

Using Academic Licensing Agreements to Promote Global Social Responsibility

Equitable Licensing of Medical Research Results
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Dr. Ashley J. Stevens
Executive Director, Technology Transfer

Senior Research Associate
Institute for Technology Entrepreneurship and Commercialization
School of Management

Boston University



Agenda

- Universities and Drug Discovery
- Licensing Approaches
- Issues

University Licensing Policies and Global Health

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

Was Zerit an isolated case?

The Public Sector and Drug Discovery

- ❑ Traditionally:
 - ❑ Public sector researchers identified disease pathways and points of intervention
 - ❑ Corporate scientists used this information to discover actual drugs
- ❑ Biotechnology shifted the boundary dramatically towards the public sector

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

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

[1] Office of Technology Transfer, Boston University, Boston MA, § Contributed equally to this study, [2] Norwegian Radium Hospital Research Foundation, Oslo, Norway, [3] Robert Wood Johnson Foundation, Princeton, NJ, [4] Sloan School of Management, Massachusetts Institute of Technology, Cambridge, MA [5] National Institutes of Health, Washington, D.C.,

[6] Office of Technology Transfer and Institute for Technology Entrepreneurship and Commercialization, Boston University, Boston, MA
¶ Corresponding Author; astevens@bu.edu



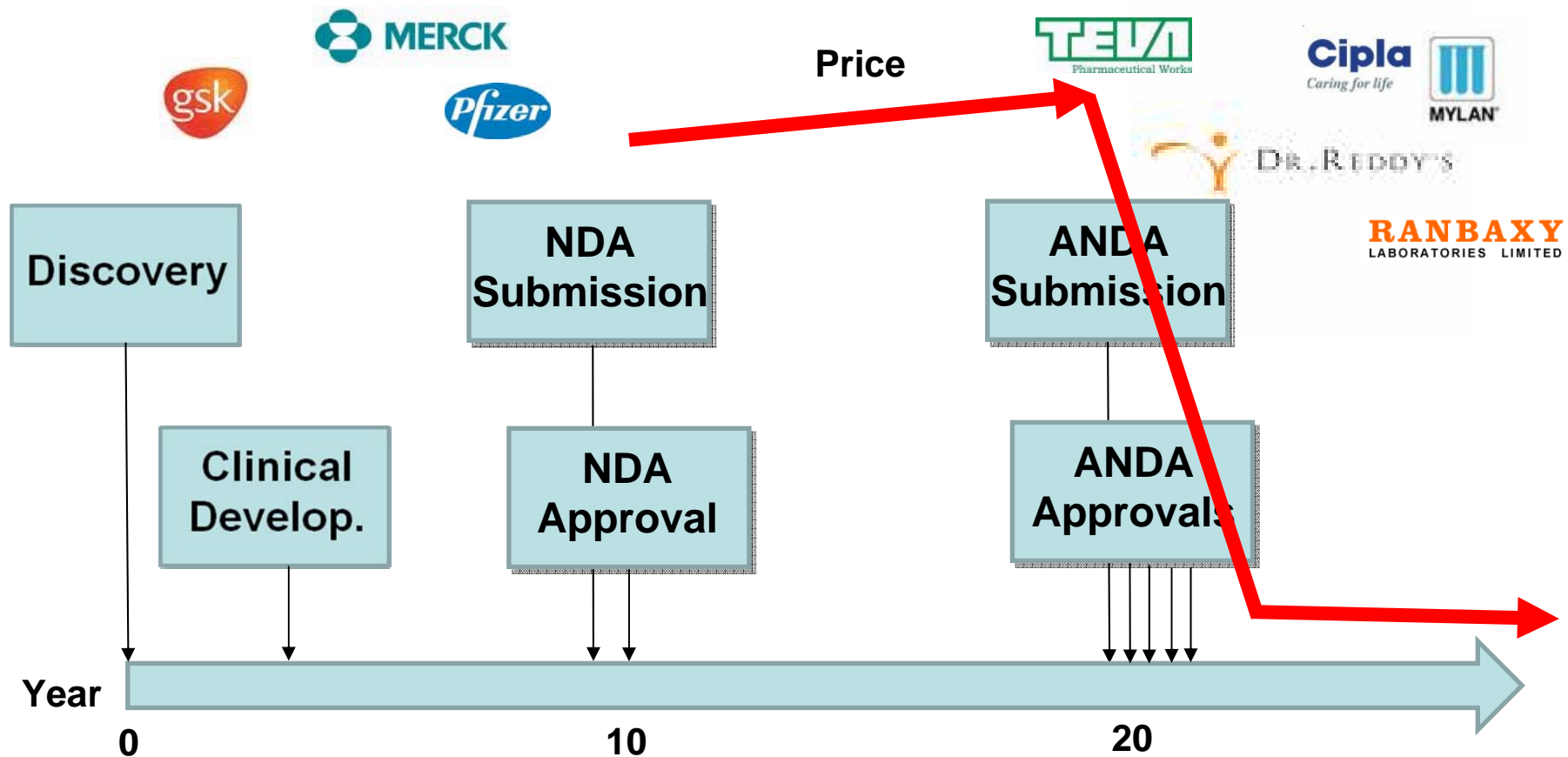
FDA Approved Products Discovered at Public Sector Research Institutes

<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

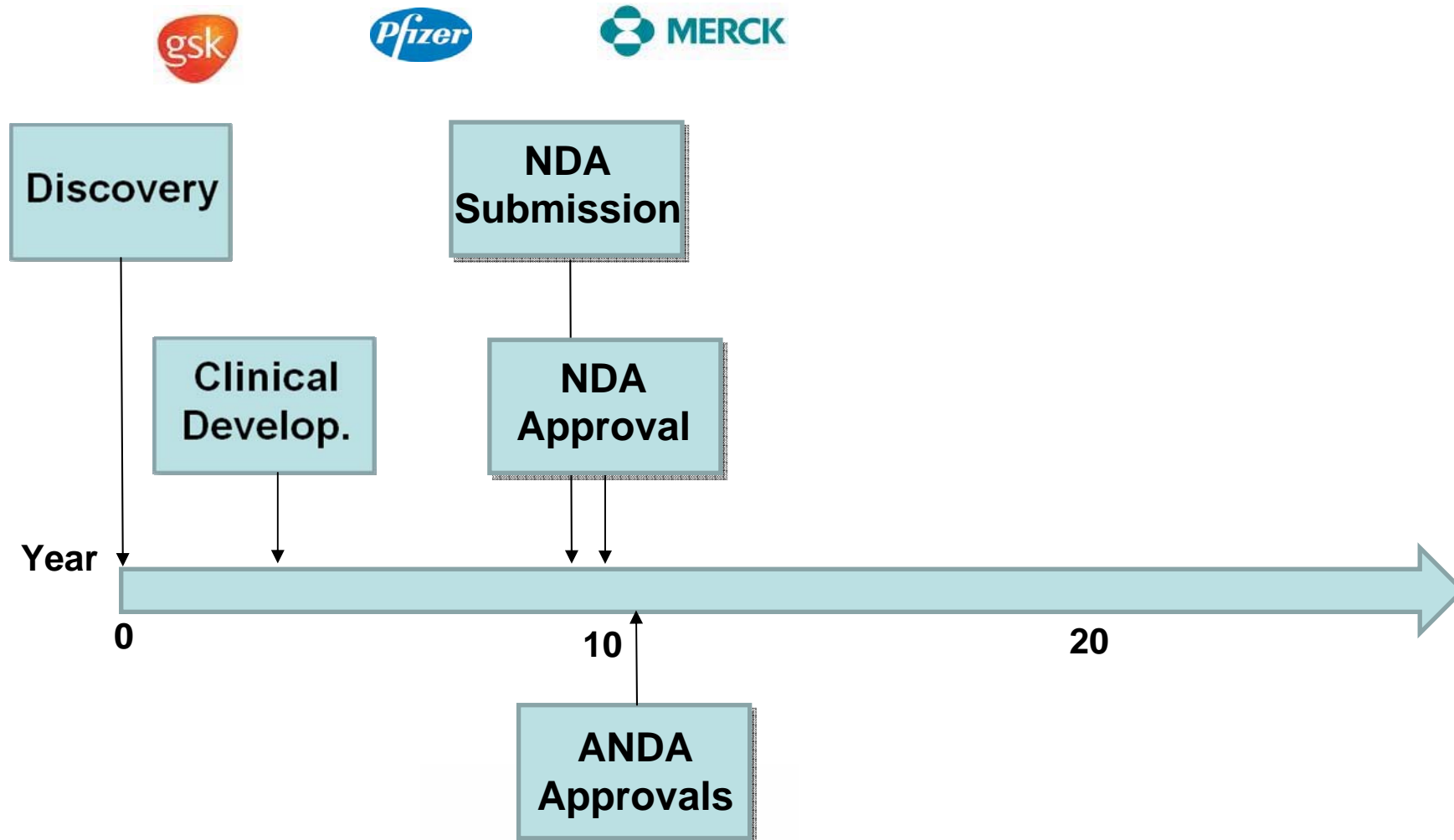
Therapeutic Category

<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

The Traditional Pharmaceutical Paradigm



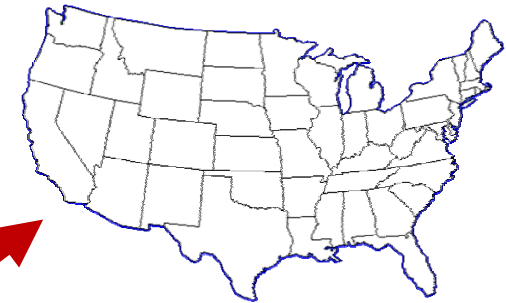
The New Pharmaceutical Paradigm



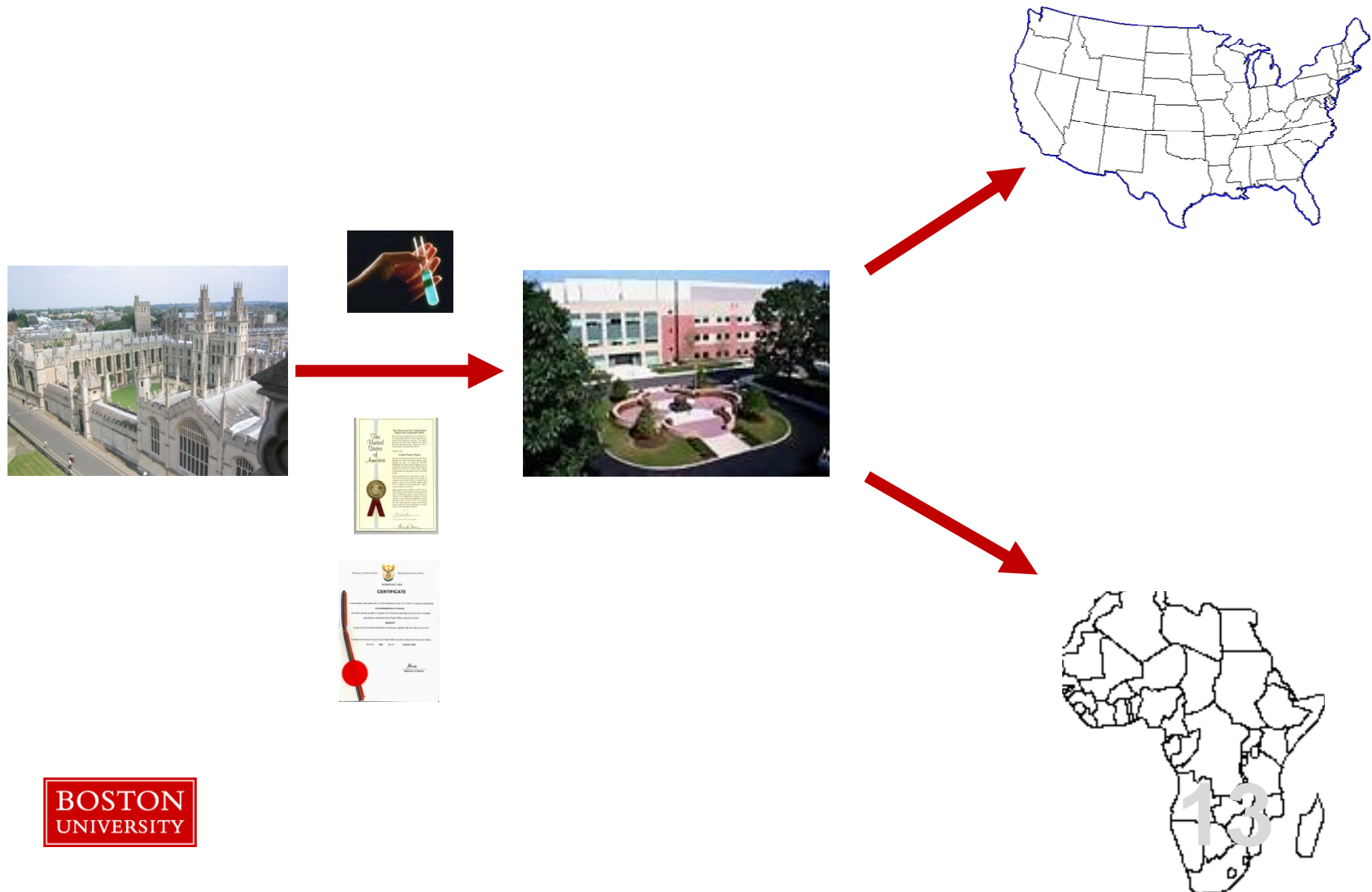
How do we achieve this?

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

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

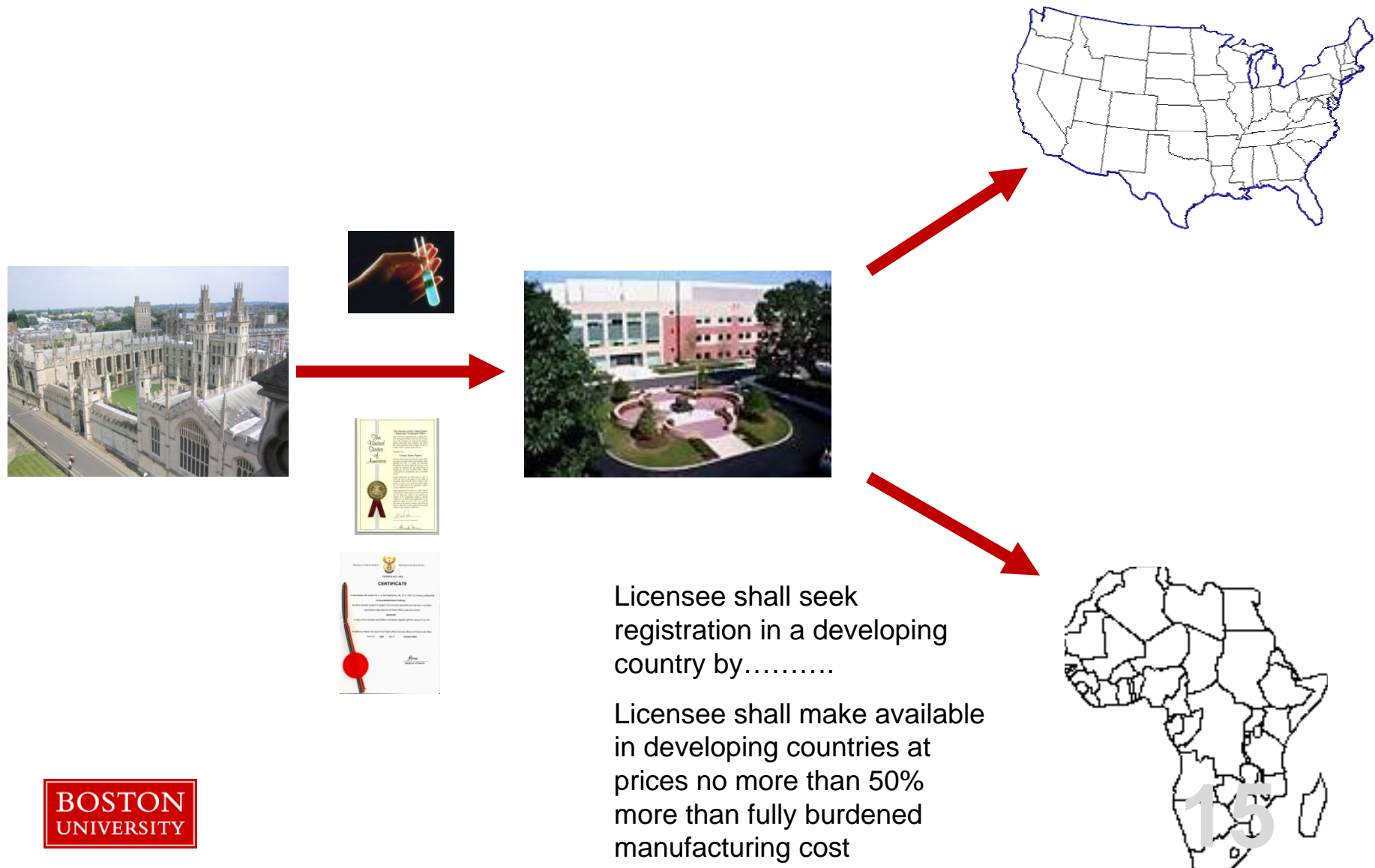


The Traditional Academic Development Model



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

Include Developing Country Milestone and Pricing



Don't Allow Patenting in Developing Countries



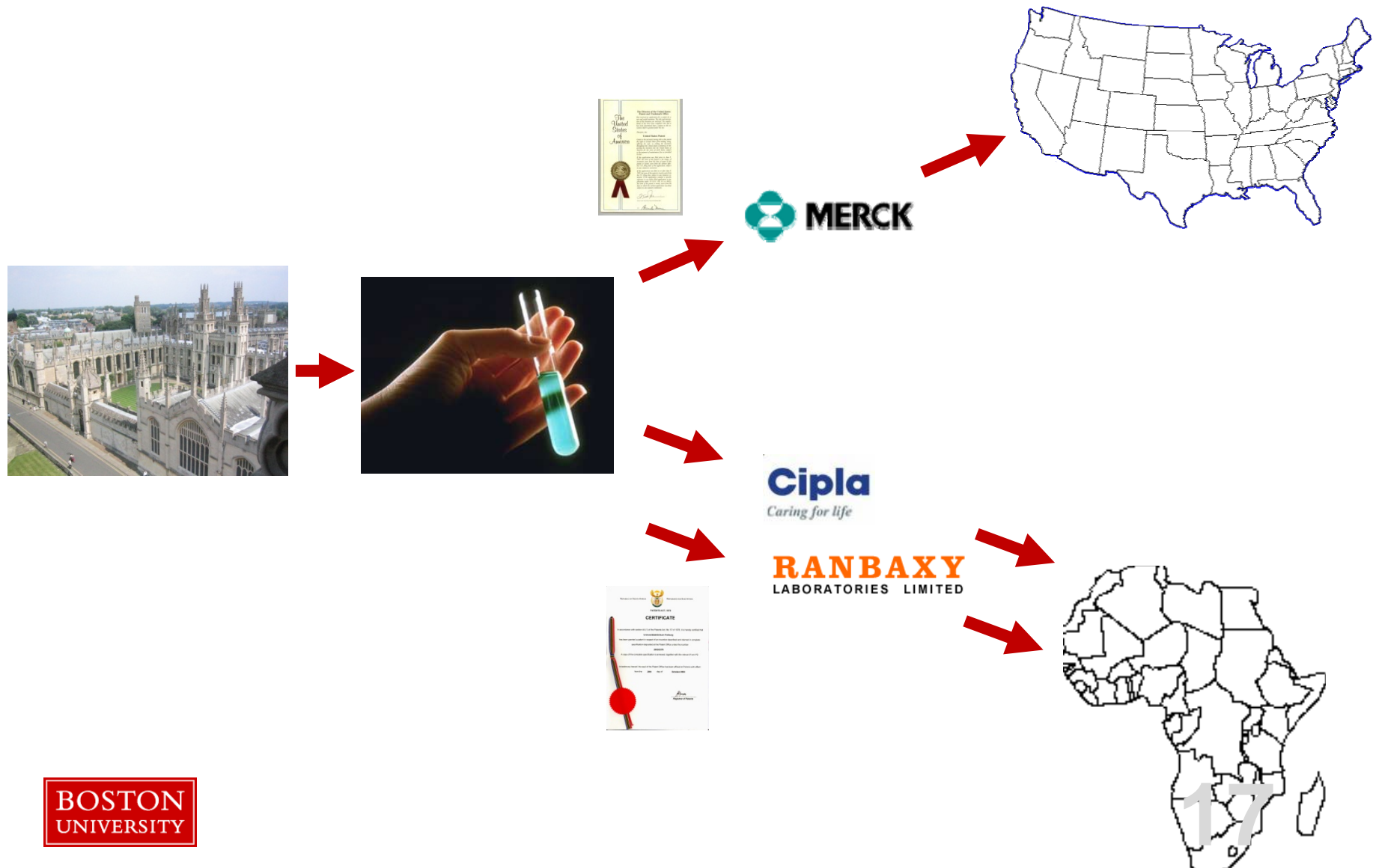
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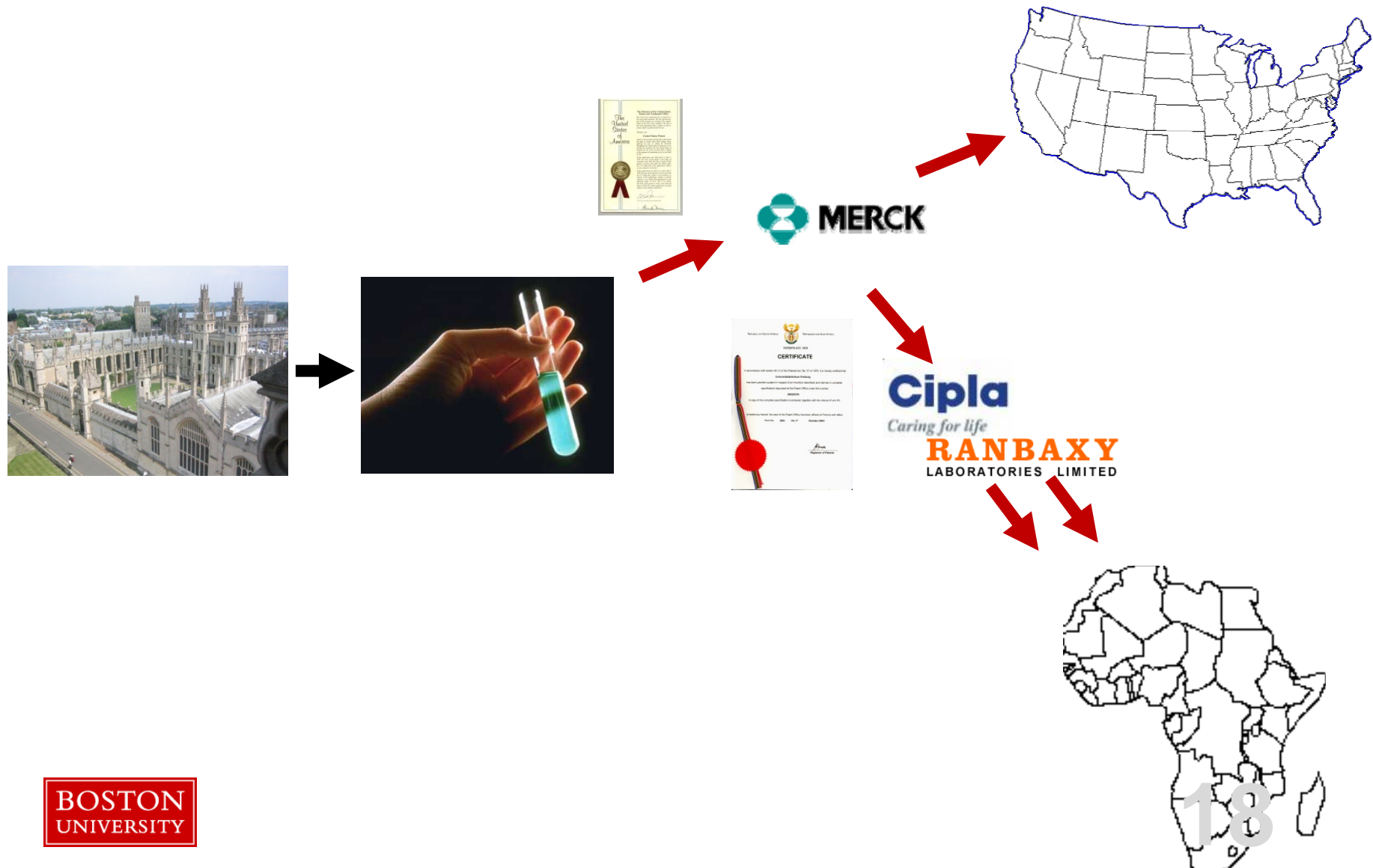
RANBAXY
LABORATORIES LIMITED

18

Separate Licensees



Mandatory Sublicensing



Non-Assert



les Nouvelles

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Using Academic License Agreements To Promote Global Social Responsibility

ASHLEY J. STEVENS & APRIL E. EFFORT — Page 85

Winning The Claim: Reverse Engineering For

Successful Patent Licensing

TERRY LUDLOW, MIKE THUMM & ANDREA GIRONES — Page 102

**Licensing In China: The New Anti-Monopoly Law,
The Abuse Of IP Rights And Trade Tensions**

PAUL JONES — Page 106

**Creative Vigilantes: Magicians, Chefs, And Stand-up Comics
Protect Their Creations Without The Law**

DANIEL SMITH — Page 117

Software & Valuation In The Information Society

DWIGHT OLSON — Page 120

What Is Patent Quality—A Merchant Banc's Perspective

JAMES E. MALACKOWSKI & JONATHAN A. BARNEY — Page 123

Copyright And Open Source Licensing Of Software Work

PRATIBHA GUPTA — Page 135

**Agreements On Research Cooperation Between Industry And University
In Germany—Revised "Berlin Contract"**

HEINZ GODDAR & HERMANN MOHNKOPF — Page 142

Recent U.S. Decisions And Developments Affecting Licensing

BRIAN BRUNSVOLD & JOHN C. PAUL — Page 144

Licensing Mechanisms

(a) Voluntary

- ❑ Require availability in developing countries
 - ❑ Include development milestones;
- ❑ Requiring affordability in developing countries
 - ❑ Specify cost+ pricing;
- ❑ Include an enforcement mechanism if the specified outcomes do not occur
 - ❑ Reserve to grant additional licenses if not available or too high priced

Licensing Mechanisms

(b) Forced Competition

- ❑ Include mechanisms to achieve competition
 - ❑ Grant non-exclusive rights in developing countries
 - ❑ Exclude developing countries from the license
 - ❑ Issue non-exclusive licenses in developing countries
 - ❑ Don't patent in developing countries
 - ❑ Require the licensee to grant sublicenses in developing countries
 - ❑ Require the licensee to not assert the licensed IP in developing countries

Key Learnings

- ❑ Global health protections can be included in standard forms of licensing agreement relatively simply
- ❑ Then it just becomes another business negotiation item
 - ❑ But a tough one!
- ❑ Must include in negotiations from day 1 in the term sheet

The Issues

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

AUTM 2007 Licensing Activity Survey

<u>Invention Disclosures</u>	<u>19,827</u>	
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	

Boston University

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

Status

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

Questions?

astevens@bu.edu