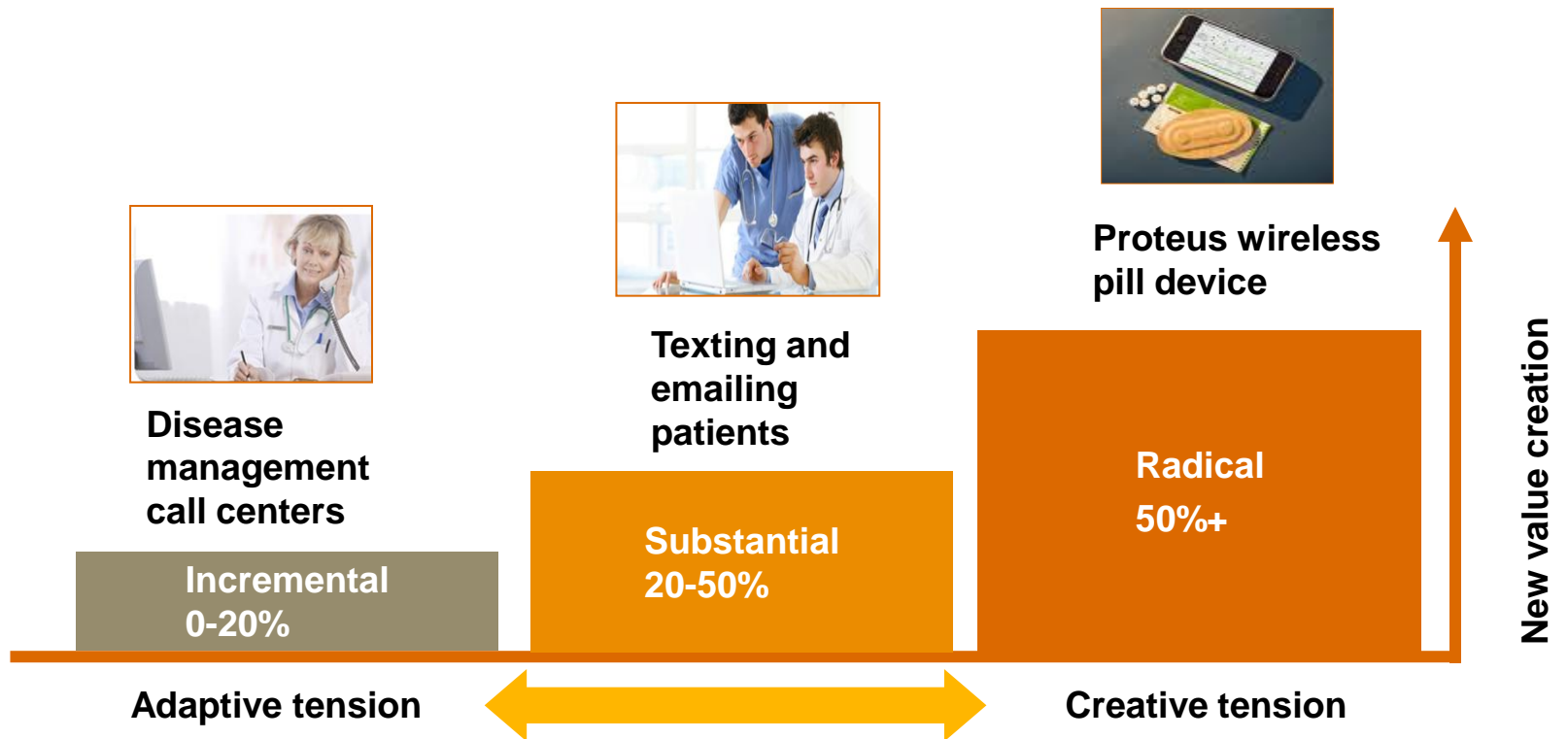
In the Innovation Cycle failure and pain create tensions that drive the innovation process that lead in turn to growth

This cycle takes place at the device, organizational, national, and global levels



All innovation is not created equal, and can be measured by new value created

Three classes of innovation



"You need creativity and invention, but until you can connect that creativity to the customer in the form of a product or a service that meaningfully changes their lives, I would argue you don't yet have innovation." A.G. Lafley, CEO, Procter & Gamble

Case example: Merck Serono's vision epitomizes the convergence of these three tensions into a new healthcare paradigm

Merck Serono:
Innovation in the new
healthcare paradigm



Molecular Dx screening IDs patients who would benefit from treatment



Wireless Easypod injection device records dosage data and transmits to clinicians



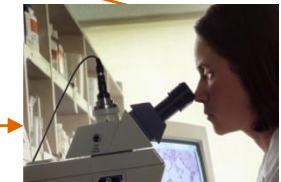
Nurse call center intervenes when notified by device of patient non-compliance



Clinical nurses in physician's office assist in treating patient



EHR Integrates patient information



Value-based reporting to NHS demonstrates compliance and improved outcomes

Personalized

System-based

Value driven

Results:

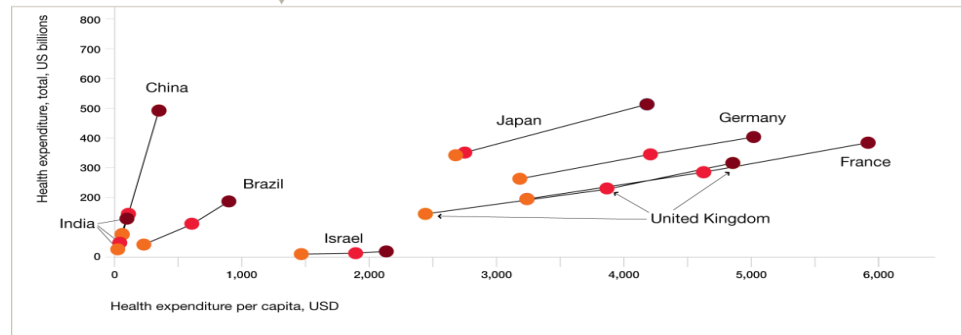
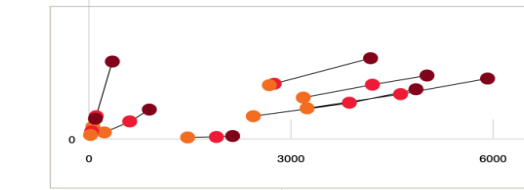
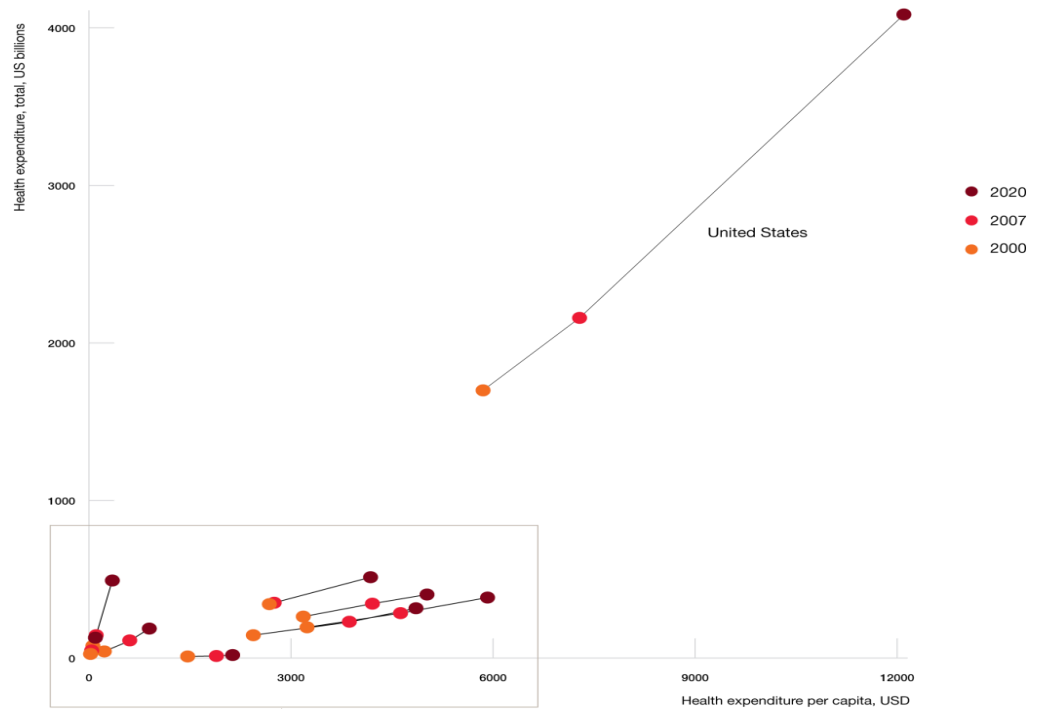
- Sales growth in a declining, off-patent brand
- Sales force reduction
- Smaller administrative costs; improved margin
- Enhanced patient outcomes at lower cost
- Better clinical integration
- More care provided in home settings at lower cost

Financial incentives

2

US continues to lead in health spending, with no expected “bending” of the cost curve. China in 2nd place by 2020

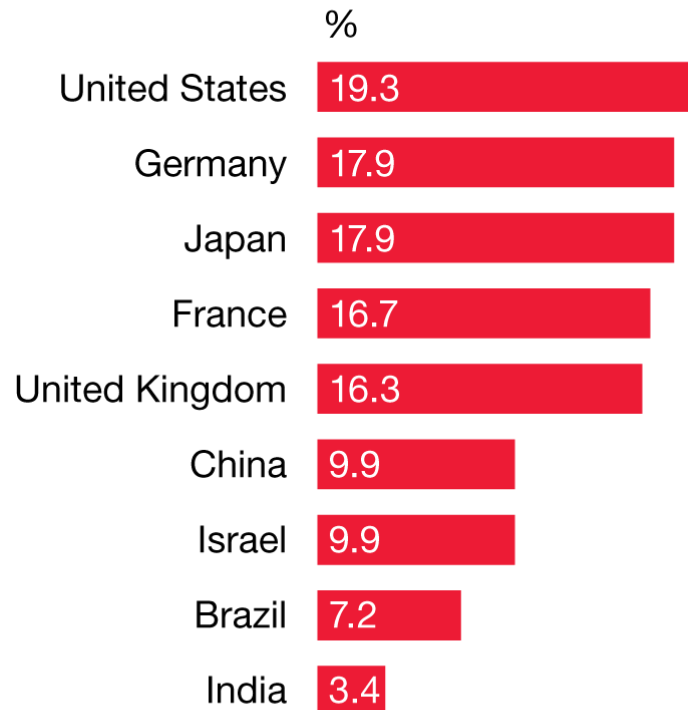
Total health expenditure vs. health expenditure per capita: 2003, 2007, and 2020 forecast



Sources: The World Bank, World Health Organization, and PwC analysis

US continues to lead in share of government spend going towards healthcare

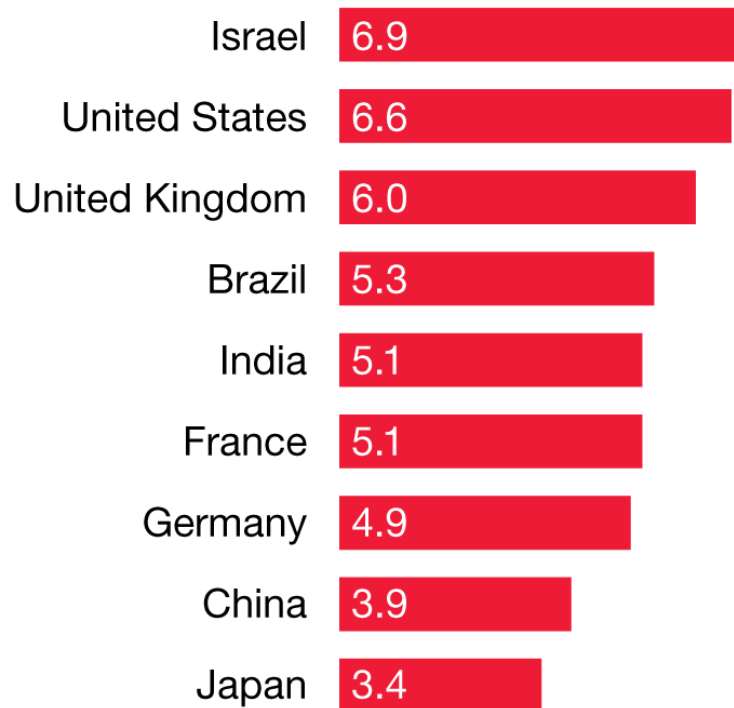
Government expenditure on health as % of total government expenditure



Source: World Health Organization, based on 2006 data, which was the latest available

Israel leads in ease of reimbursement approval

**Ease of reimbursement approval
ranking: 1=most difficult, 9=easiest**



Source: PwC survey

Innovation resources

3

Innovation networks are going global as leading US and European universities and medical schools form partnerships with research centers abroad

**MD Anderson
Cancer Center**

**American
Hospital**



- Vehbi Koc Foundation (VKF) American Hospital and MD Anderson expanding cancer care in Turkey with new radiation treatment center
- The first MD Anderson radiation treatment facility outside of the US

**Mayo
Clinic**

**Karolinska
Institute**



- Mayo Clinic has formed a strategic research relationship with Karolinska Institute of Stockholm, Sweden – the top rated medical research university in Europe
- Focus on biomedical research and genomics

**Johns Hopkins
Medical School
of Baltimore**

**King Khaled
Eye Specialist
Hospital**



- King Khaled Eye Specialist Hospital in Riyadh, Saudi Arabia has formed a partnership with the Wilmer Eye Institute of Johns Hopkins Medical School of Baltimore, MD, USA

Cleveland Clinic

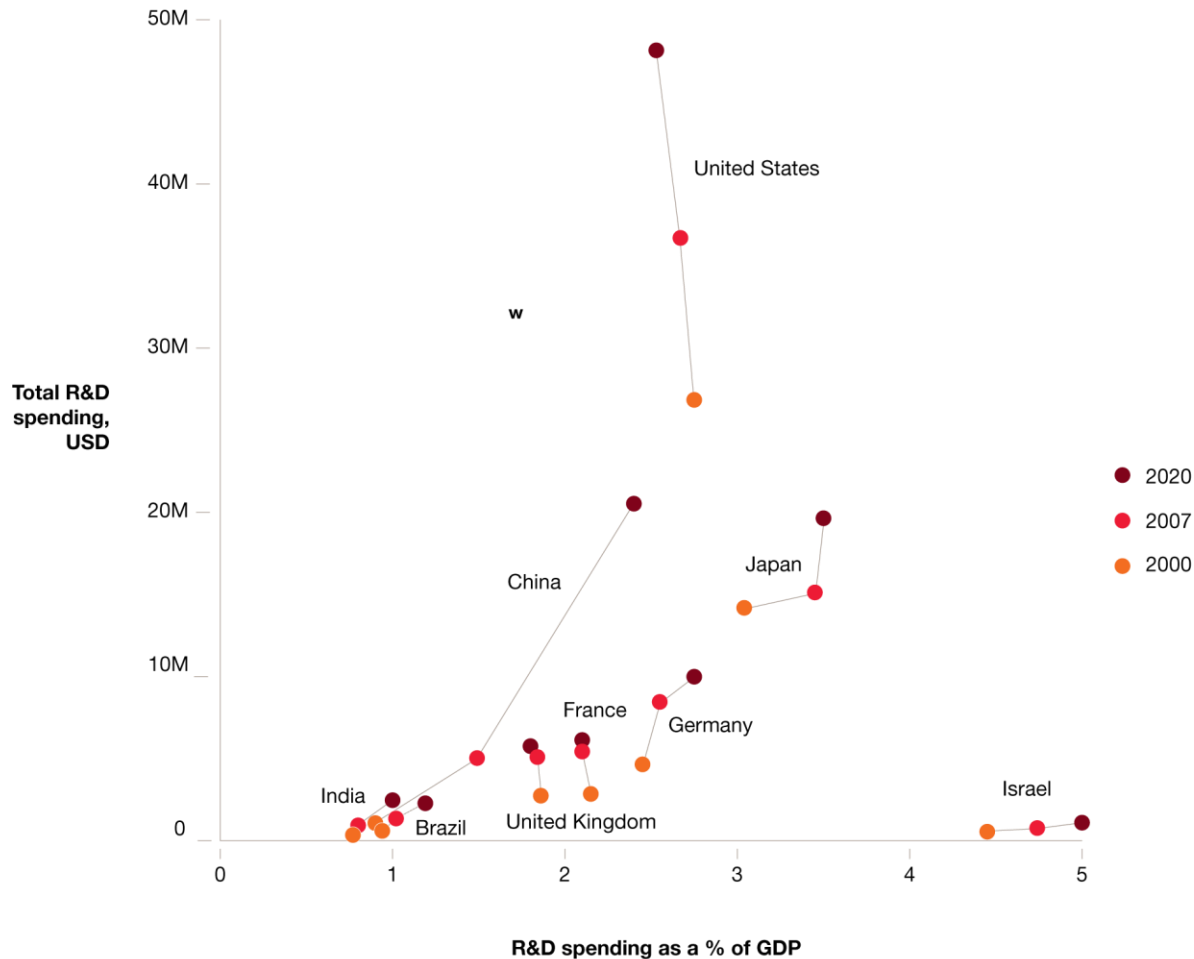


- Cleveland Clinic has partnered with Mubadala Healthcare to develop a hospital in Abu Dhabi to raise healthcare standards within the city
- Hospital will be served by Western-trained, North American-board certified physicians

- Partnerships create synergies and leverage expertise to enhance innovative output globally
- Academic leadership that has enabled innovative leadership in the US and Europe could begin to fade

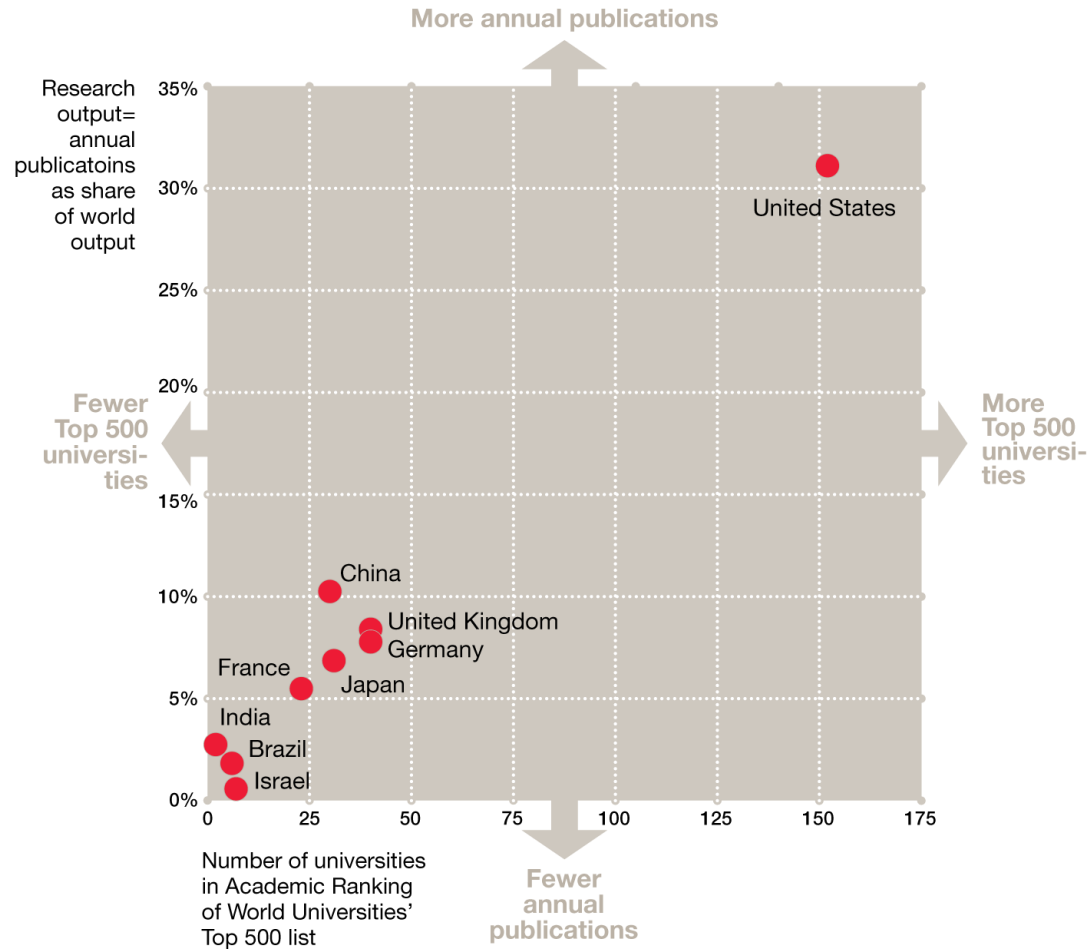
US will continue to lead in R&D spend, but China eclipsing Japan and closing fast

R&D spending as a % of GDP
vs. total R&D spending (\$USD):
2000, 2007, and forecast for 2020



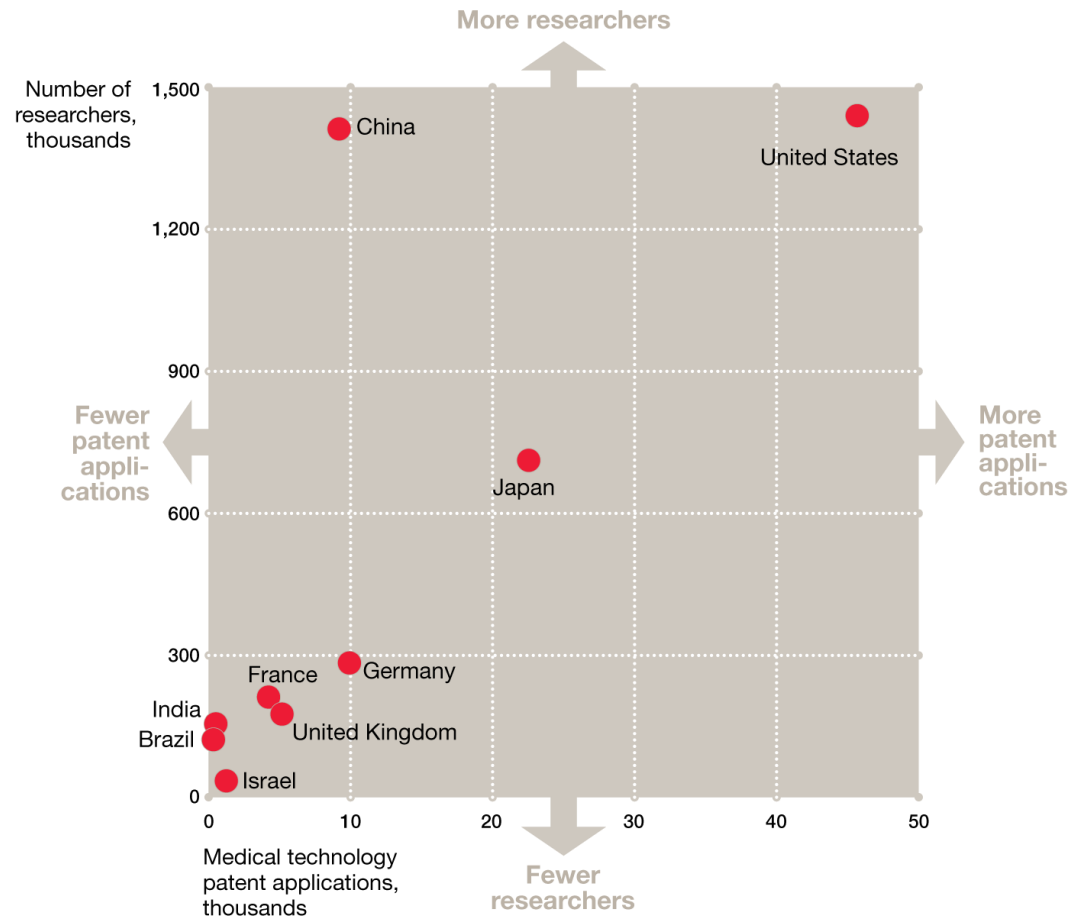
China is now #2 in research output and #5 in university leadership (but not far behind Germany, Japan, UK)

Research output vs. number of Top 500 universities



China lags in patent applications relative to # of researchers, but will close the gap aggressively as development progresses

Researchers vs. medical technology patent applications



Regulatory framework

4

Companies indicate the US is 3rd in approval time and 7th in approval ease, only Japan is more difficult than China

Regulatory approval time vs. ease of regulatory approval process

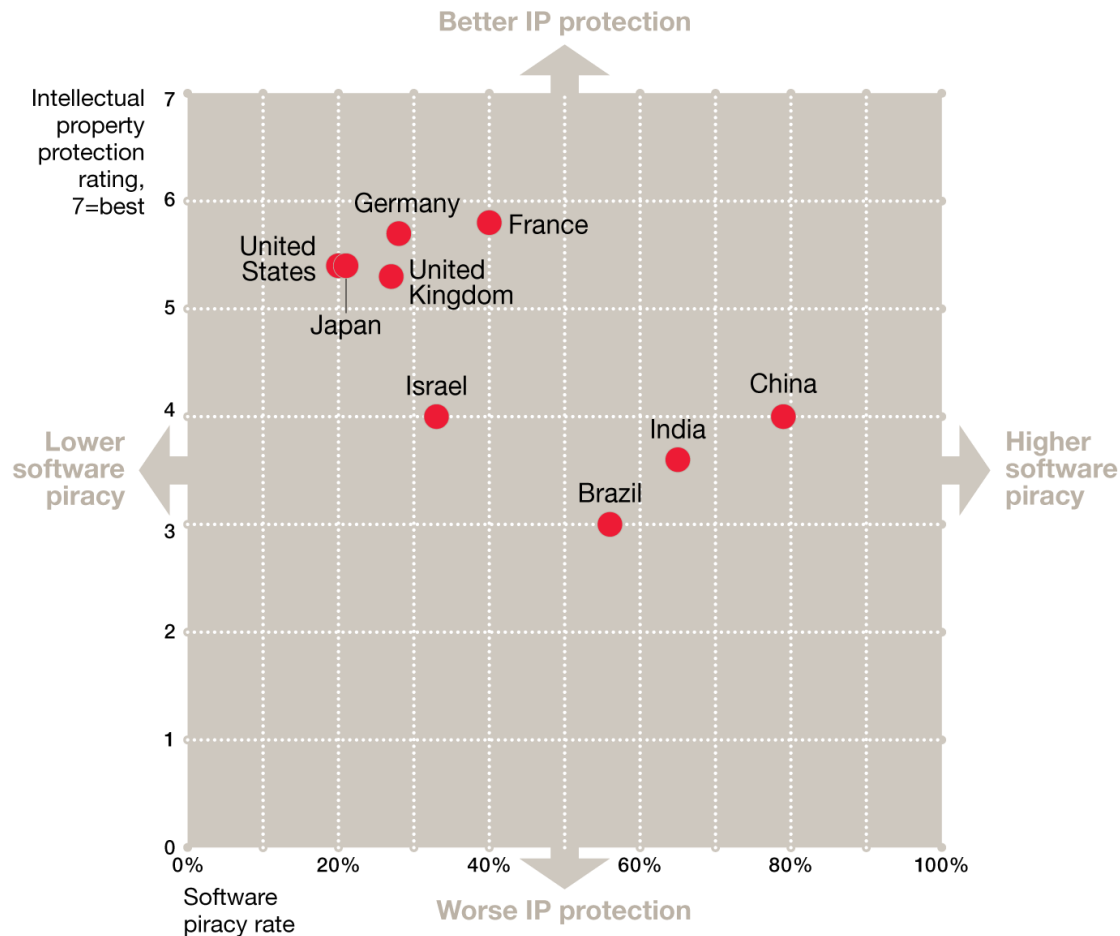


Source: PwC Survey

PwC

As the rate of patent filings in developing countries increases, so presumably will their attention to IP protection

Intellectual property protection vs. software piracy rate



The ease and cost-effectiveness of regulatory approvals of other nations supports the creation of innovation ecosystems in other countries

ThromboVision

- Millions of Americans take anti-clotting agents for MI and stroke prevention
- 20% - 33% receive no benefit
- *ThromboVision* developed a simple clinical diagnostic to measure platelet aggregation
- Received a Not Substantially Equivalent (NSE) letter from the FDA
- As a result, *ThromboVision* is going through Chapter 11 and restructuring
- *“We ran up against a brick wall with the FDA. Our company will probably become more Euro-centric, not US-centric. Once we get revenues established abroad, we’ll come back and fight another day with the FDA”*
—Ed Teitel, Founder



OrthoAccel

- Developed *AcceleDent* -- an orthodontic device to accelerate the rate of tooth movement
- Benefit is shortened orthodontic treatment time compared to braces and aligners
- Launched first in the United Kingdom, Australia and Hungary – currently remains in clinical trials in the US

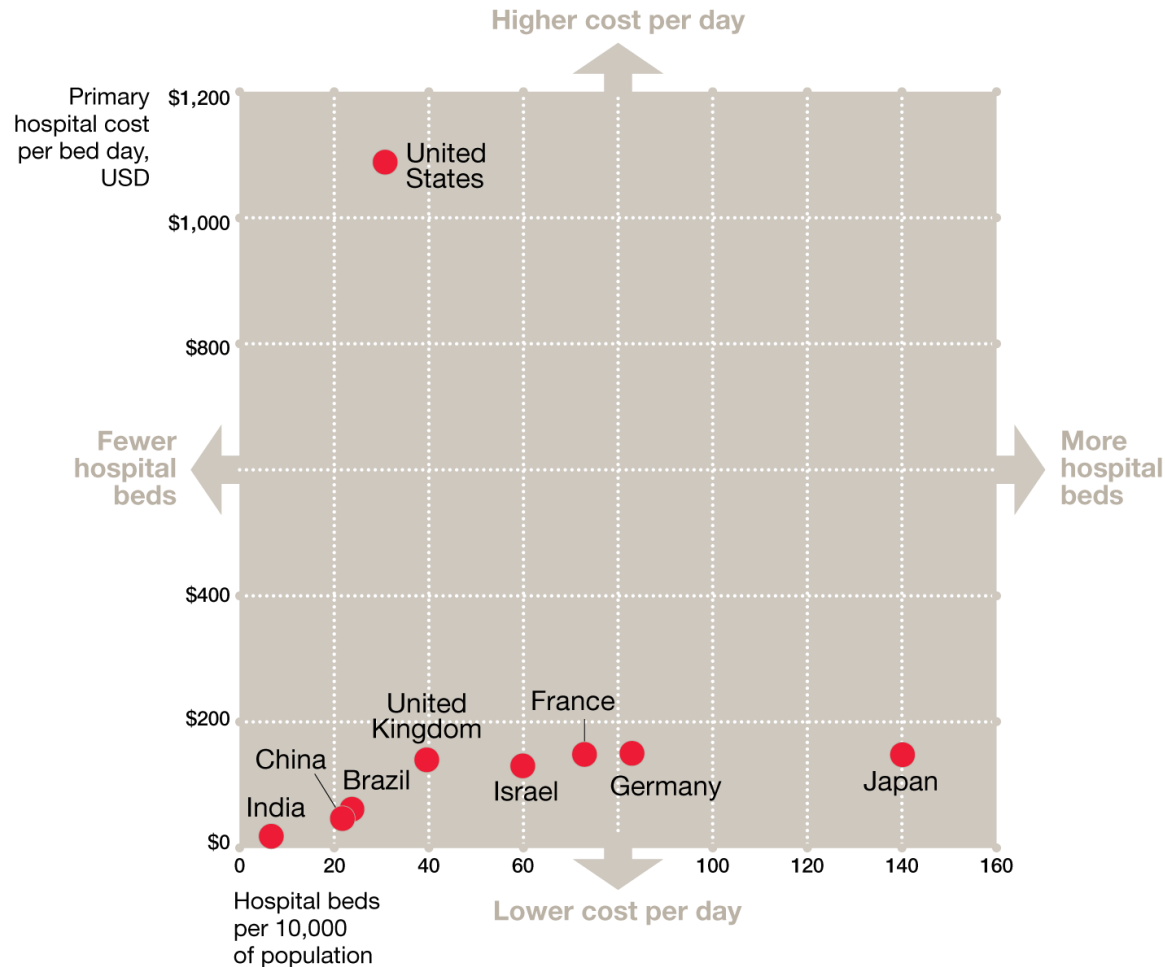


Demanding patients

5

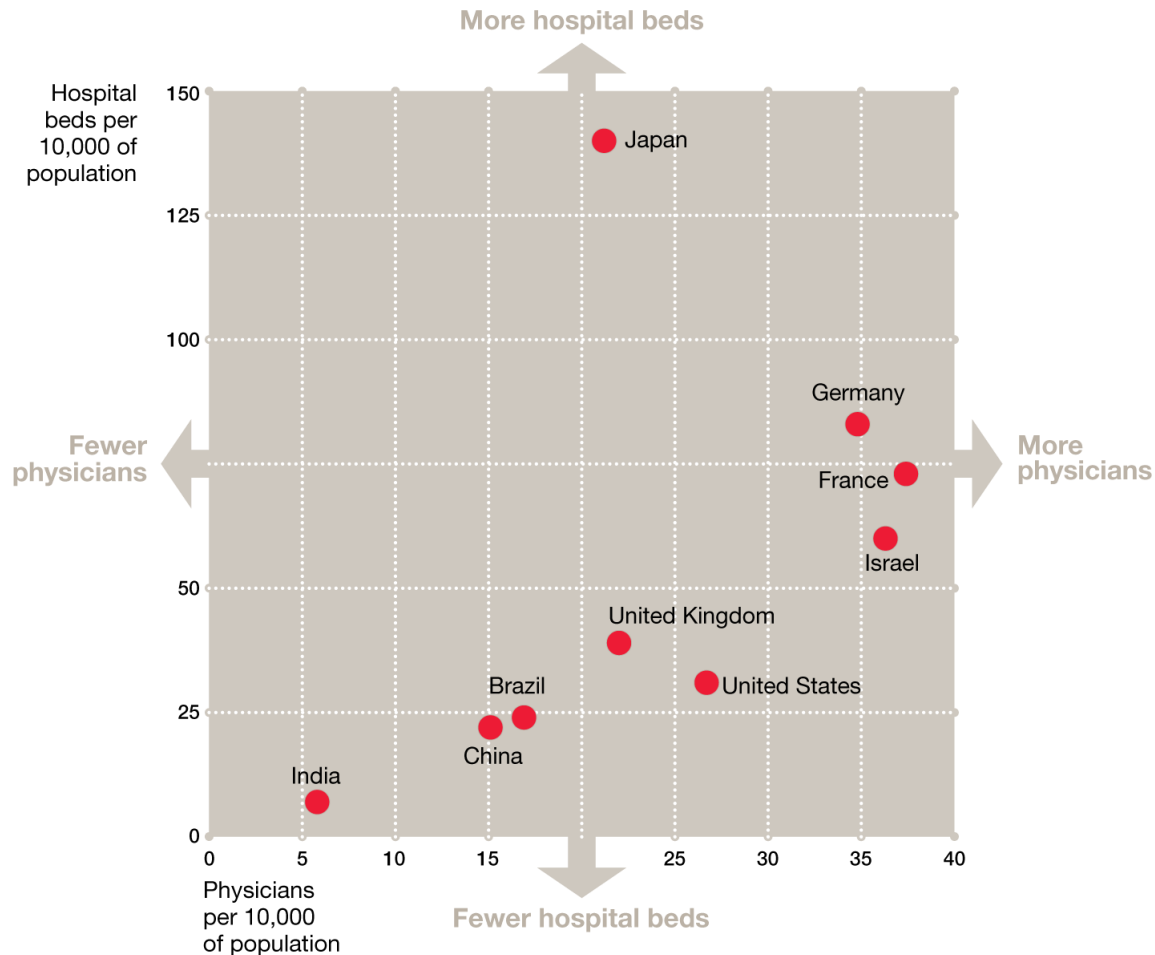
Different countries exhibit dramatically different models of medical practice

Hospital beds per capita
vs. primary hospital cost per bed day



Different countries exhibit dramatically different models of medical practice to support different models of innovation

Hospital beds vs. physicians per capita



Case study: GE Compact Ultrasound - *Why is it so tough to get paid to innovate in the US under the new paradigm?*

It requires a new business model

Product



Logiq 9 (2001)
Dimensions: 55" to 63" x 25" x 35"
Weight: ~434 lb
Cost: >\$100,000



Logiq Book (2002)/
Logiq Book XP (2007)
Dimensions: 3.07" x 13.73" x 11"/3.07" x 13.78" x 11"
Weight: ~10lb/~10.3 lb
Cost: As low as ~\$30,000/
As low as ~\$15,000



VScan (2010)
Dimensions: 5.3" x 2.9" x 1.1"
Weight: ~0.86 lb (with probe)
Cost: \$7,900

Key issues

- De-featuring existing ultrasound machines was not an adequate solution to satisfy product demands in a dramatically different market with a low-cost paradigm – radical change was required
- Value-based innovation was applied to build a compact ultrasound from the ground up that was tailored to meet local requirements of cost and portability
- Reverse innovation at work – the product found new applications in the domestic market, further expanding it

Key considerations

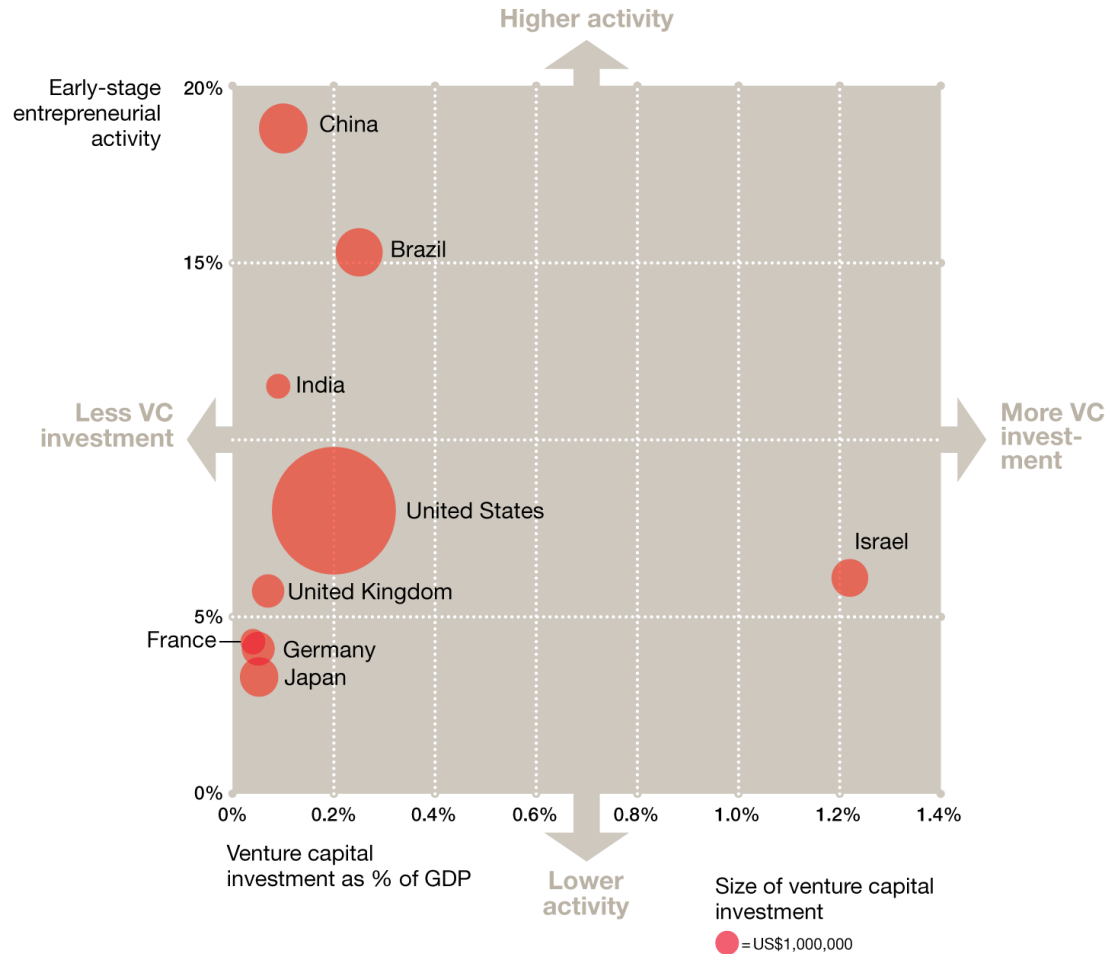
- What is the best strategy to operate in the emerging low cost environment?
- Which innovations from developing markets can be applied to its domestic markets?
- What products will require re-innovation under the new paradigm?

Investment community

6

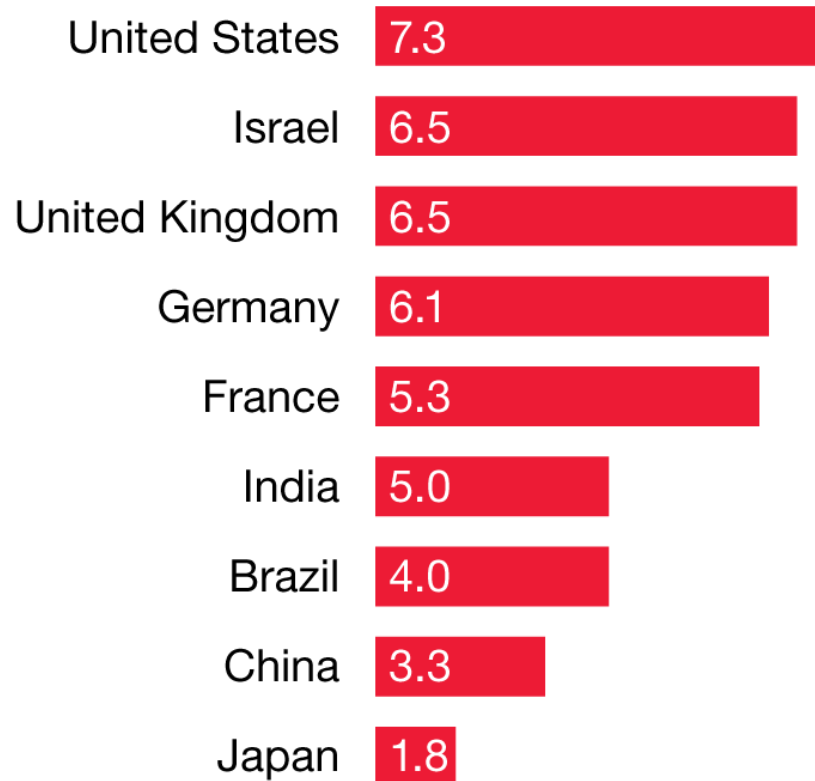
Emerging markets are becoming more entrepreneurial, and gaining greater access to venture capital

Early-stage entrepreneurial activity vs. venture-capital investment as % of GDP



Market access by country

Market access by country 1=most difficult, 9=easiest



Source: PwC survey

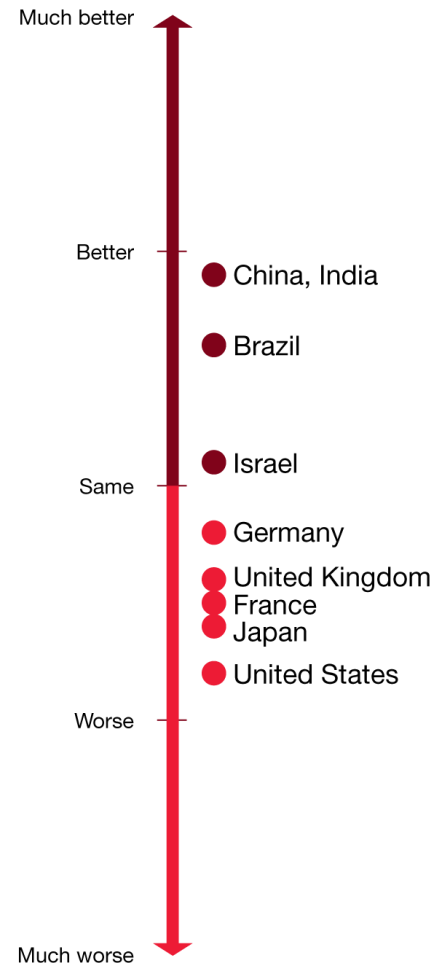
Developing markets are the only ones gaining in perceived commercialization opportunity. US is falling fastest.

Source: PwC Survey

PwC

Future expected attractiveness of the commercialization opportunity

In 2015, do you believe that the attractiveness of the commercialization opportunity will become much worse, worse, same, better, or much better?



Source: PwC survey

Case study: How will venture capital firms and innovation centers in emerging markets impact the investment environment

Innovation centers in emerging countries

healthymagination

- GE's Healthymagination proposes to spend \$6 Billion over six years on projects aimed for the Indian market

Johnson & Johnson

- Emerging Market Innovation Center (EMIC) in Shanghai
- *"The mission of the EMIC is to develop new and affordable products addressing the specific consumer needs of emerging markets"*
 - Gerson Pinto, VP of R&D, Asia Pacific & Emerging Markets, J&J

Key issues

- US-based venture capital firms will have to open local companies overseas or seek co-investment opportunities abroad
- Other nations are increasing seed investment in technology in order to generate jobs and growth
- Many countries, such as Japan and Sweden, have developed innovation strategies to foster technology innovation
- Changes in the investment arena in the last three years have resulted in the reduction of financing available to start-ups
 - Average returns for venture capital funds have declined even as the size of the funds and the deals they invest in has grown
 - Funding has migrated to later-stage investments

Case study: How will venture capital firms and innovation centers in emerging markets impact the investment environment (continued)

Venture capital firms abroad	Key considerations
Sequoia Capital	<ul style="list-style-type: none">• Will venture capitalists will find medical technologies less attractive as investments if there is less predictability of a substantial return?• Would they choose to invest in overseas markets instead?• What is the best strategy to operate in the emergence of global venture capital networks?
The Carlyle Group	
Bain Capital	
The Blackstone Group	

Source: PwC Analysis

The future of innovation



Historically, 5 pillars of Medical Device Innovation in the US

Powerful financial incentives	Leading resources for innovation	Supportive regulatory system	Demanding and price-insensitive patients	Supportive investment community
<p>The US spent more per capita on healthcare than all other countries.</p> <p>Generous coverage + high procedure reimbursement fueled physician adoption of new innovations</p>	<p>The US established itself as a world leader in AMCs</p> <p>Annual NIH grant funding exceeding \$30 billion per year supported the advancement of medicine.</p>	<p>FDA led in setting standards for safety and efficacy of medical technologies.</p> <p>Other countries would wait to see FDA's position before acting upon medical technology applications.</p>	<p>Americans' high demand for healthcare services as measured by MD visit frequency.</p> <p>Declining share of payments made OOP – from 68% to 14% over 50 years</p>	<p>Med-Tech ranked 2nd or 3rd largest category among VC and angel investors.</p> <p>VC funding averaged ~\$2.5 Billion p.a. over the last decade, enabling commercialization of innovations</p>

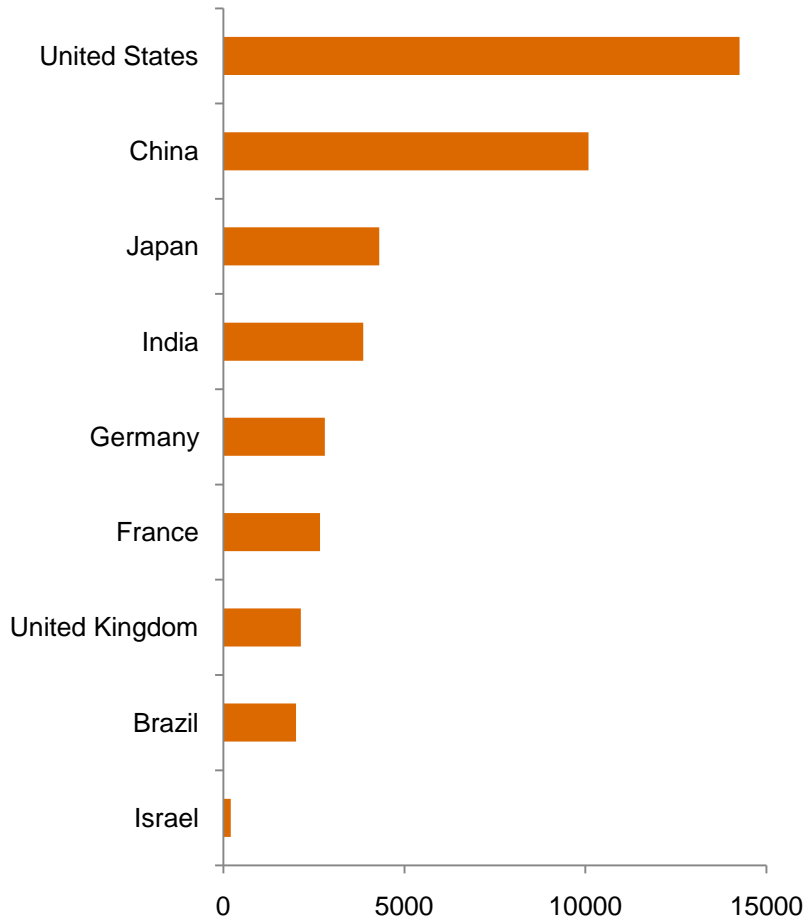
The 5 new pillars of innovation

<p>Powerful financial incentives</p>	<p>Leading resources for innovation</p>	<p>Supportive regulatory system</p>	<p>Demanding and price-insensitive patients</p>	<p>Supportive investment community</p>
<p>System & value-based incentives</p>	<p>Global Innovation Networks</p>	<p>Competing Regulatory systems</p>	<p>Individual solutions , price-sensitivity</p>	<p>Global finance networks</p>
<p>Payers press providers for greater value, exemplified by value-based reimbursement models</p> <p>Focus shifting from silo-based to integrated healthcare systems</p>	<p>Emerging markets investing in their own innovation centers</p> <p>US and EU institutions partnering with research centers globally</p>	<p>Greater ease and cost-effectiveness of regulatory approvals occurring in other nations</p> <p>Companies seeking European, Asian approvals in advance of US review</p>	<p>Personalized medicine and cost-shifting driving individualization of healthcare</p> <p>Emerging markets drive “lean innovation”, altering product and distribution processes</p>	<p>US VCs partnering with overseas counterparts and seeking co-investment opportunities</p> <p>US VCs opening offices in Israel, India, China, and Europe</p>

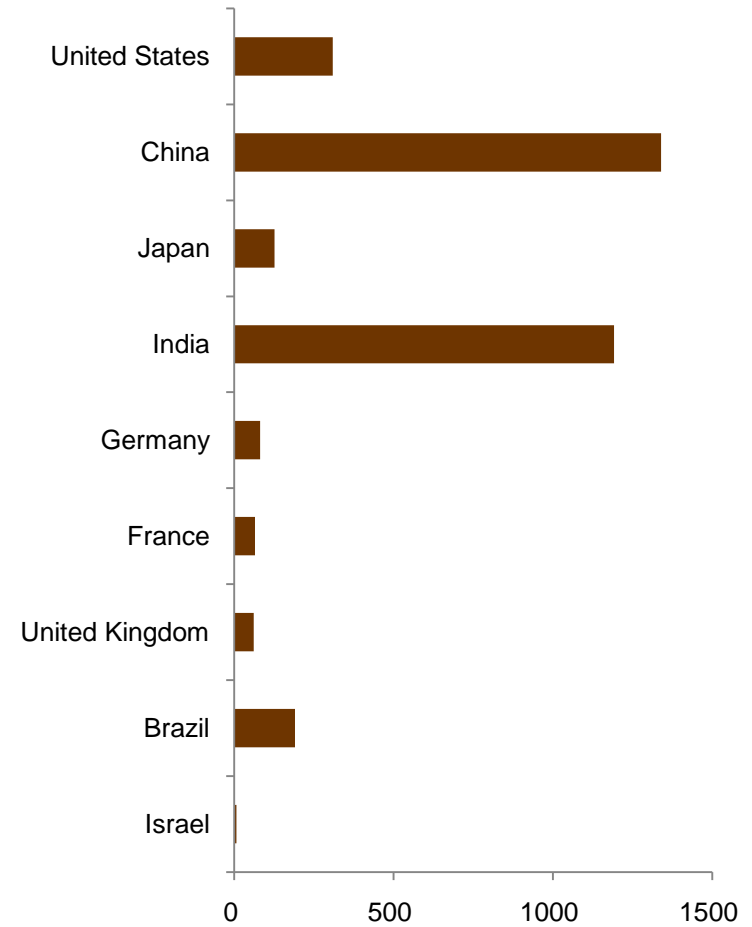
About Israel

by
Claudio Yarza, Partner
Life Sciences Practice Leader, PwC Israel

Population and GDP by country



GDP (Billion \$)



Population (Million people)

For more information, please visit our website:

www.pwc.com/InnovationScorecard

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Thank you!