

# *Pharma 2014*

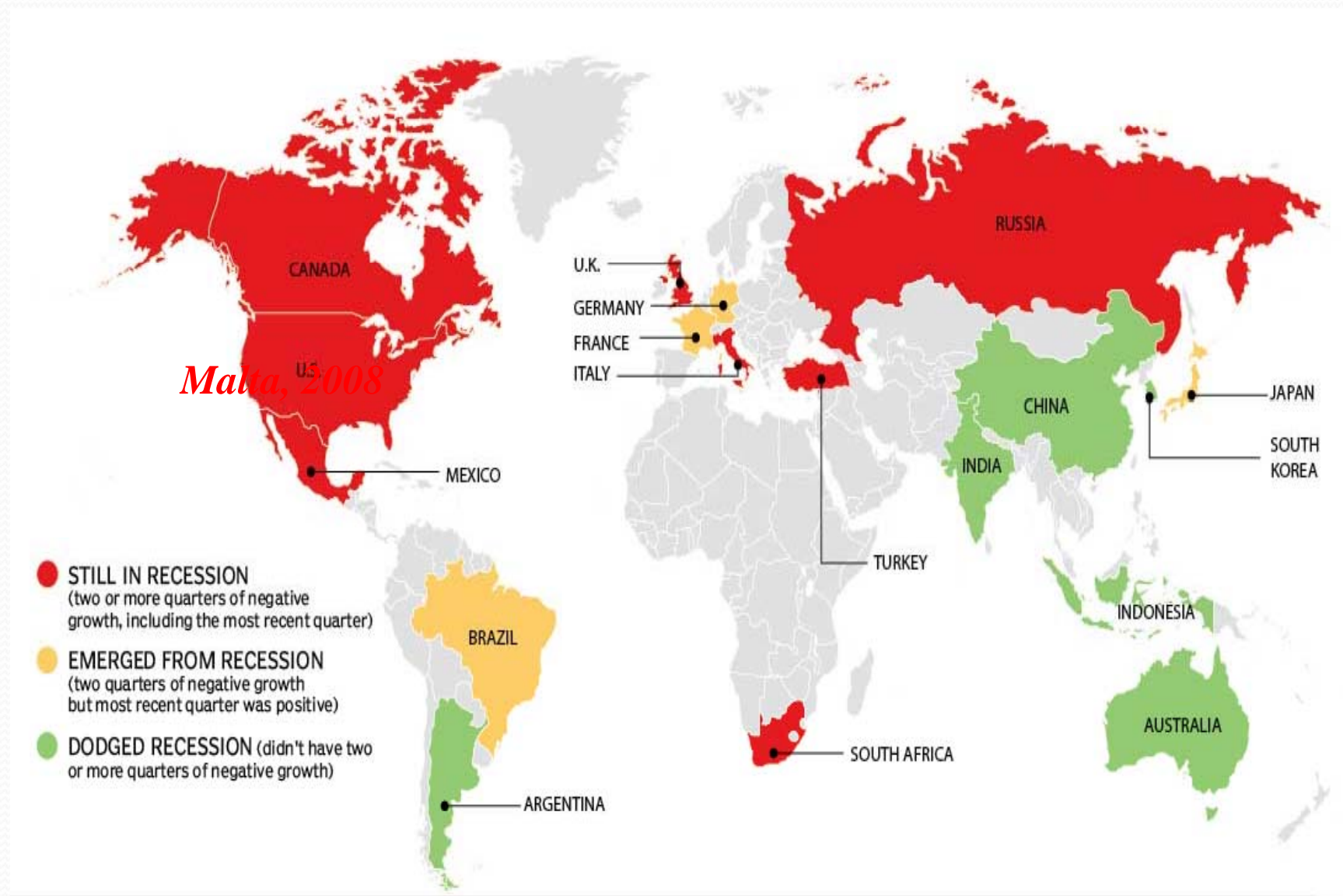
## *Rework, Renaissance or Ragnarök?*

Prof. Claude Farrugia  
Vice-President Communications, EIPG

# *Is the storm over?*

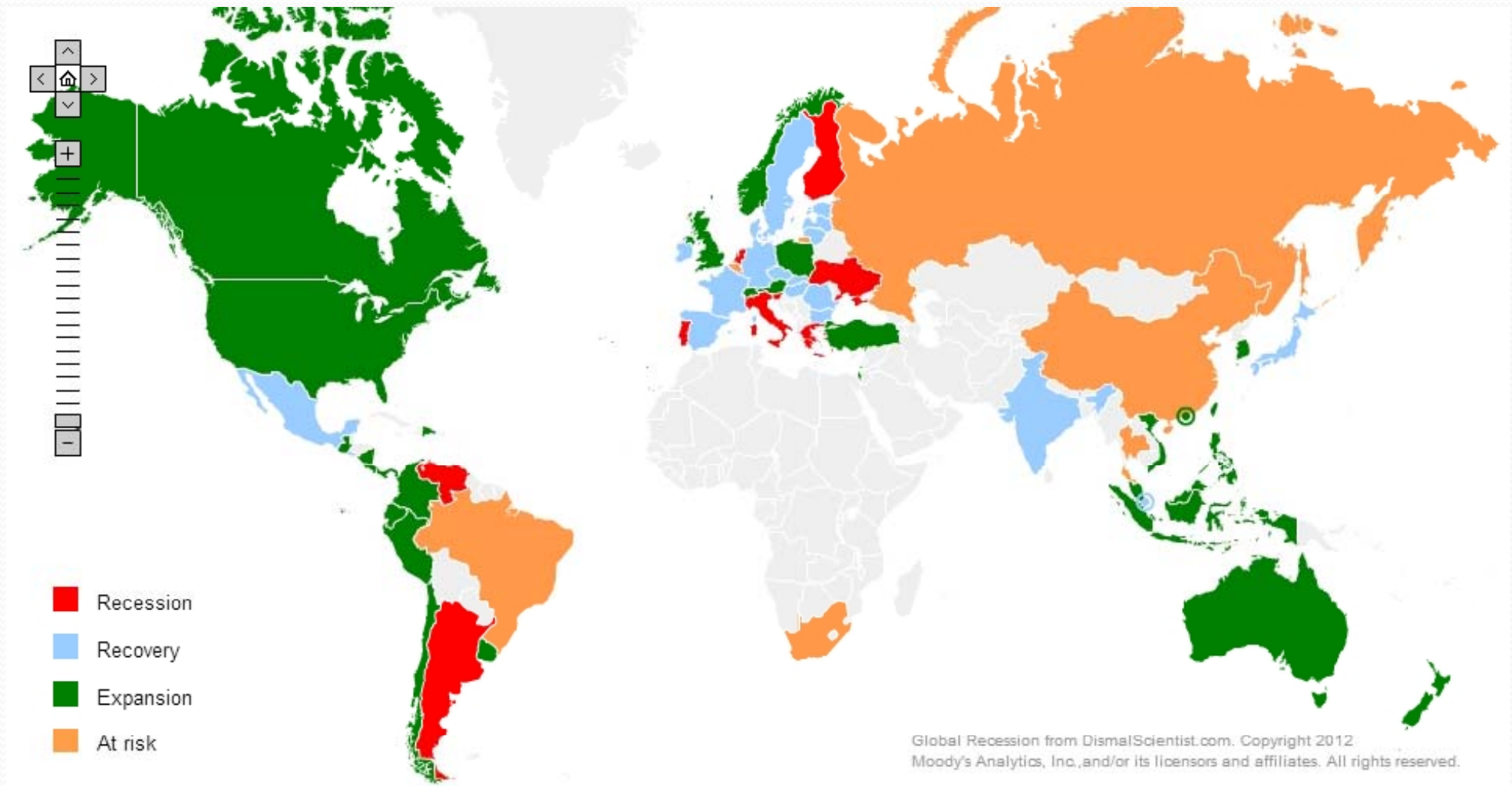


# Is the storm over?

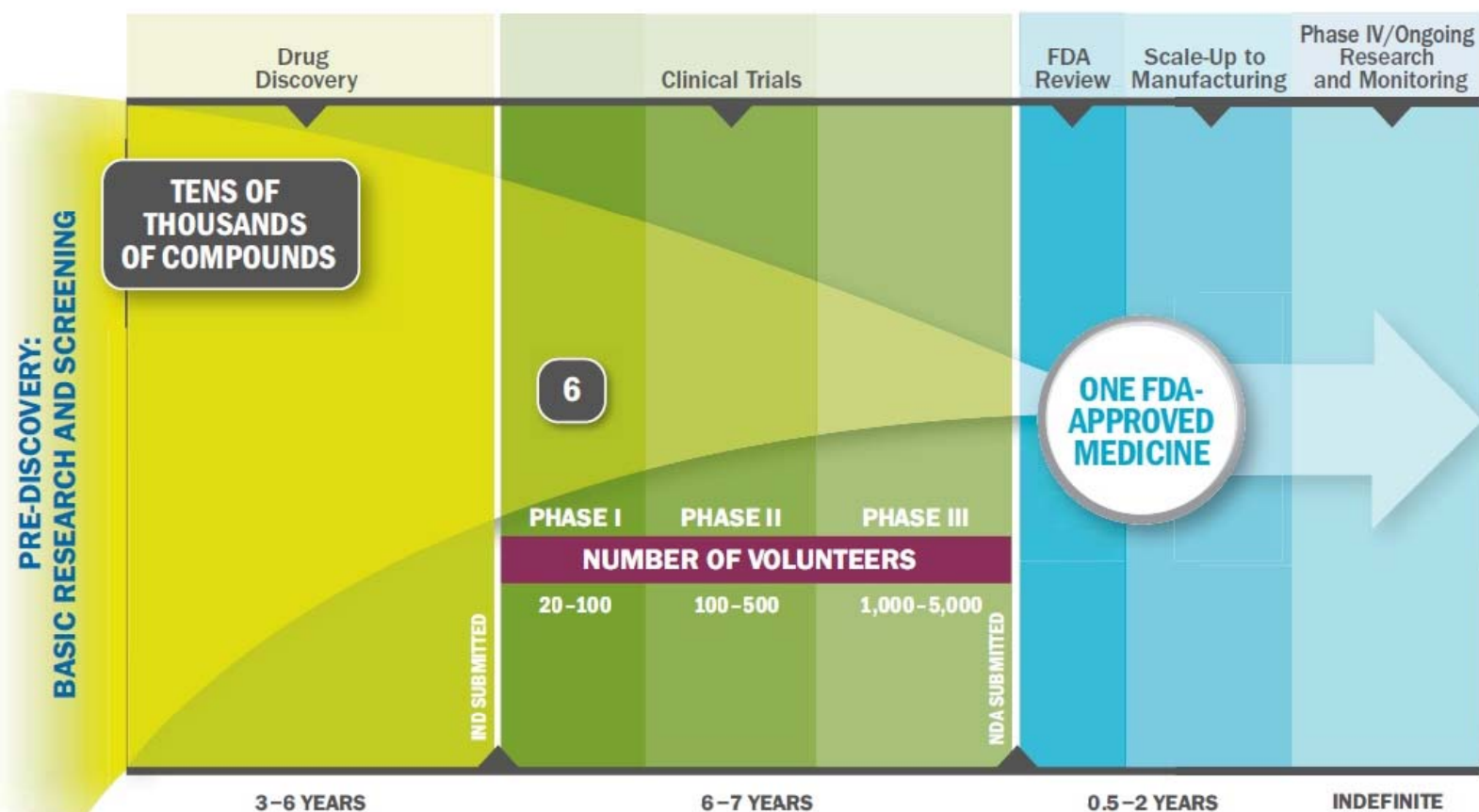




# *Is the storm over?*



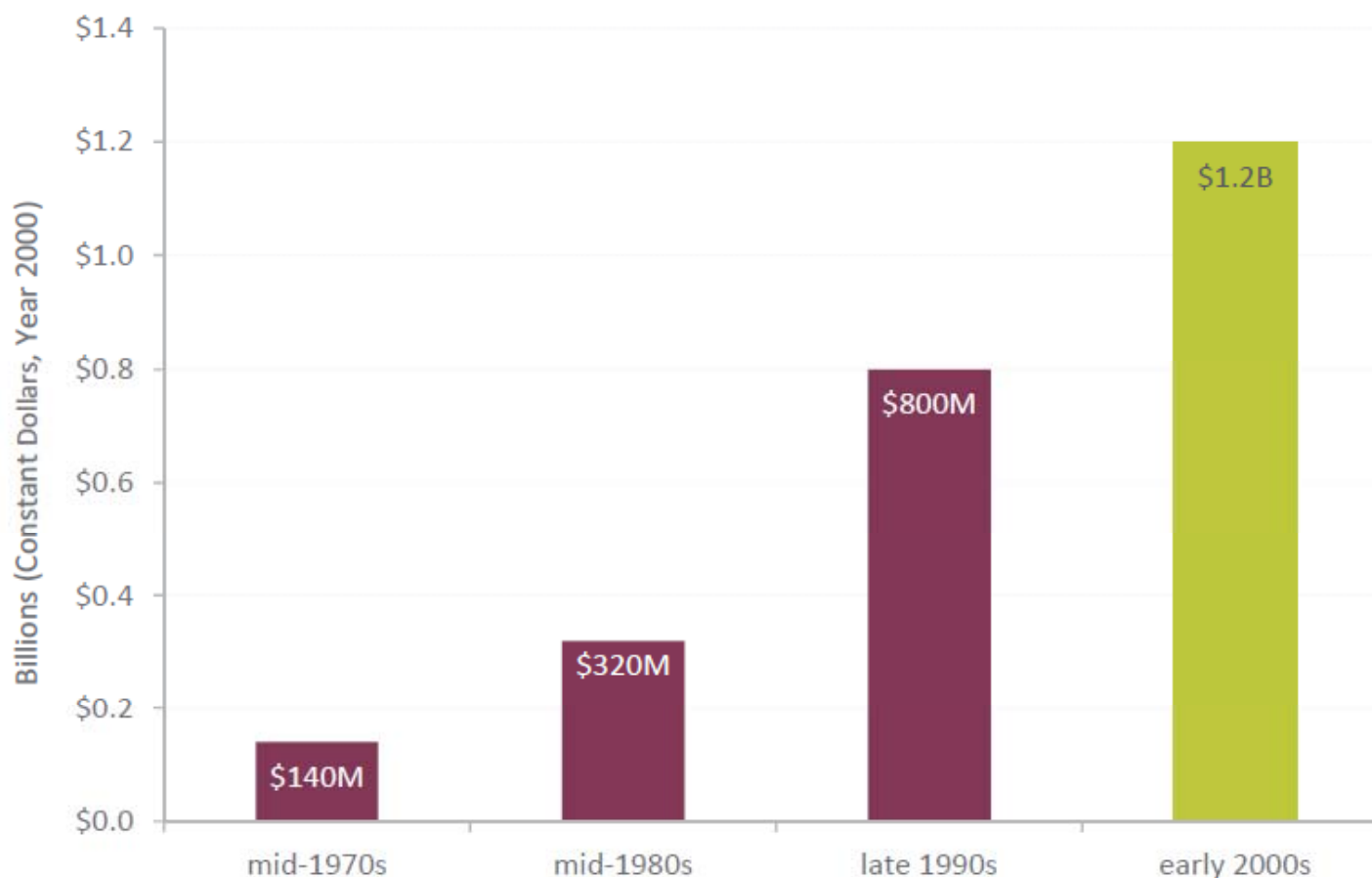
# Drug Development is Risky



SOURCE: Pharmaceutical Research and Manufacturers of America. "Drug Discovery and Development: Understanding the R&D Process." Washington, DC: PhRMA, 2014.

# Drug Development is a Costly Business

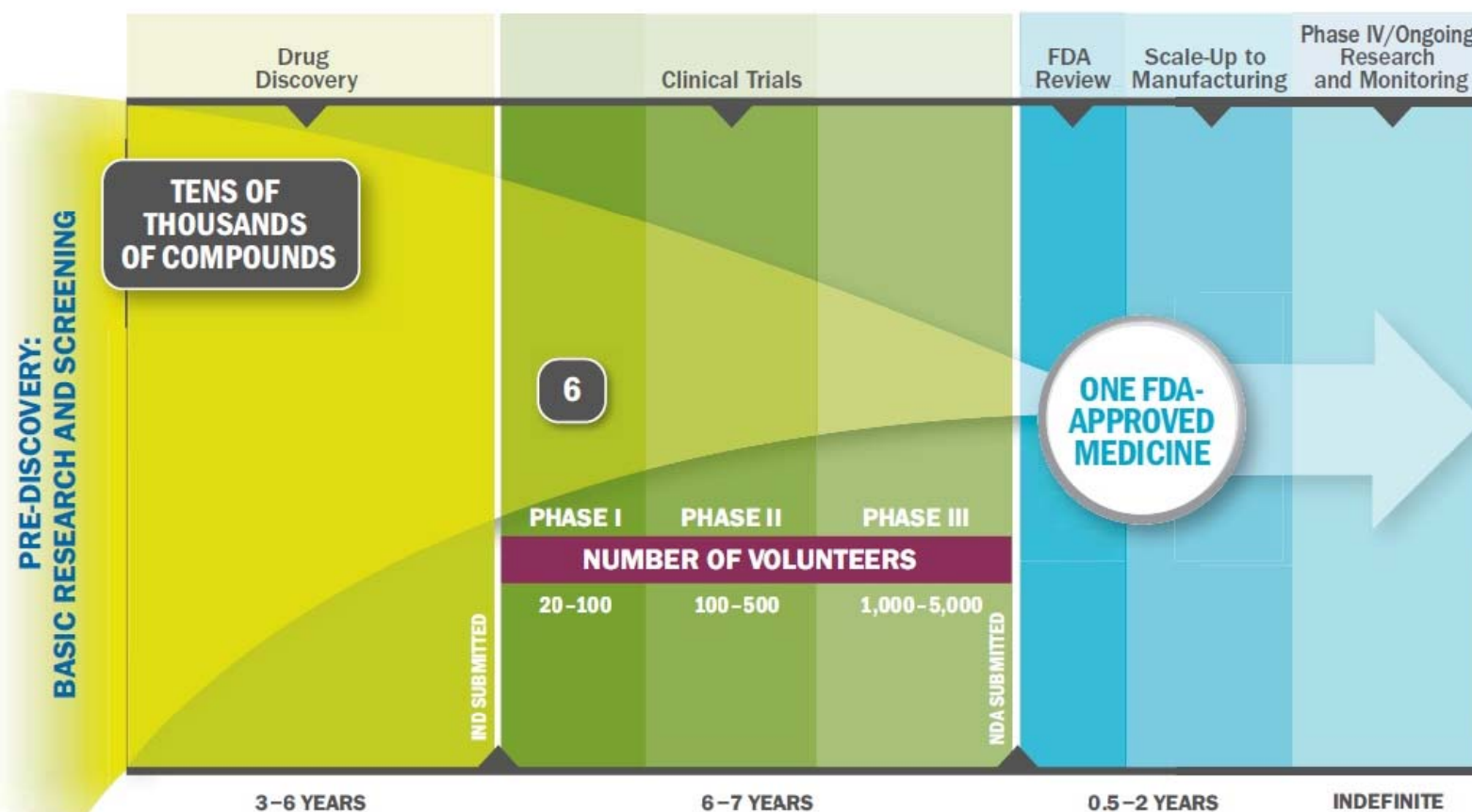
*The Average Cost to Develop One New Approved Drug—including the Cost of Failures*



SOURCE: J.A. DiMasi and H.G. Grabowski. "The Cost of Biopharmaceutical R&D: Is Biotech Different?" *Managerial and Decision Economics* 2007; 28: 469–479; More recent estimates range from \$1.5 billion to more than \$1.8 billion. See J. Mestre-Ferrandiz, J. Sussex, and A. Towse. "The R&D Cost of a New Medicine." London: Office of Health Economics, 2012; S.M. Paul, et al. "How to Improve R&D Productivity: The Pharmaceutical Industry's Grand Challenge." *Nature Reviews Drug Discovery* 2010; 9: 203–214; J.A. DiMasi, et al. "The Price of Innovation: New Estimates of Drug Development Costs." *Journal of Health Economics* 2003; 22: 151–185. Study findings originally reported in 2005 dollars. Based on correspondence with the study author, these figures were adjusted to 2000 dollars.



# Drug Development is Time-Consuming



SOURCE: Pharmaceutical Research and Manufacturers of America. "Drug Discovery and Development: Understanding the R&D Process." Washington, DC: PhRMA, 2014.

*10-15 years from start to launch*

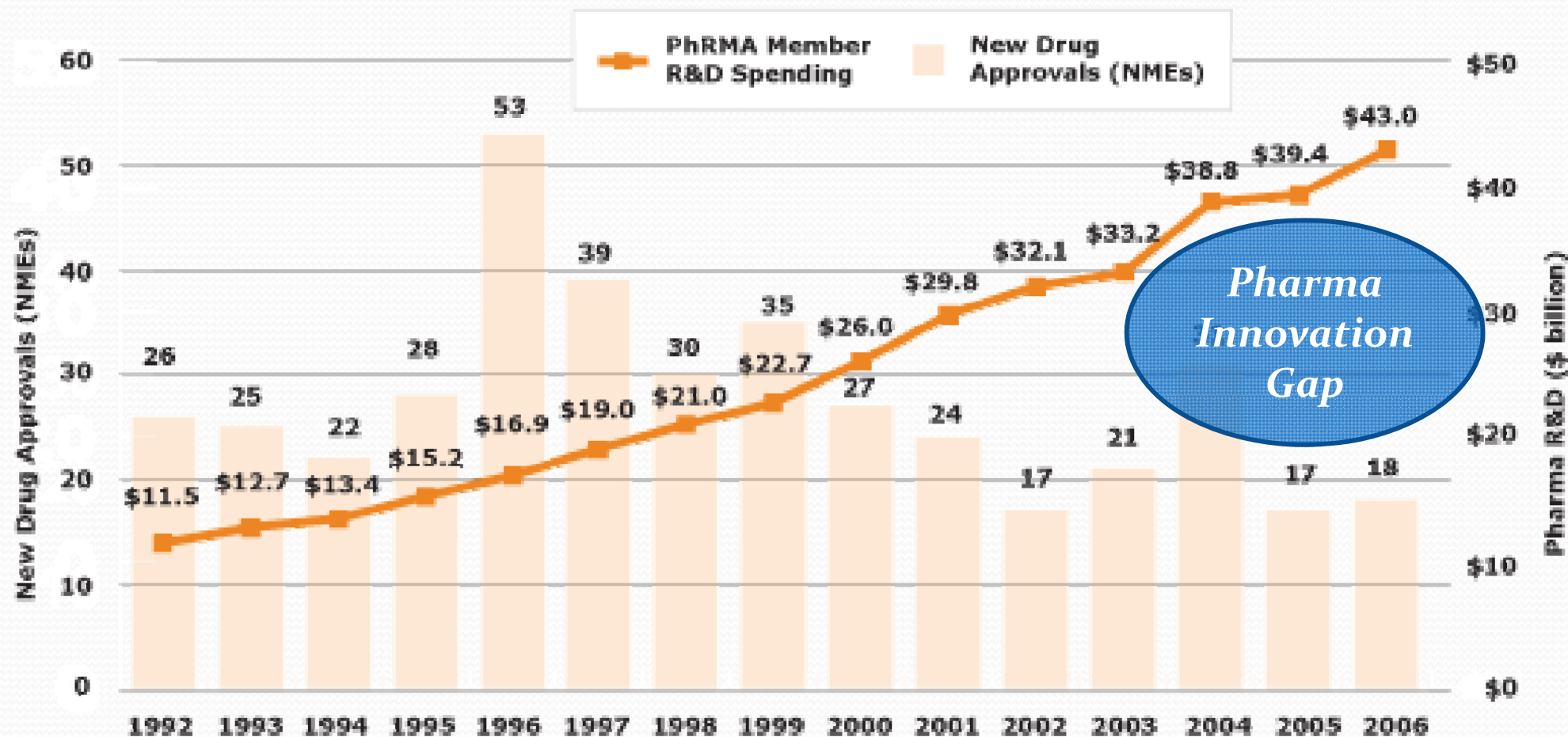
*Just to put things in perspective...*



SOURCE: Pharmaceutical Research and Manufacturers of America. "Drug Discovery and Development: Understanding the R&D Process." Washington, DC: PhRMA, 2014.



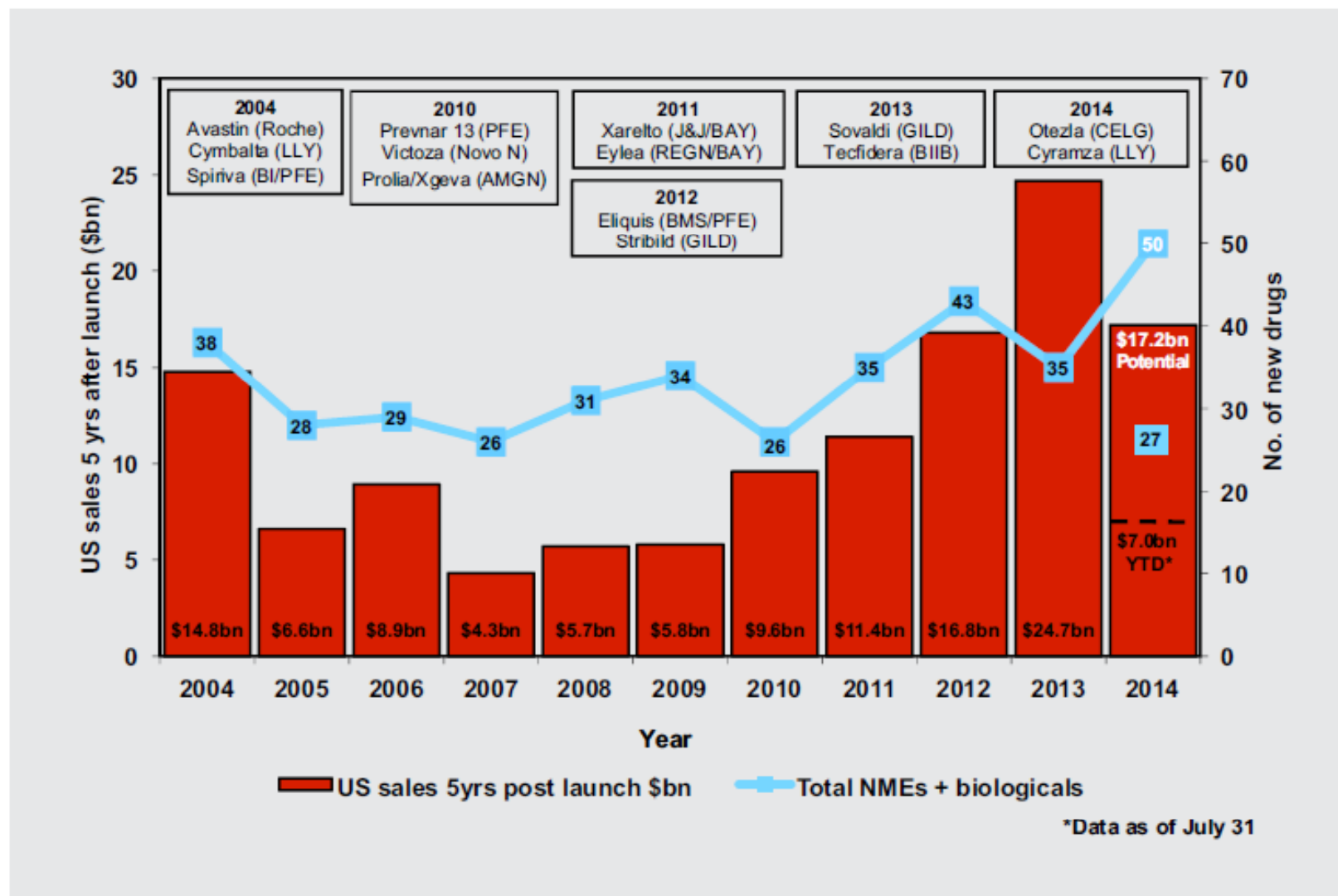
# The pharmaceutical pipeline



Source: Burrill & Company; US Food and Drug Administration

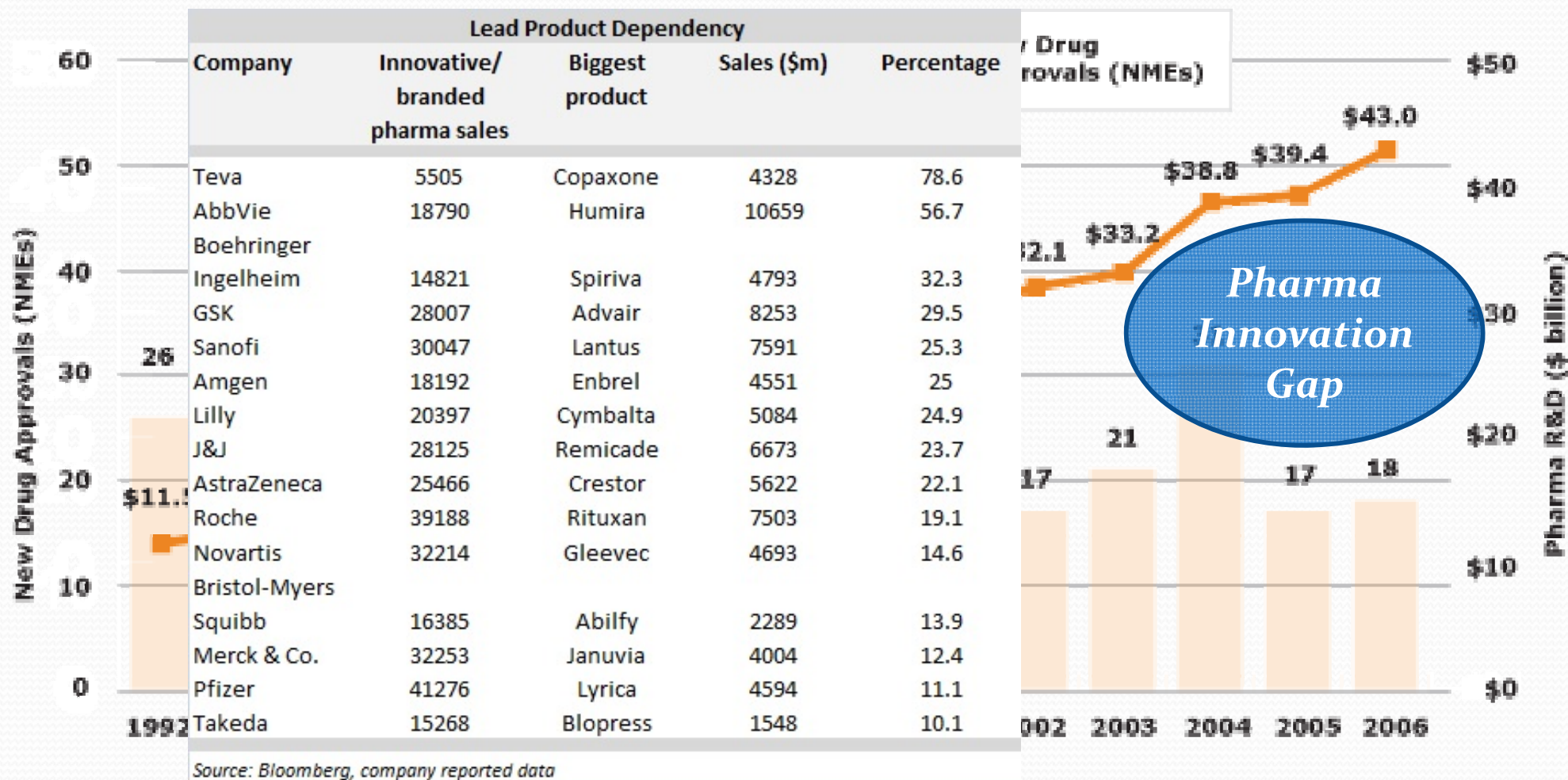
# The pharmaceutical pipeline

FDA Approval Count vs. Total USA Product Sales 5 Years After Launch





# The pharmaceutical pipeline



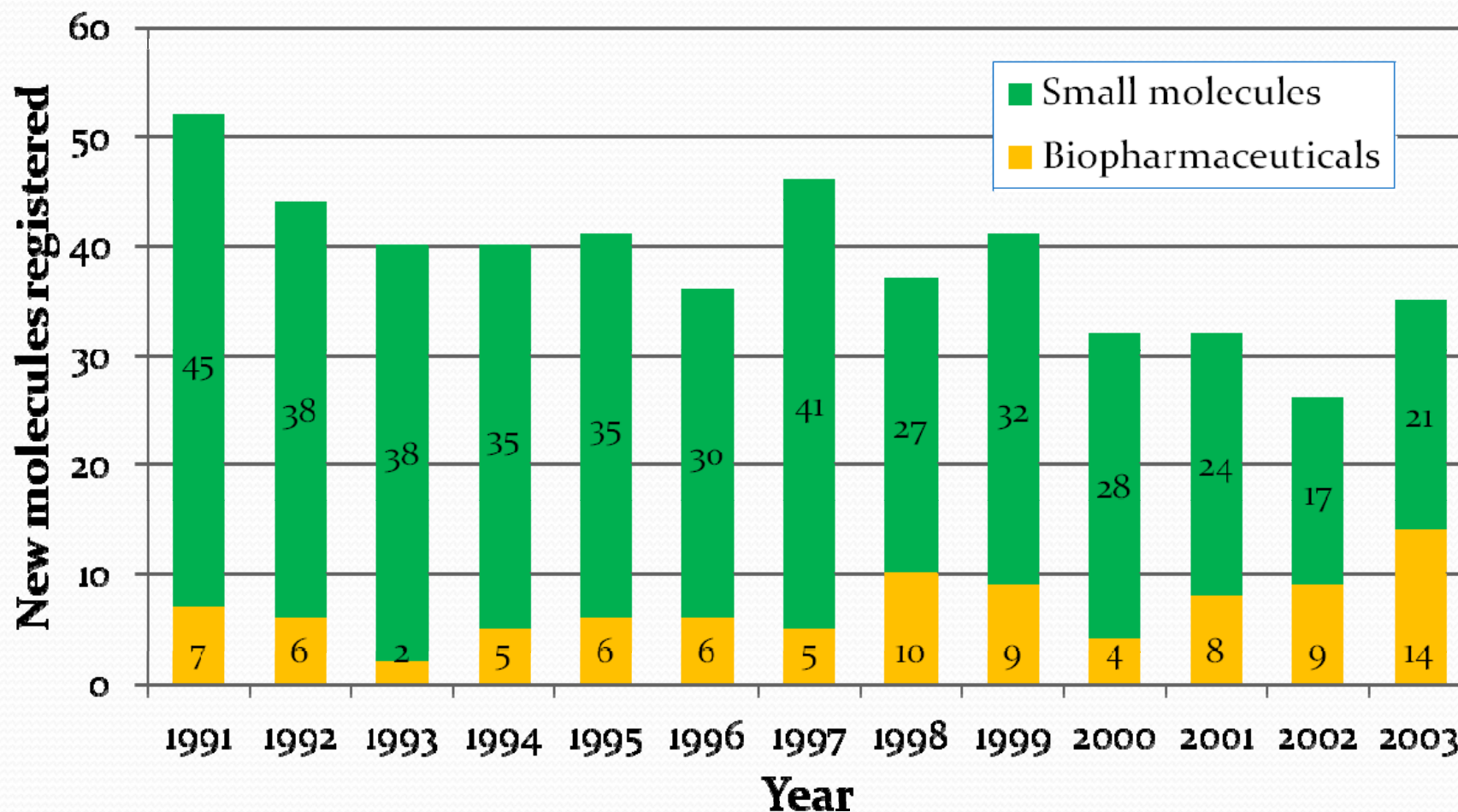
Source: Burrill & Company; US Food and Drug Administration

# Is there still a patent cliff?



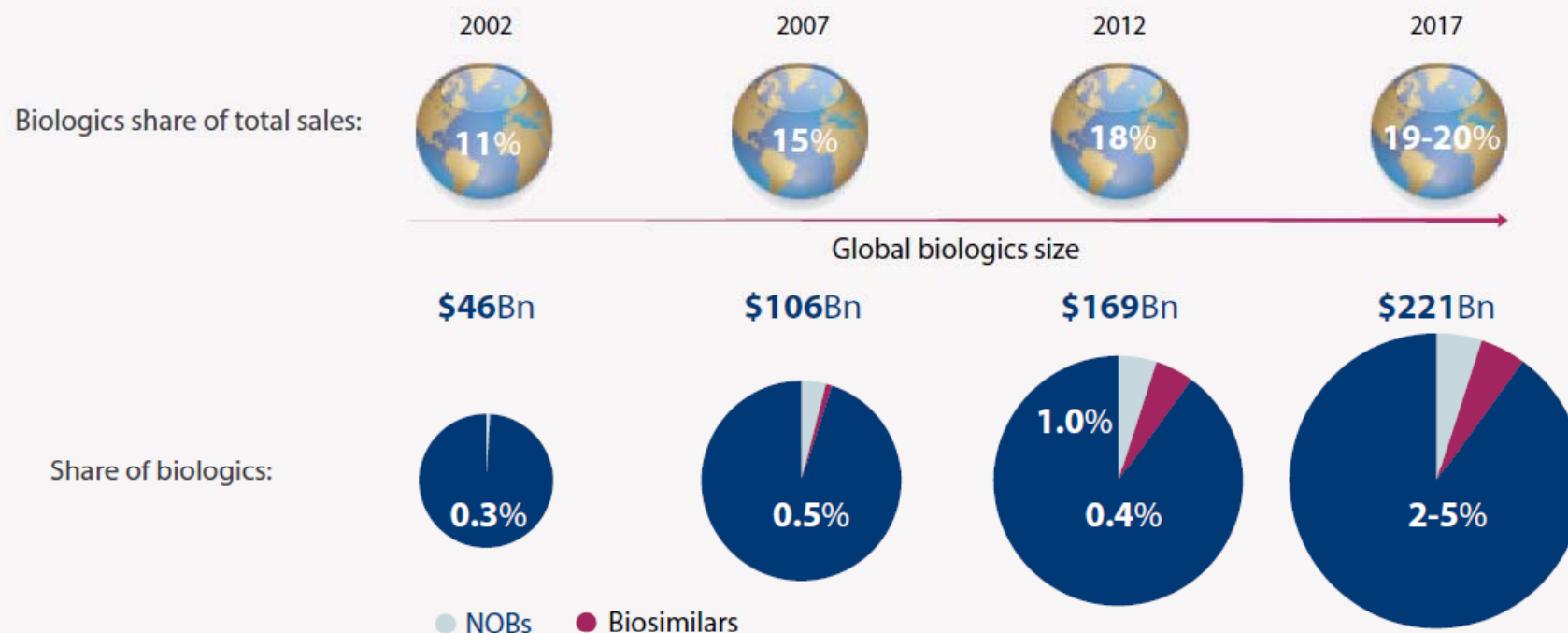


# *Biopharmaceuticals: a renaissance*



# Biopharmaceuticals: a renaissance

## The biologics market

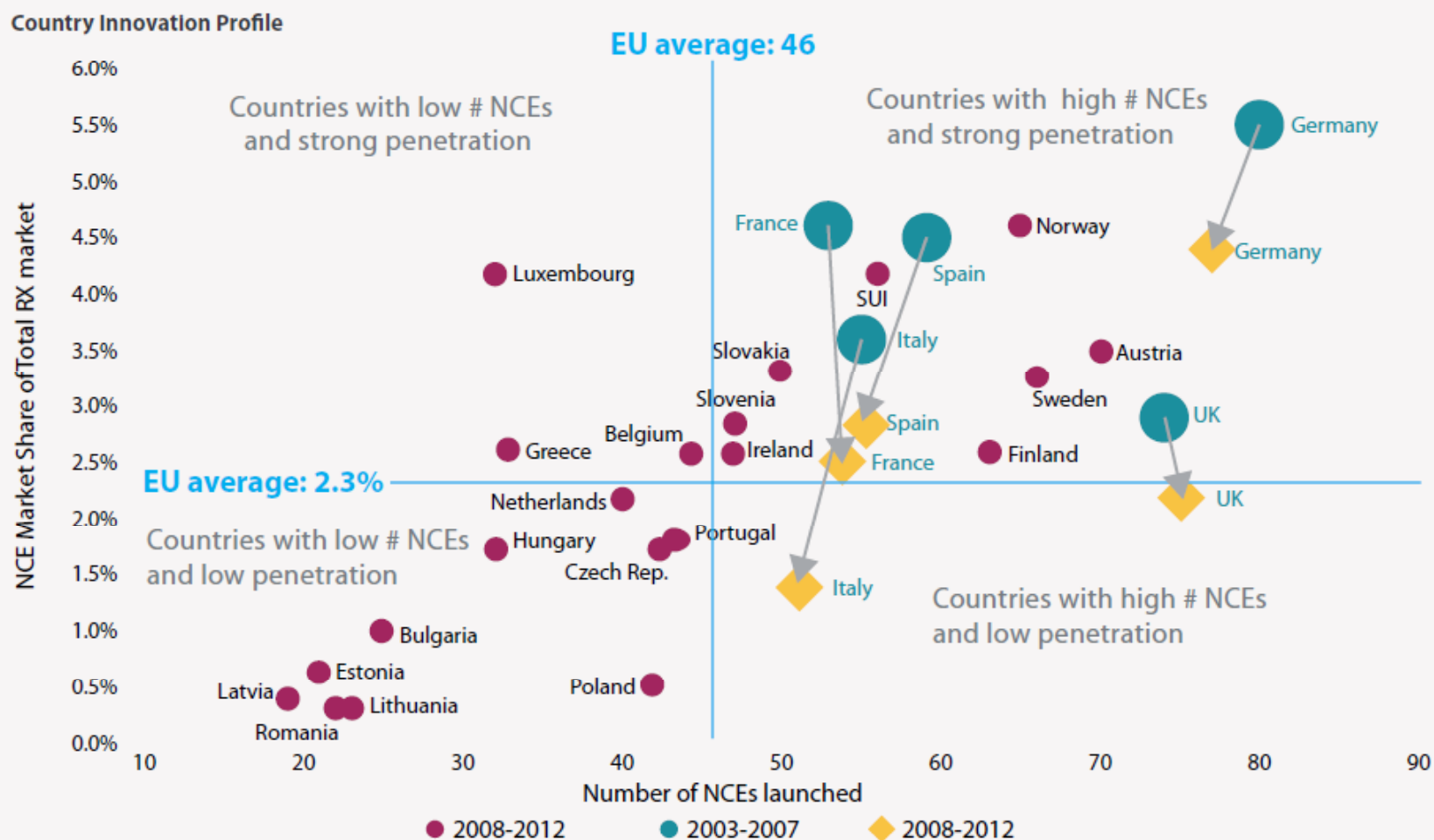


Source: IMS Health Thought Leadership, September 2013



# From pipeline to market

## NCEs launched vs. Market Share achieved



Between the time periods 2003/7 and 2008/12, NCE # and uptake decreased for all countries except Norway and Bulgaria. Movements of the top 5 European markets shown for illustration.

## ***Is Europe prepared to pay?***

**The European Union constantly considers cost-containment policies in public pharmaceutical spending.**

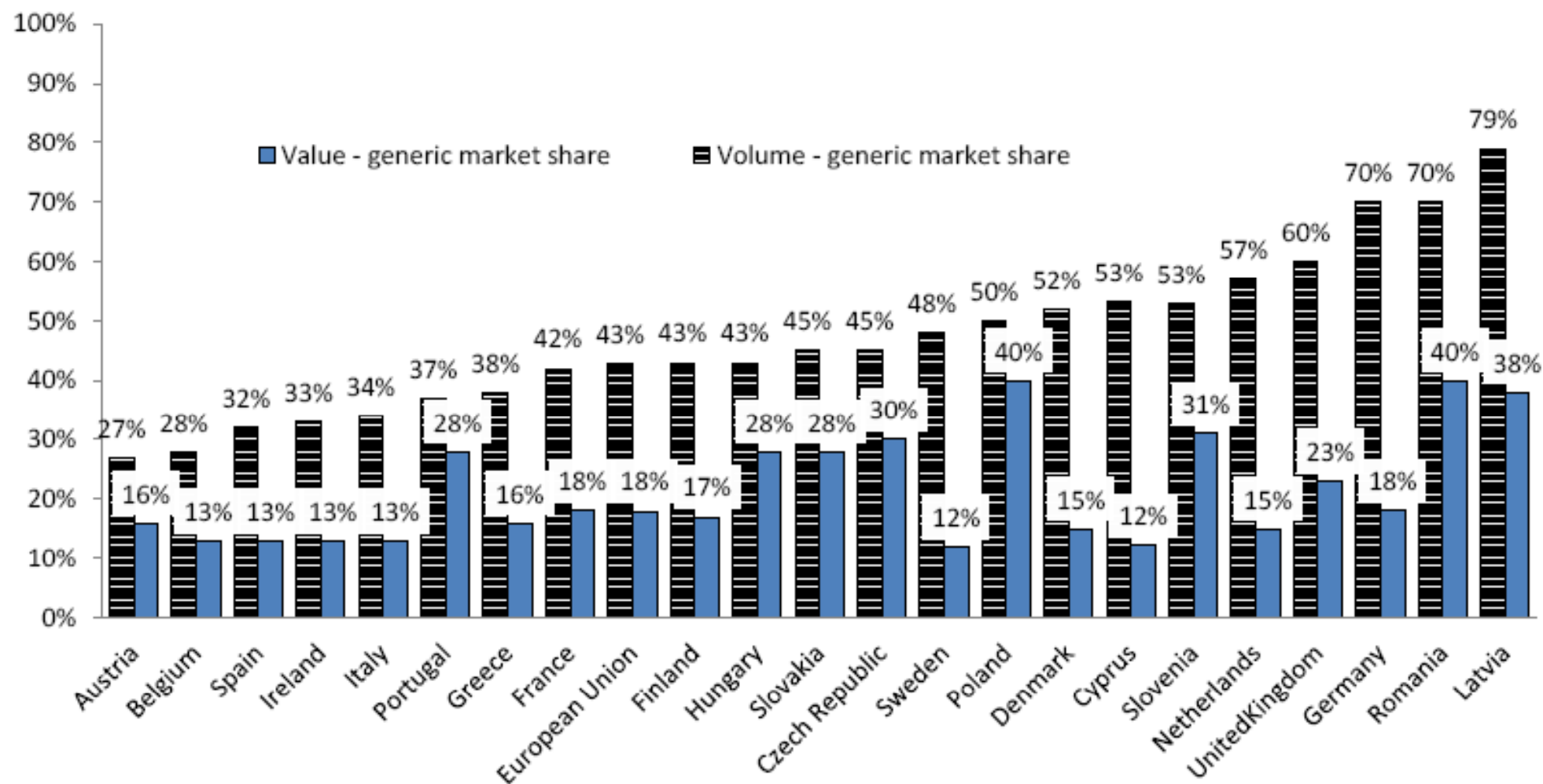
- External reference pricing as a tool to control prices and set a parameter of expenditures.
- Rebates, clawback and payback policies.
- Internal reference pricing.

**The inclusion of the most recent medicinal products in reimbursement lists or government formularies is sometimes inexplicably delayed.**



# Is Europe prepared to pay?

*In Europe, generics make up almost one half of volume sales, but merely a fraction of value sales*



# *Is Europe prepared to pay?*

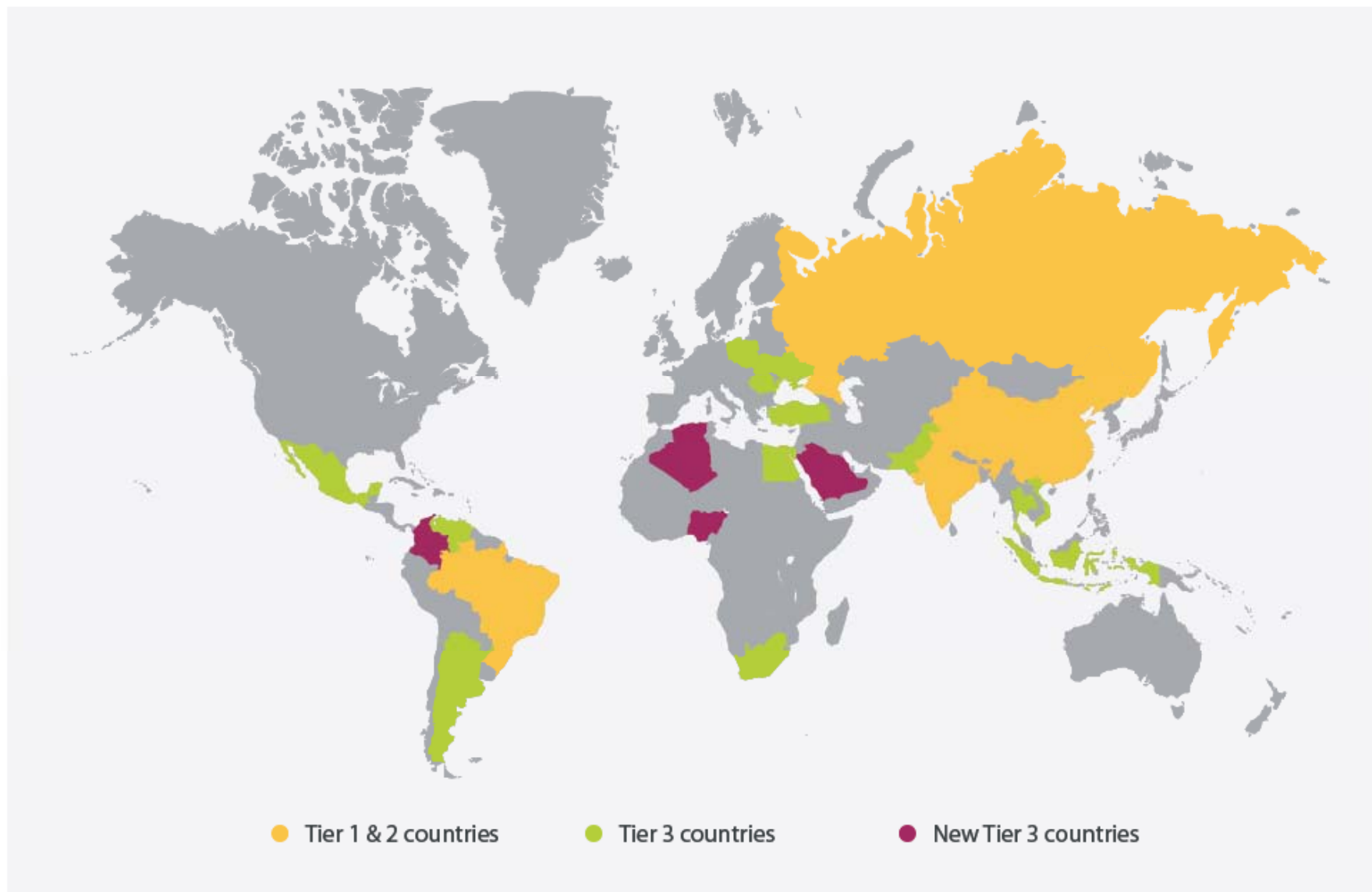
*“Europe has unfortunately slipped in terms of its willingness to pay for innovation. ... We’re now at a point where we have to take the view and I think face the reality that really it’s about the U.S. and, excitingly anew, it’s about Japan in terms of where innovation should be driven.”*

*(Sir Andrew Witty, CEO GlaxoSmithKline, 2012)*





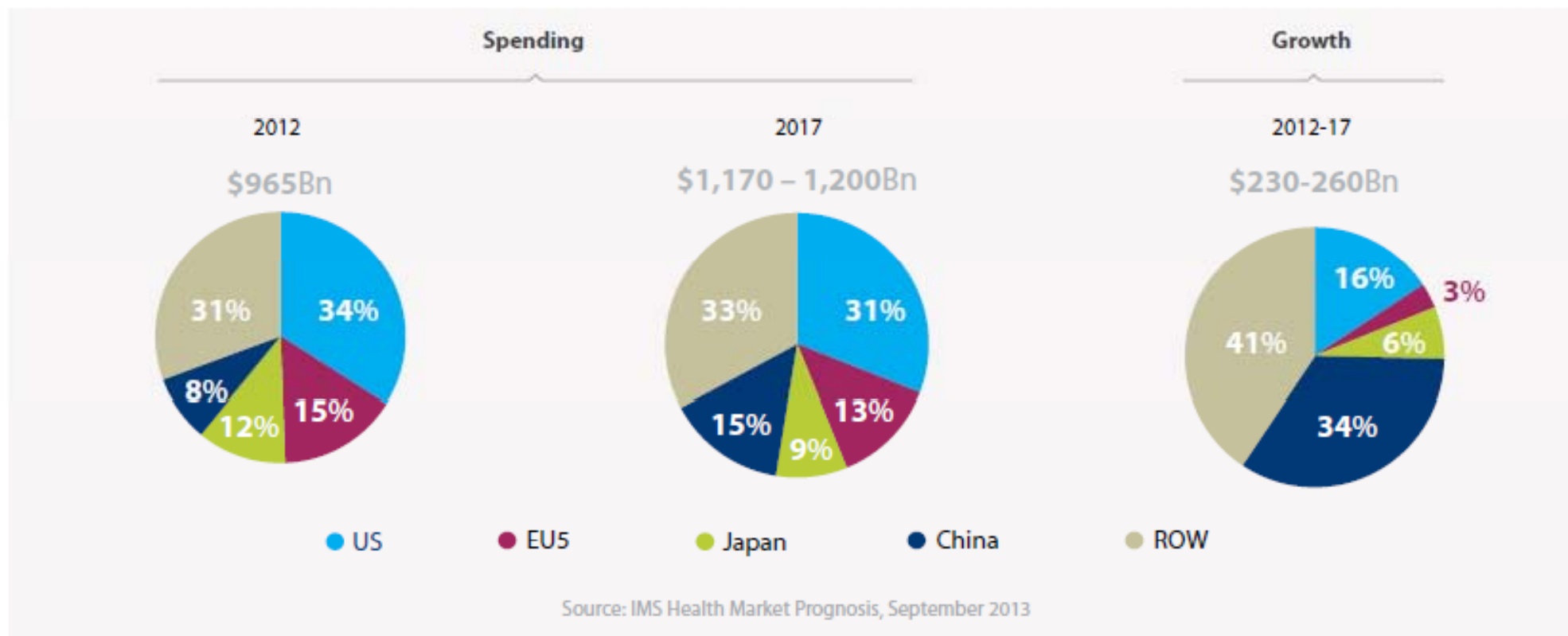
# *Enter the pharmerging markets*





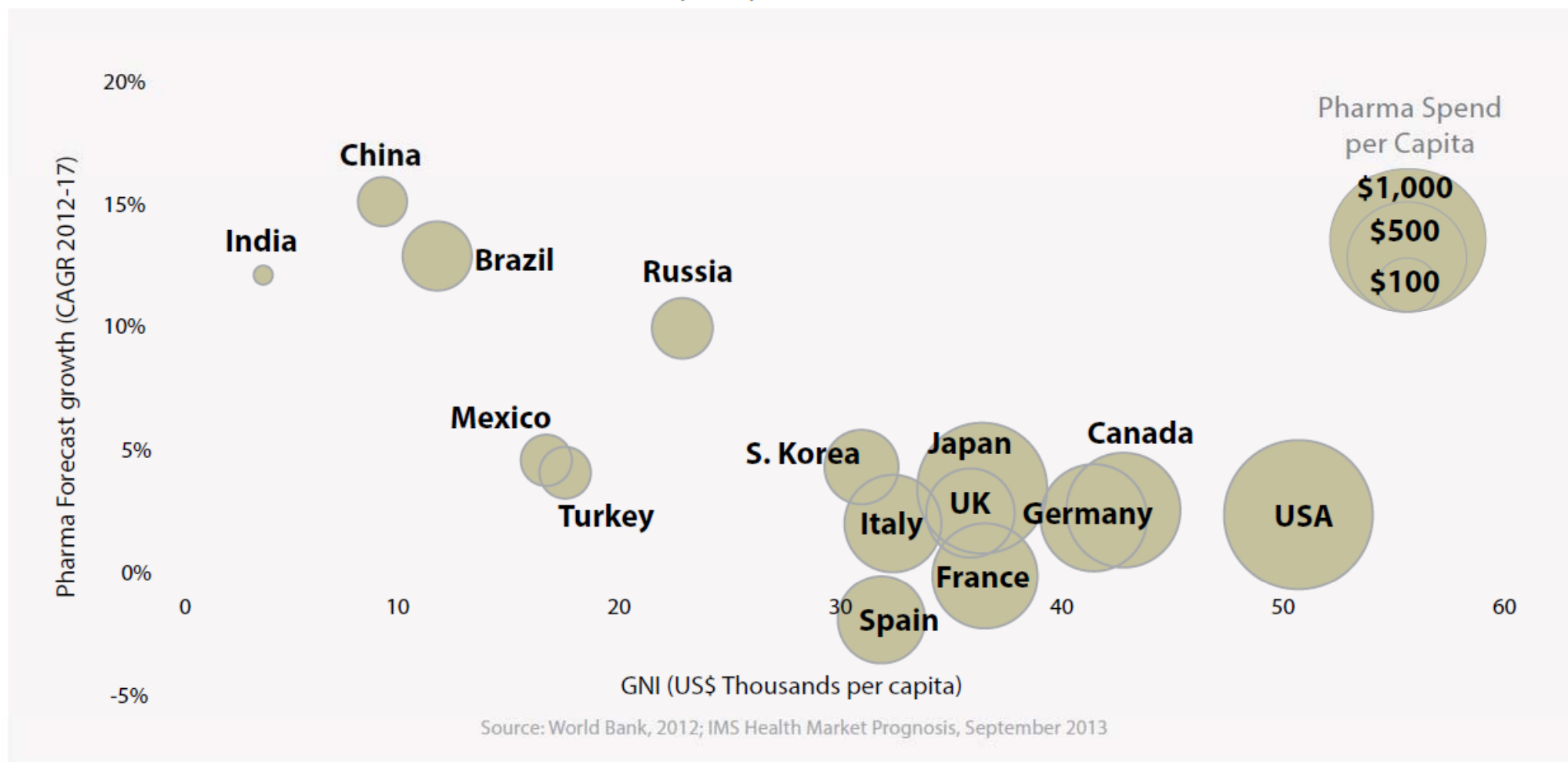
# Enter the pharmerging markets

## Geographic distribution of medicine spending



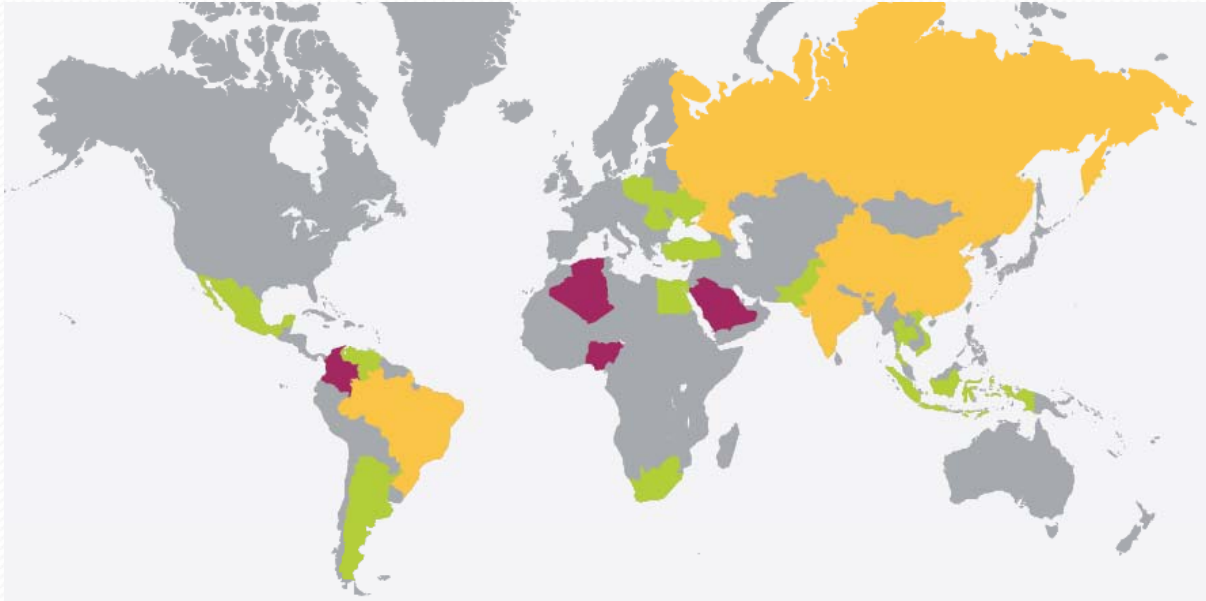
# Enter the pharmerging markets

Per capita Gross National Income 2012 (GNI) vs. Forecast Pharma Spend

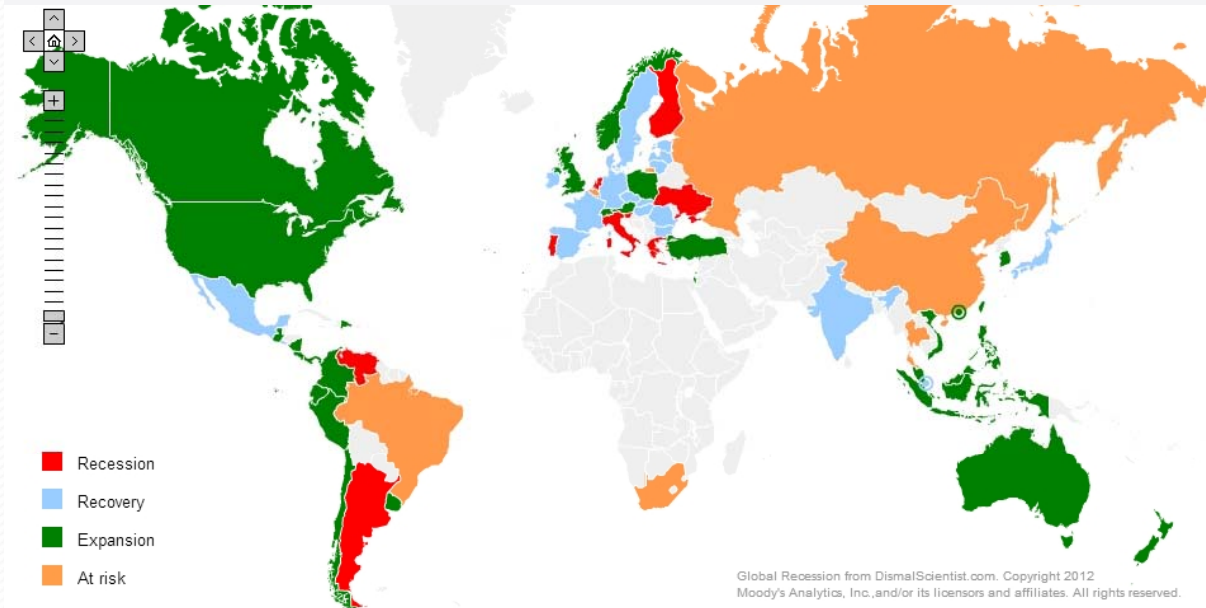




# Enter the pharmerging markets

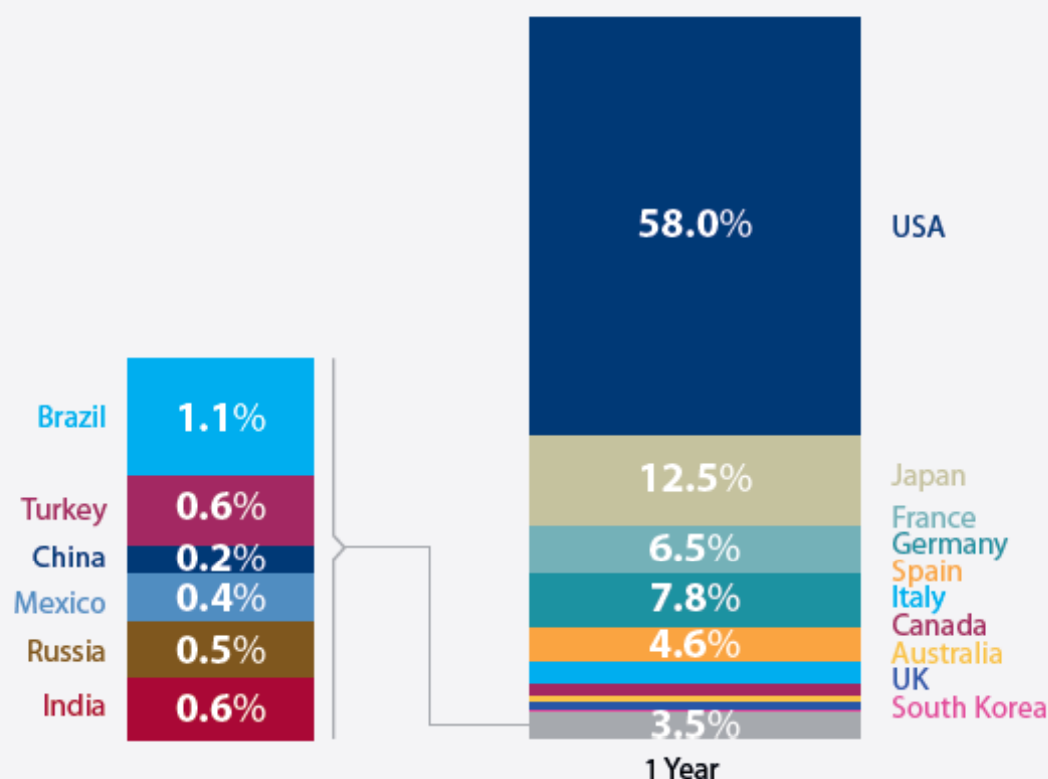


*All Tier 1 and Tier 2 pharmerging markets were, until recently, at risk or, at best, in economic recovery.*



# Enter the pharmerging markets

Pharmerging Markets Sales



Six pharmerging markets contributed only 3.5% of global first year sales

This is less than the cumulative contribution of any single European country

n=220

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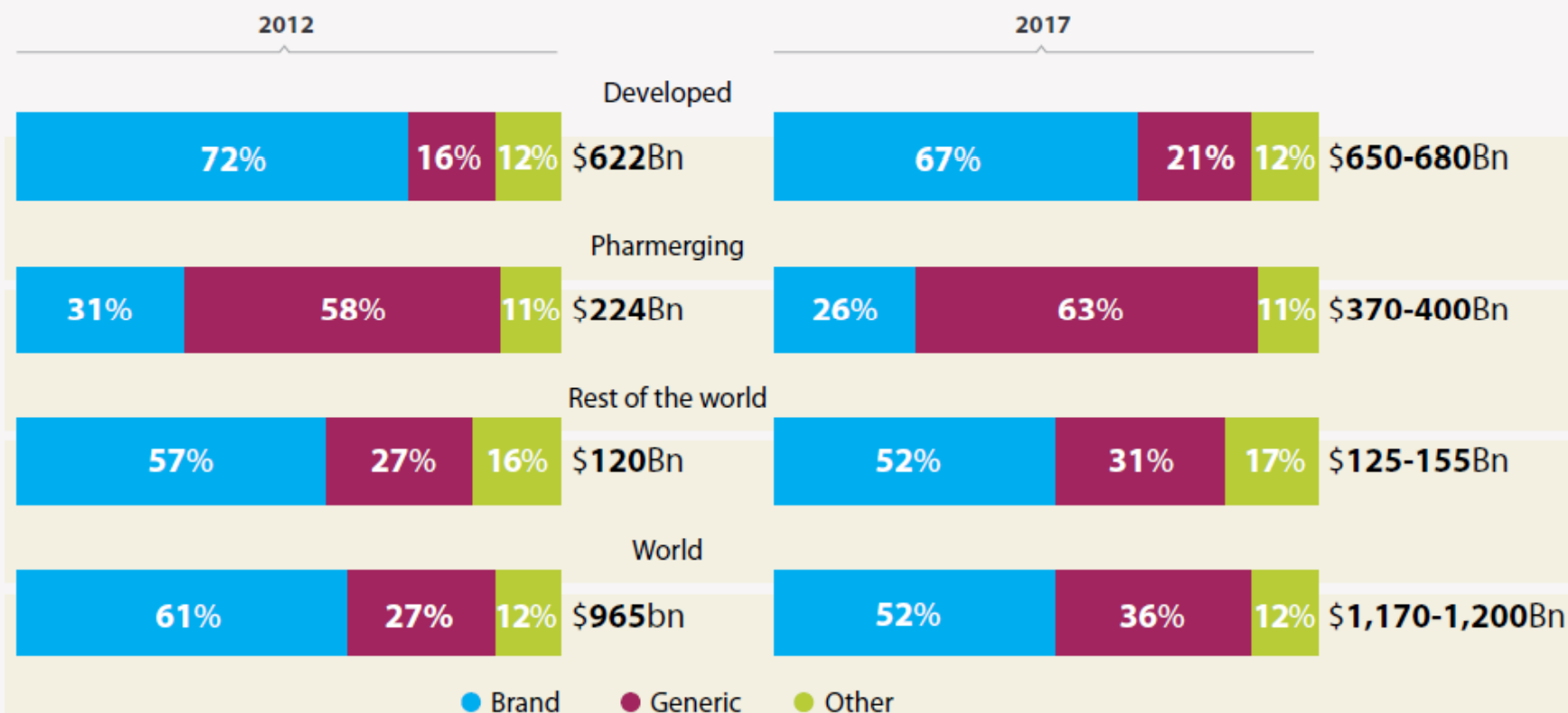
NOTE: NCE launches from 2004 to 2011, Country contribution is calculated based on the accumulative sales of these launches  
All launch years normalized for each country. The 16 selected countries are representing 80% of the total global pharmaceutical market

Source: IMS Launch Excellence IV



# Enter the pharmerging markets

## Global Spending, 2012 and 2017

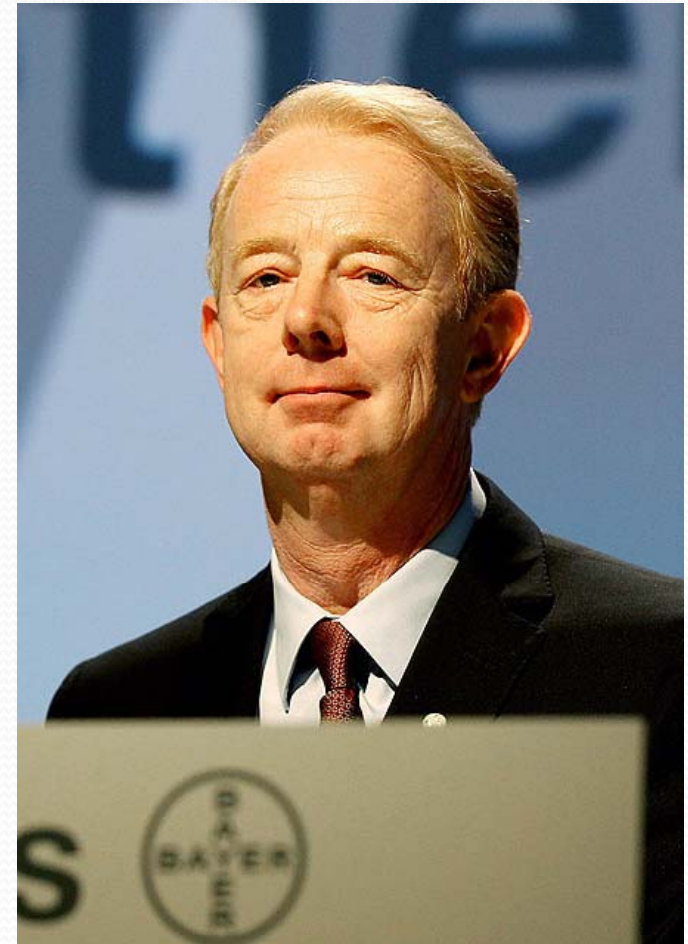


Source: IMS Health Thought Leadership, September 2013

# Pharmerging markets: the difference

*“The danger of pushing the prices of prescription drugs down, down, down is that at some point the business model of developing these drugs will lose its attractiveness. .... India is becoming very reluctant to respect IP for Western companies and that is becoming a challenge for us.”*

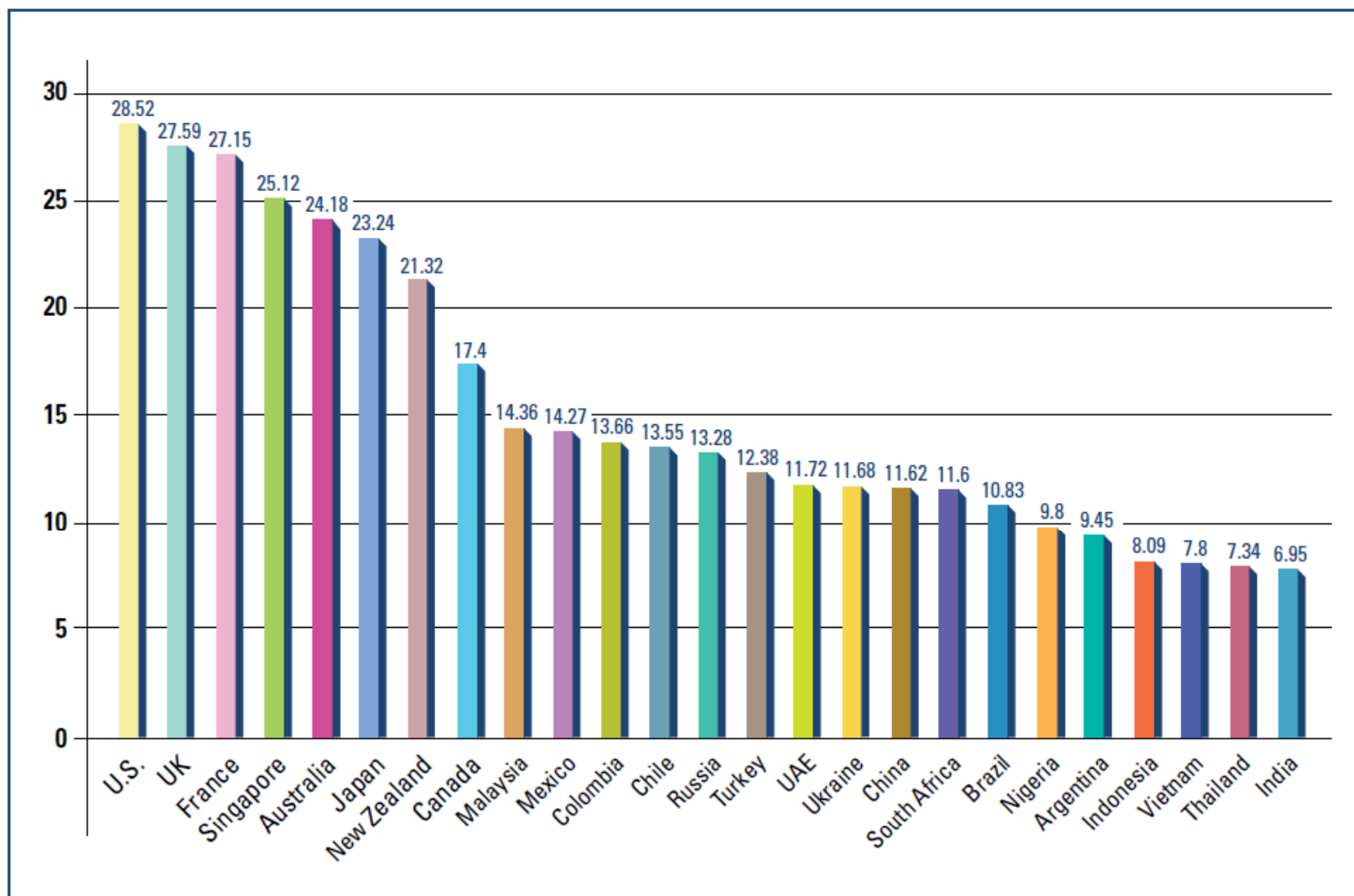
*(Marijn Dekkers, CEO Bayer, 2012)*



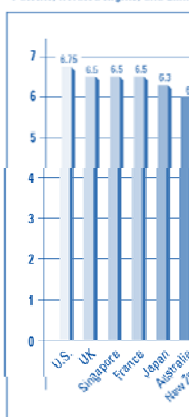


# Pharmerging markets: the difference

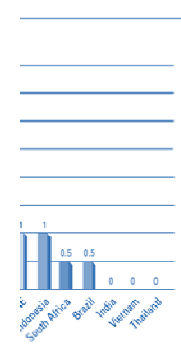
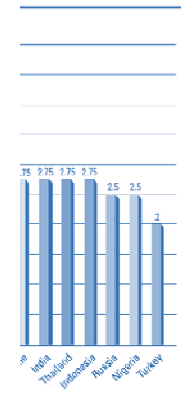
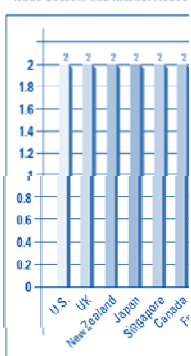
Overall Country Scores



Patents, Related Rights, and Civil



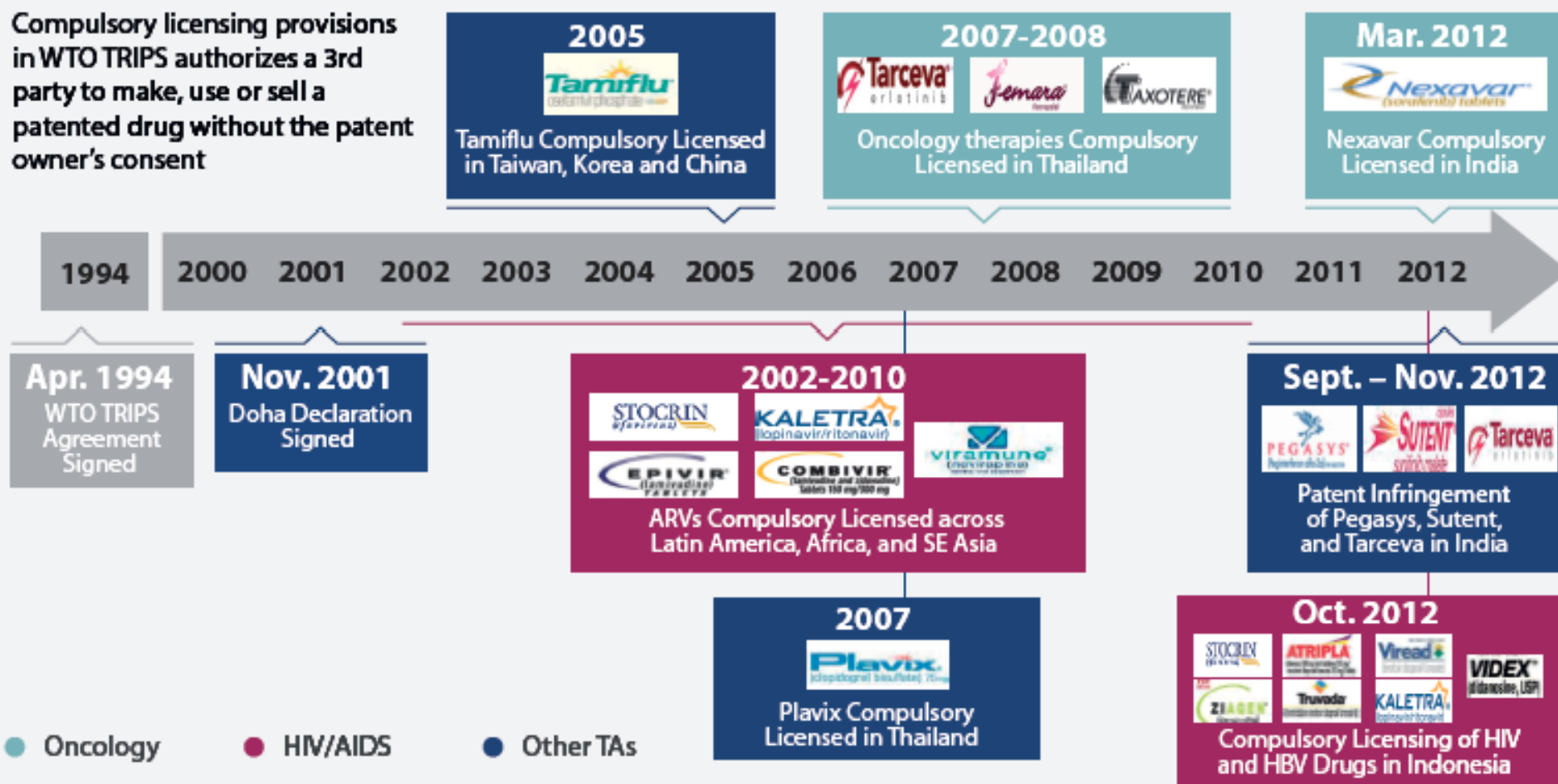
Trade Secrets and Market Access



# Pharmerging markets: the difference

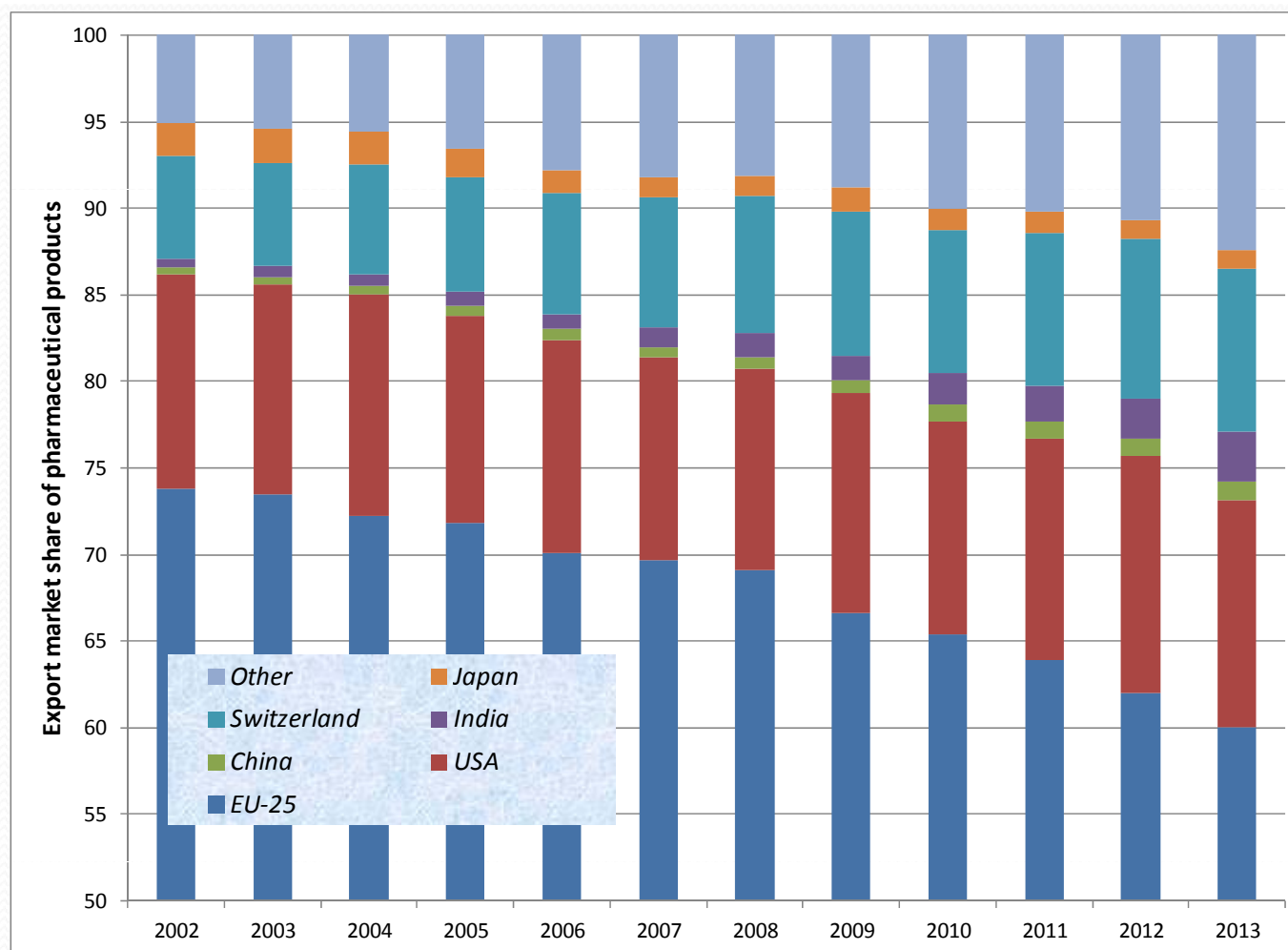
## Timeline of compulsory licensing and patent revocation in emerging markets

Compulsory licensing provisions in WTO TRIPS authorizes a 3rd party to make, use or sell a patented drug without the patent owner's consent



# Pharmerging markets or players?

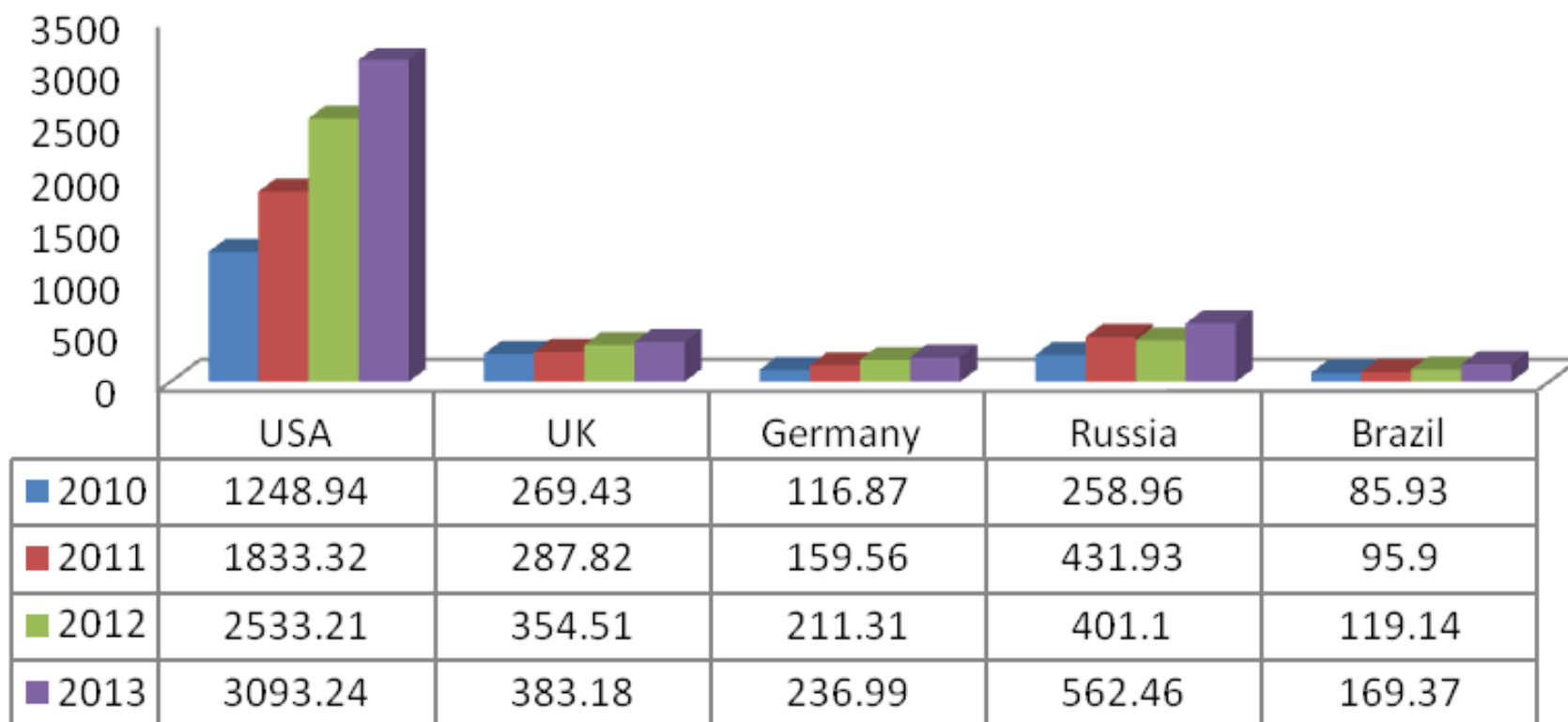
## Global share of pharma exports





# Pharmerging markets or players?

## Pharma exports from India (US \$ Million)



# *Pharmerging markets or players?*

## *Jugaad*

Literally, an arrangement or a workaround, which has to be used because of lack of resources. Practically, a creative idea, a quick, alternate way of solving or fixing problems.





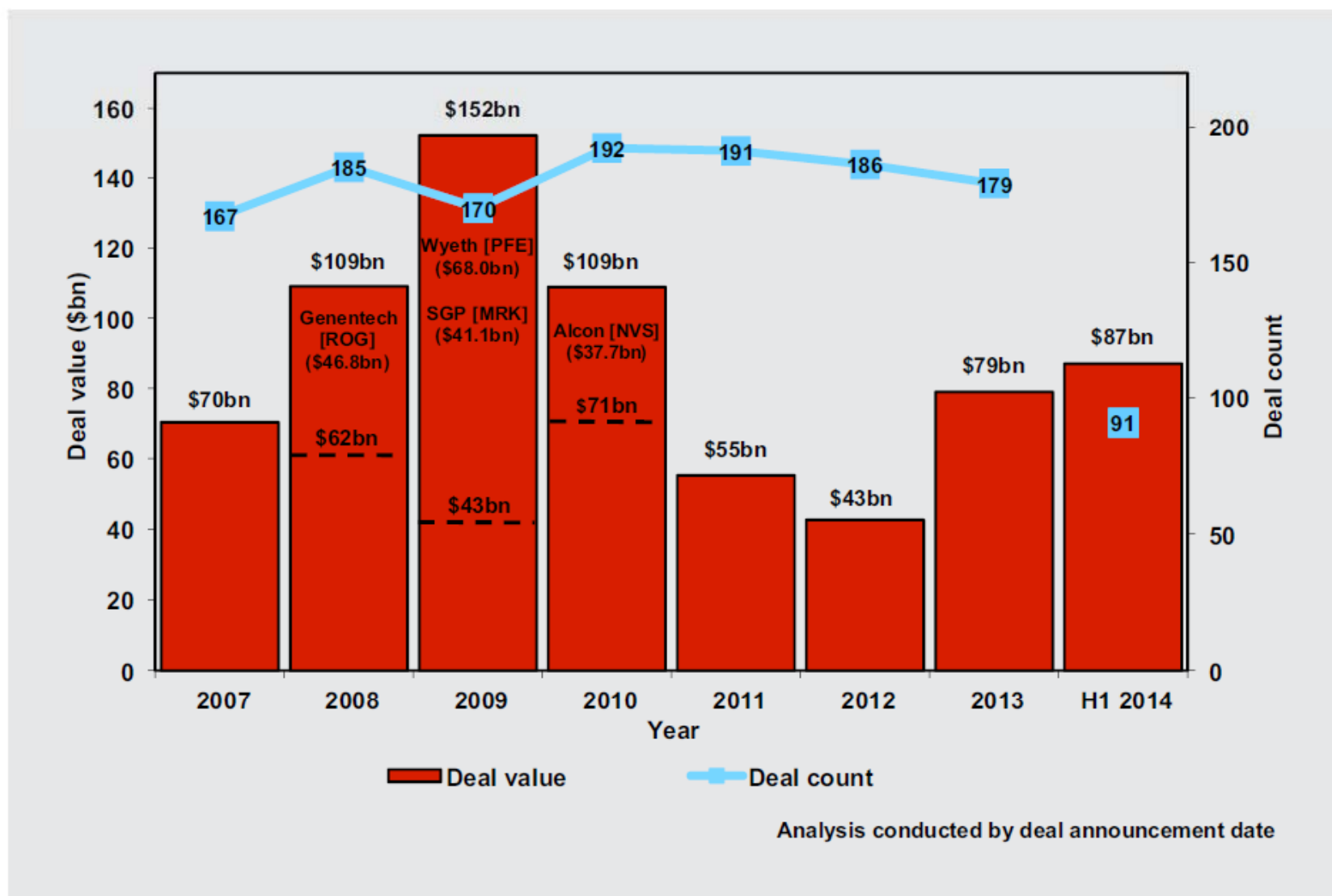
# *Pharmerging markets or players?*



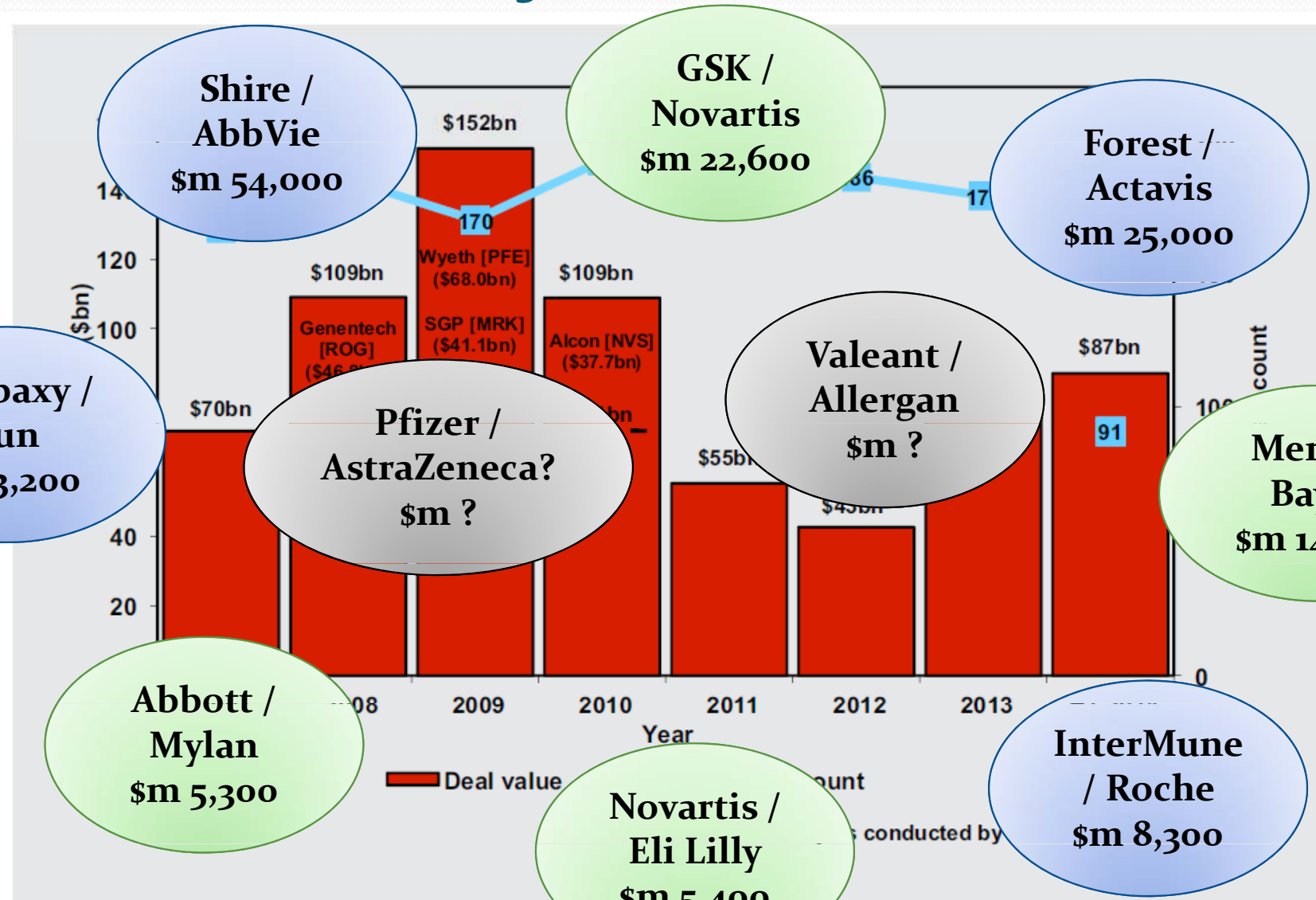
*Is there a limit to jugaad?*



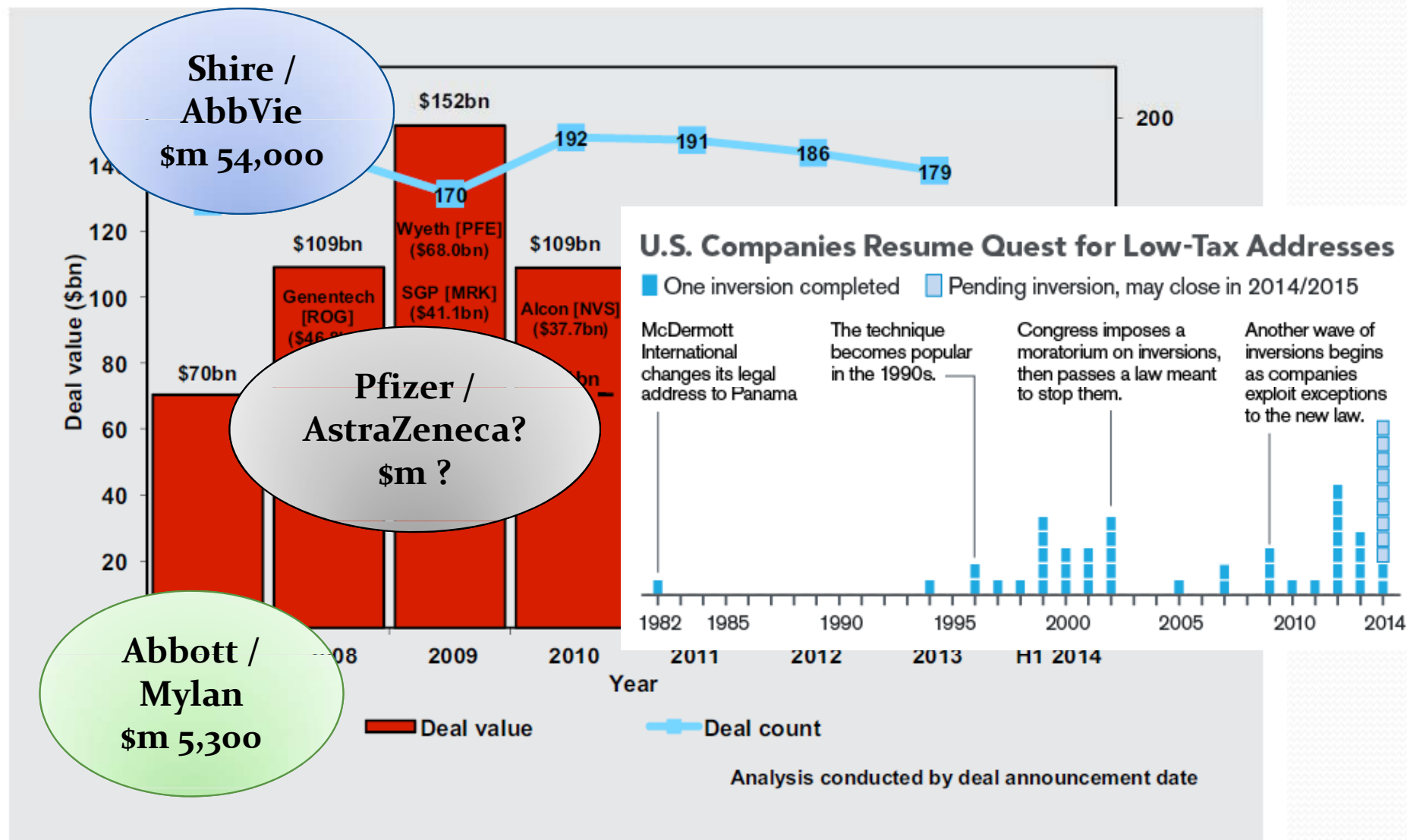
# 2014: The Year of the M&A



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# 2014: The Year of the M&A

	Enterprise value growth	Enterprise value to sales	Gross margin	Profit Margin	Sales to assets	Return on Assets	Return on invested capital	GSA to sales
Shire	45.2%	4.84	81.50%	40.09%	66%	26.46%	29.02%	47.07%
Abbvie	47.9%	4.72	75.77%	38.25%	67%	25.63%	22.45%	42.30%
Actavis	116.3%	4.38	45.46%	20.90%	47%	9.28%	-5.33%	25.79%
Forest	216.1%	7.12	79.14%	16.59%	37%	6.14%	7.12%	71.07%
Valeant	101.8%	9.70	44.79%	40.59%	29%	10.15%	-4.71%	26.03%
Allergan	49.2%	5.02	85.64%	34.76%	64%	22.25%	15.95%	55.06%
Pfizer	6.7%	3.90	72.90%	45.17%	25%	13.10%	10.39%	40.21%
AstraZeneca	18.7%	2.74	75.06%	34.39%	49%	16.85%	8.26%	51.03%
GSK	12.9%	3.46	69.07%	32.33%	63%	20.37%	25.32%	42.08%

# 2014: The Year of the M&A

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Abbvie	47.9%	4.72	75.77%	38.25%	67%	25.63%	22.45%	42.30%
Actavis	<b>Indicators of present and future growth</b>		45.46%	20.90%	<b>Operational metrics</b>		-5.33%	25.79%
Forest			79.14%	16.59%			7.12%	71.07%
Valeant	101.8%	9.70	44.79%	40.59%	29%	10.15%	-4.71%	26.03%
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GSK	12.9%	3.46	69.07%	32.33%	63%	20.37%	25.32%	42.08%

# 2014: The year of more layoffs?

	Layoffs 2013	Gross margin	Profit Margin	Sales to assets	Return on Assets	Return on invested capital	GSA to sales
Merck	8,500	63.75%	36.97%	42%	15.53%	6.31%	42.63%
AstraZeneca	5,050	75.06%	34.39%	49%	16.85%	8.26%	51.03%
Teva	5,000	52.71%	27.45%	41%	11.25%	3.77%	33.21%
Valeant	2,700	44.79%	40.59%	29%	10.15%	-4.71%	26.03%
Novartis	1,025	63.05%	25.11%	48%	14.06%	11.19%	43.89%
Eli Lilly	1,000	78.76%	30.26%	66%	19.97%	22.25%	54.76%
Sanofi	840	57.59%	29.09%	34%	9.89%	5.49%	40.37%
Endo	700	60.28%	35.49%	40%	14.20%	-14.78%	34.56%



# *The industrial pharmacist of the future*

## **Seven Skill Sets Necessary to Operate in the Pharmaceutical Industry of the Future**

- 1) Ability to Manage Decentralized Intellectual Capital Resources
- 2) Ability to Work in Joint Ventures and Across Divisions, Cultures and Countries
- 3) Ability to Integrate an Understanding of Intellectual Property Laws, Scientific Expertise and Business Strategy
- 4) Ability to Spur Creativity While Managing Commercially
- 5) Knowledge and Insight on the Decision-Making Dynamics of Payers
- 6) Expertise in the Functioning and Decision-Making of Regulatory Agencies
- 7) Human Resource Skills to Help Transform Pharmaceutical Companies

***Rework***

***Renaissance***

***Ragnarök***





# *European Industrial Pharmacists Group*

