

***Partnering Without Borders: Accelerating Global
Treatments to Patients***

The Role of Universities

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AUTM Annual Meeting

San Diego, CA

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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

Universities and Drug Discovery



SPECIAL ARTICLE

The Role of Public-Sector Research in the Discovery of Drugs and Vaccines

Ashley J. Stevens, D.Phil., Jonathan J. Jensen, M.B.A., Katrine Wyller, M.B.E., Sabarni Chatterjee, M.B.A., Ph.D., and Mark L. Rohrbaugh, Ph.D., J.D.

ABSTRACT

BACKGROUND

Historically, public-sector researchers have performed the upstream, basic research that elucidated the underlying mechanisms of disease and identified promising points of intervention, whereas corporate researchers have performed the downstream, applied research resulting in the discovery of drugs for the treatment of diseases and have carried out development activities to bring them to market. However, the boundaries between the roles of the public and private sectors have shifted substantially since the dawn of the biotechnology era, and the public sector now has a much more direct role in the applied-research phase of drug discovery.

METHODS

We identified new drugs and vaccines approved by the Food and Drug Administration (FDA) that were discovered by public-sector research institutions (PSRIs) and classified them according to their therapeutic category and potential therapeutic effect.

RESULTS

We found that during the past 30 years, 153 new FDA-approved drugs, vaccines, or new indications for existing drugs were discovered through research carried out in PSRIs. These drugs included 93 small-molecule drugs, 36 biologic agents, 15 vaccines, 8 *in vivo* diagnostic materials, and 1 over-the-counter drug. More than half of these drugs have been used in the treatment or prevention of cancer or infectious diseases. PSRI-discovered drugs are expected to have a disproportionately large therapeutic effect.

CONCLUSIONS

Public-sector research has had a more immediate effect on improving public health than was previously realized.

From the Institute for Technology Entrepreneurship and Commercialization (A.J.S.) and Office of Technology Development (A.J.S., J.J.J.), Boston University School of Management, Boston; the Norwegian Radium Hospital Research Foundation, Oslo (K.W.); and the Office of Technology Transfer, National Institutes of Health, Bethesda, MD (S.C., M.L.R.). Address reprint requests to Dr. Stevens at Boston University School of Management, 53 Bay State Rd., Boston, MA 02215, or at astevens@bu.edu.

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Number of Products

| <u>Type of Product</u> | <u>Number</u> |
|---------------------------|---------------|
| New Chemical Entity | 93 |
| Biologic | 36 |
| Vaccine | 15 |
| Over the counter | 1 |
| <u>In-vivo diagnostic</u> | <u>8</u> |
| Total | 153 |

- ❑ This paper investigates the contribution of public-sector research institutions (PSRIs) outside the US to pharmaceutical innovation.



Bringing The Study Upto Date

| | <u>2011 Study</u> | <u>New Drugs</u> | <u>Total</u> | <u>% Change</u> |
|-----------------|-------------------|------------------|--------------|-----------------|
| U.S. | 153 | 59 | 212 | 39% |
| <u>Non-U.S.</u> | 31 | 55 | 86 | 177% |
| Total | 184 | 114 | 298 | 62% |

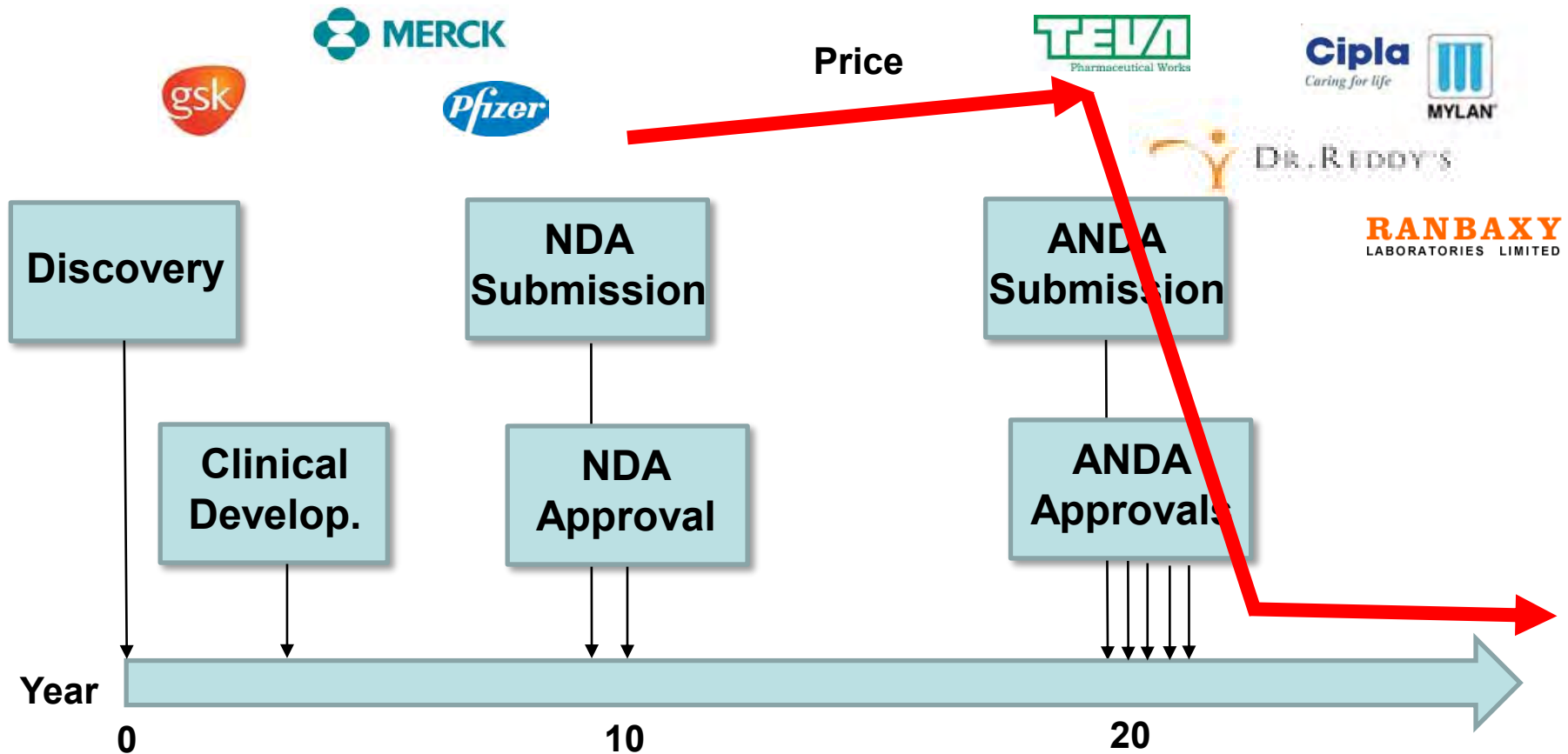
Let's think about how we get a public sector discovered drug to the global market



The Traditional Academic Development Model



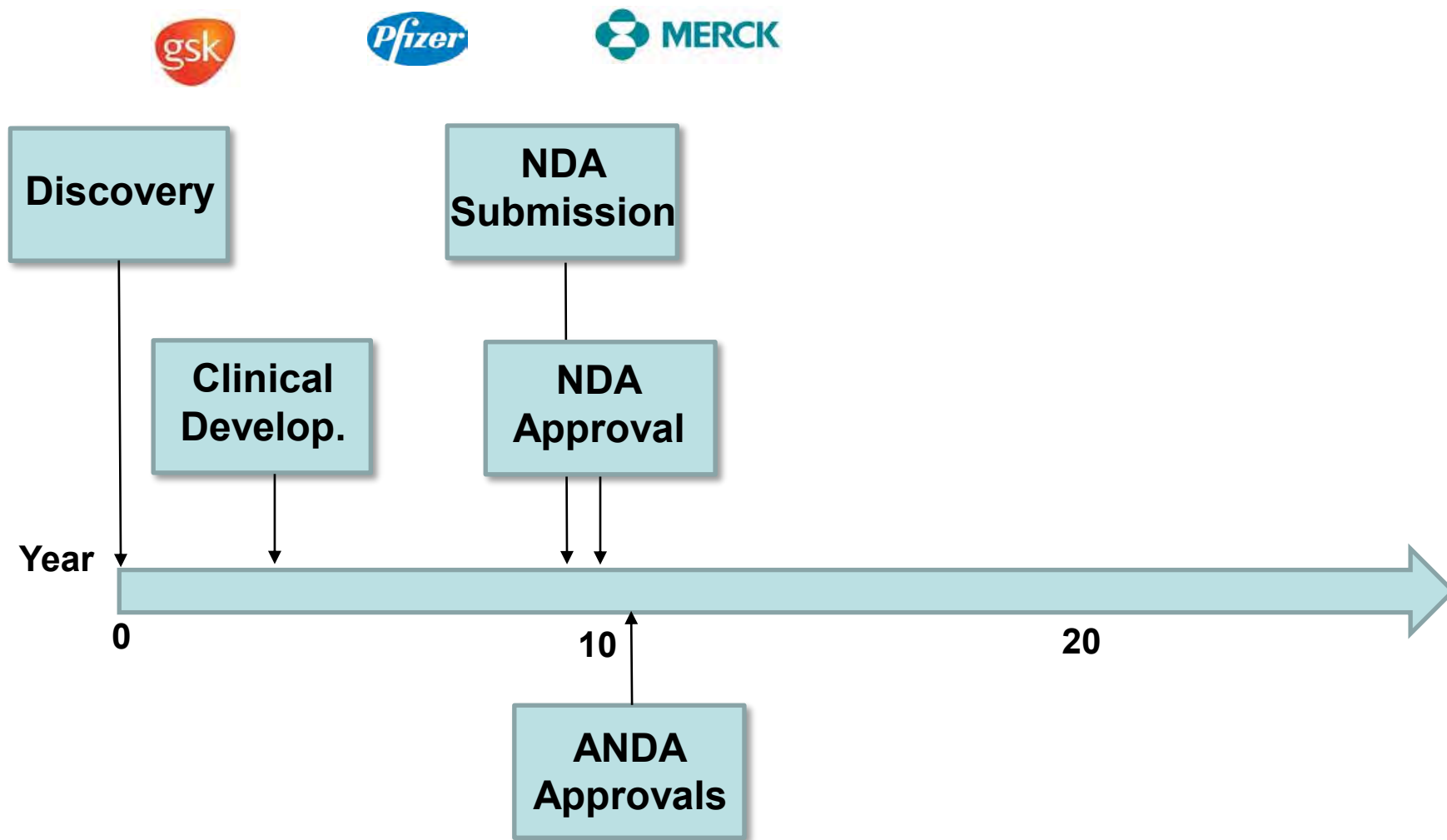
The Traditional Pharmaceutical Paradigm



How do we modify this process to achieve affordability?

- ❑ We could try to change the patent system to achieve this
- ❑ 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

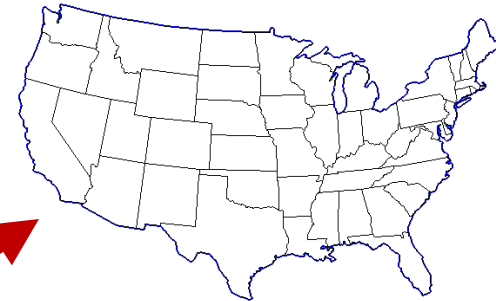
The New Pharmaceutical Paradigm



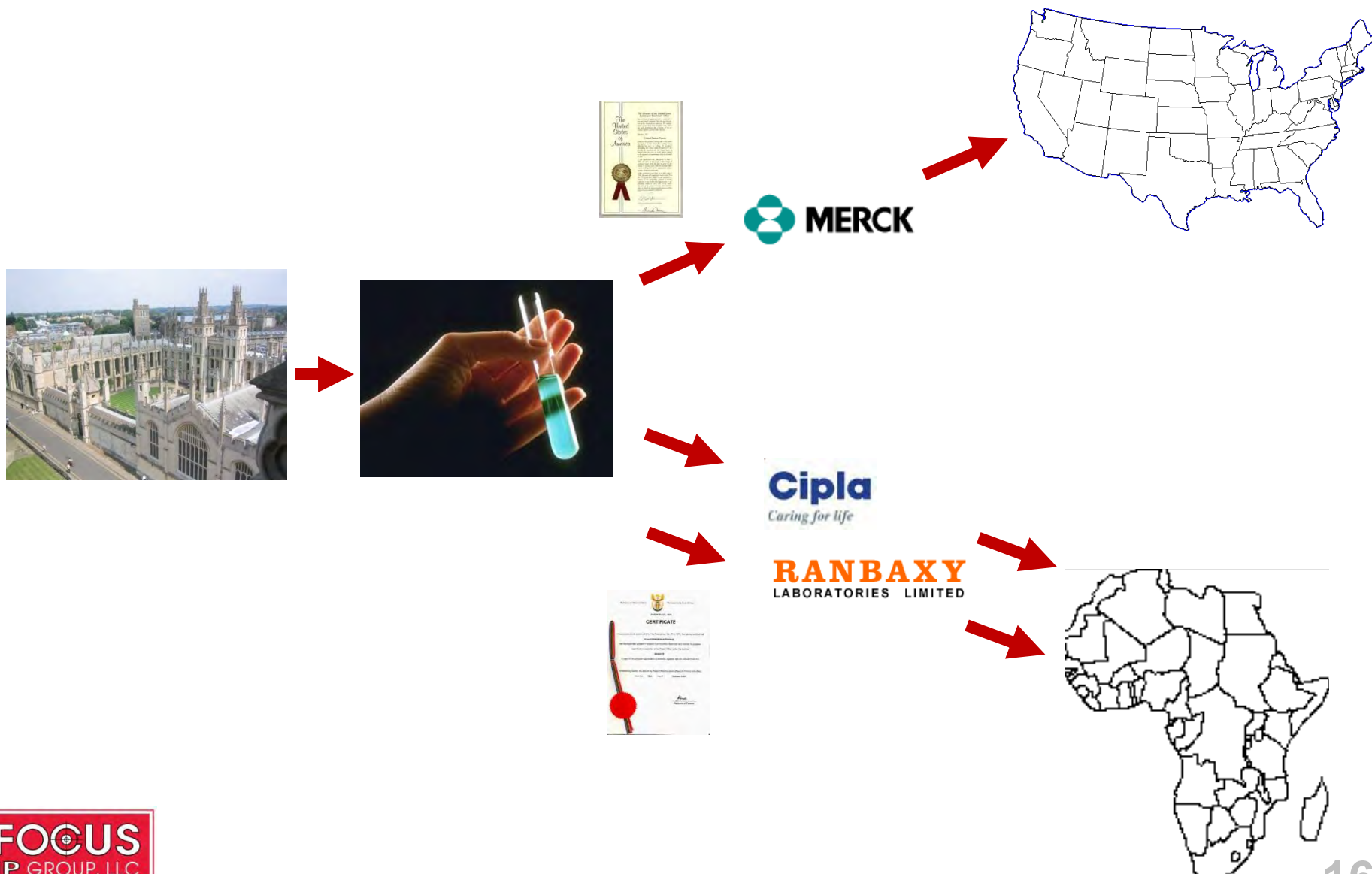
Include Developing Country Milestone and Pricing



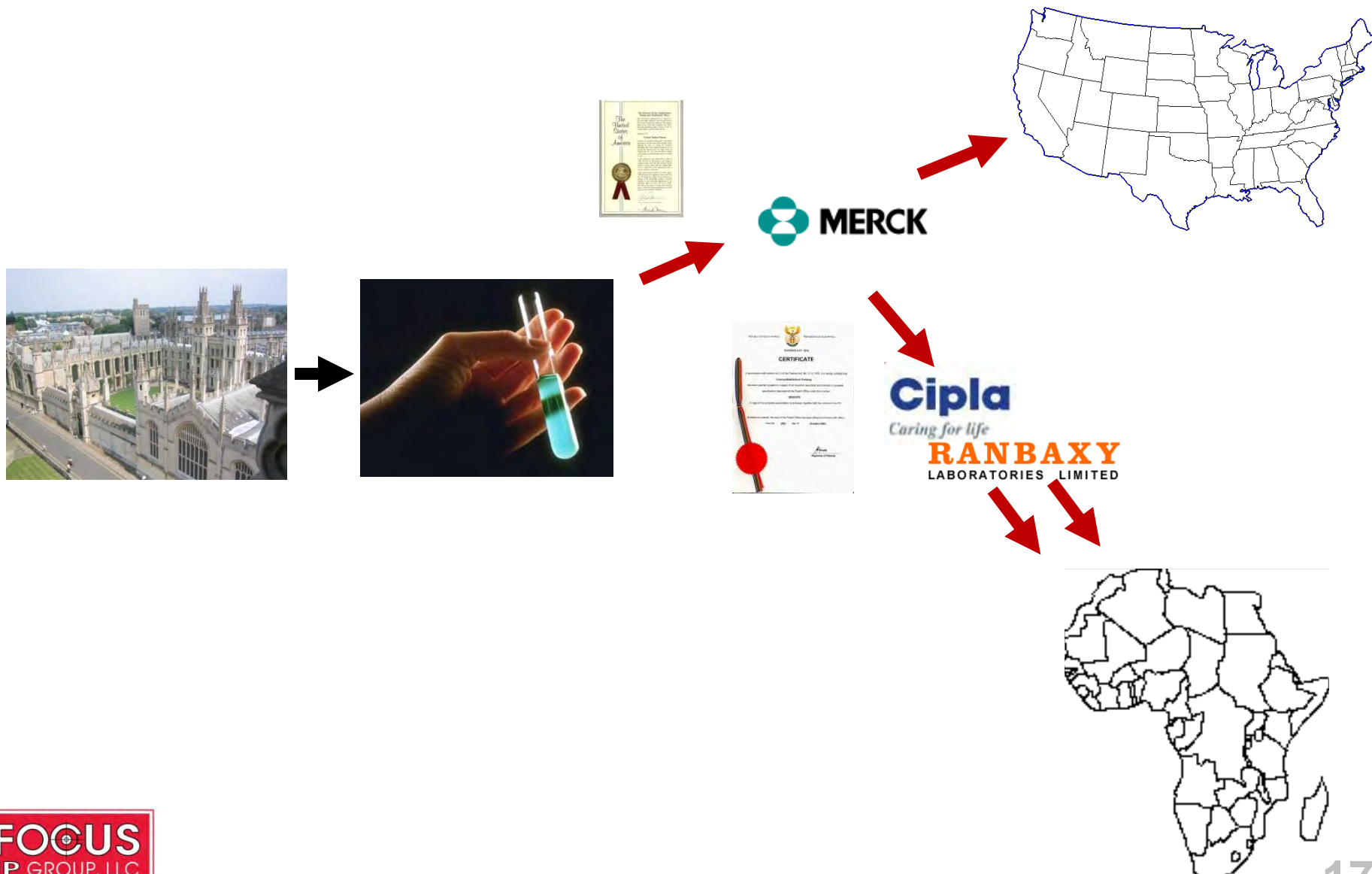
Don't Allow Patenting in Developing Countries



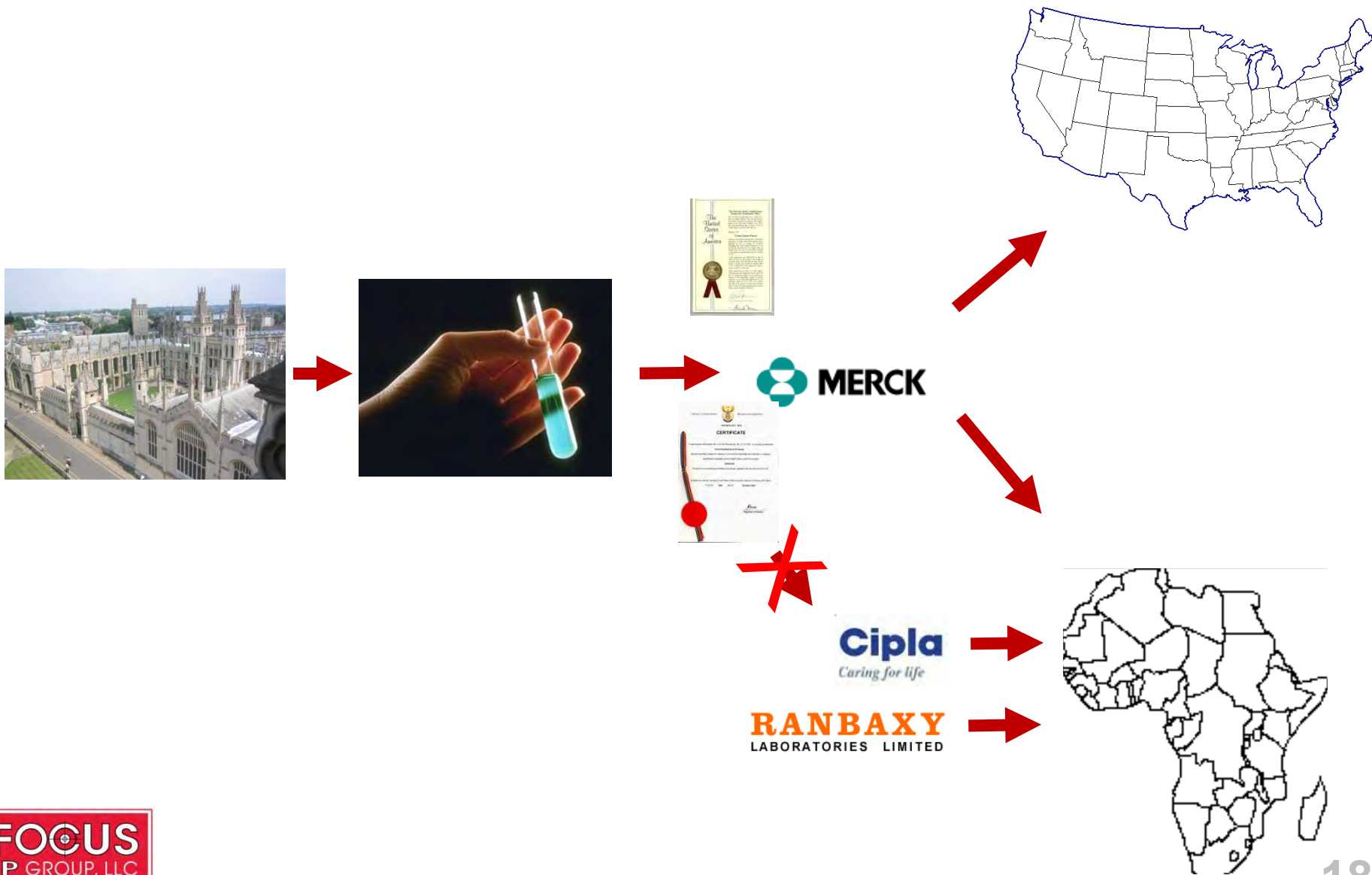
Separate Licensees



Mandatory Sublicensing



Non-Assert



les Nouvelles

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The Association of
University Technology
Managers

Advancing Discoveries for a Better World

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WELCOME TO AUTM, a living, dynamic, global network of more than 3,500 technology transfer professionals who work in academic, research, government, legal and commercial settings. AUTM is dedicated to promoting and supporting technology transfer through education, advocacy, networking and communication.

Act Now!

Must-read Article for AUTM Members
Be sure to read:
["Universities, Inventors, and the Bayh-Dole Act,"](#) by Sen. Birch Bayh, Joseph P. Allen and Howard W. Bremer
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The Kauffman Foundation "Solution"

The *Harvard Business Review* has published its list of "Ten Breakthrough Ideas

What's Going On...

AUTM Licensing Activity Survey Summaries Now Available

Purchase the [AUTM U.S. Licensing Activity Survey: FY2008](#)

Purchase the [AUTM Canadian Licensing Activity Survey: FY2008](#)

[Read more about the surveys](#)

Register for the AUTM 2010 Annual Meeting

The AUTM 2010 Annual Meeting, [Building a Stronger Community](#), will take place March 18 – 20, 2010 at the Hilton New Orleans Riverside, New Orleans, LA USA

Technology Transfer News

Read the Latest Technology Transfer Articles

[University Inventions Sparked Record Number of Companies in 2008](#)
Published in *The Chronicle of Higher Education* 2/15/10

[UC Davis aims to turn more of its tech into business](#)
Published in *University Business* 2/8/10

[U-South Dakota researcher's germ-killing socks go into production](#)
Published in *Serkadis* 2/3/10

[Gecko's lessons transfer](#)

AUTM Announces Global Health Initiative

AUTM announced the launch of a new [Global Health Initiative](#) that promotes licensing practices that support access to essential medicines by developing countries. The initiative includes a [Global Health Toolkit](#) created by AUTM members.

In keeping with this initiative, AUTM endorsed the [University Principles on Global Access to Medicines](#). These principles were developed by a team that included AUTM leadership. Read the [press release](#) about the AUTM Global Health Initiative and AUTM's endorsement of the Principles.

Your institution can endorse the Principles [here](#).

9 [POINTS](#) [Read the Nine Points to Consider in Licensing University Technology](#)

[Endorse the Nine Points to Consider](#)

Patent Reform

Patent Reform has been introduced into the 111th Congress. AUTM has joined the Association of American Universities, the American

[Read the latest blog](#) from Alan Bentley about the hot debate topics at the 2010 Annual Meeting.

AUTM announces plenary speakers for 2010 Annual Meeting. [Read the blog](#) for details.

Will this Be Your First Annual Meeting?

Get the most out of your first meeting by learning from other members. Check out the [blog posted by Vinay Tannan](#), Ph.D., Licensing Associate, UVA Patent Foundation. Vinay recalls his experience as a first time attendee at the 2009 Annual Meeting. Hassan Nagvi also [shares his experiences](#) as a first-time attendee.

Not Receiving AUTM E-mails?

Be sure to "white list" AUTM. For details, [click here](#).

1/14/10

[New License Agreement with University of Colorado Gives Viral Genetics, Inc., Right to Develop Cancer Therapies](#)
Published on *PRNewswire* 12/8/09

[Sathguru Signs MoU with University of Florida to Facilitate Technology Commercialization in Asia](#)
Published on *BusinessWire India* 12/4/2009

[Nikon Corporation Acquires License From Harvard University For 'STORM' Super Resolution Microscopy](#)
Published on *PRNewswire*, 12/3/2009

[Champions Biotechnology Enters into Licensing Agreement with Yale University and Southern Research Institute for the Repurposing of Bithionol for Oncology](#)
Published on *PRNewswire*

[Duke University and Jubilant Organosys Announce Intent to Enter Global Research and Drug Development Partnership](#)
Published on *BusinessWireIndia.com* 11/11/09

[Universities Endorse Global Access Principles](#)
Published on *Bloomberg.com*

Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies

Background

Universities have a fundamental role in fostering public health. Their greatest contributions may occur through discovery of new knowledge, education of students, and dissemination of knowledge for others to build upon through publications, library collections, and most recently, open courseware.

In addition, universities in the developed world work to facilitate the commercialization of the health-related inventions of academic researchers by developing and disseminating these technologies for the public good. We have created new methods to deploy cutting-edge knowledge toward potential public benefit by enticing risk takers to invest in our early stage technology in the hope of possible downstream commercial applications. In recent years, the licensing practices involved in such commercialization have expanded to promote explicitly global access to university-developed technologies, ensuring that advances in health reach those who need them most.

This sensitivity to global health was reflected in *Nine Points to Consider in Licensing University Technology*, a statement endorsed by nearly seventy universities and other organizations since the spring of 2007. In acknowledgement that conventions in this field are ever evolving, and building on recent experience, the institutions named below believe a more concrete statement of goals as well as licensing practices would help to promote further progress in advancing health in developing countries. The principles

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the Equitable Dissemination of Medical Technologies and invites your institution to do the same. These principles were developed by a team comprised of AUTM leaders, including Jon Soderstrom, AUTM immediate past president, of Yale University; and Ashley J. Stevens, AUTM president-elect, of Boston University. These guidelines discuss best practices for universities when considering the equitable dissemination of medical technologies.

Your institution can support these Principles by becoming a signatory to the document. Please ensure you have the necessary authority from your institution prior to signing.

[Click here](#) to download the Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies (PDF file)

[Click here](#) to endorse the Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies on behalf of your institution.

The [AUTM Global Health Toolkit](#) includes AUTM position documents, relevant papers and articles on global health issues and sample licensing clauses.

Current Signatories:

| Institution | Signing Date |
|--|---------------------|
| Association of University Technology Managers | 11/09/2009 |
| Boston Univ | 11/09/2009 |
| Brown Univ | 11/09/2009 |
| Harvard Univ | 11/09/2009 |
| Univ of Pennsylvania | 11/09/2009 |
| Yale Univ | 11/09/2009 |
| Oregon Health & Science University | 11/09/2009 |
| National Institutes of Health | 11/10/2009 |
| University of Illinois Chicago | 11/10/2009 |
| University of Illinois Urbana-Champaign | 11/11/2009 |
| Centers for Disease Control and Prevention | 11/12/2009 |
| University of Vermont and State Agricultural College | 11/19/2009 |
| Duke University and Duke Medicine | 12/01/2009 |
| University of British Columbia | 01/10/2010 |
| Bilkent University | 01/27/2010 |
| El Colegio de México | 01/27/2010 |
| New York University | 02/04/2010 |
| Tecnologico de Monterrey | 02/13/2010 |

Boston University

- ❑ Adopted global health licensing principles in October 2007
- ❑ Non-assert approach
 - ❑ Limited to public sector programs
 - ❑ Trade dress protection
- ❑ Included global health protections in:
 - ❑ Therapeutics and prophylactics
 - ❑ Diagnostics
- ❑ Not included in:
 - ❑ Tools
 - ❑ Devices
- ❑ Still going strong 9 years later
 - ❑ http://www.bu.edu/otd/files/2013/10/StartUp_ExclusiveLicense_12-10-12_Clean_ForDistribution.pdf

- ❑ 2.07 [If for a healthcare technology Non-suit. University and Licensee on behalf of themselves and any successors-in-interest to the Licensed Products and Licensed Processes covenant that they will not, before or after the Effective Date of this Agreement, assert any claim of patent infringement (including direct infringement, contributory infringement, and induced infringement) under any of the patents in the Patent List, any Licensed Processes or any Orange Book Patent Right for manufacture, - 10 - use, sale, offer for sale or importation of Licensed Products against any third party engaged in the manufacture, use, sale offer for sale, or importation of Licensed Products in or for Non-Suit Countries for sale to Public Sector entities. The above notwithstanding, this non-suit provision will only apply to products which when offered for sale to End Users are in a Trade Dress that is different from Licensee's Trade Dress in every respect.