

# Patents & Health

**Dr. Brian W Tempest**

**[www.briantempest.com](http://www.briantempest.com)**

**Seminar on the Relationship between Patent Systems and the Availability of  
Medicines in Developing Countries and Least Developed Countries**

**World Intellectual Property Organisation (WIPO), Geneva, Switzerland**

**2 December 2015**

**Hale & Tempest**

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Dr Brian Tempest advises Companies, Banks, High Net Worth Individuals and Mutual Funds on their Strategy in the Emerging World based on his wide experience in China, Japan and India. Brian is the Editor of the Journal of Generic Medicines and represents the global generic industry as a Non Executive Director on the United Nations Patent Pool. Previously he worked for Ranbaxy Laboratories since 1995 holding the position of Managing Director and Chief Executive Officer until 2005. He was then Chief Mentor and Non Executive Director until 2008 when he retired. He is one of the few westerners to have led a Sensex Nifty 50 Indian blue Chip MNC and as a result has a valuable insight into India. Brian has also worked for Glaxo as Regional Director Far East and Regional Director Middle East & Africa from 1985 to 1992.

Brian has worked in the Pharmaceutical Industry for the last 44 years and has managed Healthcare businesses in North America, South America, Europe, Africa, Middle East, Australasia, China, Japan and India. He has also led many Investor Meetings held around the world from Tokyo to Las Vegas. He is now a Non Executive Director of Religare Capital Markets, Fortis Healthcare, SRL Diagnostics and Glenmark Pharmaceuticals. He is a member of the SCRIP Global awards panel. Brian speaks at global conferences and more information on these presentations can be found on his website [www.briantempest.com](http://www.briantempest.com). He is also an international advisor to UNCTAD and MAPE. Brian has a PhD in Polymer Chemistry from Lancaster University in 1971 and in 2009 he became Chairman of the Advisory Board for the Lancaster University Management School, UK. He is a Fellow of the Royal Society of Medicine and a Fellow of the Royal Society of Chemistry and is a Chartered Chemist. He is also Executive Chairman of Hale & Tempest Co Ltd

# Patents & Health

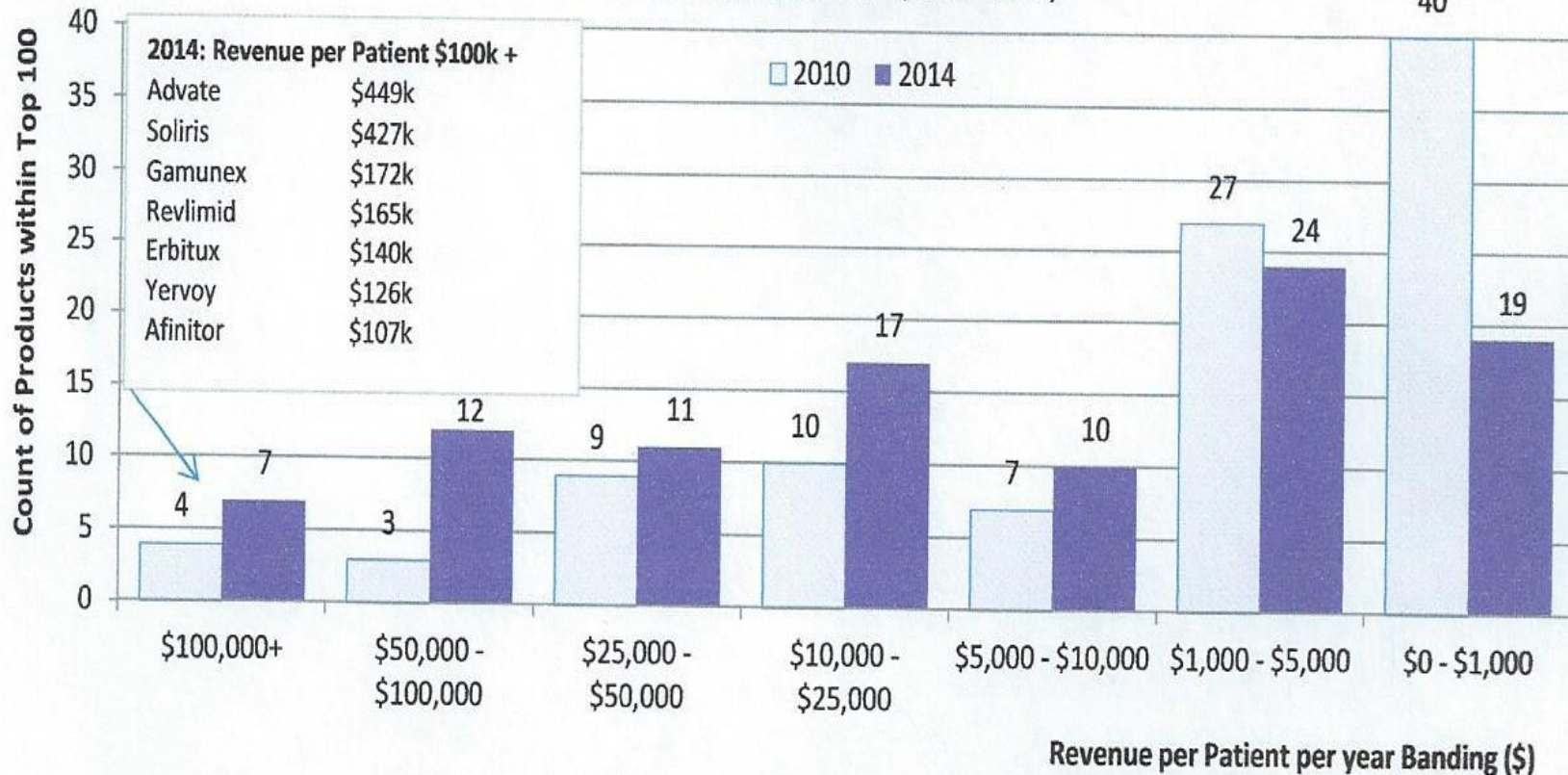
- Does a 20 year patent work in the Health sector?
- Are patented cancer medicines too expensive?
- How will the poor access the expensive patented cancer medicines?
- If only the super wealthy can access the new patented cancer medicines... Does the free market function?... Is there something wrong?

# USA Medicines getting More Expensive

source: Evaluate 2014

Count of Drugs in USA Top 100 by Revenue per Patient per Year Price Band in 2014

Source: EvaluatePharma® (22 SEP 2014)

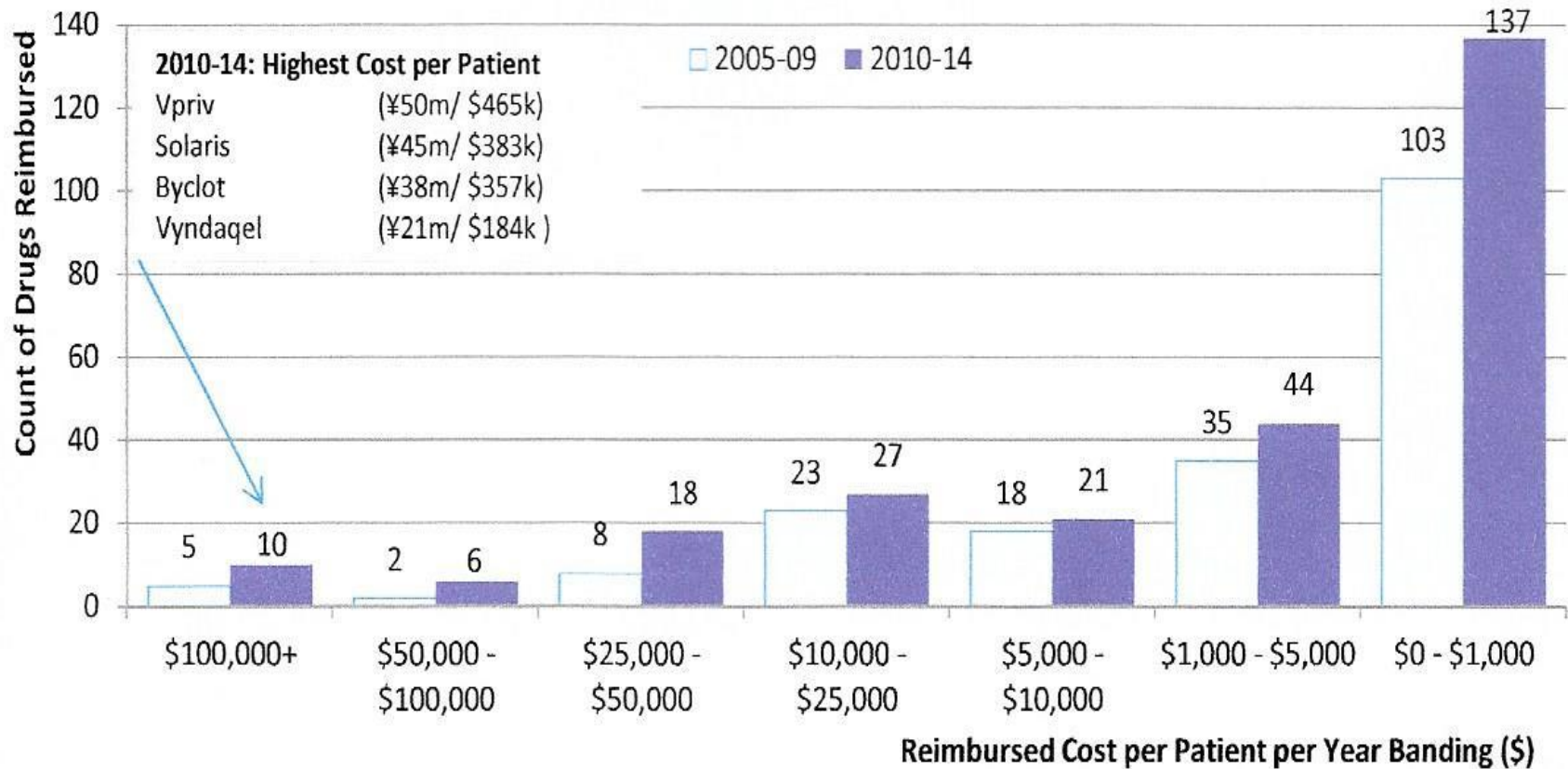


# Japan Drug Price Increases

source: Evaluate 2015

Count of New Drugs in Japan by Cost per Patient per Year Price Band in 2010-14 vs. 2005-09

Source: EvaluatePharma® (9 MAR 2015)



# USA Healthcare Costs

source: [thinkprogress.org/health/](http://thinkprogress.org/health/)

HEALTH

## Americans Who Battle Cancer Are Twice As Likely To Go Bankrupt, Even If They Have Health Insurance

BY [TARA CULP-RESSLER](#)  MAY 16, 2013 3:05PM

# Monoclonal Antibodies Complexity

source: Roche 2014



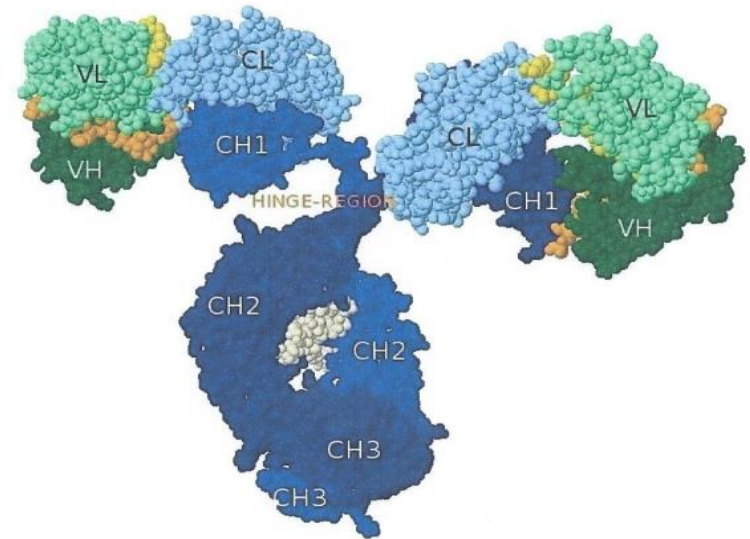
## *atorvastatin*

Molecular weight  
= 558 Daltons  
0 amino acids



## *Interferon-alpha*

Molecular weight  
= 19,625 Daltons  
~165 amino acids



## *Antibody (IgG)*

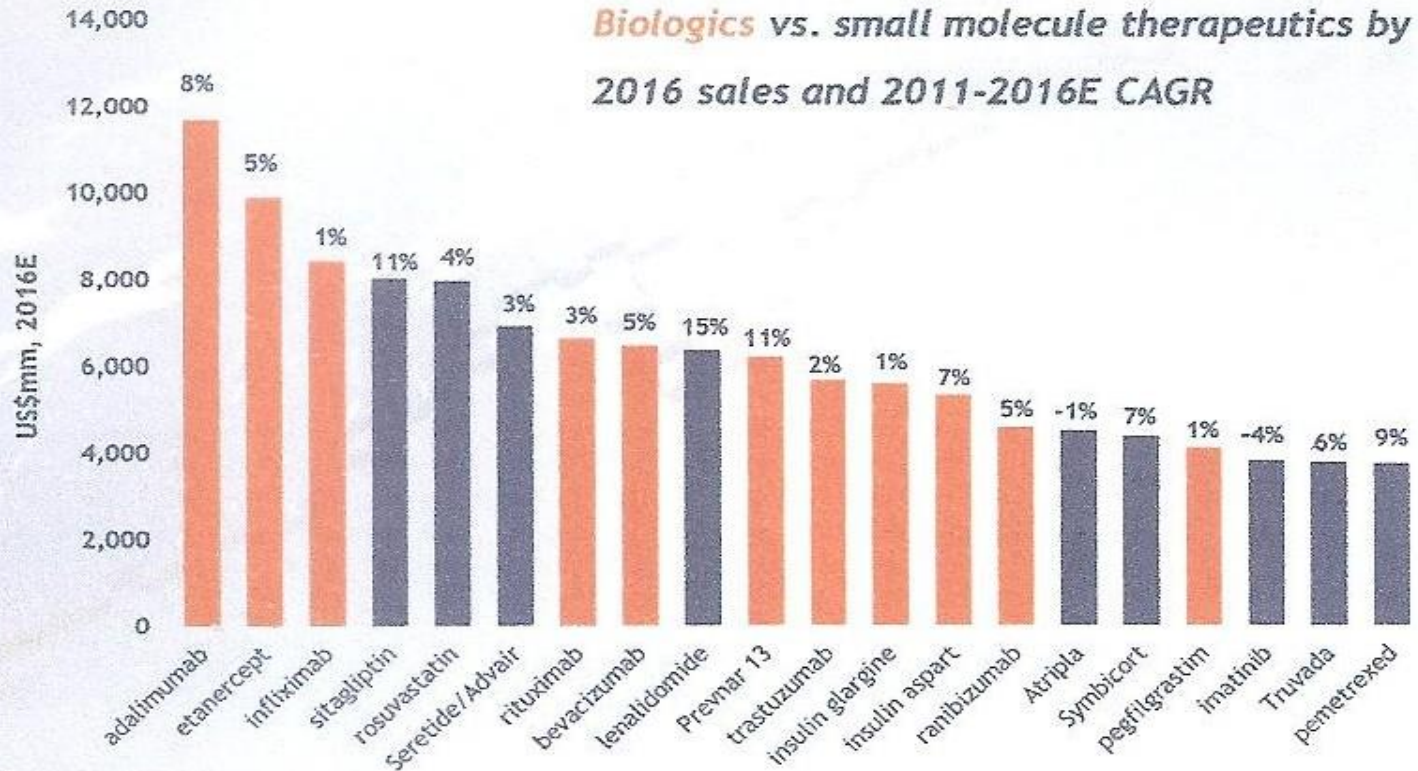
Molecular weight  
= 150,000 Daltons  
~1,300 amino acids

Source: <http://www.path.cam.ac.uk/~mrc7/mikeimages.html>

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# In 2016, Biologics will be Half the Top 20

Source: Cowen

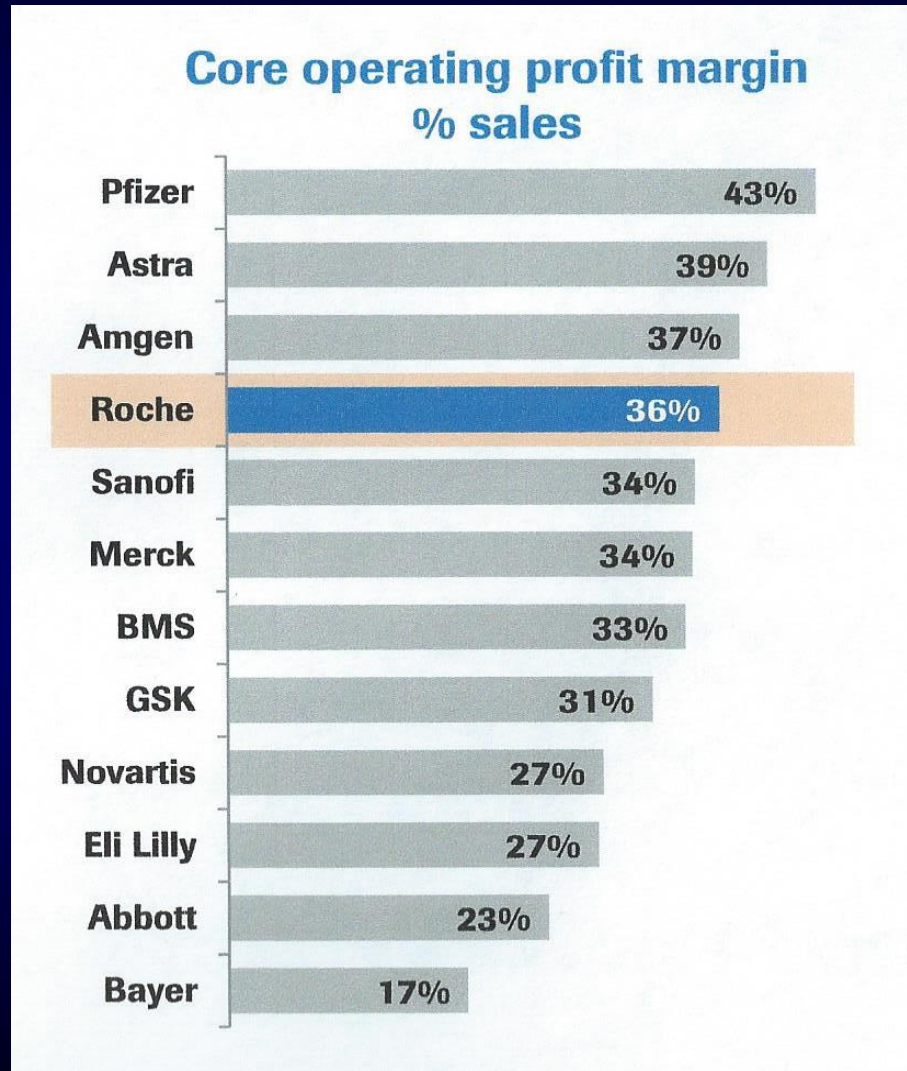


source: Cowen & Co/Thomson Pharma estimates



# Big Pharma Profit Margins from Biologics

source: Fiscal Year 2011 Roche 2014



# 40% Brazil Hospital Contract Sales 2014

source: Evaluate August 2015

## Key Products: Ranked on 2014 government Contract Sales

| Product      | R\$ million | US\$ million |
|--------------|-------------|--------------|
| 1. Humira    | \$603.60    | \$257.12     |
| 2. Enbrel    | \$322.05    | \$137.17     |
| 3. Herceptin | \$243.21    | \$102.07     |
| 4. Soliris   | \$211.85    | \$90.25      |
| 5. Remicade  | \$179.50    | \$76.38      |

Top 5 Products in 2014 account for 40% of total government contract sales.

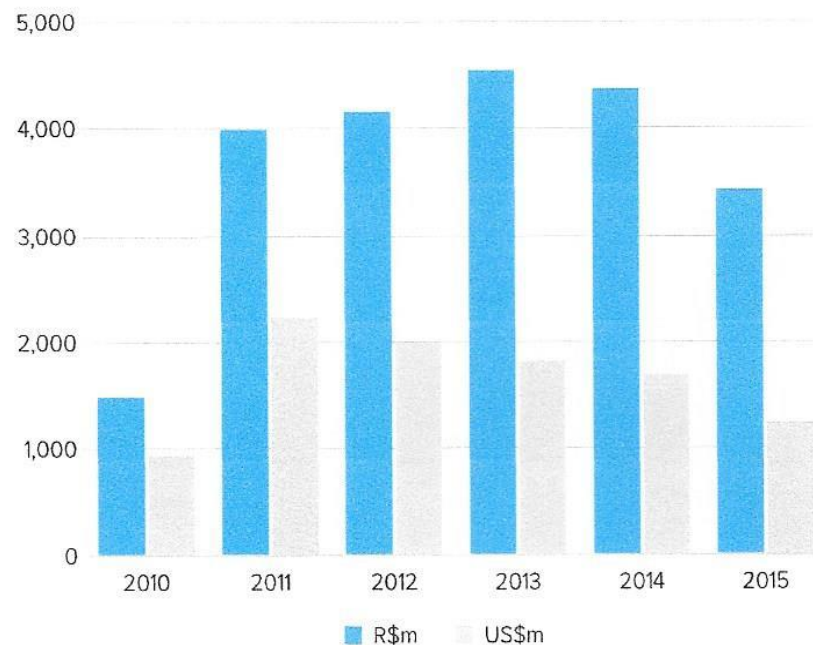
Soliris not approved in Brazil, but eligible for import due to therapeutic benefit over current alternatives.

Government contract sales prices are often lower than the reimbursement prices which operate as a price guide.

Government sales contracts cover predominantly hospital and specialty channel sales.

## Total Government Contract Sales by Year (R\$ m/ US\$ m): 2010-15

Aggregated total contract sales in two currencies indicating domestic market growth and declining trend of the Brazilian currency against the US dollar.

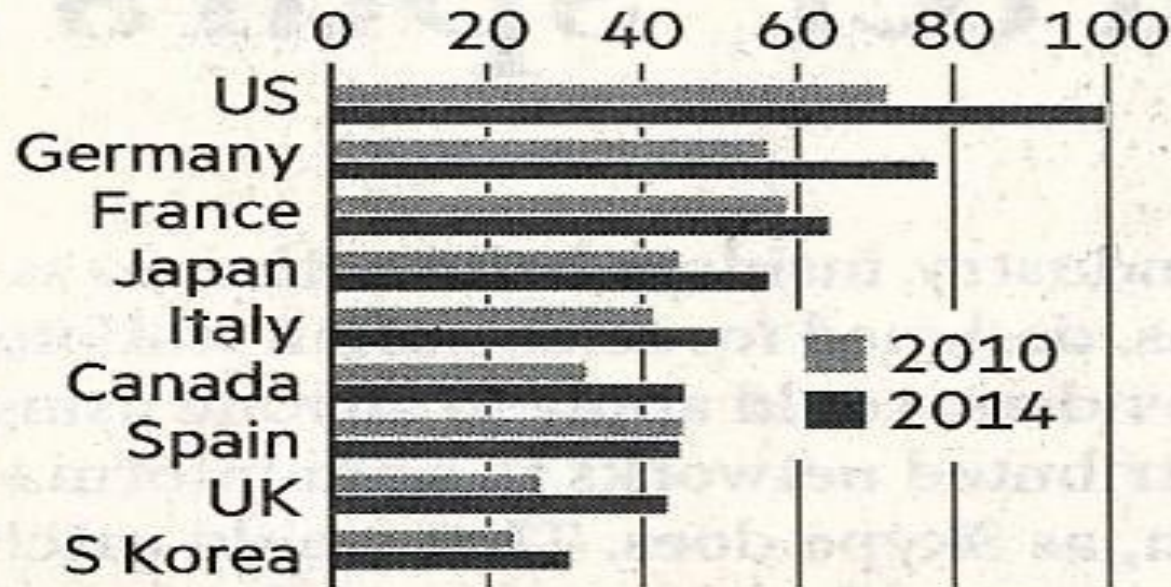


# Rising Cancer Drug Spending

source: FT 3 June 2015

## Cancer drug spending per head

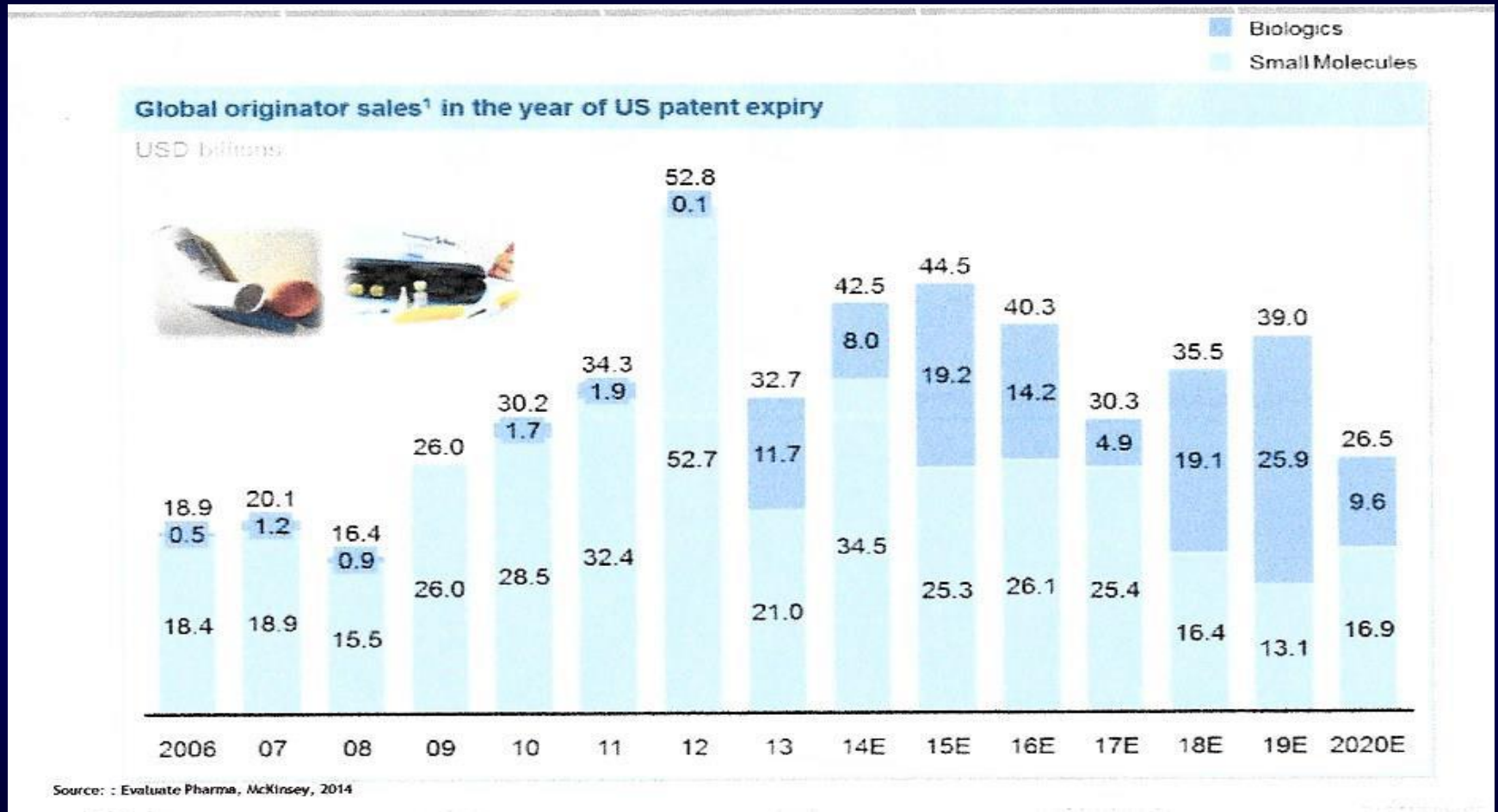
Therapeutic oncology drug spend per capita (\$)



Source: IMS Institute for Healthcare Informatics

# By 2020, Patent Expiries 40% Biologics

source: Evaluate 2014, EGA June 2015



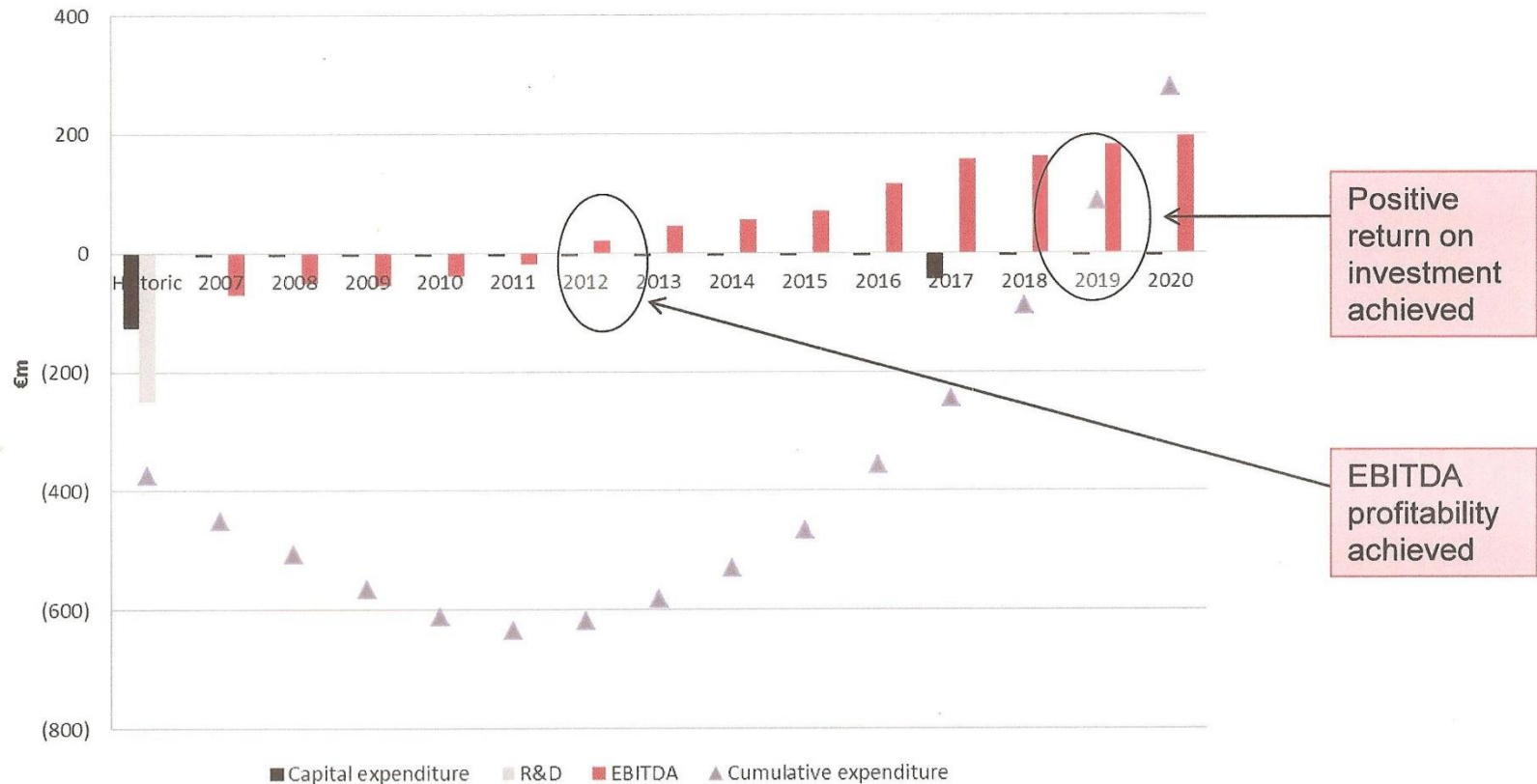
# Eight Hurdles with Biosimilars

source: Brian Tempest Research September 2015

- **Cost of manufacturing facility**
- **Cost of clinical trials including innovator costs**
- **Cost of sales reps to encourage doctor usage**
- **Strong interface between patent company and patients**
- **Doctor anxiety on changing therapy for very ill patients**
- **Multiple competitors in biosimilars**
- **Pharmacy interchangeability, except Australia**
- **Break even on investment**

# Sandoz Business Model by an Analyst

source: Pharmacloud June 2012

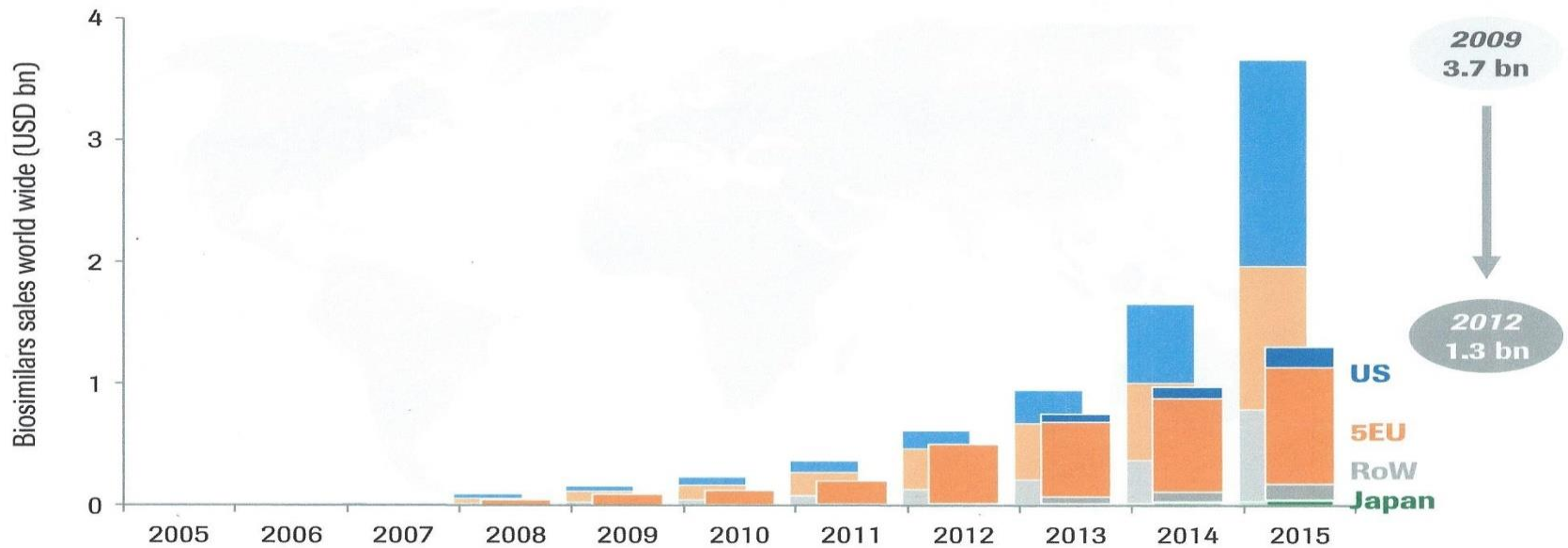


Source: Pharmacloud

# Biosimilar Global Sales vs Forecast

source: Roche 2014

## Market uptake barriers are likely to limit biosimilars sales potential



Source: Data Monitor for 2009 estimate

54

# Sanofi R&D - 72% Biologics & 50% mAbs

source: Pharma Times 15 January 2015

PharmaTimes  
DIGITAL

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## Sanofi and BI ink biologics manufacturing deal

WORLD NEWS | JANUARY 15, 2015 Tweet 13 8+1 0

[KEVIN GROGAN](#)

Sanofi has signed up Boehringer Ingelheim as its partner to manufacture monoclonal antibodies.

Under the terms of the agreement, the French drugmaker will have access to Boehringer's capabilities in Biberach, Germany to transfer and manufacture therapeutic mAbs. Initial product transfers will begin in early 2015.



Sanofi says that the rationale behind the deal, the financial terms for which were not disclosed, is to reinforce its manufacturing capacity "to support upcoming product launches". Some 72% of its R&D projects are in biologics, nearly half of which are mAbs.

Wolfram Carius, head of biologics at Sanofi, said Boehringer is "a highly capable and experienced partner to complement our continued alliance with Regeneron and the investments we are making in building our own internal capabilities".

**Links** Tweet 13 8+1 0

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**Tags**

[biologics](#) | [Boehringer Ingelheim](#) | [Sanofi](#) | [manufacturing](#)

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# USA FDA NME Approvals Doubling

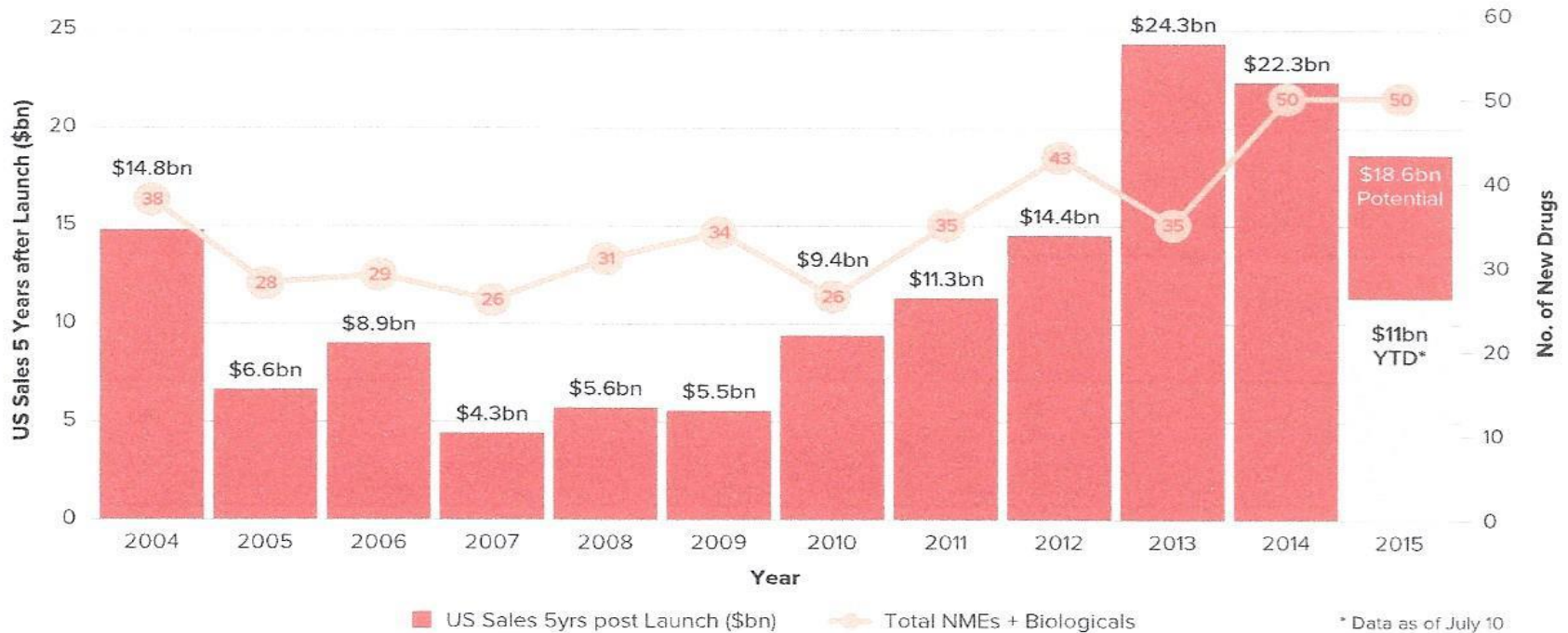
source: Evaluate July 2015

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

Source: EvaluatePharma<sup>®</sup> July 2015

2004 – Avastin (Roche), Cymbalta (LLY), Spiriva (BI/ PFE), Lyrica (PFE)  
 2010 – Prevnar 13 (PFE), Victoza (Novo N), Prolia/Xgeva (AMGN)  
 2011 – Xarelto (J&J/BAY), Eylea (REGN/BAY)  
 2012 – Eliquis (BMS/PFE), Stribild (GILD)

2013 – Sovaldi (GILD), Tecfidera (BIIB)  
 2014 – Opdivo (BMY), Harvoni (GILD)  
 2015 – Orkambi (VRTX), Ibrance (PFZ)



# Bayer Comments

source: February 2 2014 Bayer

FEBRUARY

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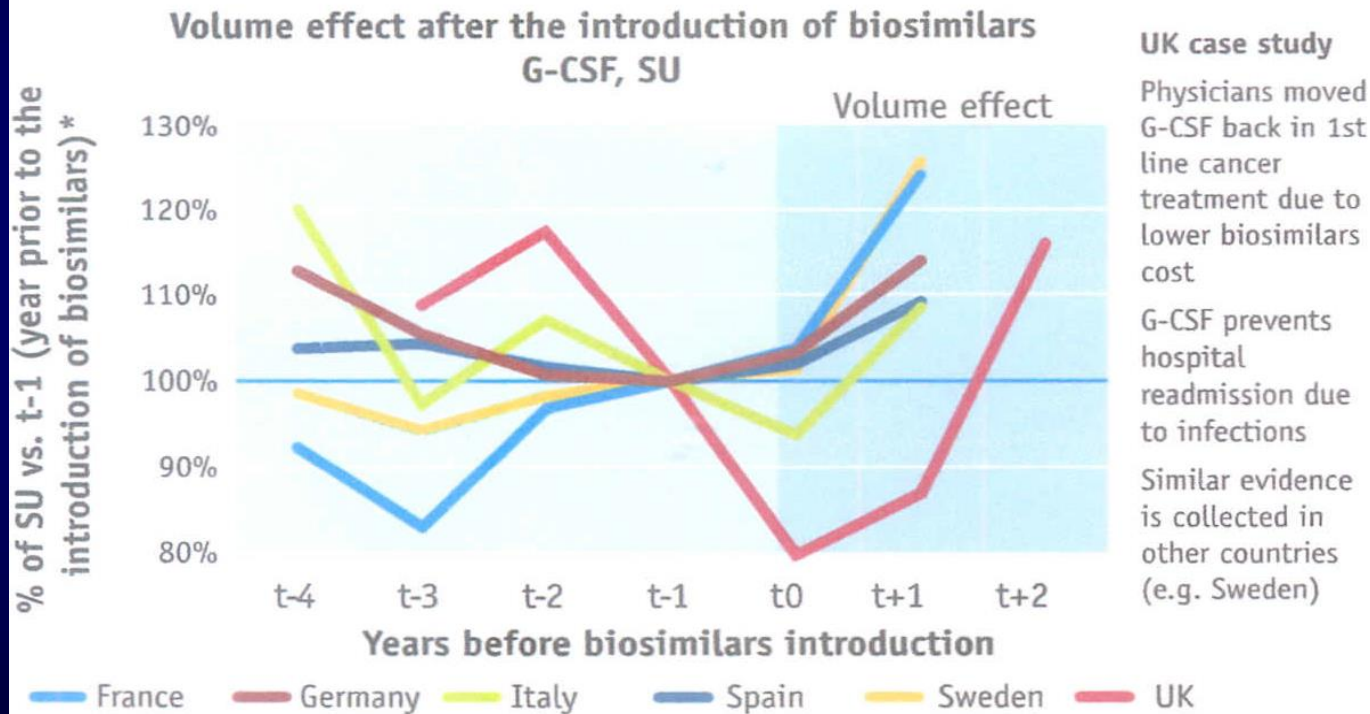
## BAYER CEO: 'WE DON'T MAKE MEDICINE FOR POOR INDIANS'

POSTED BY N. BROWN ON FEBRUARY 2, 2014 IN AFRICA, ASIA, ECONOMICS, HISTORY, IMPERIALISM, INDIA, LATIN AMERICA, NEWS AND ANALYSIS, SCIENCE AND TECHNOLOGY, THEORY, US/CANADA, WWII | 14 COMMENTS

# Access in EU Improving from Biosimilars

source: IMS December 2011

FIGURE 6: AS SHOWN BY G-CSF, THE INTRODUCTION OF BIOSIMILARS CAN GENERATE A SPILL-OVER EFFECT ON OFF-PATENT BIOLOGIC MOLECULES  
Opportunity for biosimilars players only or also for innovators?



Source: IMS MIDAS, MAT Q4 2010, NHS. \*t-1 =100%, t0 = year of biosimilars introduction

Source: IMS Health

# Global Biosimilars

source: brian tempest research 1 September 2015

- Celltrion from South Korea with 2 brands/huge capacity
- Samsung Biopsis from South Korea with 2 brands
- Novartis/Sandoz
- Pfizer
- Amgen/Actavis/Allergan
- Innovator with authorised generic
- **now 10<sup>th</sup> brand and beyond**
- India - DRL, Intas, Zydus, Hetero, Cipla, Emcure, Biocon
- Europe – Polpharma, Biocad, E Merck
- USA - Epirus, Harvest Moon
- Latam – Bionovis,
- China – FosunPharma, Gen Sci etc
- Asia – Incepta Biotech, Kalbe, Hanwha Chemical

# Pfizer Biosimilars

source: Pfizer presentation January 2015

## Delivering Novel & Differentiated Future Potential Products

Large, High Quality R&D Pipeline with Mix of NMEs and New Indications



### Oncology

lbrance<sup>™</sup>  
(palbociclib)  
notuzumab  
B-cell Leukemia  
PD-L1\*/PD-1  
4-1BB,OX40  
EGFR NSCLC  
Daco, PFE-X775  
ALK/ROS 2<sup>nd</sup>  
Gen-NSCLC  
SMO Hematol  
GSI TNBC  
BiFx Ab, ADC



### CVMed

bococizumab  
(PCSK9) –  
Hyperlipidemia  
Type 2 Diabetes -  
SGLT2  
Diabetic  
Nephropathy –  
PDE5, CCR2/5,  
AMPK B1



### Vaccines

Prevenar<sup>®</sup> 13  
Adult-CAPiTA  
Expanded  
serotype  
pneumococcal  
*Staphylococcus  
aureus*  
*Clostridium  
difficile*  
Therapeutic  
vaccines  
Active cancer  
immunotherapy  
Neonatal  
infections  
(CMV,RSV,GBS)



### Inflammation

Xeljanz<sup>®</sup> LCM  
Oral Psoriasis  
Pso Arthritis  
Ulc Colitis  
Crohn's  
Topical  
(AD & PSO)  
Ankyl Spondyl  
MAdCAM UC,  
Crohn's, Other  
Nextgen iJAK  
multiple areas



### Neuroscience & Pain

Neuro –  
Dopamine  
Modulation,  
PDE10i HD  
GDNF Precision  
delivery  
γ-Secretase  
modulator AD  
Pain –  
tanezumab,  
GABA<sub>A</sub> PAM



### Rare Disease

rivipansel VOC  
SCD  
LAGH\*\*\*  
Myostatin DMD  
Hemophillia –  
F7, Gene Tx F9\*\*



### Biosimilars

trastuzumab  
infliximab  
rituximab  
bevacizumab  
adalimumab



#### Recent Business Development

\*avelumab - Merck KGaA Darmstadt, Germany Biopharmaceutical Division

\*\* Spark Therapeutics, Inc.

\*\*\*OPKO Health, Inc. (Awaiting Regulatory Clearance)

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# New Japanese Biosimilar Company

source: Fujifilm

## Developing New Drugs For Better Lives



**Fujifilm is using its cutting-edge research to open up new horizons in medicine.**

Fujifilm is researching innovative drugs that have the potential to improve lives of patients suffering from Alzheimer's disease, cancer and other conditions.

Fujifilm is developing a candidate drugs for Alzheimer's disease, thanks to research in collaboration with the Center for iPS Cell Research and Application(CiRA) at Kyoto University in Japan. These efforts have been made possible through the integration of Fujifilm Group's medical technology with proprietary technology developed over the years in its imaging technology field.

Fujifilm's goal is to create new hope for people through medical research.

*80<sup>th</sup>*  
Anniversary

# FUJIFILM

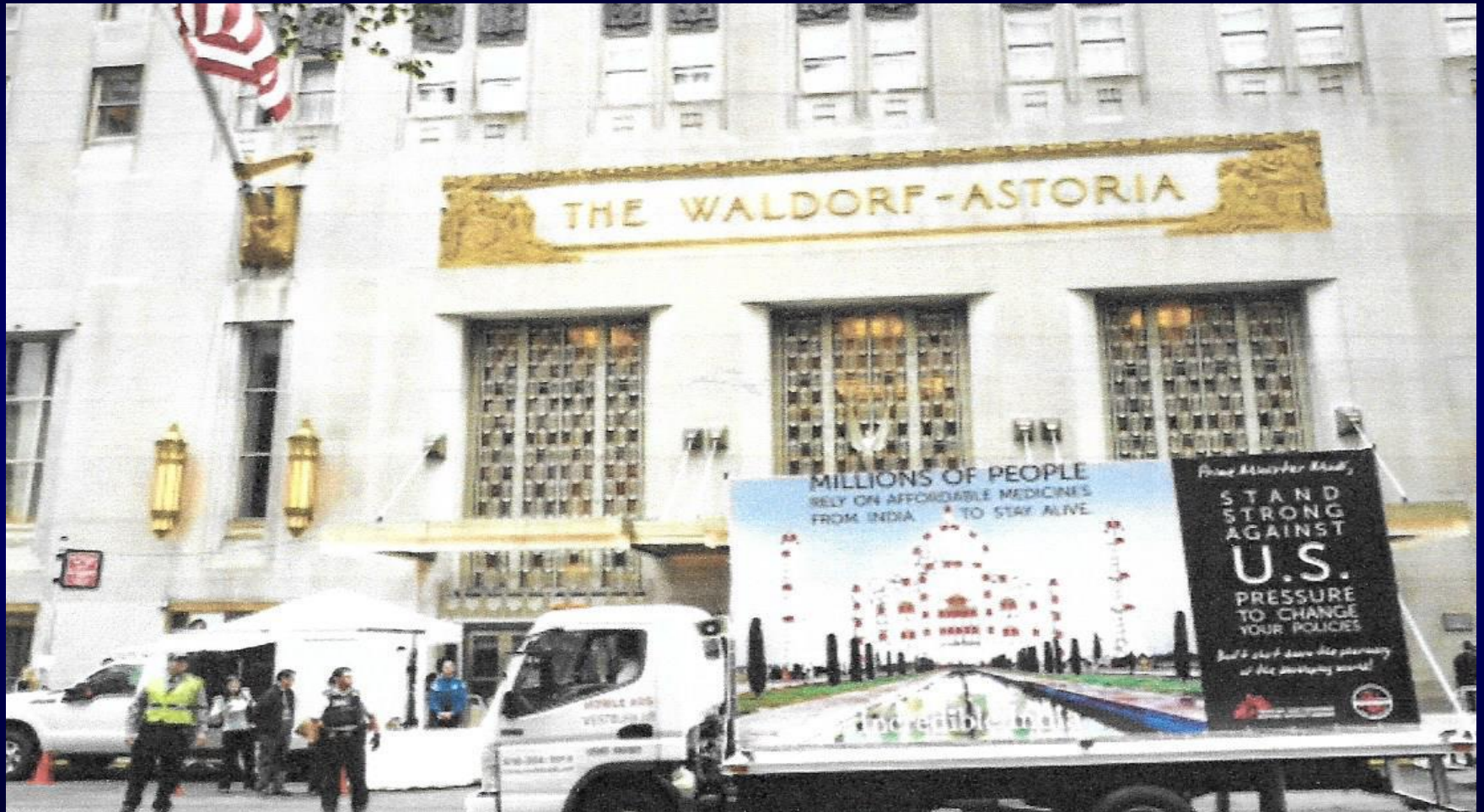
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# Modi In New York

source: October 2015



# Modi & Patents

source: HT 27 September 2015

## Modi promises to protect patents

Says India committed to protecting IPR, bringing creativity; CEOs express enthusiasm

40% of the world's entertainment industry.

They included News Corp's Rupert Murdoch, his son James Murdoch and top executives of ABC, Comcast, Time Warner, Discovery, Sony, ESPN and Disney.

In tweets about the meeting, Modi said he told them, "Digital technology has a vital role in making democracy stronger & in overall human resource development.

And, he "explained to media CEOs why India is a great opportunity for them & how many regional languages makes India even more special to invest in."

The CEOs seemed "enthusiastic", he added.

Many of the media companies present in the room are already in India, with others looking for a chance to get in — to them the Prime Minister said India was a challenge and an opportunity.

IPR is a major concern for some US companies, especially in the pharma sector, who have sought to mount pressure on the Indian government to bring it in line with their commercial interests. However, it's a separate conversation India is having with these firms and their backers in the US, who have appealed for changes.

Government spokesman Vikas Swarup said the Prime Minister urged media barons to think of starting a communications university or a chair for further progress in this sector.

Modi met Wall Street leaders such as J P Morgan's Jamie Dimon, KKR's Henry Kravis, who told him his government was on the right track. He heard pretty much the same later at a dinner he hosted for 42 CEOs of Fortune 500 companies, with an appeal to speed up the pace of change.



■ Prime Minister Narendra Modi poses for a group photo with CEOs of US companies in New York on Thursday

Companies pledge over ₹90,000 crore for electronics manufacturing

M Rajendran  
m.rajendran@hindustantimes.com

NEW DELHI: Electronics is perhaps the biggest success story of Prime Minister Narendra Modi's in India campaign, with as investments of over ₹90,000 crore over the next five to 10 years.

A number of global firms announced big investment for India, including iPhone maker Foxconn, which plans to establish 10-12 facilities in the country by 2020 at an estimated investment of \$20 billion. "They have up projects worth \$1-2 billion in August 2015," a liaison officer of the company in Mumbai told PTI.



# Access by the poor of expensive patented medicines

- **Compulsory license eg India, Thailand - single controversial events**
- **Voluntary license from Innovator to Generic Companies eg Gilead**
- **UNITAIDS Patent Pool eg HIV, Hep C, TC – multiple events, 59 generic licenses for HIV medicines in 5 years**
- **Exports from one LDC Country to another LDC country eg Bangladesh, Uganda**

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# Thank You

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