IP Ecosystem, Entrepreneurs, and Sustainable Technology Companies

Harold H. Shlevin, PhD
Advanced Technology Development Center
Enterprise Innovation Institute
Georgia Institute of Technology
shlevin@gatech.edu
Harold H. Shlevin

• 25+ years leadership experience in pharma, medical devices & vaccines companies.
  –CEO Solvay Pharmaceuticals
  –Founder CIBA Vision Ophthalmics,
  –Founder Tikvah Therapeutics
• PhD, University of Rochester Medical School, Postdoc. Mayo Clinic
• Assistant Professor – Mayo Medical School
• Multiple advisory boards of for profit and not-for-profit organizations
• Strong regional technology leader
Research is the transformation of money into knowledge.

Innovation is the transformation of knowledge into money.

—Dr. Geoffrey Nicholson, 3M
(inventor of the Post-it note)
“Virtually every combination of industry relationship or economic development activity can be found at Georgia Tech, and in a very real sense, the university is an operating partner with Georgia state government in the implementation and management of a variety of technology-focused initiatives. Perhaps more than any other research university in North America, economic development is an integral, critical component of the mission of the Georgia Institute of Technology, and this has been true from its very inception.”

—Southern Growth Policies Board, 2002
Building an Ecosystem

Nutrients → Signs of Life → Natural Selection → Incubation → Growth → Renewal → Nutrients
• Over half a billion dollars total R&D on campus for FY2009!
Nutrients

- Recruiting research talent—worldwide
- Georgia Research Alliance (GRA)
  - Eminent Scholars
  - Facilities/equipment
- Reinventing academic disciplines
  - College of Computing
  - Emory/GT Biomedical Engineering Dept.
Signs of Life

- Emphasis on interdisciplinary research
- Research centers
  - Over 100 on campus, from textiles to nanoscience
  - BME, Nanotech, MARC, MiRC, GEDC, Broadband Institute, GTEC Tissues, etc.
- GRA Phase Zero awards
Natural Selection

Commercialization Services

- Intellectual property protection (OTL)
- VentureLab
  - Business plan
  - Management
  - Money
- GRA Phase I and II awards
- GT Edison Fund
- SBIR Assistance
Intellectual Property Goals

- Reward the faculty for creation of valuable IP
- Support innovation & strengthen research programs
- Strengthen global reputation
- Attract top-quality faculty & students
- Add value to intellectual property
- Strengthen industry relationships
- Create successful entrepreneurs
- Strengthen local technology community
- Help human-kind
Converging Challenges

• Increasing number of disclosures drives overall demand
• “The World is Flat”
  – Increasing GT demand for overseas filings
    • Drives patent cost from ~$15K to ~$100K
  – Increasing competition for research partnerships from overseas universities
• Increasing ratio of biotech at GT (requires overseas protection)
• USPTO proposed limitations on claims, etc.
IP Mgmt./Evaluation

Screens

Export Control

Industrial Contracts

Dept. Chairs / Deans / GTRI

Invention Disclosures

Technology Analysis

Need more information / development

Technology Evaluation

Rights to Faculty?

Protect IP?

$ 

Initiate IP Prot.

$ 

External Counsel

Market Analysis

Market Evaluation

Patent Application

Responsibility

GTRC

EI2 / CS

...continued
IP Business Development

- Standard Templates
- COI Review
  - Conflict of Interest Plan
- Business Plan
- Georgia Research Alliance
- Startup / Spinout
- Industrial License
- VentureLab
- Tech. Marketing
- Licensee?
  - Rights to Faculty?
- Term Sheet Negotiation
  - Compliance Review
  - License Negotiation
  - External Counsel
- Consulting
  - Rights to Faculty?
- Marketing White Paper
- Standard Templates

Responsibility:
- GTRC
- EI2 / CS

...continued
VentureLab

- Founded September 2001
  - Now a model for other universities
  - Part of Enterprise Innovation Institute
- Staff has substantial private-sector experience
- Faculty-focused process
  - Risk identification and mitigation
  - Venture-backable innovations
- Goal: Successful startup companies based on Georgia Tech research
VentureLab

- Market
- Milestones
- Meetings
- Management
- Money
Money

• Assistance with small-business grants from eleven Federal agencies.

• Grants and loans to startups based on Georgia university research.

• Equity investments in startups with a connection to Georgia Tech.
Georgia SBIR Assistance

• Small business R&D funding available from eleven Federal agencies
  – NASA, DOD, DOE, NIH, EPA, etc.
• Grants, not loans or equity!
• For help with SBIR and STTR process, visit <http://www.innovate.gatech.edu/sbir>.
• Up to $850K available across two phases of development
Georgia Research Alliance

• Recruiting Eminent Scholars from all over the world to Georgia

• Investing in university capital equipment
  – Over $600 million in last 15 years

• Innovation grant program
  – Phase 1: up to $50K to university R&D
  – Phase 2: up to $100K to university (must be matched—equity, SBIR, sale of services, etc.)
  – Phase 3: up to $250K loan to company (must be repaid upon success or leaving Georgia)
## GRA Matching Funds

Provides up to 4:1 non-dilutive leverage for initial outside investment:

<table>
<thead>
<tr>
<th>Phase</th>
<th>Description</th>
<th>Georgia Research Alliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>$50K grant to university</td>
<td>$50K grant to university</td>
</tr>
<tr>
<td>Phase II</td>
<td>$100K validation investment</td>
<td>$100K matching grant to univ.</td>
</tr>
<tr>
<td>Phase III</td>
<td>$250K loan</td>
<td>$250K loan</td>
</tr>
</tbody>
</table>

Total: $100K $400K
• Market
• Milestones
• Meetings
• Management
• Money
Incubation

- Advanced Technology Development Center (ATDC)
- GRA Phase III loans
- Ga. Seed Capital Fund
- Minority Business Enterprise Center
- National VC attention
- Centers of Innovation
  – Statewide tech areas
ATDC Offerings

- Consulting
  - Strategic business advice
- Community
  - Interaction with other entrepreneurs
- Connections
  - Connections to people and resources
- Centre
  - Facilities designed for startups
- Credibility
  - Instant recognition
Cycle of Renewal

- Serves as a bridge to Georgia Tech services and resources
  - Expand interaction with key local, state, national and international corporations
  - Seminars, workshops & technology briefings
  - Access to test beds, research labs, unique equipment & expertise
Cycle of Renewal

- Successful companies
  - Sponsoring research
  - Hiring GT graduates
  - Spinning off new companies

- Successful graduates
  - Charitable giving
  - Angel investment
  - Mentoring

- More nutrients for the ecosystem!

Klaus Advanced Computing Bldg.
## Importance of Patents to Pharmaceutical Innovation

<table>
<thead>
<tr>
<th>INDUSTRY</th>
<th>Would NOT have been Introduced</th>
<th>Would NOT have been Developed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals</td>
<td>65</td>
<td>65</td>
</tr>
<tr>
<td>Chemicals</td>
<td>30</td>
<td>38</td>
</tr>
<tr>
<td>Petroleum</td>
<td>18</td>
<td>25</td>
</tr>
<tr>
<td>Machinery</td>
<td>15</td>
<td>17</td>
</tr>
<tr>
<td>Electrical Equipment</td>
<td>1</td>
<td>11</td>
</tr>
</tbody>
</table>

Mansfield, Mgmt Sci., Feb., 1986
Selected Advances in the 20th Century

1900–1929
- 1900 – U.S. life expectancy is 45
- 1908 – Tuberculosis vaccine
- 1922 – Insulin for diabetes
- 1924 – Tetanus vaccine
- 1928 – Discovery of penicillin

1930s & 1940s
- 1932 – First antibiotic (sulfa drugs)
- 1935 – Discovery of cortisone
- 1938 – First epilepsy Rx
- 1948 – First chemotherapy Rxs

1950s
- 1950 – Discovery of prednisone
- 1951 – First Rx for depression
- 1953 – First leukemia Rx
- 1954 – Polio vaccine
- 1958 – First diuretic to treat high blood pressure

1960s & 1970s
- 1963 – Measles vaccine
- 1967 – First beta blocker
- 1968 – First anti-rejection medicines for organ transplants
- 1972 – Advances in anesthesia
- 1977 – First non-surgical treatment for ulcers
- 1978 – First biotech product (synthetic human insulin)

1980s
- 1981 – First ACE inhibitor to treat high blood pressure
- 1986 – First monoclonal antibody treatment
- 1987 – New class of depression medicines (SSRIs)
- 1987 – First AIDS Rx
- 1987 – First statins to lower cholesterol

1990s
- 1993 – First Alzheimer’s Rx
- 1994 – New breast cancer Rx
- 1995 – AIDS Rx advance (HAART)
- 1995–97 – Four new classes of oral diabetes Rxs
- 1997–98 – Advance in Parkinson’s Therapies

*Note: “Other” includes medical care provided by private employers for employees at their work site, government spending for non-specified medical care by service usually delivered in schools, military field stations, and community centers.

Medicines Account for a Small Share of Health Spending Growth

In 2006, U.S. National Health Expenditures were $2.1 trillion; without prescription medicines, the total would have been $1.9 trillion.

Total Health Care Expenditures With and Without Prescription Medicines
1960–2006

There is an ecosystem of science and biotechnology. Public organizations, patient organizations, universities, Congress, FDA, all of this is an ecosystem that is envied in the rest of the world.

– E. Zerhouni, Director of NIH

...in the late 1980s only 41% of the top 50 innovative drugs were of American origin, in the late 1990s...[it had] climbed to 62%....

In 1990, the pharmaceutical industry spent 50% more on research in Europe than in the U.S. In 2001, the situation was reversed with 40% more spent in the U.S.²

—Gunter Verheugen, Vice-President of the European Commission for Enterprise and Industry

*Note: Reflects the number of compounds in clinical trials or awaiting approval as of June of each year. Compounds in development for multiple regions are counted in each region for which regulatory approval is sought, and multiple indications are counted only once.

Sources: ¹Adis R&D Insight, Custom data run, February 2009, January 2010; ²G. Verheugen, “Address to the Concluding Session of the European Track” (Lyon) 2005.
Developing a new medicine takes an average of 10–15 years; the Congressional Budget Office reports that “relatively few drugs survive the clinical trial process.”

The Cost of Developing a New Drug Has Increased

Cost to Develop One New Drug

Probability of Success for New Drugs Is Small

Approximately 20% of self-originated new drugs that enter clinical testing will receive U.S. marketing approval.¹

Clinical Approval Success Rates by Therapeutic Class¹

Few Medicines Are a Commercial Success

Note: Drug development costs represent after-tax out-of-pocket costs in 2000 dollars for drugs introduced from 1990–94. The same analysis found that the total cost of developing a new drug was $1.3 billion in 2006. Average R&D Costs include the cost of the approved medicines as well as those that fail to reach approval.

Why Make the Investment?

“Without the sense of security which property gives, The land would still be uncultivated”

F. Quesnay, 1773
For Further Information

Harold H. Shlevin
Manager, Advanced Technology Development Center
Georgia Institute of Technology
<shlevin@gatech.edu>

(404) 385-7372