The Role of Universities in Biotech Product Development and Capacity Building

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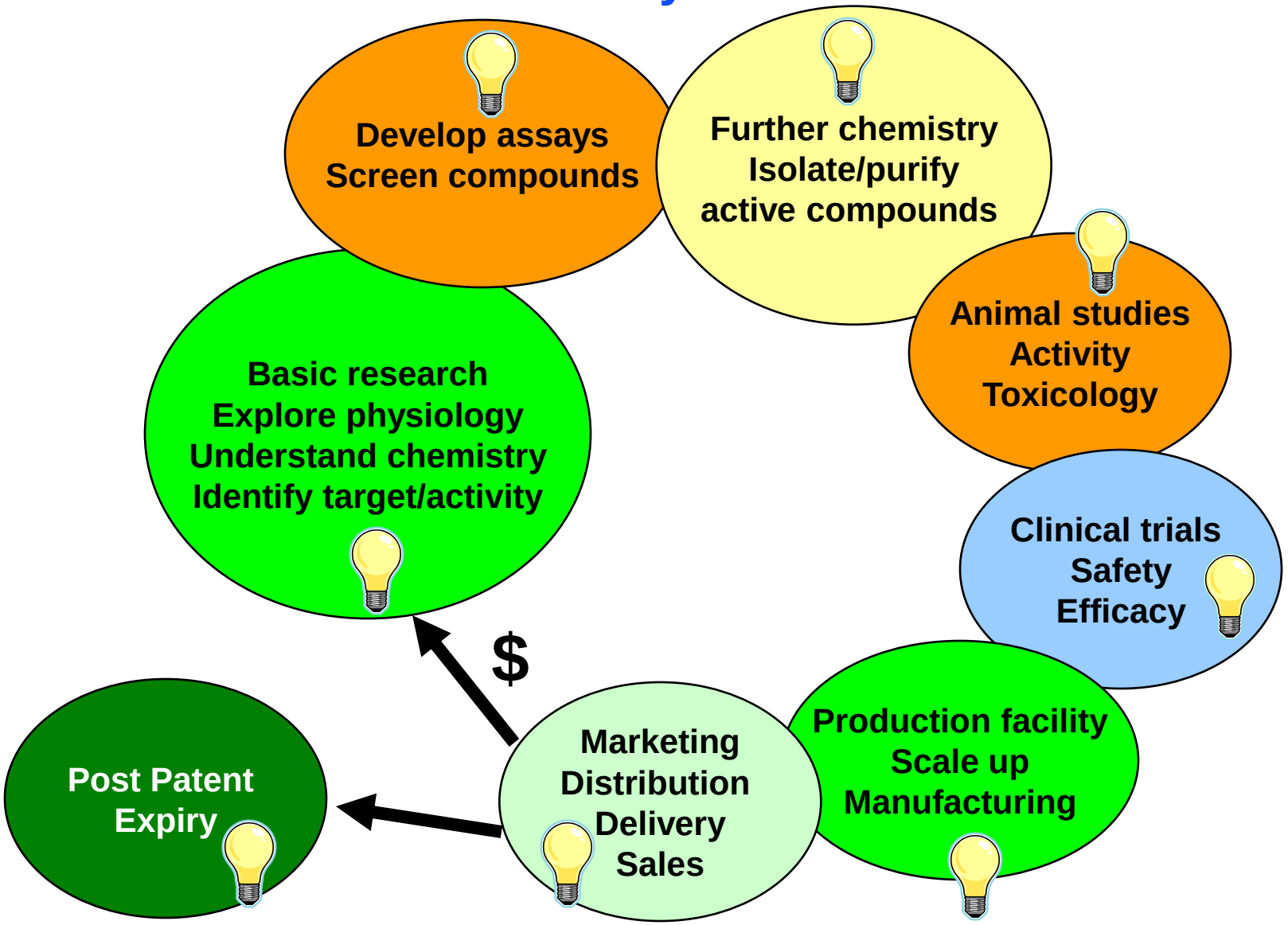
Fundamental Principles of the University

- Mission:
  - Research or Knowledge Generation
  - Education/Training
  - Public Service
- Dissemination of Research Results or "Knowledge Transfer"
- Education of Students for the Workplace
- Technology Transfer (for research or product development)
- Public Benefit

Elements of the Healthcare Biotechnology Innovation Ecosystem



Innovation is a Process
Universities - One Piece of the Puzzle

- Generation of an idea
- Further knowledge and understanding
- Market demand for a product
- Intellectual property protection
- Partner to develop into a product
- Investor(s) to finance development
- Capability to develop and manufacture

➢ A nurturing environment is important!

Universities as Innovators
Basic Research

- Typical funding resources: Government, Internal, Charitable Foundation
- Inquiry/curiosity of faculty to understand natural phenomena should be encouraged
- Inadvertent discoveries can lead to new areas of inquiry
- Basic research provides the foundation for the discoveries of the next generation
- Ex: Cohen-Boyer recombinant DNA invention – important research tool (Stanford/UCSF)

Universities as Innovators: Applied Research/Animal Studies

- Typical funding resources: Government, Charitable Foundation, Industry
- Work toward a goal to solve a societal problem
- Generate better understanding of a disease and other approaches
- Define and enhance patent protection at this stage – incentive for development!
- Collaborate with industry partner
- Ex: Drugs to treat African sleeping sickness and leishmaniasis (UNC-Chapel Hill)

Universities as Innovators: Human Clinical Trials

- Typical funding resources: Government, industry
- Provide access to state-of-the-art healthcare and medicines; fulfill public service mission
- Operate county hospitals and specialized centers
- Collaborate with industry on getting drug approval
- Ex: Phase I NIH-sponsored clin trial for malaria vaccine (Vanderbilt/Stanford)

Universities as Innovators Technology Transfer

- Research => discoveries
- Incentives for industry partner (public benefit, patent protection, return on investment)
- Resources (research funding, investment into development, venture capital)
- Development and commercialization partnerships (universities generate ideas, but do not commercialize products)

…continued…

Technology Transfer, continued

- One discovery => multiple products, e.g. therapeutic, diagnostic, research tool, vaccine
- Need patent protection and appropriate licensing to ensure development of each product
- Reserve right to continue research
- New uses of existing products
- Encourage start-ups
  - Caution: One Size Does Not Fit All!

Benefits to Working With Universities: Capacity Building

- Research infrastructure
- Researchers
  - Ex: Research capacity building in Kenya and Malawi (Columbia)
- Education/training
  - Ex: Infectious Disease Res Training Program – clinical and basic research training in Kenya (UCSF)
- Multidisciplinary research centers
- Research administration (funding, IP)
- Technology transfer (MTAs, licenses)
  - Ex: TT educational program in Philippines (U of Queensland)
  - Ex: Visiting delegations from many countries (all universities)

Association of University Technology Managers (AUTM)

- Annual Meeting - 2007
  - Special Interest Groups: International members, TMGH
  - Workshops: Humanitarian licensing, genetic resources
- Eastern Regional Meeting 2007
  - Plenary: BioVentures for Global Health
- Board-Vice President for International Relations
- Scholarship for Developing Economies Members to attend AUTM event
- Technology Managers for Global Health

  http://www.tmgh.org/

Nine Points to Consider

http://www.autm.net/aboutTT/Points_to_Consider.pdf

- University should reserve the right to practice licensed inventions and allow other non-profit and governmental organizations to do so
- Exclusive licenses should be structured in a manner that encourages technology development and use
- Strive to minimize the licensing of future improvements
- Universities to anticipate and help manage technology transfer-related conflicts of interest.
- Ensure broad access to research tools
- Enforcement action should be carefully considered
- Be mindful of export regulations
- Be mindful of the implications of working with patent aggregators
- Consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agriculture technologies for the developing world.

Benefits to Working With Universities: Collaborative Research

- Joint research and clinical projects
- Knowledge sharing
- Material exchange
- Public-Private Partnerships (PPP)
  - Ex: Gates Fdtn-funded research on tech with license to non-profit for cheaper anti-malarial and to for-profit for other uses (UCB)
- Government-University-Industry Collaborations
  - Ex: NIH HIV Vaccine Trial Network funding vaccine in So. Africa and US with university start up and UNC-Chapel Hill

Benefits to Working With Universities: Regional Programs

- Natural products
  - Ex: Joint research with Thai scientists on anti-TB drugs from Thailand natural products screening program (Nat'l Jewish Medical and Research Ctr)
- Sustainable research programs
- Sustainable agriculture programs
  - Ex: Collaborative research with Peruvian universities and farmers on ag curriculum development and sustainability of tuber crop (UCD)
- Specialized Centers
  - Ex: Int'l Pediatric AIDS Initiative Centers (Mexico, Romania, 7 African locations) (Baylor)

Universities and Global Health Immersion at All Levels

- Agriculture and ag sustainability
  - Ex: Access to ag innovations (PIPRA, UCD)
  - Ex: Insect-resistant eggplant in India, Bangladesh and Philippines (Cornell)
- Curriculum development
  - Ex: New African Institutes of Science and Technology in Tanzania (multidisciplinary: health sciences, biomedicine, agriculture, environmental engineering, business under organizing principle of global health) (UCSF)
  - Ex: Ten year curriculum development and teacher training program to upskill Bhutanese teachers, e.g. multigrade teaching (UNE, Aust)

Universities and Global Health Immersion at All Levels, continued

- Healthcare
  - Ex: Nutritional fortification and children growth charts for WHO and individual countries (UCD)
  - Ex: Research on micronutrient nutrition (U of Otago, NZ)
  - Ex: Professional training for healthcare management and primary care nurses (Thailand) (UNE, Aust)
  - Ex: : 3-year program-International Center for Training in Emergency Medicine, Trauma and Disaster Preparedness in India Phase 1: Train the Trainers; Phase 2: expand to rural environment (Columbia)
  - Ex: License for treatment of glaucoma to start up company who has committed 1% of net sales to glaucoma treatment in developing countries (Yale)

Universities and Global Health Immersion at All Levels, continued

- Daily Living
  - Ex: Darfur Cookstove (LBNL)
  - Ex: Engines that use clean burning fuels (China) (UBC)
  - Ex: Arsenic Project: Use local cell phone network to access database on arsenic levels in Bangladeshi wells (Columbia)
  - Ex: Water purification units to disinfect against viruses and bacteria that causes cholera, typhoid, dysentery and other diseases (LBNL)
- Educational exchanges
  - Ex: Two Thai scholars enrolled in Doctor of Health Service Management Program (UNE, Aust)
  - Ex: Train South African scientists on treating MDR tuberculosis with inhaled drugs rather than injected drugs (Nat'l Jew Med and Res Ctr)

Benefits to Working With Universities: Ancillary Benefits

- Creation of new jobs
- Enhancement of workforce
- Tax revenue
- Company formation
- Entrepreneurial environment
- Local economic development

Other Resources

- Public Intellectual Property Resource for Agriculture (PIPRA)
  - » http://www.pipra.org/
- IP Management in Health and Ag Innovation (MIHR and PIPRA)
  - » http://www.iphandbook.org/
- BioVentures for Global Health
  - » http://www.bvgh.org/

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