

# **INSTITUTE OF MEDICINE COMMITTEE ON THE U.S. COMMITMENT TO GLOBAL HEALTH**

## **Sharing Information, Knowledge and Materials**

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# Agenda

- q The Scale of the Problem – Universities and Drug Discovery
- q Licensing Approaches
- q Issues

# University Licensing Policies and Global Health

- q Problem first surfaced in 2001 with Yale and Zerit
- q d4T discovered by Drs. Tai-Shun Lin and William Prusoff
- q Funded by NIH and Bristol-Myers
- q Exclusively optioned then licensed to Bristol-Myers
- q On list of Essential Medicines developed by *Medécins Sans Frontières*
- q Requested waiver of S. African patent
- q Initially rejected by BMS – Yale powerless
- q Story in NY Times
- q BMS agreed not to assert S. African patent

# Universities and Drug Discovery



# The Contribution of Public Sector Research to the Discovery of New Drugs

Jonathan J. Jensen,<sup>[1],§</sup> Katrine Wyller,<sup>[2],§</sup> Eric R. London,<sup>[3]</sup> Sabarni K. Chatterjee,<sup>[5]</sup> Fiona E. Murray,<sup>[4]</sup> Mark L. Rohrbaugh,<sup>[5]</sup> and Ashley J. Stevens<sup>[6],¶</sup>

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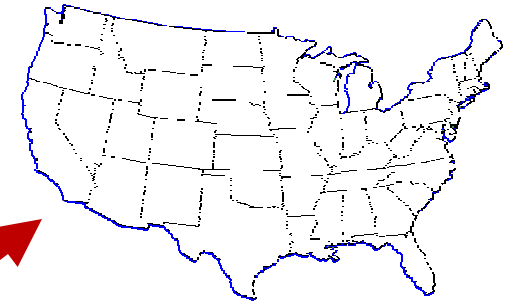
# FDA Approved Products Discovered at Public Sector Research Institutes

<u>Type of Product</u>	<u>Number</u>
New Chemical Entity	90
Biologic	30
Vaccine	16
Over the counter	1
<u>In-vivo diagnostic</u>	<u>8</u>
Total	145

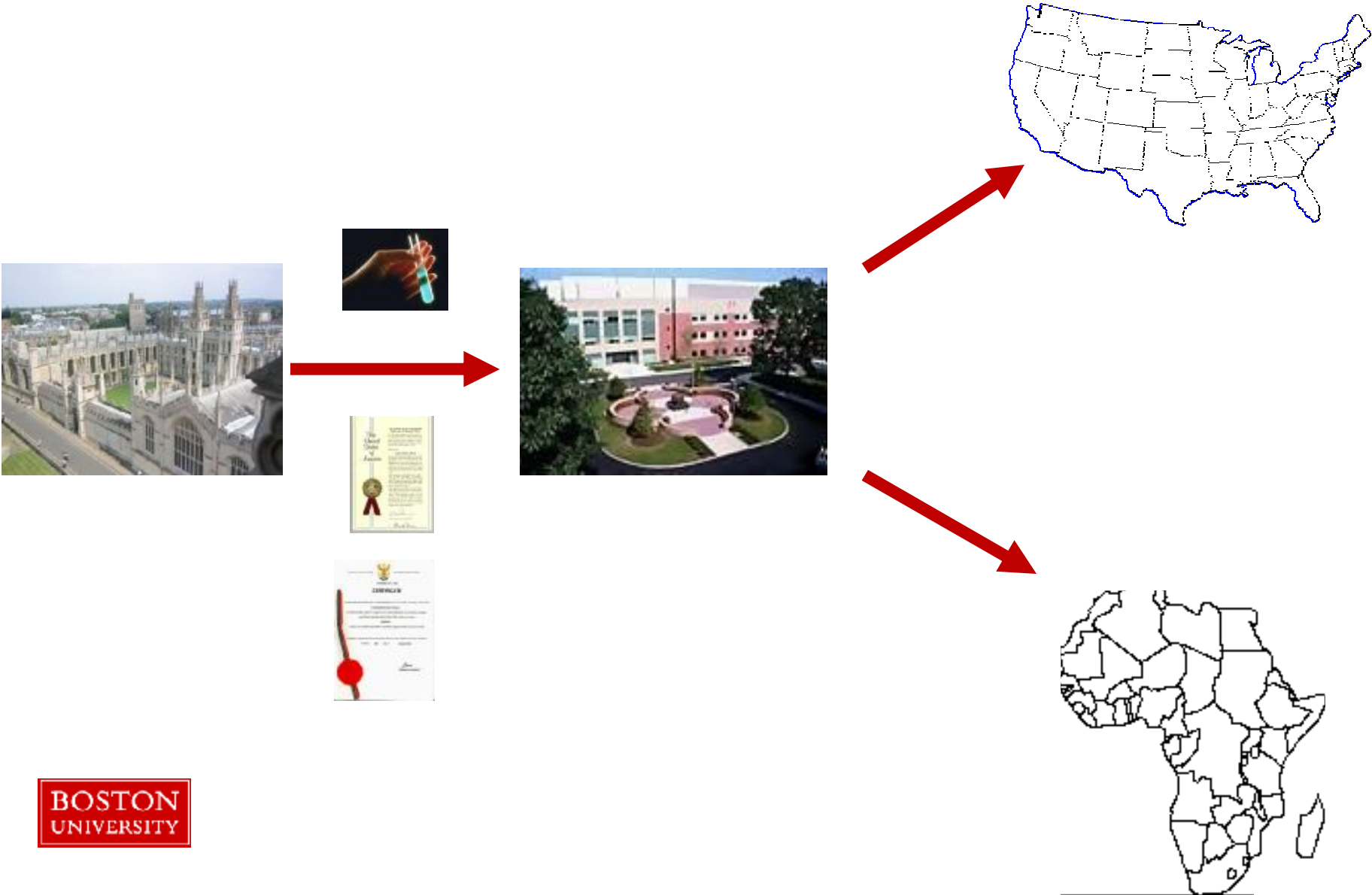
# Therapeutic Category

<u>Therapeutic Area</u>	<u>Number</u>
Oncology	37
Infectious Disease	36
Cardiology	12
Metabolic	12
CNS	10
Dermatology	7
Renal	7
Ophthalmology	6
Gastroenterology	4
Immunology	4
Women's Health	3
Allergy	2
Pulmonary	2
Anaesthesiology	1
Dental	1
<u>Urology</u>	<u>1</u>
Total	145

# Let's think about how we get a public sector discovered drug to the global market

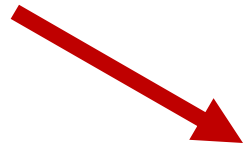
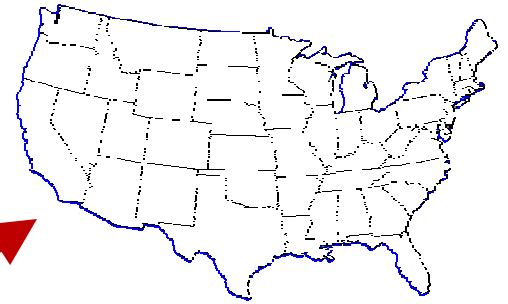


# The Traditional Academic Development Model



**How do we modify this process to  
achieve affordability?**

# Include Developing Country Milestone and Pricing

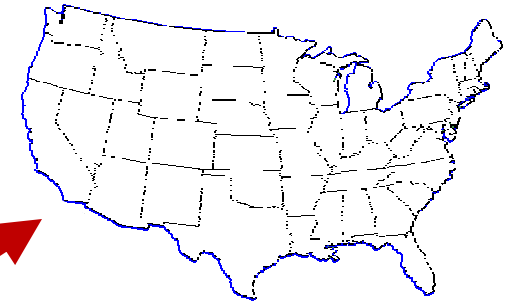


Licensee shall seek registration in a developing country by.....

Licensee shall make available in developing countries at prices no more than 50% more than fully burdened manufacturing cost



# Don't Allow Patenting in Developing Countries

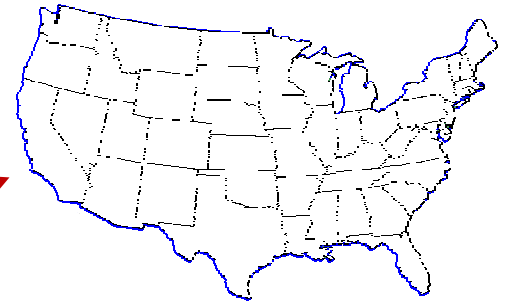


**Cipla**  
Caring for life

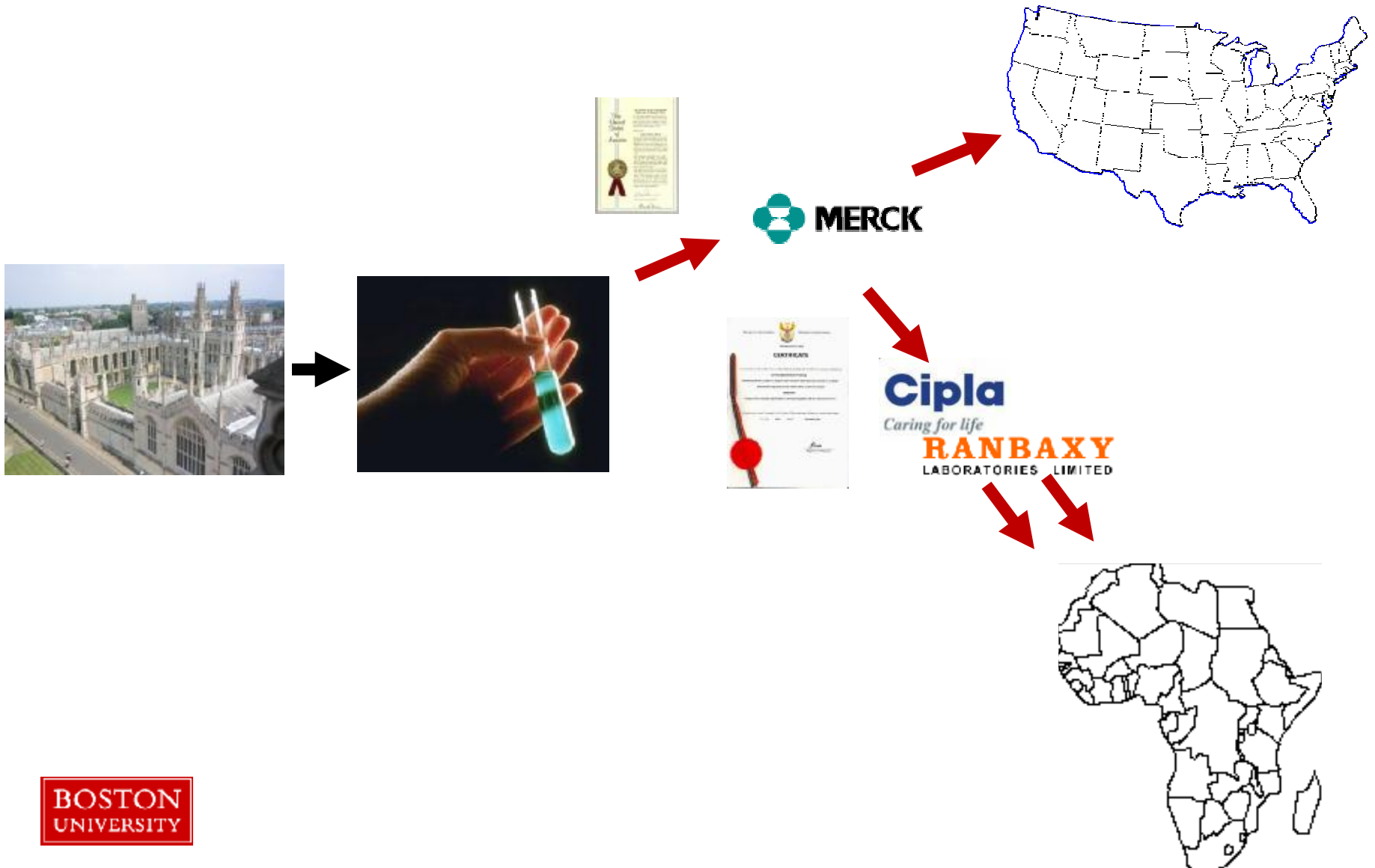
**RANBAXY**  
LABORATORIES LIMITED



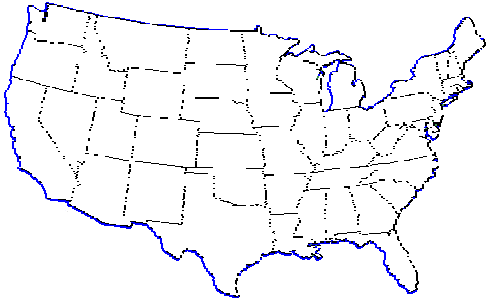
# Separate Licensees



# Mandatory Sublicensing



# Non-Assert



# les Nouvelles

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## Recent U.S. Decisions And Developments Affecting Licensing

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## The Issues

- q Academic technologies are embryonic, high risk and uncertain
  - q “A hot academic technology is one that two companies are interested in”
  - q “First do no harm”
- q Where is the motivation for Universities to include global health protections?
  - q Makes the negotiation more difficult
    - q Potential show stopper
  - q Reduces income (maybe)
  - q Rarely any incentive compensation to motivate Licensing Managers
  - q Part of academic social mission
  - q Culture of academic licensing
- q Power lies with corporate licensees
  - q Gilead, Glaxo, J&J in leadership position on voluntary licensing
  - q What licensing approaches will be acceptable to corporations?

# AUTM 2007 Licensing Activity Survey

<b><u>Invention Disclosures</u></b>	<b><u>19,827</u></b>	
New US Patent Applications filed	11,797	59.5%
US Patents Issued	3,622	18.3%
Licenses Signed	4,391	22.1%
Start-Ups formed	555	2.8%
Active Licenses	30,351	

# Financial Performance

<u>Financial Contribution</u>	<u>Number</u>	<u>%</u>
Loss making	68	52.3%
Gross profitable	27	20.8%
Net profitable	14	10.8%
<u>Self sustaining</u>	<u>21</u>	16.2%
Total	130	

## The Issues

- q AUTM leadership totally committed
  - q Establishing a task force
  - q UNITAID, UAEM, Gilead attended 2009 Annual Meeting
- q Need a forum to discuss and develop a consensus policy
  - q e.g., “Global health protections will be included whenever healthcare products are licensed”
    - q Over 50% of Orange Book listings include patents held by others
  - q What is the role of the emerging patent pools?
    - q UNITAID
    - q Could universities issue “global health” licenses to the pool?
      - q *cf* Government Rights license
    - q Then grant “Exclusive but for” to the primary developer
    - q What if the pool license is a deal breaker?
      - q “First do no harm”

# Boston University

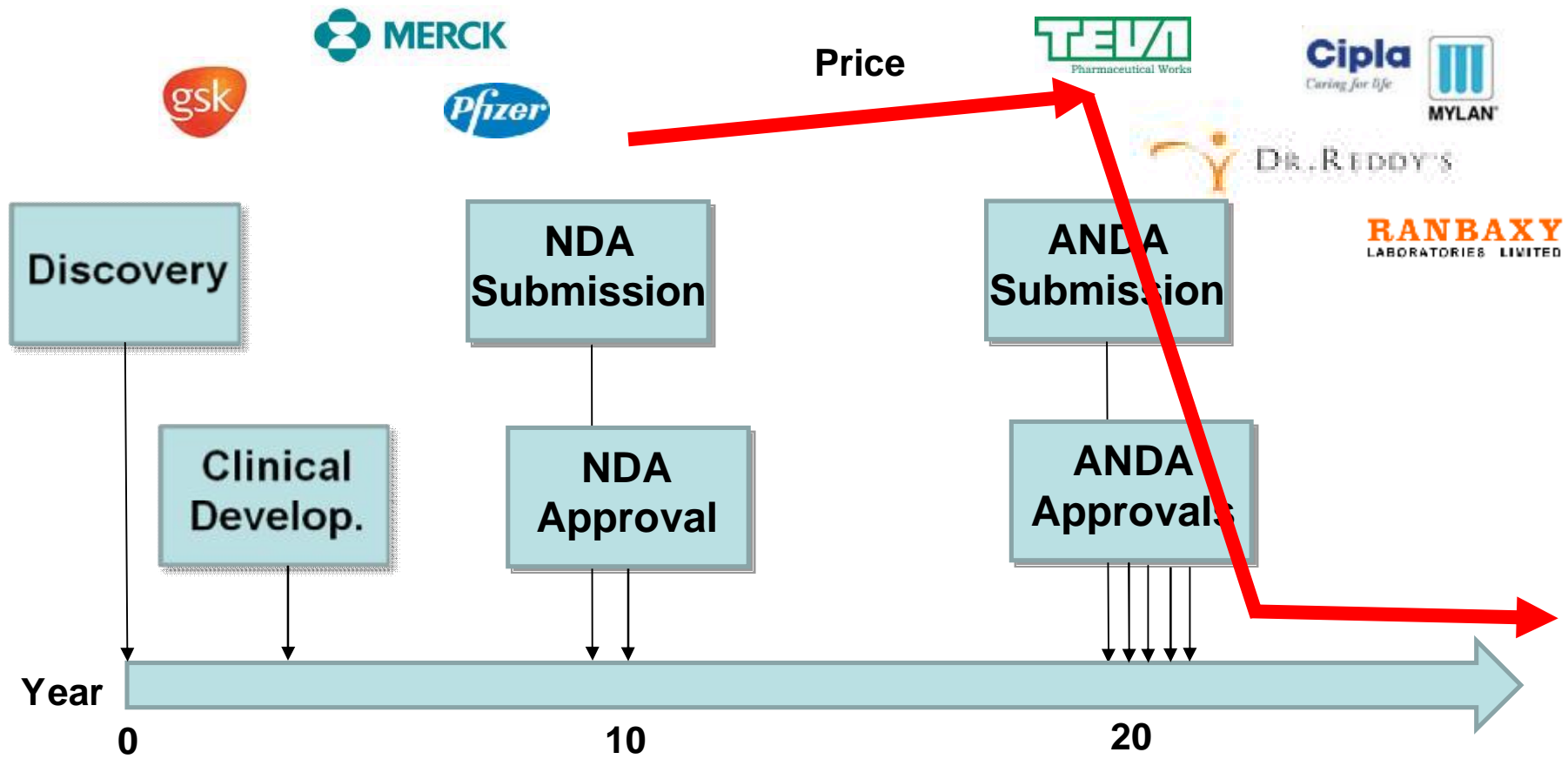
- q Adopted global health licensing principles in October 2007
  - q Process underway to make it a University policy
- q Non-assert approach
  - q Limited to public sector programs
- q Four licenses completed to date
  - q All faculty start-ups
  - q One preferred an alternative approach to non-assert
  - q First one approaching a big pharma partnership
- q Including global health protections in:
  - q Therapeutics and prophylactics
  - q Diagnostics
- q Not including in:
  - q Tools
  - q Devices

# Questions?

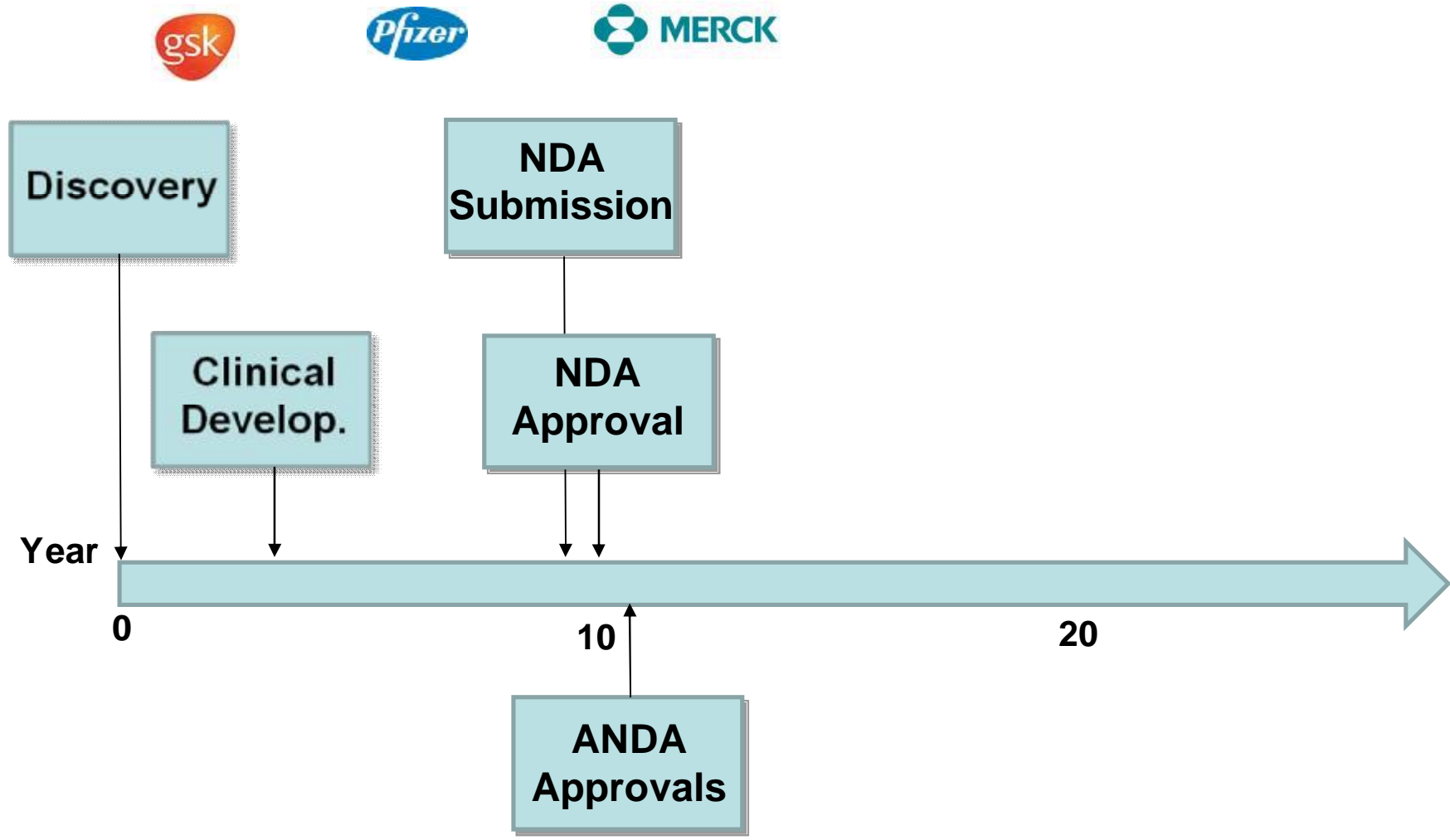
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# A New Pharmaceutical Business Paradigm

# The Traditional Pharmaceutical Paradigm



# The New Pharmaceutical Paradigm



- q We could try to change the patent system to achieve this
- q Or we could change the licensing system
- q The problem isn't the patent system
  - q Patents just give you control over what happens to your IP
  - q An essential component of the innovation system
  - q We should be very cautious about changing it
- q It's much easier (and less risky!) to change licensing behavior
  - q E.g. PCT Treaty signed 1970
  - q Came into effect in 1978

# Licensing Mechanisms

## (a) Voluntary

- q Contractually requiring availability in developing countries
  - q Requiring the licensee to include developmental milestones;
- q Contractually requiring availability and affordability in developing countries without specifying the way this will be obtained
  - q Require the licensee to develop the product in developing countries and to sell it using cost+ pricing;
- q Specifying desired outcomes of availability and affordability in developing countries and including an enforcement mechanism to achieve competition if the specified outcomes do not occur
  - q Reserving a march-in right to grant additional licenses to be exercised if the product is not made available in developing countries in a timely manner or if prices in developing countries are too high;

# Licensing Mechanisms

## (b) Forced Competition

- q Specifying mechanisms to achieve competition
  - q Excluding developing countries from the license and issuing non-exclusive licensees in developing countries separately
  - q Granting only non-exclusive rights in developing countries
  - q Requiring the licensee not to patent in developing countries
  - q Requiring the licensee to grant sublicenses in developing countries at low or zero royalty rates
  - q Requiring the licensee to commit to not assert the licensed IP in developing countries