Shifting paths of pharmaceutical innovation: Implications for the global pharmaceutical industry

Tariq Sadat
PhD Candidate
School of Economics, Finance and Marketing,
RMIT University, Australia

Roslyn Russell
Professor
School of Economics, Finance and Marketing,
RMIT University, Australia

Mark Stewart
Senior Lecturer
School of Economics, Finance and Marketing,
RMIT University, Australia

Background

- Study rationale

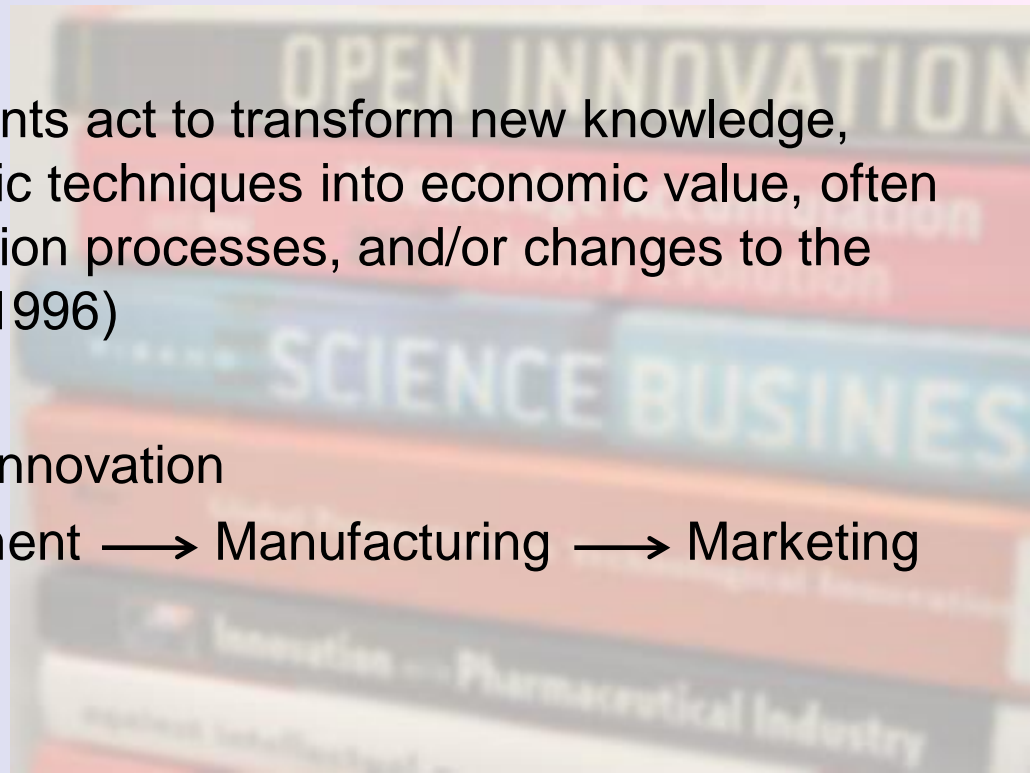- Relationship between pharmaceutical and biotechnology

Overview of presentation

- Conceptualisation of pharmaceutical innovation

- Evolving paths of pharmaceutical innovation models within the historical context

- External and internal forces affecting pharmaceutical innovation models

- How large pharmaceutical companies (or 'big pharma') are adapting their innovation strategies

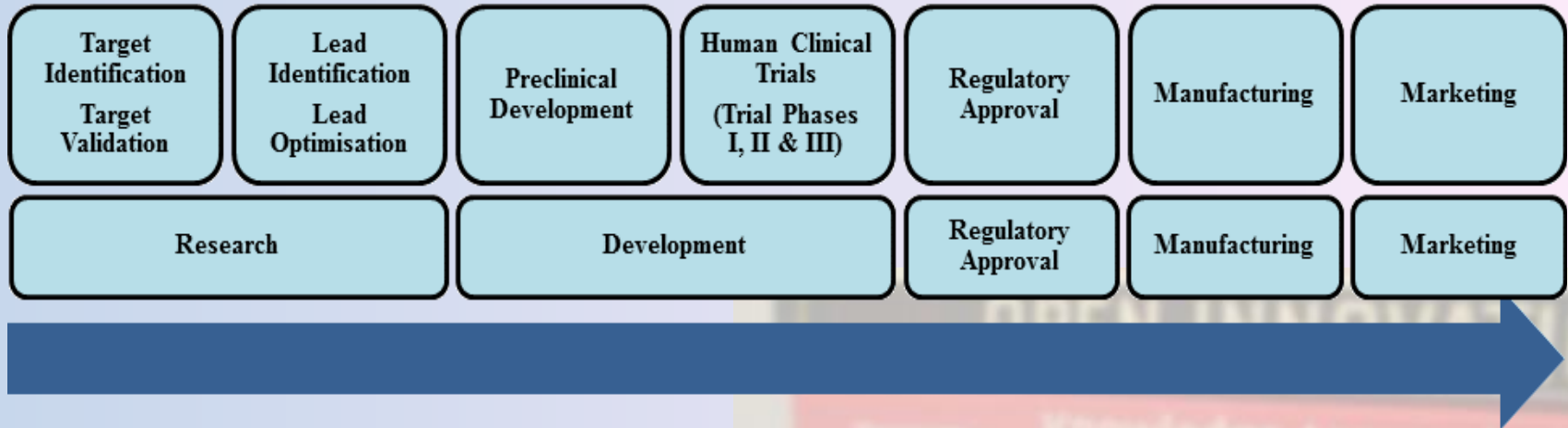- Implications for the global pharmaceutical industry landscape
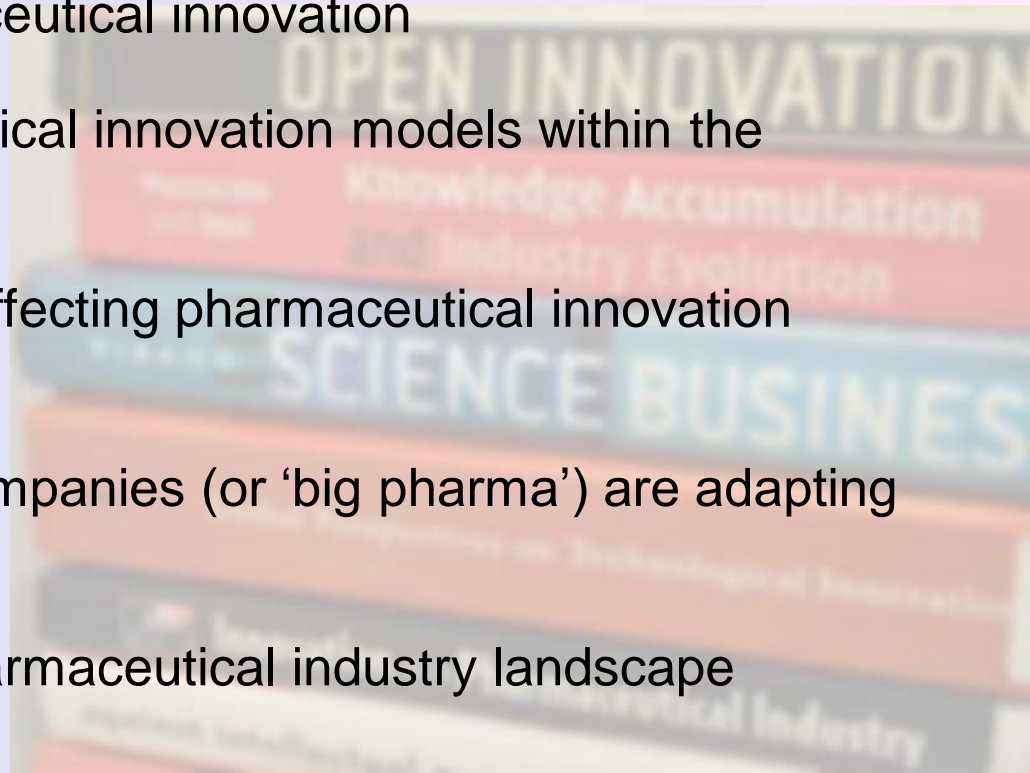
Conceptualisation of pharmaceutical innovation

- Classical view of innovation (Schumpeter, 1939)

  ➤ new function of economic production, such as new products, new means of production, new form of organisation, or new markets

  ➤ giving economic value to an invention

- Technological innovation

  ➤ 'the process whereby agents act to transform new knowledge, inventions, and/or scientific techniques into economic value, often through products, production processes, and/or changes to the organisation' (McKelvey, 1996)

- Value Chain of technological innovation

  ➤ Research ⟶ Development ⟶ Manufacturing ⟶ Marketing

Conceptualisation of pharmaceutical innovation

- Value chain of pharmaceutical innovation

Target Identification / Target Validation	Lead Identification / Lead Optimisation	Preclinical Development	Human Clinical Trials (Trial Phases I, II & III)	Regulatory Approval	Manufacturing	Marketing
Research		Development		Regulatory Approval	Manufacturing	Marketing

- An additional step in the pharmaceutical innovation value chain
  - ➢ Mandatory regulatory (marketing) approval of a new drug by regulatory agencies (e.g. US FDA, or UK MHRA) based on experimental proof of the drug's safety and efficacy in human.
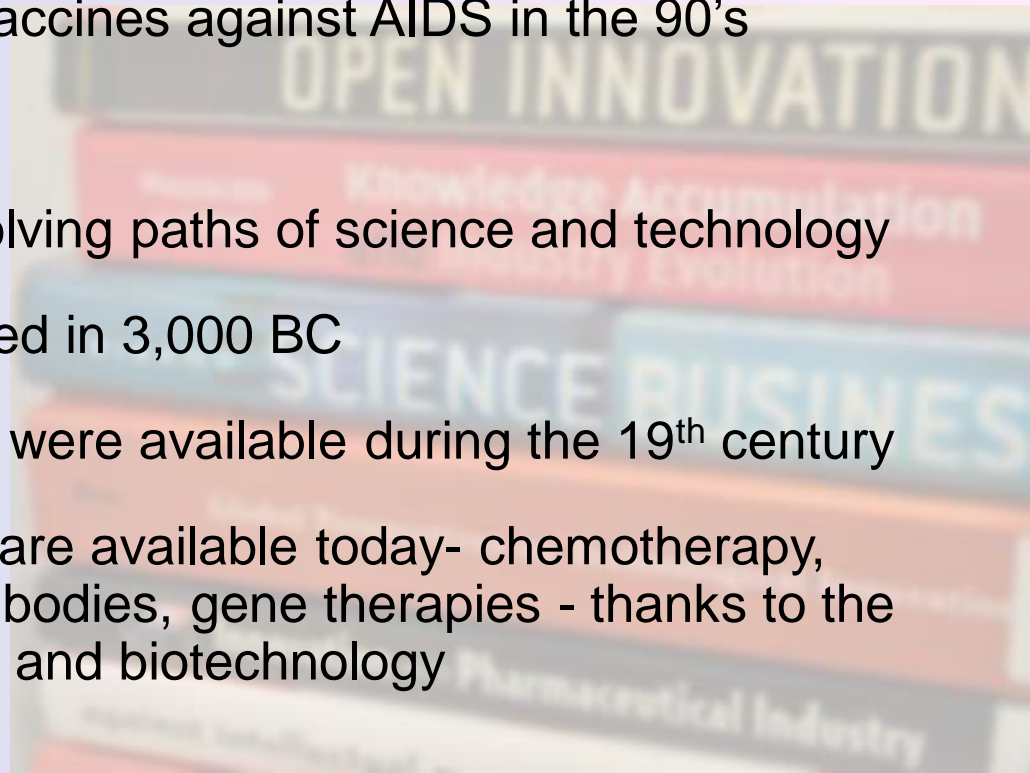
Forces producing pharmaceutical innovation

- **Demand pull**
  - Innovation occurs when a need is recognised in the economic system

  - Outbreak of HIV/AIDS in the early 80's triggered the need for a cure

  - Innovation of drugs and vaccines against AIDS in the 90's

- **Technology push**
  - Innovation follows the evolving paths of science and technology

  - Cancer was first recognised in 3,000 BC

  - Surgery and radiotherapy were available during the 19th century

  - Various cancer treatment are available today- chemotherapy, vaccines, monoclonal antibodies, gene therapies - thanks to the applications of bioscience and biotechnology
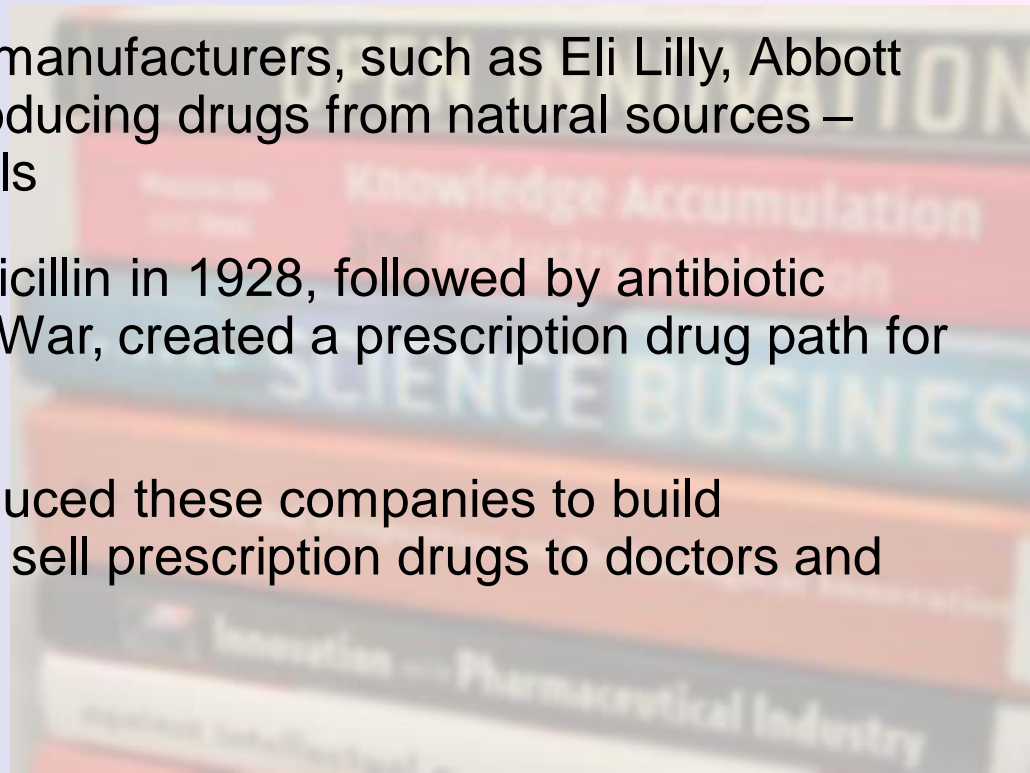
Conceptualisation of pharmaceutical innovation

- **In summary**
  - ➢ Innovation is a function of the value that is embodied in a new product, new market or a new form of organisation

  - ➢ The value is created by firms through innovation activities

  - ➢ The value is delivered through commercialisation of a new product, penetration into a new market, or bringing an organisational change

  - ➢ In pharmaceutical innovation, a new drug or a new drug market represents the value that is created by pharmaceutical companies

  - ➢ Cyclical 'demand pull' and 'technology push' forces are creating new paths to pharmaceutical innovation

  - ➢ Pharmaceutical companies are adapting their R&D and business models to create value along the new paths

Historical evolution of pharmaceutical innovation models

- **The path to prescription drugs – the 'integrated model'**

  ➢ Pharmaceutical industry originated in Europe and the US around mid-19th century

  ➢ In Europe, chemical companies like Ciba, Sandoz, Bayer, Hoechst led the early pharmaceutical industry leveraging organic chemistry based research and manufacturing

  ➢ In the US, pharmaceutical manufacturers, such as Eli Lilly, Abbott and SmithKline, started producing drugs from natural sources – plants, animals and minerals

  ➢ Fleming's discovery of Penicillin in 1928, followed by antibiotic demands during 2nd World War, created a prescription drug path for many of these companies

  ➢ The 'demand-pull' force induced these companies to build capabilities to produce and sell prescription drugs to doctors and hospitals

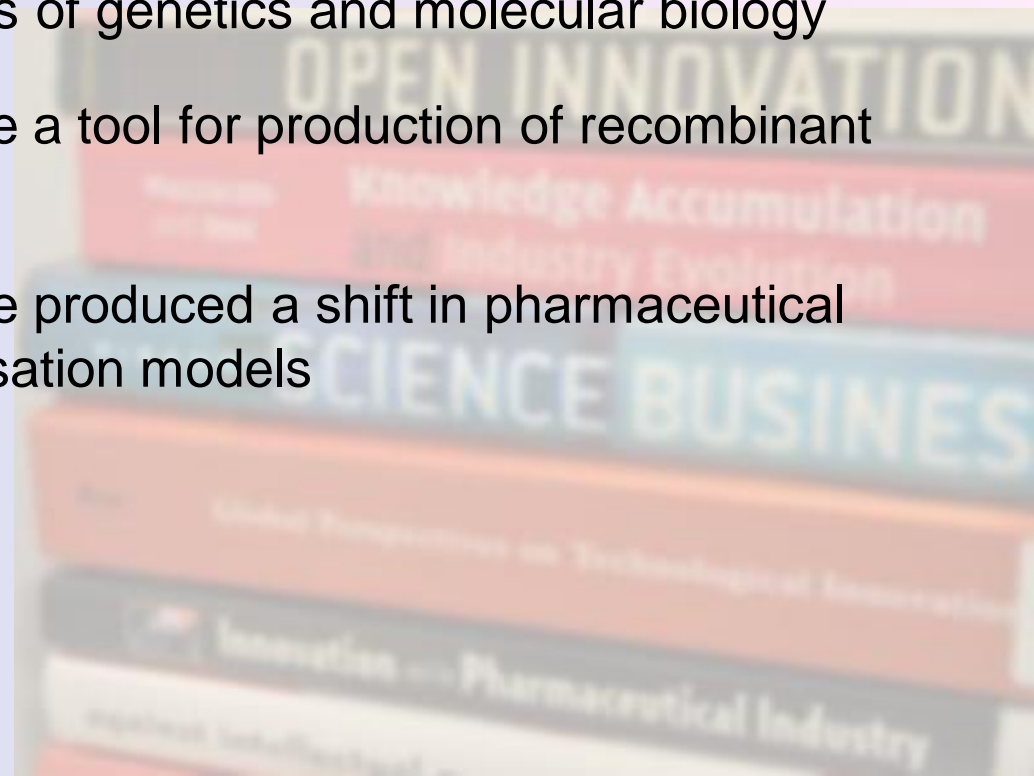# Historical evolution of pharmaceutical innovation models

- ***The path to prescription drugs – the 'integrated model'***

  ➢ Through government supports these companies intensified R&D programs that facilitated the applications of microbiology, enzymology and biochemistry

  ➢ They became large integrated and oligopolistic companies with R&D, manufacturing, marketing and distribution capabilities

  ➢ Pharmaceutical became an R&D-intensive innovative industry based on:

    ✓ Target-based drug discovery,
    ✓ Economies of scope in R&D,
    ✓ Public and national institutional supports for health research,
    ✓ Strong Intellectual Property (IP) regime, and
    ✓ Stringent drug approval procedures

Historical evolution of pharmaceutical innovation models

- ***The path to biotechnology R&D – the 'collaborative model'***

  - ➢ Discovery of DNA in the early 1950s and genetic engineering in the 1970s created a new path for pharmaceutical R&D – the 'biotechnology' path

  - ➢ Biotechnology became a research tool in drug discovery based on knowledge and applications of genetics and molecular biology

  - ➢ Biotechnology also became a tool for production of recombinant protein drugs (e.g. insulin)

  - ➢ The 'technology-push' force produced a shift in pharmaceutical industrial and commercialisation models
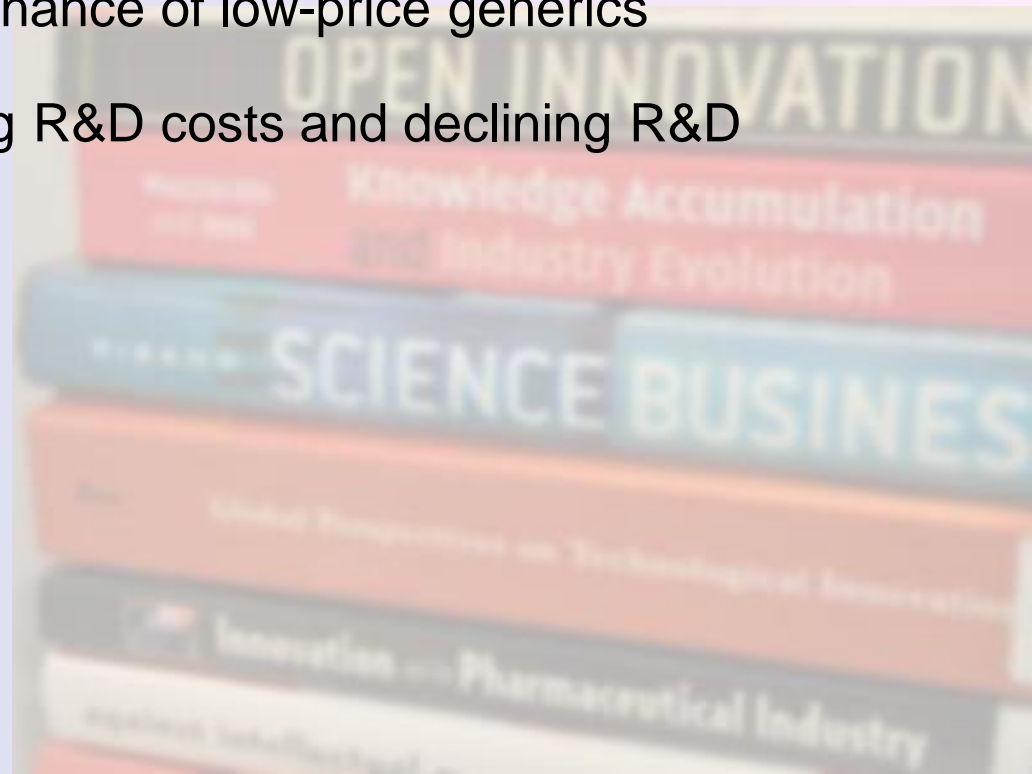
Historical evolution of pharmaceutical innovation models

- ***The path to biotechnology R&D – the 'collaborative model'***

  - ➢ Hundreds of university research spin-off companies emerged to commercialise biotechnology R&D, but lacked capital and organisational capabilities

  - ➢ They collaborated with large pharmaceutical companies to support their R&D; a few of them, Amgen, Genentech, Biogen, turned into large integrated companies (big biotechs)

  - ➢ The large pharmaceutical companies, through collaborations and acquisitions, exploited biotechnology applications in drug R&D, and produced novel billion-dollar value 'blockbuster drugs' (e.g. GlaxoSmithKline's anti-ulcer drug Zantac)

  - ➢ Through selling 'blockbuster drugs', and through series of mergers and acquisitions, the large pharmaceutical companies grew even larger, and became what we know as 'big pharma' today

Current evolution of pharmaceutical innovation models

- ***The path to creating and delivering value – the 'open innovation models'***

    ➢ A number of external and internal forces are making big pharma's integrated model unsustainable

    ➢ External market forces are payers, government policies, emerging market dynamics and dominance of low-price generics

    ➢ Internal forces are spiralling R&D costs and declining R&D productivity

Current evolution of pharmaceutical innovation models

- ***The path to creating and delivering value – the 'open innovation models'***

    1. Government policies – healthcare reforms and drug price controls

    ➢ WHO 2010 World Health Report describes various government reforms to extend affordable healthcare services

    ➢ The 2010 Affordable Care Act in the US extended healthcare coverage to previously uninsured 32 million citizens through mandatory subsidised health insurance

    ➢ The 2009 healthcare reform in China brought the entire 1.2 billion population under primary medical services, including 300 essential medicines, through basic medical insurance system

Current evolution of pharmaceutical innovation models

- *The path to creating and delivering value – the 'open innovation models'*

    1. Government policies – healthcare reforms and drug price controls

    ➢ Traditionally regulatory approval of new drug based on safety and efficacy has been the biggest hurdle to market entry

    ➢ Now it's the reimbursement criteria assessed and set by payers

    ➢ Other pricing hurdles include, for example -
        ✓ Discounts on Medicare drugs in the US,
        ✓ Price cap and compulsory licensing of patented drugs in India,
        ✓ 'Value-based pricing' based on new drug benefits in the UK,
        ✓ Reference pricing of new drugs in Germany,
        ✓ Number of price-controlled drugs doubled to 700 in China, and forced discounts on 400 medicines

Current evolution of pharmaceutical innovation models

- ***The path to creating and delivering value – the 'open innovation models'***

  2. Emerging markets – China, India, Latin America and Africa

  ➢ Emerging market share of global drug spending to reach from 20% in 2011 to 30% in 2016

  ➢ Drug spending in the US and Europe to shrink from 58% to 49%

  ➢ The African pharma market size will double to $45 billion by 2020

  ➢ There are challenges, however, in emerging markets –
    ✓ Weak regulatory controls and IP protection
    ✓ Lack of health insurance programs and thus inability to support expensive drugs
    ✓ Large gap in per capita drug spending between developed and emerging markets, estimated to become $609 and $91, respectively, in 2016
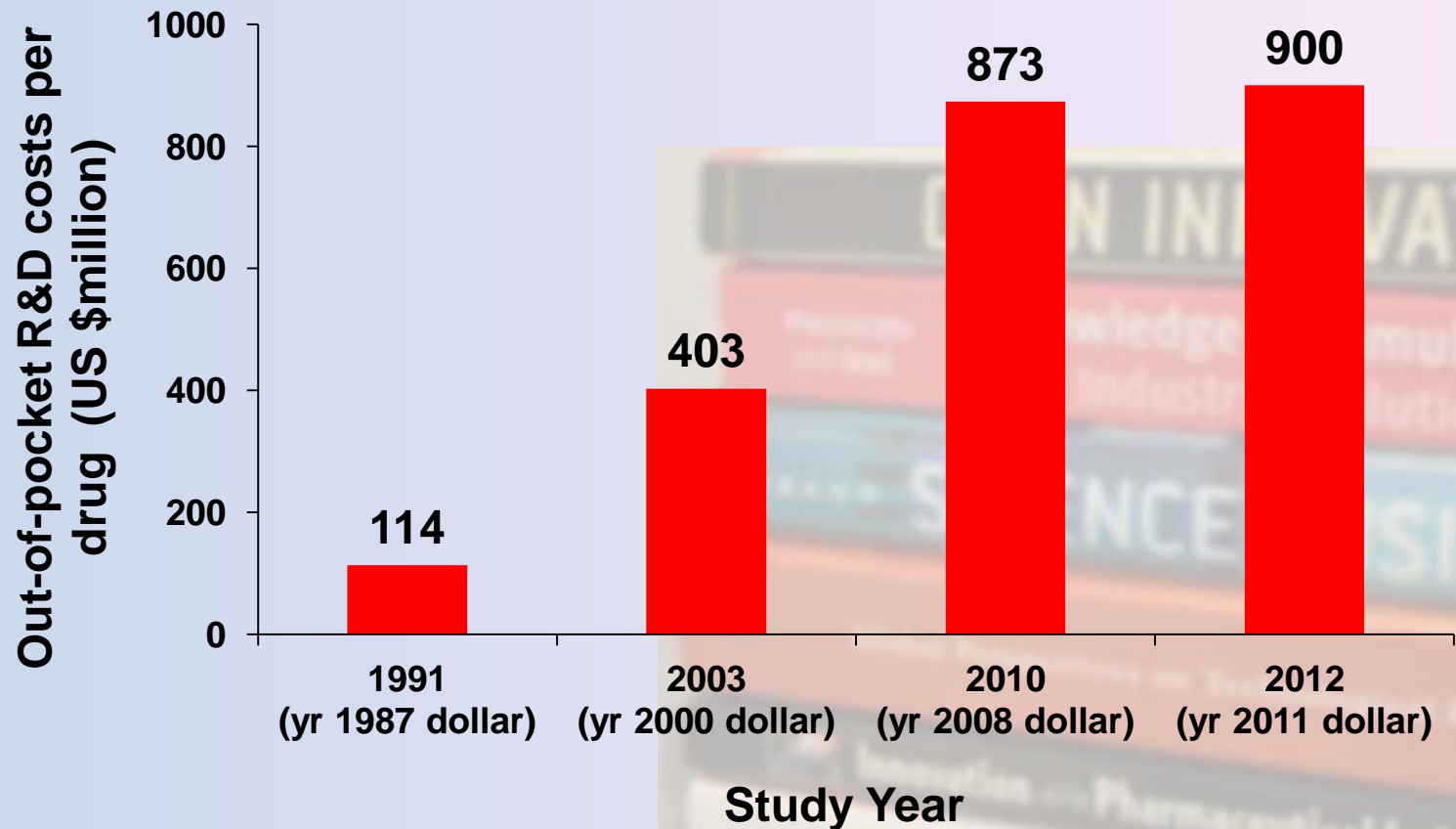
Current evolution of pharmaceutical innovation models

- ***The path to creating and delivering value – the 'open innovation models'***

    3. Patent cliff – the end of 'blockbuster era' for big pharma

    ➢ $148 billion in potential loss between 2012-18 due to patent expiry

    ➢ Top ten drugs losing patent in 2013 generated $15 billion in the US in 2012 and going to lose $8 billion of that value by 2016

    ➢ Drug spending in developed markets will shrink $127 billion between 2011 and 2016 due to growing share of low-price generics

    ➢ Between 2011 and 2016, global brand drug spending will grow by only 8%, compared to 80% growth in generic drug spending

    ➢ Spending on specialty drugs (biologics, orphan drugs) for cancer, HIV, hepatitis C and rare diseases is also growing pretty fast

Current evolution of pharmaceutical innovation models

- *The path to creating and delivering value – the 'open innovation models'*

    4. Spiralling R&D costs and declining R&D productivity

Bar chart — Out-of-pocket R&D costs per drug (US $million) vs Study Year:
- 1991 (yr 1987 dollar): 114
- 2003 (yr 2000 dollar): 403
- 2010 (yr 2008 dollar): 873
- 2012 (yr 2011 dollar): 900

Current evolution of pharmaceutical innovation models

- ***The path to creating and delivering value – the 'open innovation models'***

   4. Spiralling R&D costs and declining R&D productivity

Company	Total R&D Spending 1997-2011 ($ billion)	Number of Approved Drugs	Average R&D Spending Per Drug ($ billion)
AstraZeneca	59.0	5	11.8
GlaxoSmithKline	81.7	10	8.2
Sanofi	63.3	8	7.9
Roche	85.8	11	7.8
Pfizer	108.2	14	7.7
Johnson & Johnson	88.3	15	5.9
Eli Lilly	50.3	11	4.6
Abbott Laboratories	36.0	8	4.5
Merck	67.4	16	4.2
Bristol-Myers Squibb	45.7	11	4.2
Novartis	83.6	21	4.0

Current evolution of pharmaceutical innovation models

- ***The path to creating and delivering value – the 'open innovation models'***

  - ➢ In response to the external and internal forces, big pharma is taking new innovation paths - leading to 'open innovation' models

  - ➢ Big pharma is creating value through exploiting evolving scientific and technological knowledge

  - ➢ Many big pharma companies are creating open innovation networks with leading academic researchers, and biotechnology and pharmaceutical companies to boost drug R&D

  - ➢ Examples of open innovation networks – TransCelerate Biopharma in the US, Pfizer's 'Global Centers for Therapeutic Innovation', J&J's four innovations centres

Current evolution of pharmaceutical innovation models

- *The path to creating and delivering value – the 'open innovation models'*

  ➢ Big pharma's open innovation approaches to creating value –

    ✓ Mergers, acquisitions and in-licensing deals with pharmaceutical and biotechnology companies to extend their portfolio with specialty drugs

    ✓ Expanding R&D, manufacturing and sales networks in emerging markets through capital investments, and joint ventures and collaborations with local companies

    ✓ Joint ventures with generic manufacturers in emerging markets to capture the value of global generic market that will almost double from $240 billion in 2011 to $430 billion in 2016

Current evolution of pharmaceutical innovation models

- *The path to creating and delivering value – the 'open innovation models'*

  - ➤ Big pharma's various open innovation approaches to delivering value to customers –
    - ✓ Collaborations with payers (insurance companies) to identify treatment responsive patients and improve healthcare practices

    - ✓ Risk-sharing agreements with payers to share the costs of new drugs showing limited or no treatment results

    - ✓ Personalised medicines for specific patient subgroups showing a particular disease trait, identifiable through diagnostic tests

    - ✓ Healthcare delivery models such as training rural doctors and patients in emerging markets, and raising awareness through patient education programs
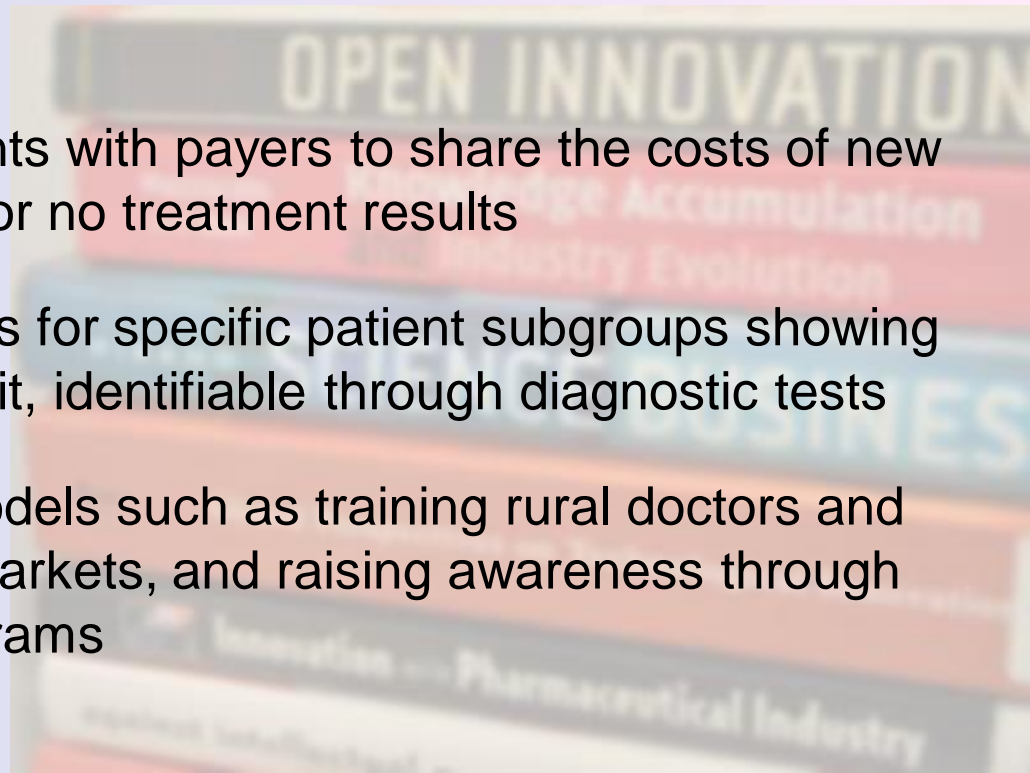
Conclusion

- **Perceived value**

  - The value of new drugs depends on their performance and benefits

  - The value is determined by value users based on their performance, and also based on market-specific needs (e.g. poor patients in emerging markets)

  - The value of pharmaceutical innovation is no longer embodied in new drugs and new markets alone, or commanded by pharmaceutical companies

  - The benefits of new drugs perceived by value users embody the value of pharmaceutical innovation. This can be called the 'perceived value'

  - The 'perceived value' is created by both big pharma and value users through various value propositions – consistent with the idea of 'open innovation'.
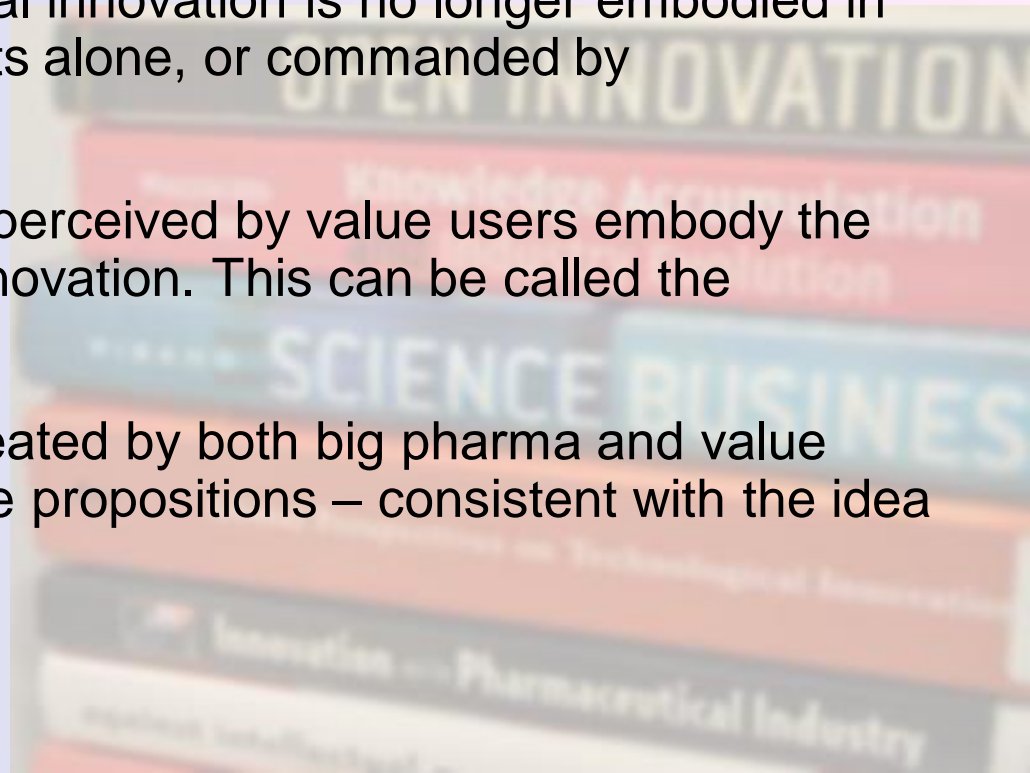
Conclusion

- **New landscape of pharmaceutical industry**

  - ➤ Division of value proposition between developed and emerging markets becoming evident

  - ➤ In developed markets, the value of high price specialty drugs chronic and rare diseases, and low price generics for common diseases are replacing the value of blockbuster prescription drugs

  - ➤ In emerging markets, value is created through increasing stakes in large volume generics manufacturing, and through discounts and price cuts on expensive specialty drugs

  - ➤ Big pharma's success of innovation lies in seeking ways to capture value from new market opportunities

  - ➤ Big pharma's path forward makes a shift from product-centric innovation towards market-centric innovation

Questions?