

Biotechnology: *Introduction*

Soon Jae Park, Ph.D.

2010.10. 27.



Biotechnology- *Application*



Biotechnology products

➤ **Recombinant Bio drug**

● **Cytokines, Hormones, etc**

By use of recombinant technology, cytokines, hormones (hGH, EPO, etc) are artificially produced in Bacteria or Animal cells

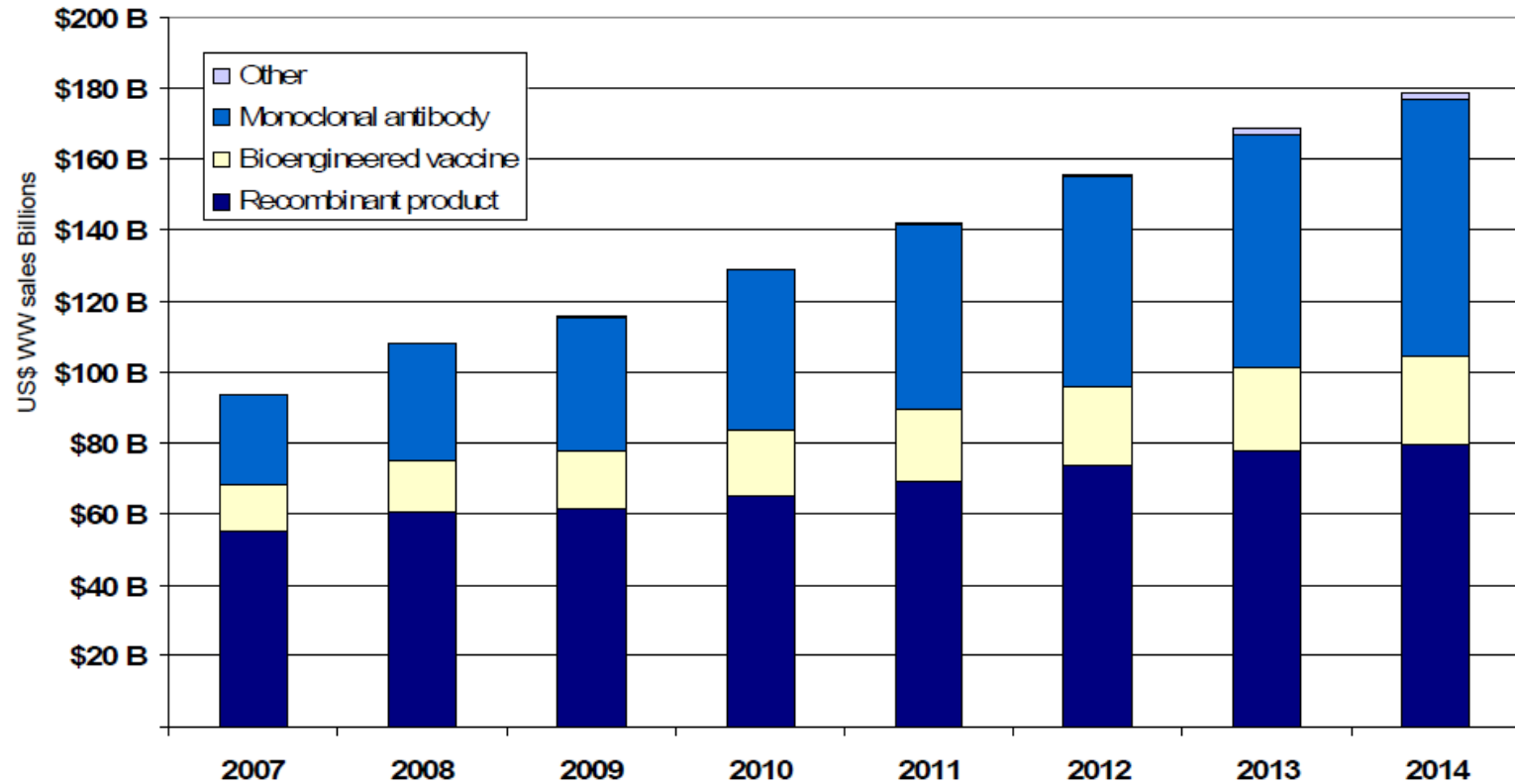
● **Monoclonal Antibody drug**

Man-made antibody is injected to block ligand-receptor interaction

➤ **Vaccine**

Antigen is injected in order to induce immune protection

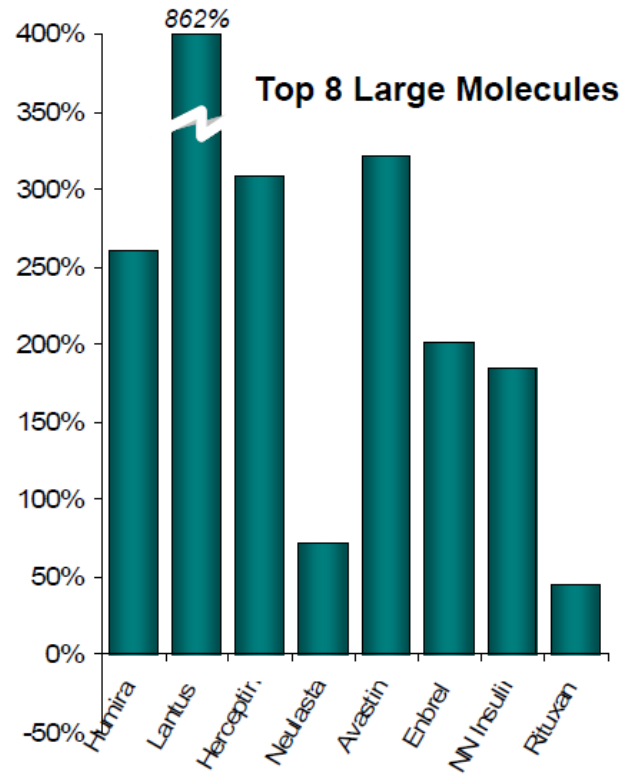
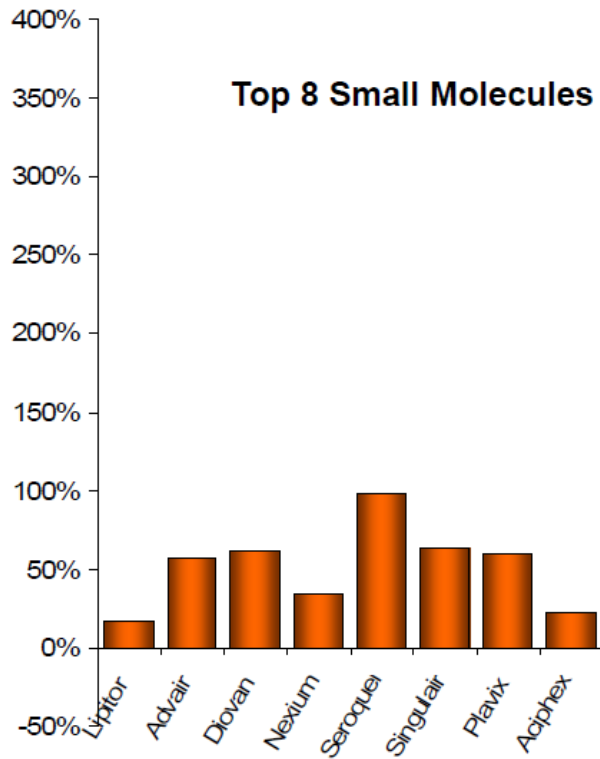
The Market For Biologics... Is Growing And Attractive



**Source: Biologics Insight Briefing | Defined Health | Feb. 2009*

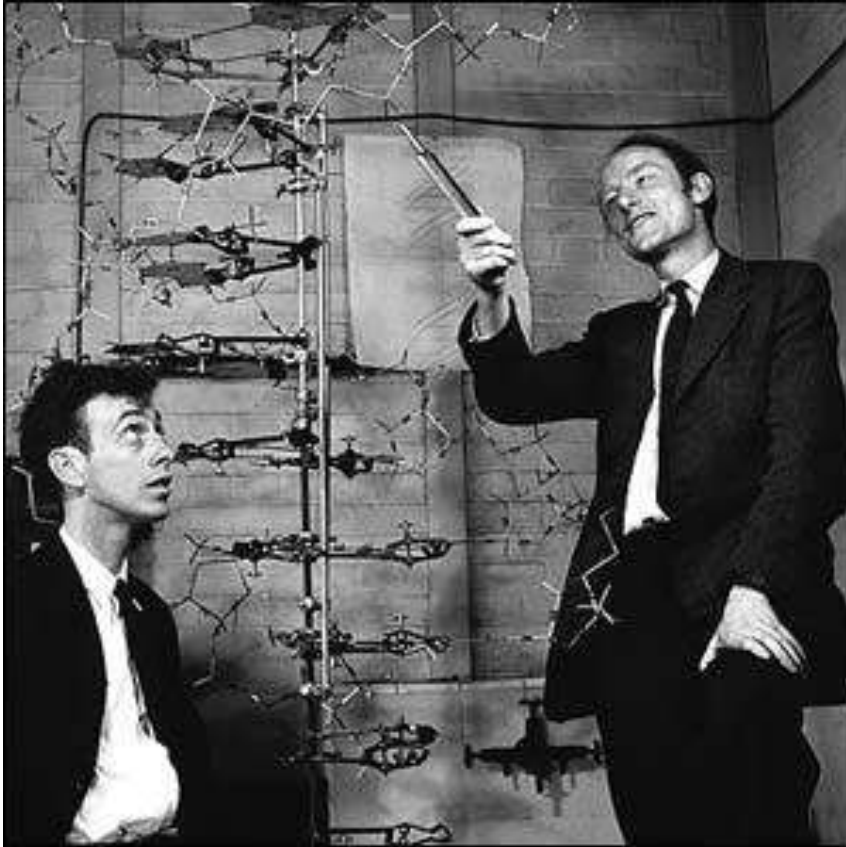
As That Is Where The Exponential Growth Is...

2004-2007 **Growth** of the Top 10 Small and Large Molecules (ranked by 2007 sales)



*Source: *Biologics Insight Briefing | Defined Health | Feb. 2009*

History Of Biotechnology



1953: James Watson & Francis Crick

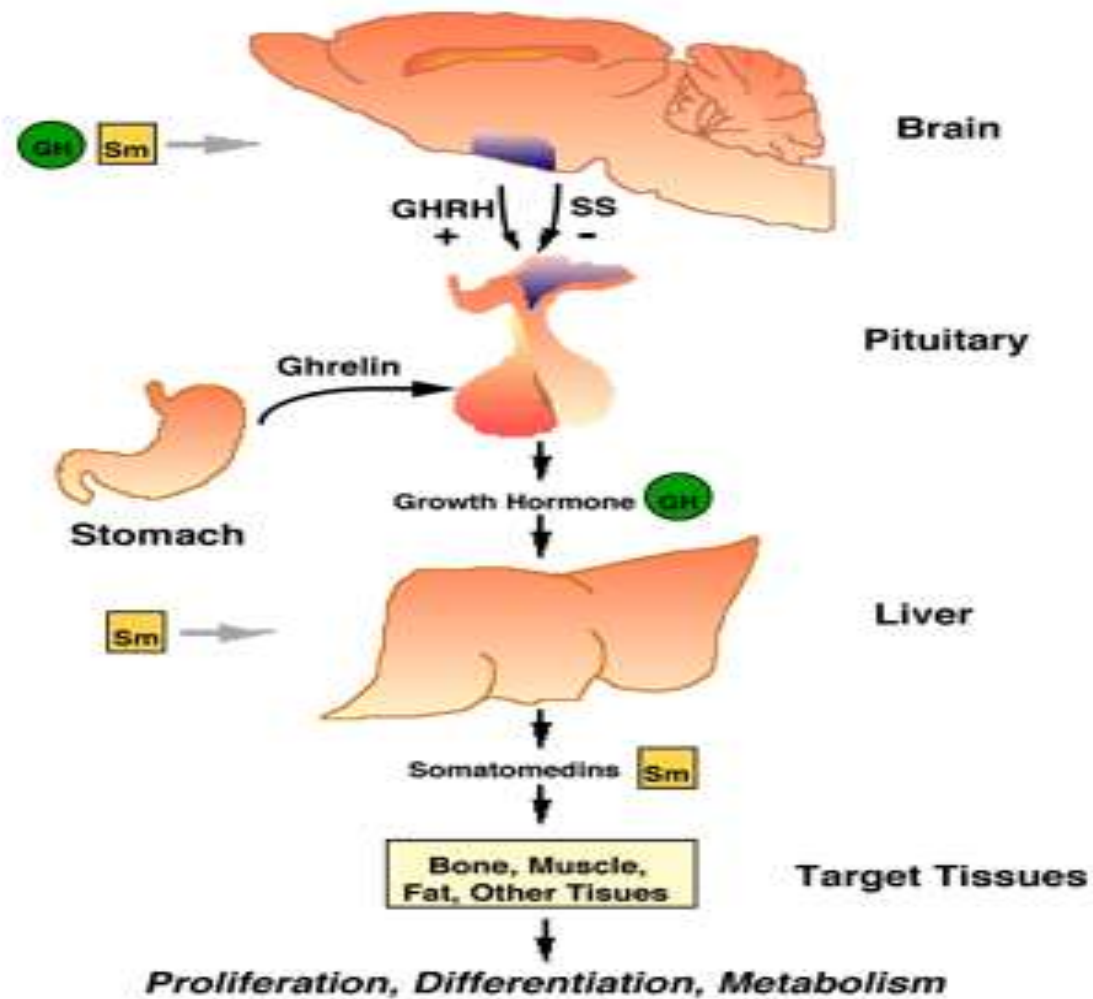


1972: Stanley Cohen & Herbert Boyer

The Creation of Genentech - 1977



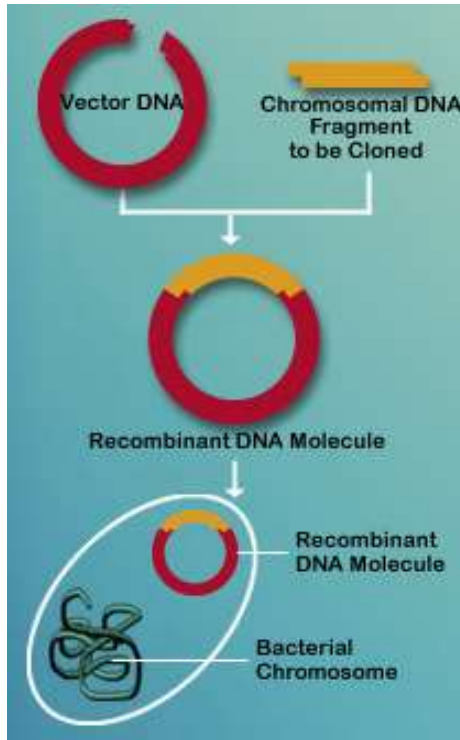
Human Growth Hormone



Two sides of growth hormone



Production of Recombinant Bio drug



(Cloning)

(Fermentation)

(Purification)

(Fill & Finish)

Value Chain of Bio Drug development



- Vector Selection
- MCB
- WCB

- Medium Selection
- Fermentation Optimization

- Purification Determination
- Protein Characterization
- Sugar Characterization
- Formulation
- Fill & finish Technology

- Toxicology
- PK, PD (Small animal Monkey)
- Pharmacology

- Clinical trial ph I, Ph II, ph III

- Regulatory Affairs
- MKT & sales

6 ~ 8 years

Approved Biopharmaceuticals

- Over 140 therapeutic proteins and peptides approved by FDA

- > More than 20 MAb's

- > Only 2 MAb's before 1997

- 20 Top-selling Biopharmaceuticals

- > EPO

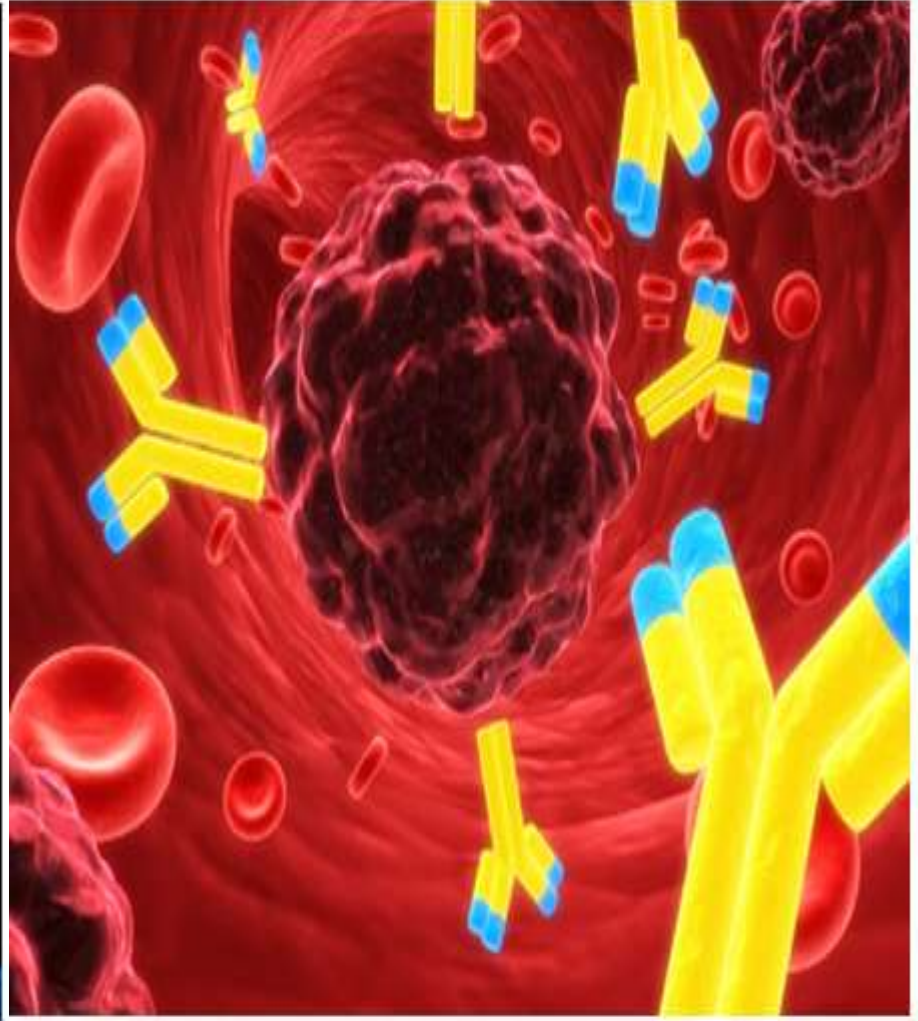
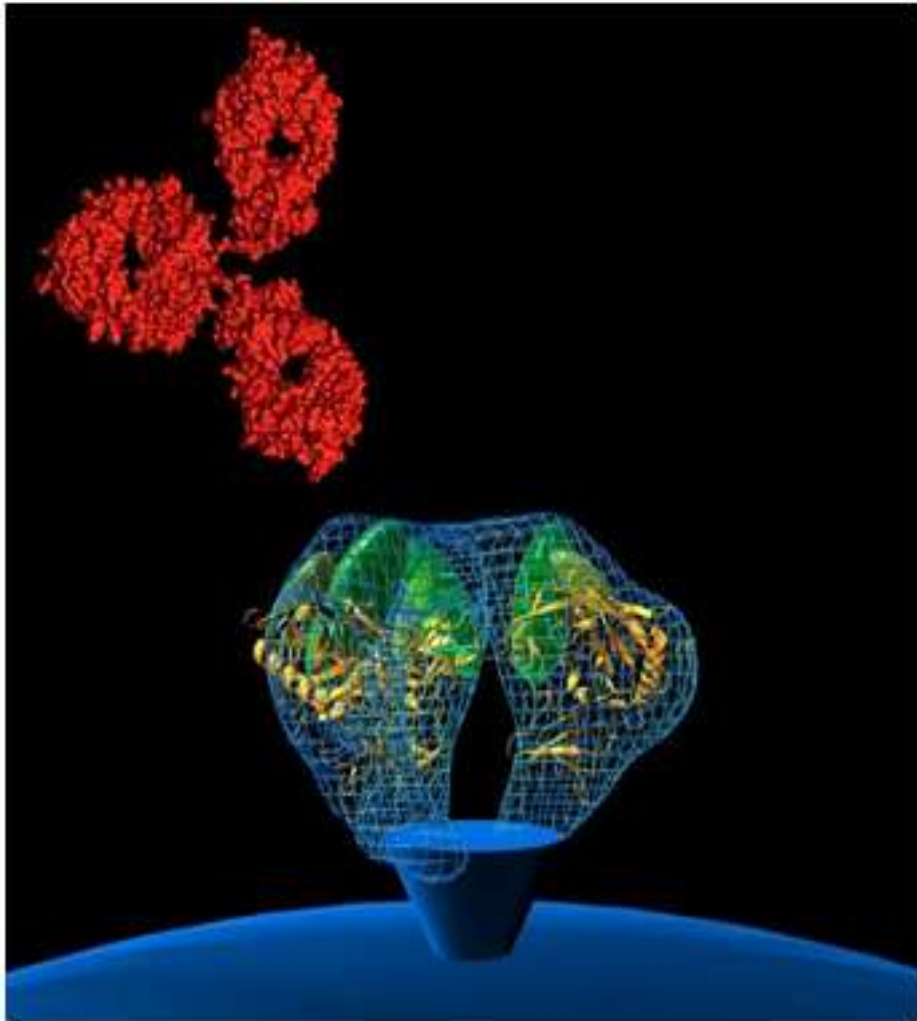
- > Insulin

- > Interferons

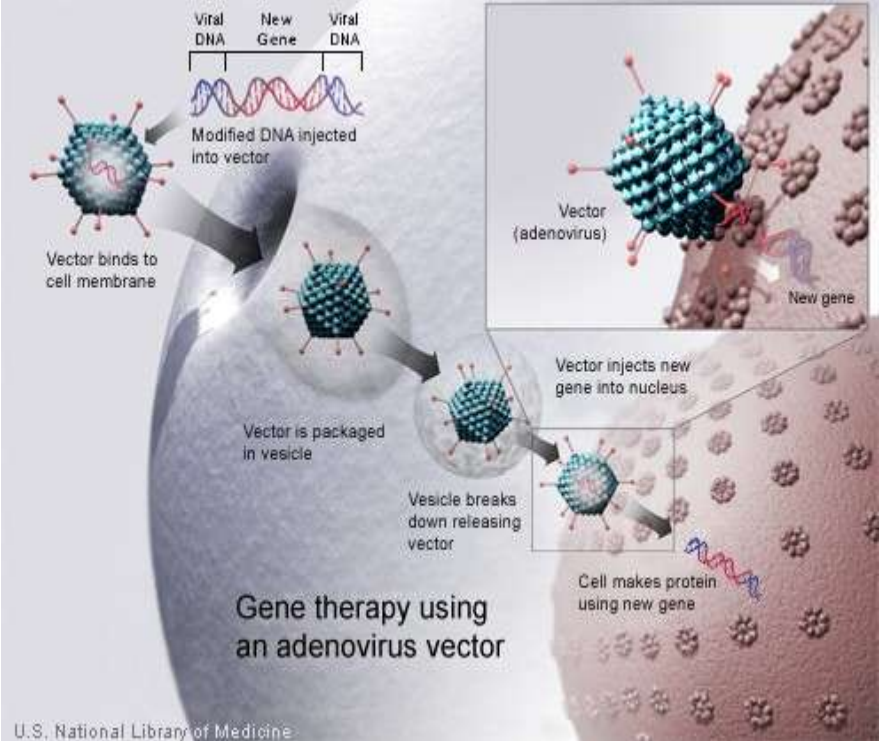
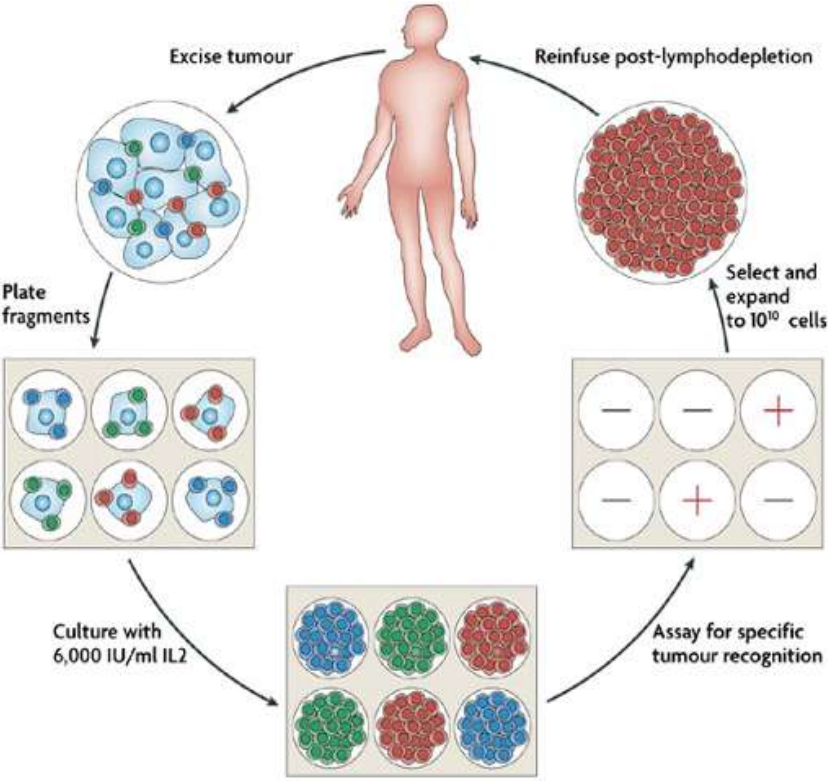
- > TNF blockers

- > 6 MAb's

Monoclonal Antibody / Vaccine

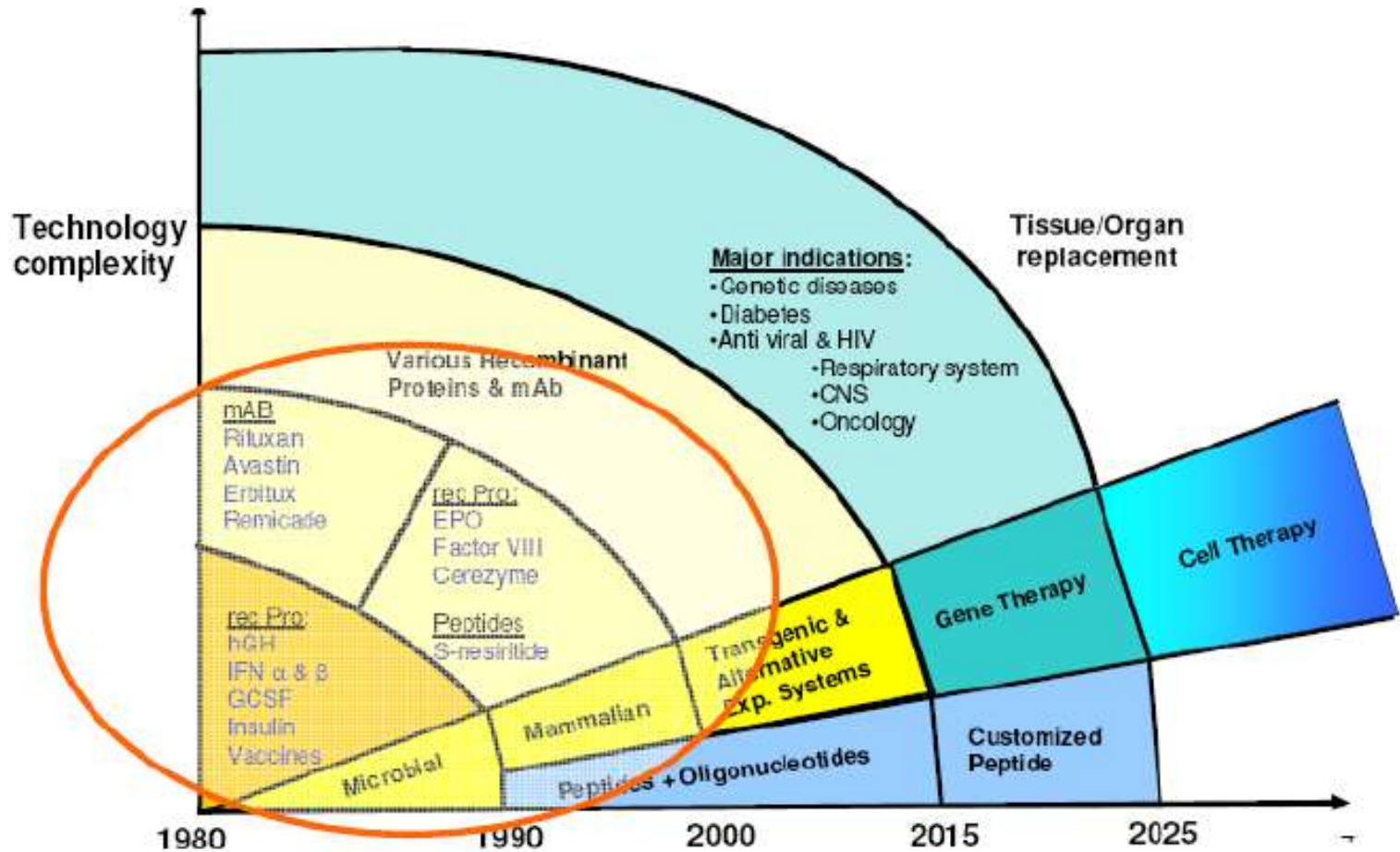


Gene Therapy & Cell Therapy



Nature Reviews | Cancer

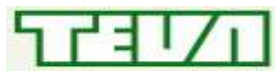
A Trend Towards Biological Pharmaceuticals



Biosimilars (Follow-on Biologics)

are new versions of existing biopharmaceuticals whose patents have expired. They are produced using the same core genetic material and are approved on the basis that they are equal to **the reference product** in terms of both **safety** and **efficacy**.

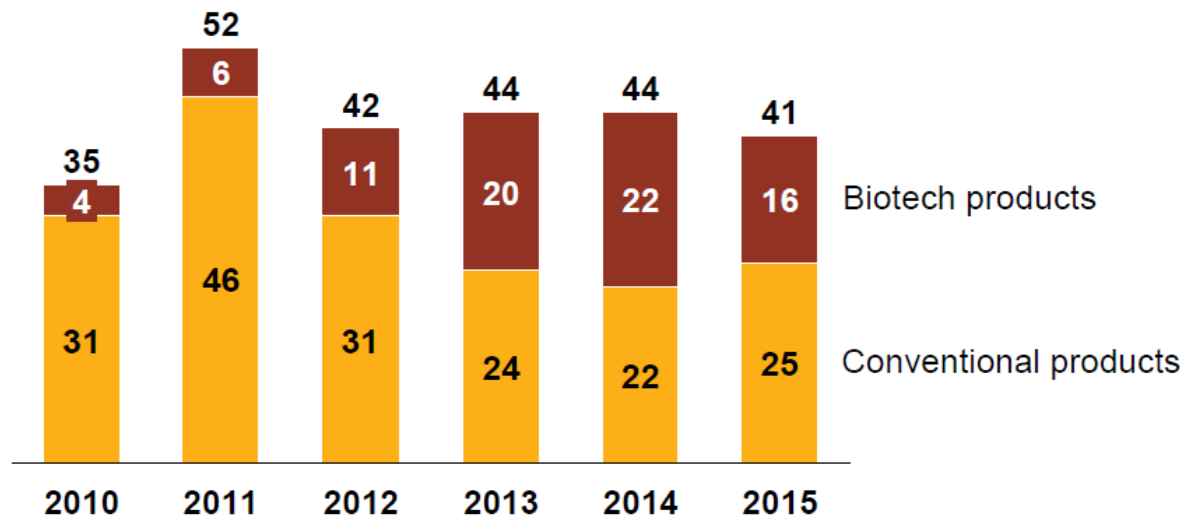
Global Players on Biosimilars



Good News for Biosimilars

Patent expiries will drive growth of biosimilars

Annual sales¹ of expiring products in year of US patent expiry, in USD bn

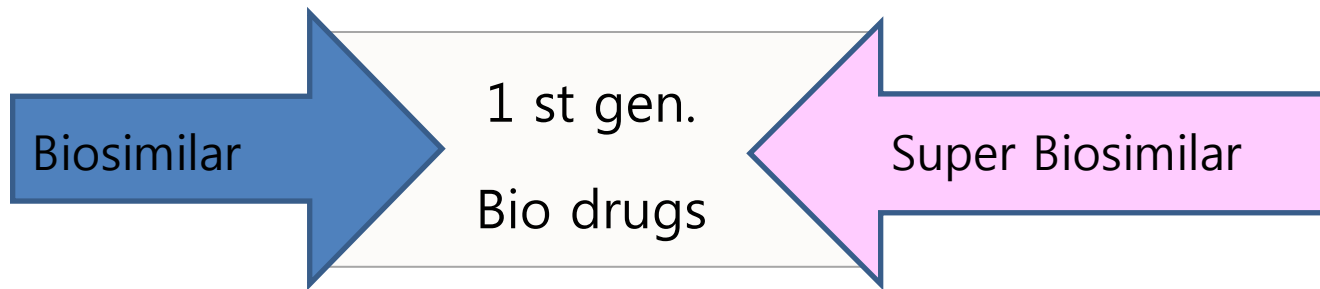


- Among key biotech products losing exclusivity: Recombinant insulins, beta interferons, trastuzumab, rituximab, infliximab and etanercept
- Biotech products approaching 50% of FDA approvals

¹ Source: worldwide sales of expiries based on Evaluate Pharma and internal estimates 2007

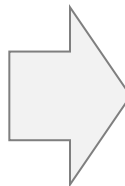
*Source: Sandoz Day | Hannes Teissl | Sep. 2008

Super-Biosimilar (Bio better)



<Long acting technology>

Increased in vivo half life
 Maintaining activity
 Low immunogenicity



Less frequent injection
 Low side effect



\$4.1 B

\$2.7 B

\$1.8 B

\$1.2 B

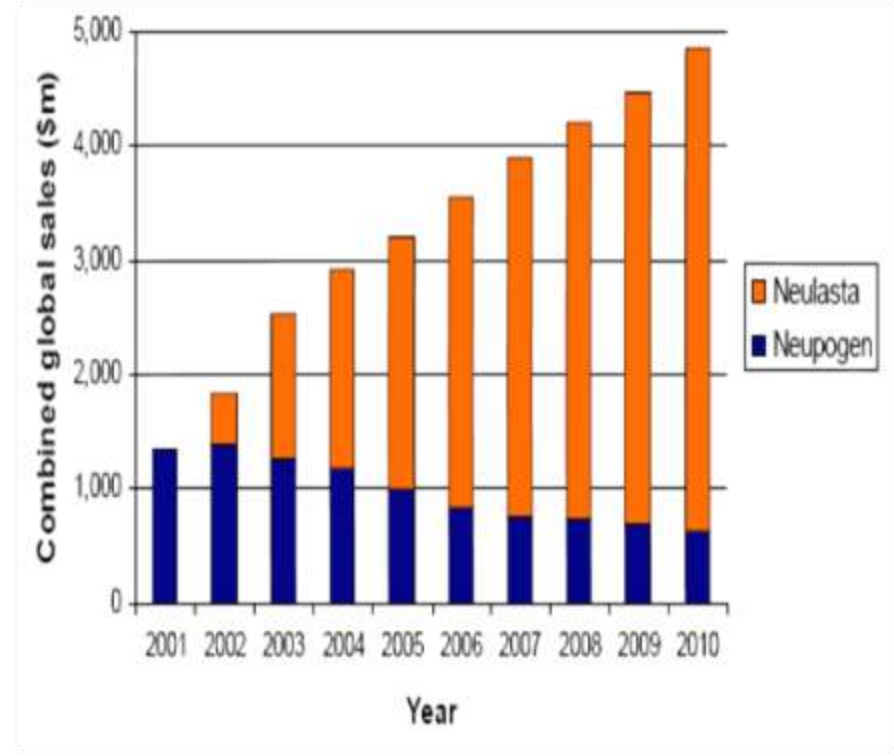
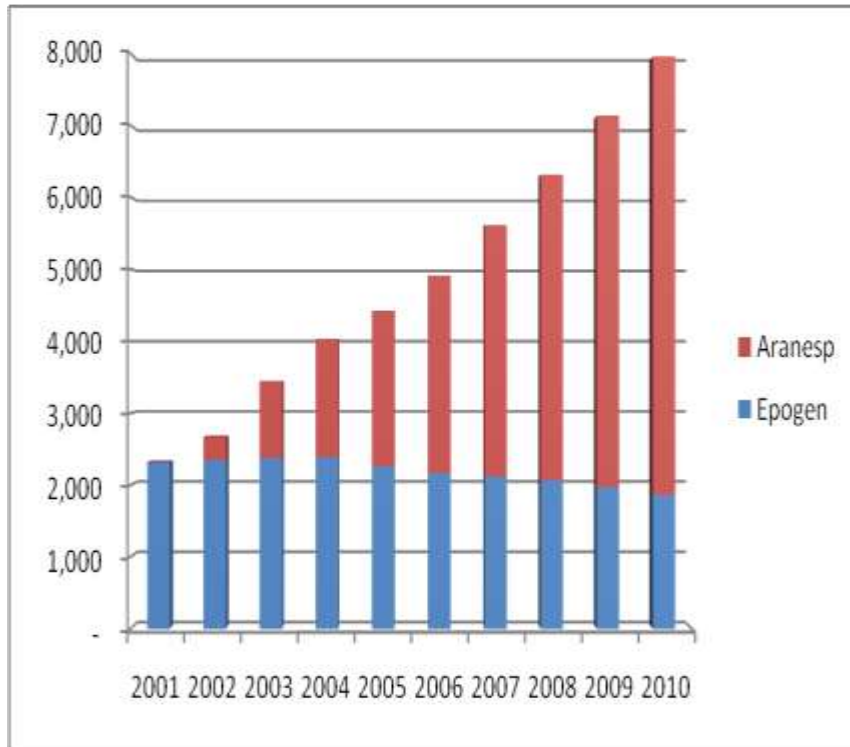
2001

2002

2000

2002

Market is moving toward to Bio-better

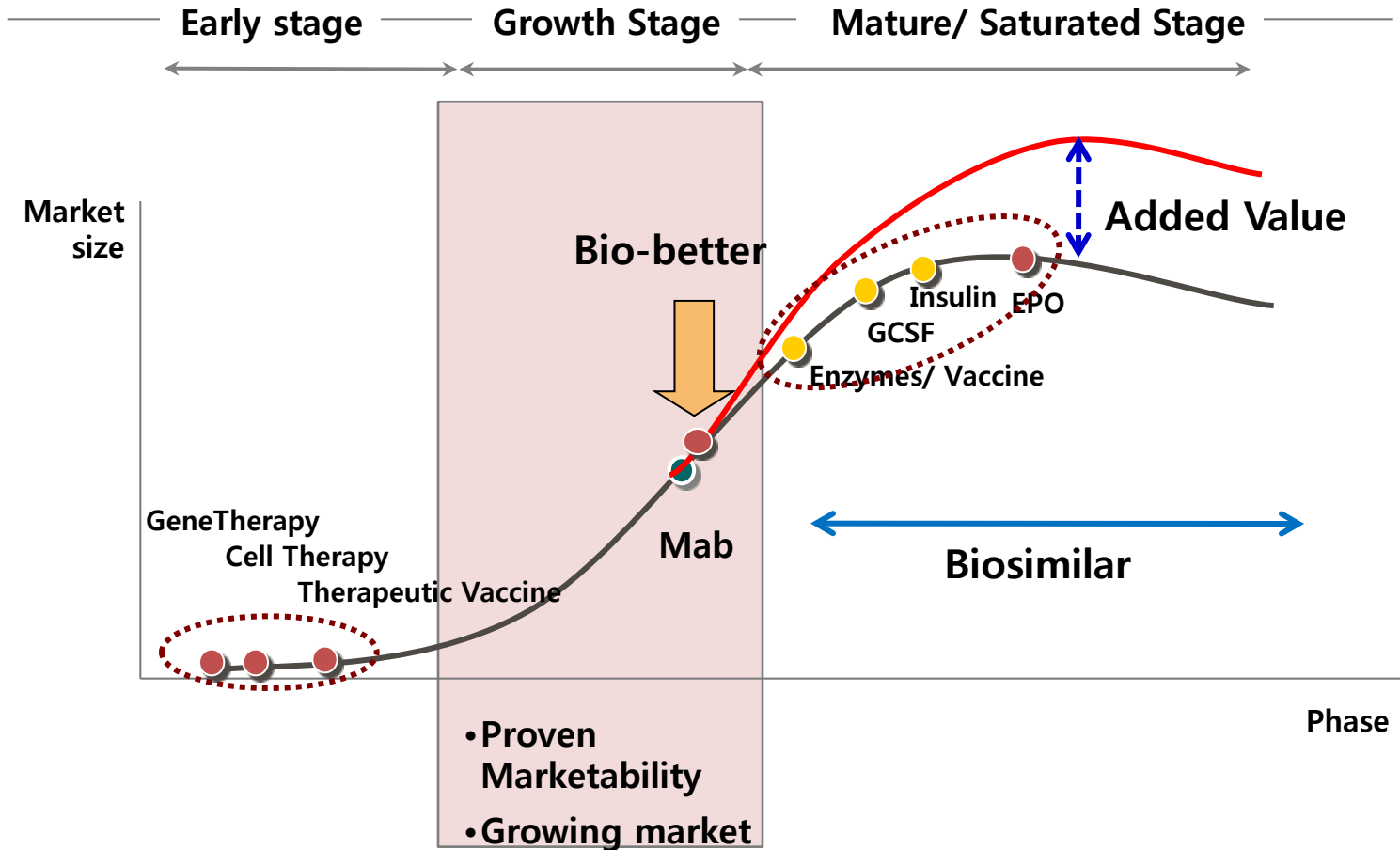


Aranesp (**Glyco**-EPO; long acting EPO)
Epogen (EPO, 1st generation)

Neulasta (**PEG**-GCSF; long-acting GCSF)
Neupogen (GCSF, 1st generation)

Source: Datamonitor 2008

Life Cycle of Bio Drugs – *as of today* -



Thank you !

Alteogen Inc – *Biosimilar & Biobetter*