



# **Generics Will Play An Increasingly Important Role In The Pharma Industry**

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**Naples , April 28-29<sup>th</sup> , 2007**



Association of Radiotherapy and Oncology of the Mediterranean arCa

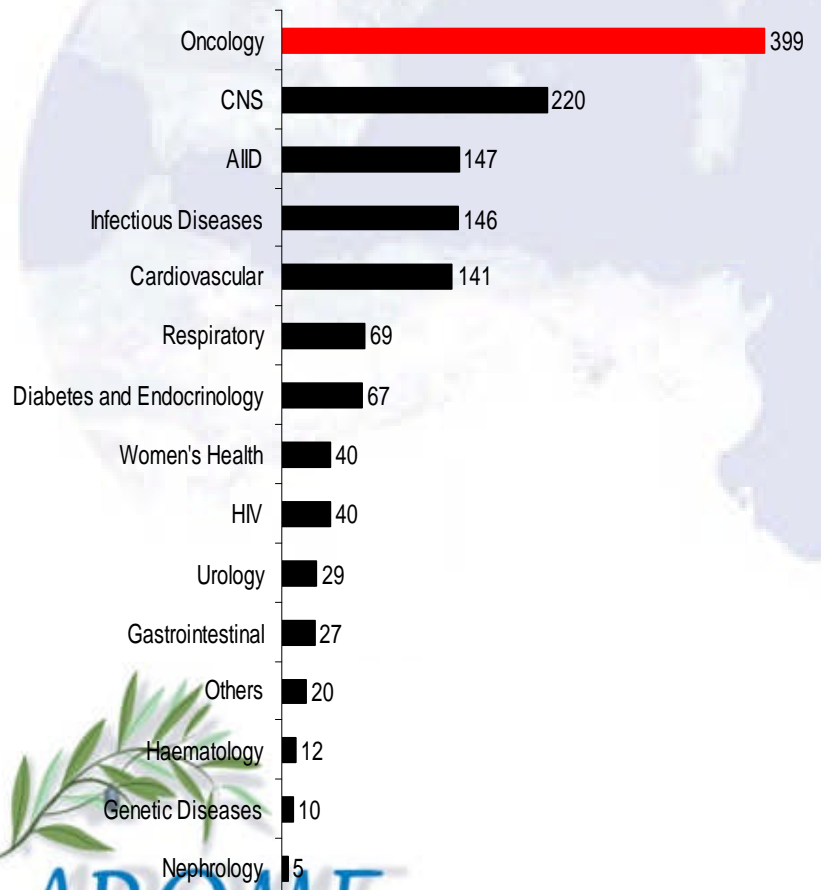
# A Combination Of Characteristics Make Oncology Unique

- **Large unmet medical needs**
- **Regulatory review times are among the shortest**
  - More than 30% of FDA fast track approvals are in oncology
  - Speed to market can be very fast for products that address high unmet need
- **Data driven market**
  - Clinical trials/data , pillar of the marketing mix
  - KOLs, cooperative groups, academic institutions are instrumental to impact practice and drive product uptake and market adoption
- **Highly segmented market / Small target audience**
  - Same physician often play researcher ,clinical investigator and prescriber roles
  - Only small skilled sales force (e.g.100-300 Reps ) required
- **Favorable reimbursement and pricing environment**
  - Premium pricing acceptable and Off-label use common but risk of market access restrictions and / or price reductions and/or strict therapeutic guidelines
- **Long product life cycle**

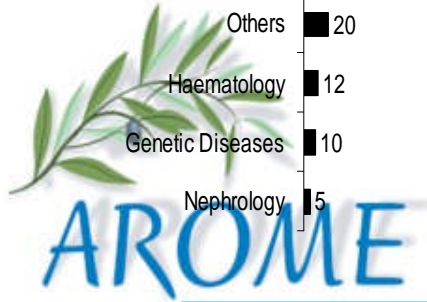
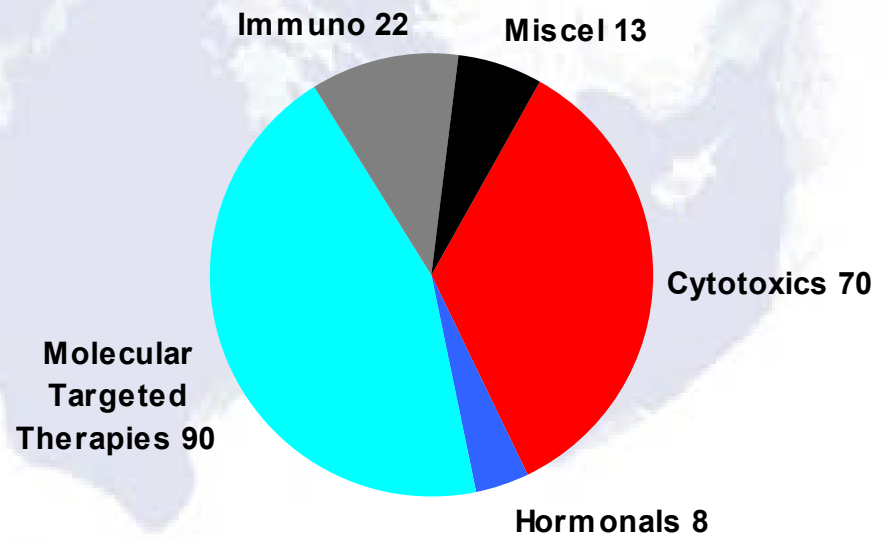


# More Anticancer products In late Stage Development Than Any Other Therapeutic Area

**Number of R&D projects by therapeutic class**



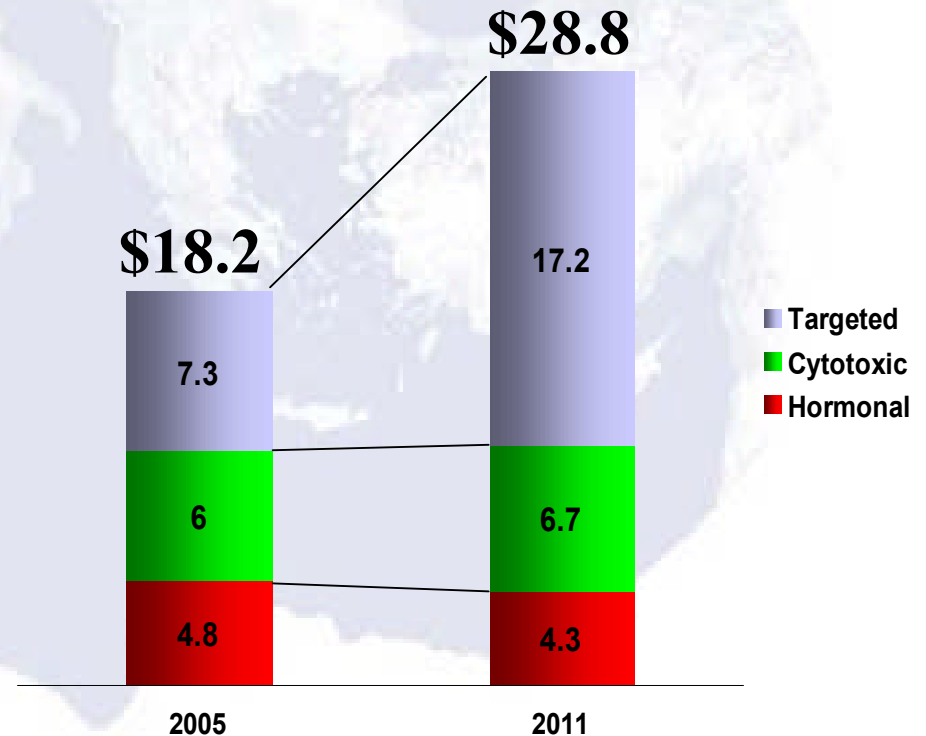
**Drugs in Phase II and III development for 11 tumor types by drug class**



# The Oncology Market Has Strong Growth Potential

- **Increasing incidence of cancer with increasing longevity**
  - 50% increase in incidence WW by 2020 with 15 millions new cases/year
- **High level of unmet medical needs**
- **Cytotoxics and hormonal therapies to remain the cornerstone of cancer treatment**
  - The dynamic of these markets will consist entirely of generics , reformulations and chemical modifications of existing drugs
- **Launch of novel premium priced targeted therapies**
  - Which use will substantially increase due to line extension and further incorporation into standard treatment regimen
- **Oncology market increasingly fragmentated**
  - Differentiation being based on key growth drivers rather than primary malignancy site.

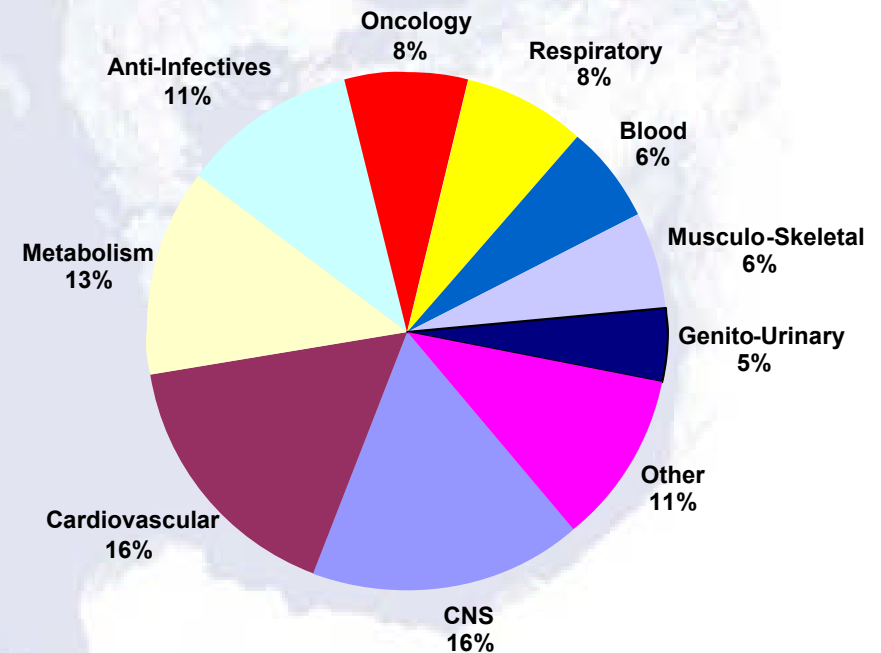
WW oncology market \*  
In billion \$



# Healthcare Expenditure Is Rising In Most Major Markets

- **Global pharma market is worth over \$600 billion with sustained growth over the last 10 years**
  - USA by far the largest market
    - Percentage of total healthcare spending attributable to pharmaceuticals increased by 78.6% from 1994 to 2004
- **Several factors have driven the rise in healthcare spending**
  - An aging population
  - Diseases are now more treatable
  - Rising drug prices
- **Cancer is among the most significant contributors of healthcare spending**

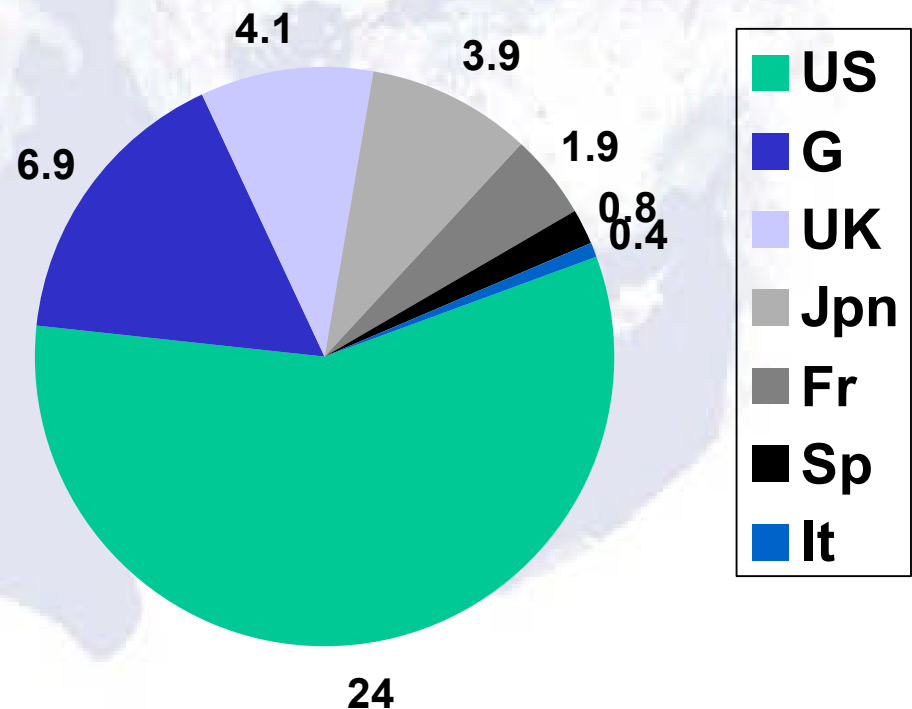
## U.S. Pharma Market \$263 billion in 05



# Cost-Containment Policies Being Implemented To Increase Generic Penetration

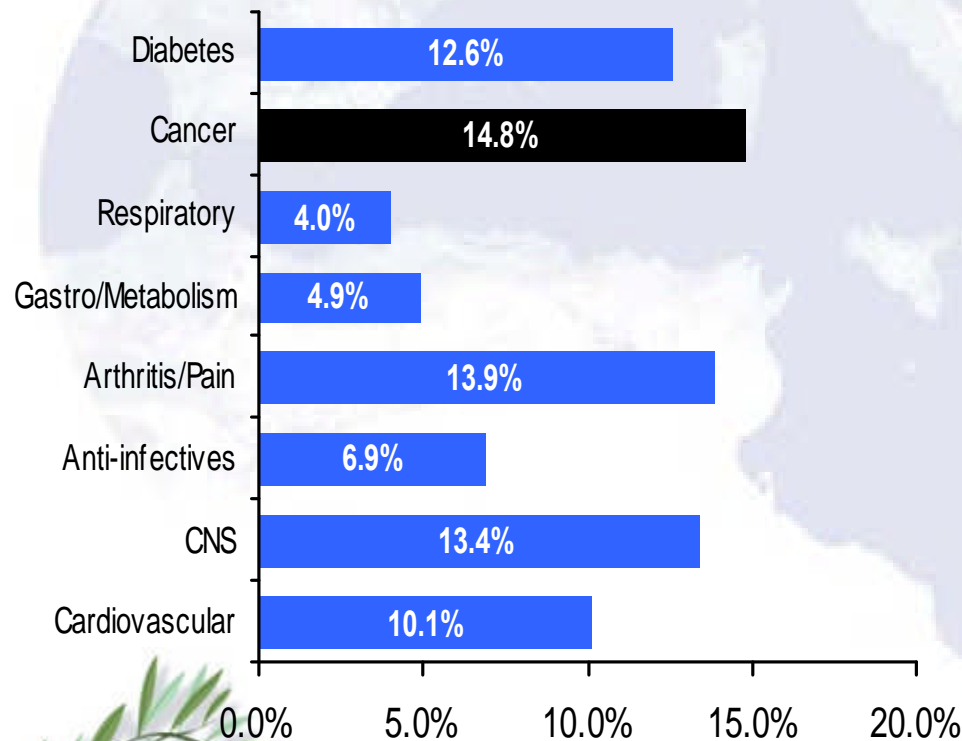
- **Global generics market has considerably changed over the last five years**
  - Estimated to be worth \$60 billion
    - 23% of global pharmaceutical MS by volume and 8% by value
  - Its growth outpaces proprietary growth and remains double digit
  - Increased pricing pressure and growing competition have led to consolidation within the sector
- **There is an estimated \$157 billion of 2005 branded sales that could be exposed to generic competition over the next 10 years**

Generics sales ( \$ billion )

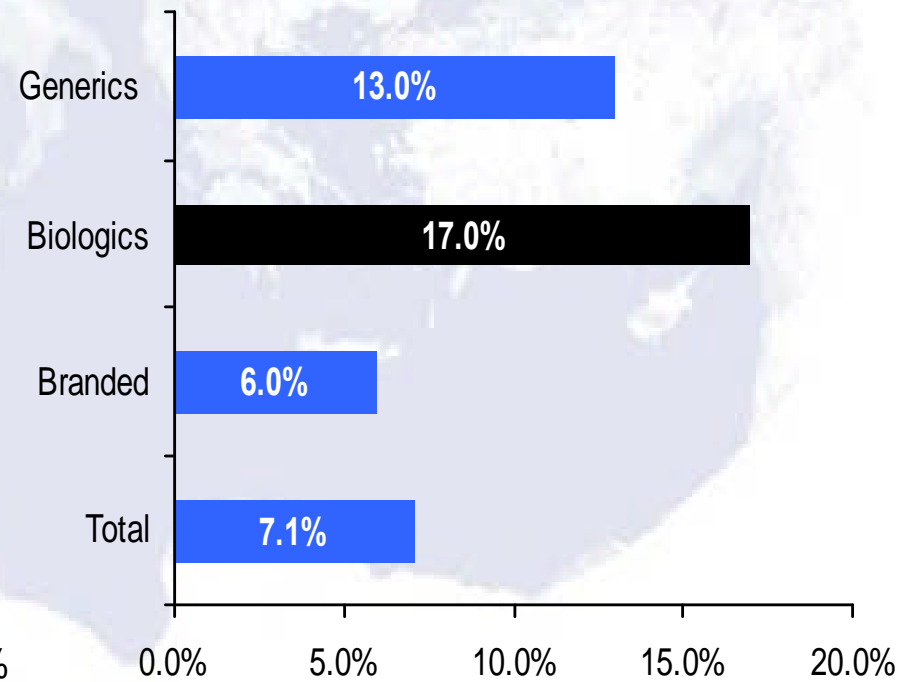


# Oncology And Biologics Are Driving Growth Of Global Pharmaceutical Market

Growth by therapeutic class\*

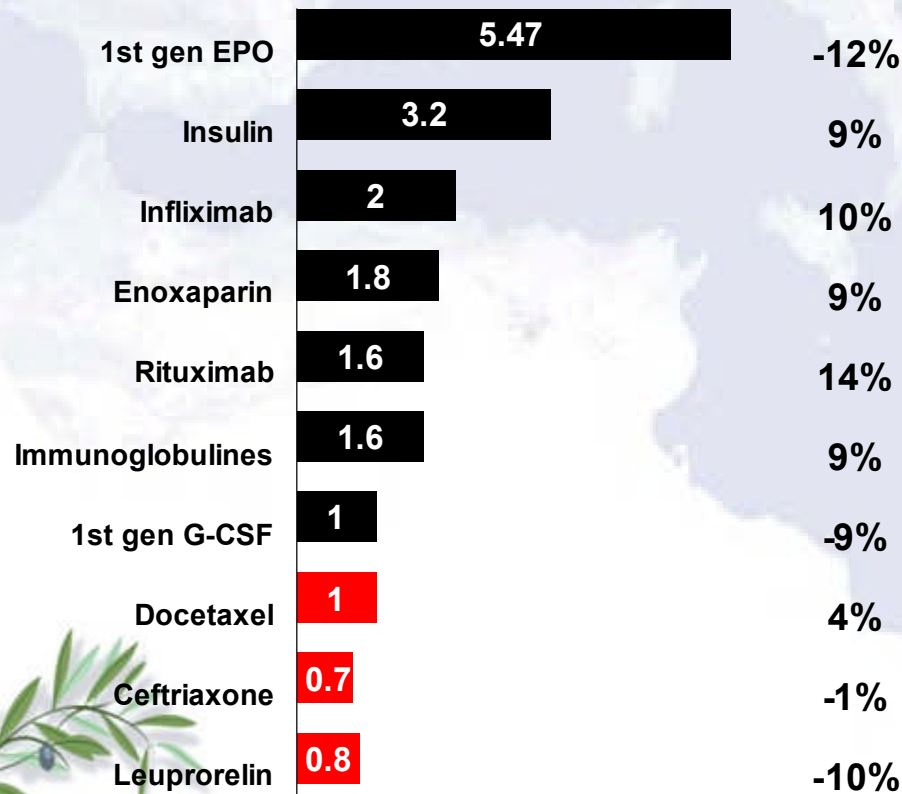


Sales growth by product type\*

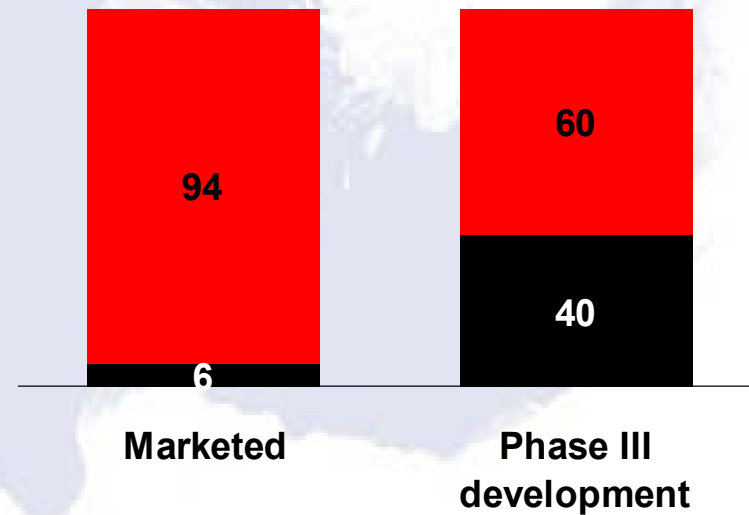


# Increased Use Of Biologics Is Changing The Hospital Injectable Business

**Hospital pharma sales**  
 € billions, percent growth  
 (MAT June 2005)

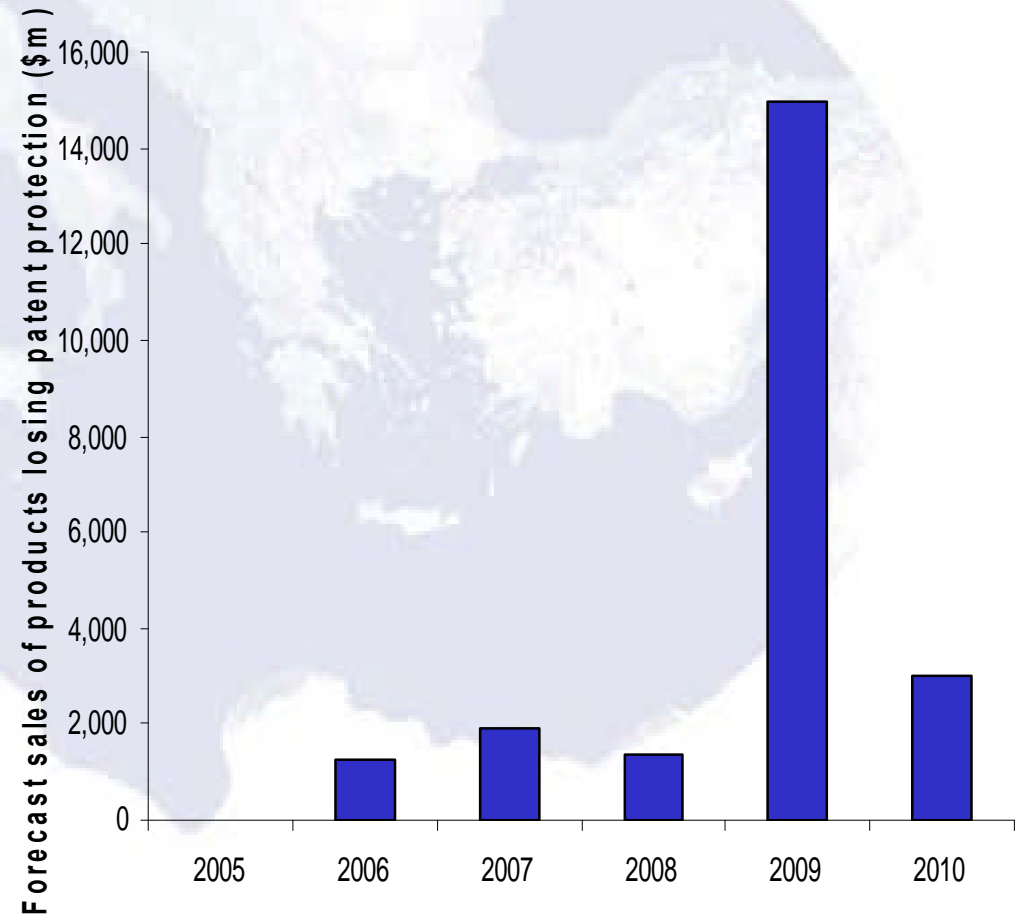


**Biologics share  
 of total pharma products**  
 Percent



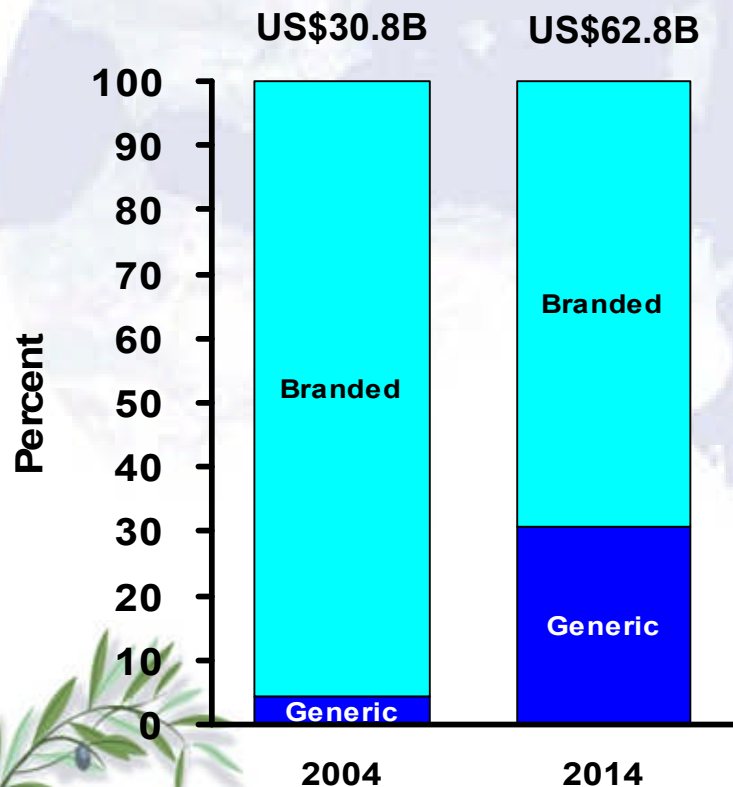
# Significant Number Of Oncology Products Losing Patent Protection To 2010

- In 2009 ~ **\$15 billion** worth of oncology product sales will be at risk from generic erosion
- **Key cytotoxics and biologics losing patent protection between 2007 and 2010**
- **Price erosion** is likely to be rapid in major markets for simple to develop and manufacture products



# Growth In Generics Oncology Products Outpacing Branded Growth

Oncology market  
2003 to 2014\*

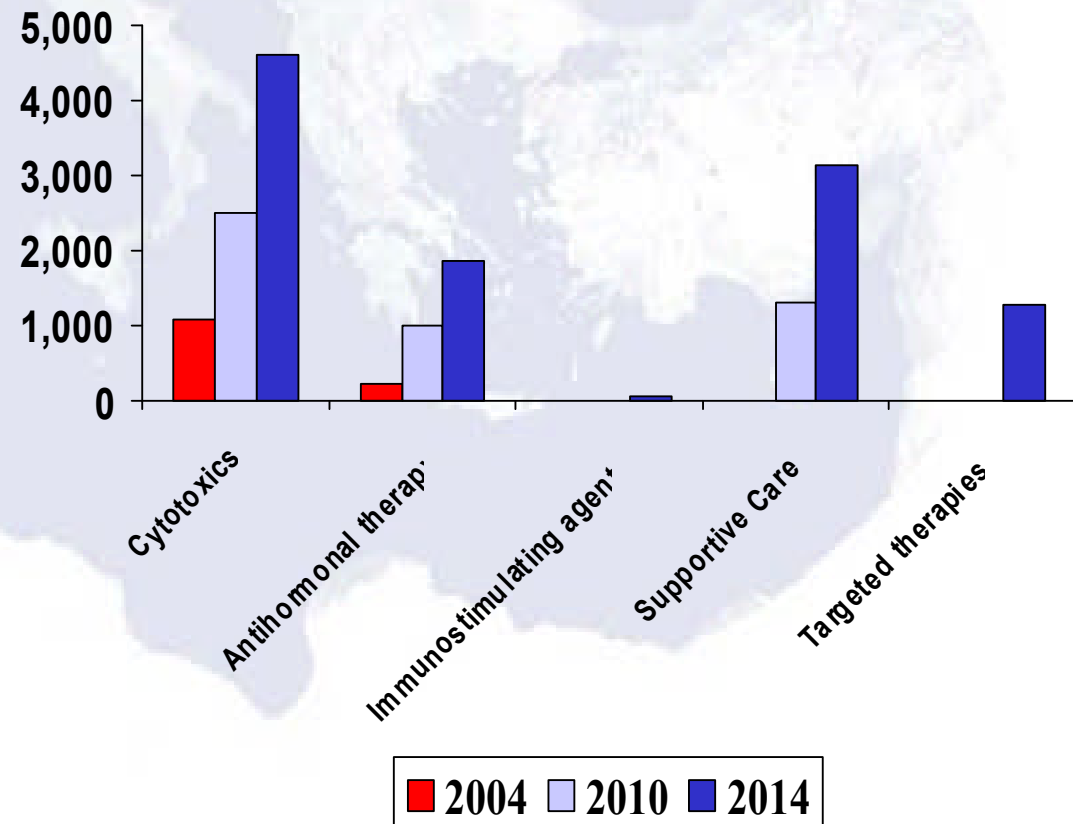


- **Oncology market expected to have a CAGR from '04 to '14 of 7.4%**
- **Generics oncology market expected to have dramatic growth by 2014**
  - In value from US\$1.3B to US\$10.9B
  - In MS from 4.3% to 30.9%
- **Generics oncology growth driven by:**
  - Large number of patent expiries
  - Growth of bio-generics
  - Increased market share of generics
  - Increase in cancer incidence

# Sustained Growth Expected In All Segments Of Generic Oncology Market . . .

- **Generic cytotoxics expected to remain the largest class**
  - in value (\$4.6B) with 15.6% 10-year CAGR
- **Strong growth in supportive care products from 2008 onwards**
  - Growth and profitability of biogenerics dependent on number of competitors and finalisation of regulatory frameworks

Generic oncology sales by therapeutic class in top 7 markets



## ... And Regions

### Generic oncology sales growth 2004 to 2014 (US\$ B)

Country	2004	2014	10 yr CAGR
US	656	5,226	23.1%
Germany	154	1,544	25.9%
France	142	1,674	28.0%
UK	103	977	25.2%
Italy	78	690	24.4%
Spain	45	536	28.1%
Japan	146	377	10.0%
Total	1,324	11,024	23.6%



# Factors Influencing The Generics Industry

## Pros

- Governments globally to continue to support increased use of generics
- Strong pipeline of patent expiries in the short term
- Increased consolidation activity
- Increasing use of alliances for product development, co-promotion and licensing

## Cons

- High earnings volatility
- High risk associated with IP litigation
- Government initiatives leading to reduced pricing for both proprietary and generic products
- Shortening generic product life cycles
- Increasing price erosion
- New entrants from low cost countries
- Longer-term pipeline sees trend to complex therapeutics
- Increasing compliance standards
- Regulatory environment favours innovators



# What Does This Mean For Injectable Generics Companies

## **The old key success factors for injectable generics companies... Not enough**

- Globally competitive supply chain
  - Cost-effective and efficient development / Manufacturing (vertical integration e.g. API)
  - Sales and distribution
  - Reliability of supply
- Economies of scale in chosen segment
  - Broad portfolio in target market
  - Benefits from extensive geographic reach
- First to market position

## **A diverse product portfolio is becoming the standard business model**

- The generics market is defined by low margin while diversified portfolio are offering improved profitability



# Generic Industry Consolidation Is Leading To A More Diverse Business Model

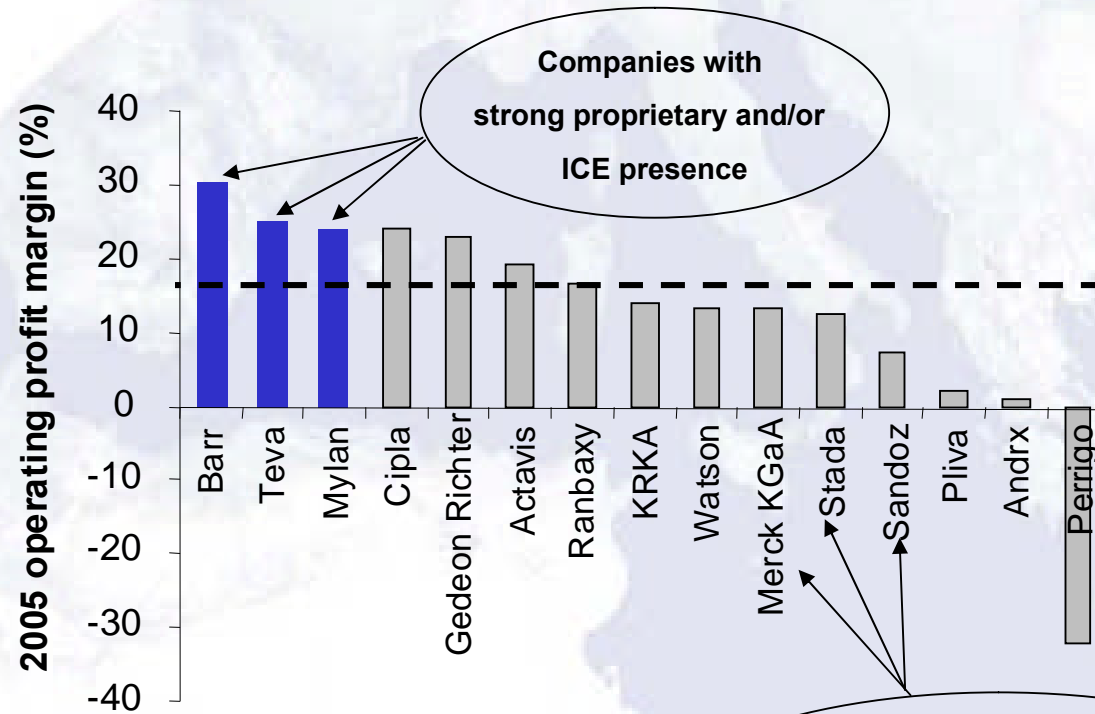
5 types of generics currently being offered, along with proprietary products, exposing companies to different parts of the value chain

Low value ← → High value

	Commodity Generics	Speciality Generics	Branded Generics	Super Generics	Biosimilars	Proprietary Products
Teva	✓	✓	✓		✓	✓
Sandoz	✓	✓	✓		✓	
Merck	✓	✓	✓	✓	✓	
Watson	✓	✓	✓	✓		✓
Mylan	✓	✓	✓	✓		✓
Stada	✓	✓	✓		✓	
Pliva	✓	✓	✓		✓	✓
Ranbaxy	✓	✓	✓	✓		
Barr	✓	✓	✓	✓	✓	✓
Andrx	✓	✓		✓		✓



# Many Companies Moved Beyond The Concept Of Commodity Generics



Companies with strong proprietary and/or ICE presence

The average operating\* profit in the generics market in 2005 was 16.1% compared to 24.8% for the top branded pharma\*\*

Companies with lower profit margins are those more focused on production of commodity and bulk generics rather than specialist or branded products



# Conclusion

- **Cancer treatment paradigm is changing**
  - Inclusion of targeted therapies into standard treatment regimens and this trend will continue well into the future
    - Line extensions and horizontal expansion strategies into other tumor types
    - Several other targeted therapies and pipeline products are expected to impact the oncology market
  - Both clinical development and commercial strategy will evolve
- **And cost is increasing significantly**
  - Driven by premium pricing , treatment duration/survival prolongation and availability of new therapeutic options
- **Generics will play an increasingly important role**
  - A combination of patent expiries and cost-containment policies will drive growth in the generics market
  - This could aid cost reduction of cancer treatment, which will increase somewhat with the potential high cost of targeted therapies.
- **A diverse product portfolio is becoming the standard business model in the generics market**

