

Intellectual Property Trends in the Global Health Sector

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Innovation & Global Health

- The use of innovation as a tool for attaining global health has never been more relevant.
- The rapid movement of populations through globalization can disseminate diseases across the globe.
- Significant health threats to previously unexposed populations.

Challenges

- Insufficient incentives to develop cures for diseases primarily afflicting the poor.
- The global health community faces the task of developing effective strategies for addressing these challenges.

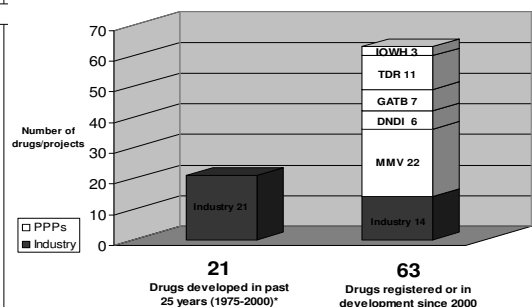
Change of Paradigm

- The center of gravity of global health research, development and manufacture is shifting noticeably toward emerging economies.
- Several institutions both public and private in countries like India, Brazil, China, and South Africa have increased their investments and adjusted their industrial policies.
- Stimulate greater biomedical and biotechnology research toward the development of diagnostics and therapeutics for endemic and neglected diseases (i.e. malaria, dengue, rotavirus, HIV/AIDS, etc).

New Stakeholders & Models

- Shift to significant funding of non-profit pharmaceutical companies – Public Private Partnerships (PPPs) or Product Development Partnerships (PDPs)
- Rockefeller Foundation, Gates Foundation, Global Donors, NIH/NIHF, etc.
- Results driven, non-profit, partner with many types of organizations to get the job done
- Opportunities for NIH/OTT

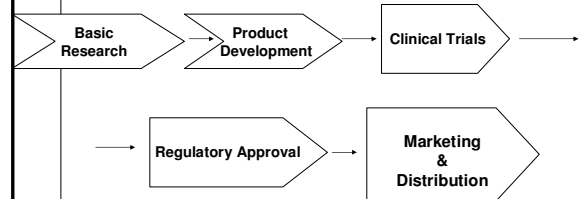
PPPs/PDPs Expand Development Pipelines*



PPPs Business Models

- Similar to for-profit companies, may contract out or partner for research, development, regulatory, manufacture, sales, etc
- Strategic Alliances: shifting from founder to partner
- Profit opportunity may help engage experienced, for profit partner. May help reduce cost and pricing.
- Same IP approach as for-profit companies – comply with patents.

Changing Roles Along the Pipeline



Product Markets

- Product Markets will varies with the disease and the country
- Private, profitable (e.g., AIDS)
- Private, small to medium (e.g. rotavirus)
- Private, modest to small (e.g., malaria, Tb)
- Public, not profitable (e.g. dengue, Chagas, leishmaniasis, etc)

IP Strategy in Support of Global Health Mission

- Freedom to operate (FTO) – anticipate potential IP roadblocks and gain early access to the IP
- Industrial engagement – provide incentive to industry to partner to develop and deliver vaccine or drug (e.g. market risk reduction)
- Negotiation leverage – advance public health goals through negotiation (e.g. NIH)

Filing Patents

- Resources (financial, human)
- Technical/R&D Capacity
- Manufacturing facilities
- Mission focus
- Partners
- Local Incentives (e.g. IP legislation)

Technical Challenges

- Large vs. Small Molecules
- Small molecules are easier and cheaper to produce
- Biologics are more difficult and more expensive
- If there are fewer partners for vaccines or biologics will there be fewer market competition and/or technical challenges (e.g. CT) (????)

IP, Market, R&D Challenges

- Small molecules may have more market competition
- Biologics may have less market competition (e.g., vaccines with multiple antigens, adjuvants, etc.)
- Facilities (R&D, QC, Manufacturing)
- IP in profitable markets may be more important up front to reduce risk for reluctant partner vs. QC

Size of the Companies

- Would influence negotiation terms
- Public Funding
- NGOs involvement
- Risk reduction
- Development Focus
- Markets

International Technology Transfer Negotiations

- **Trust**
- **Flexibility**
- **Commitment**
- **Sharing knowledge & information**
- **Know organizations' strengths and limitations**
- **Strategic Partnership**

Current Activities & Opportunities

- **NIH OTT (TT developing countries & emerging economies)**
- **International Technology Training Program (NIH OTT)**
- **Workshops in the Field (Indo-US Fund, WIPO, MIHR, WHO-TDR)**
- **Neglected Diseases Database (NIH & US Universities)**

Current Activities & Opportunities...

- **Handbook of Best Practices (MIHR/PIPRA)**
- **AUTM TMGH**
- **AUTM 2006 Annual Meeting Focus**
- **LES (Social responsibility panels)**
- **BIO Global Health Track**
- **DCVMN**

Potential Outcomes—Health for All?

- It is expected that new models & approaches will promote well-recognized, good licensing practices that meet regional and national health priorities and standards.
- As a result, these activities should:
 - enhance public availability of new technologies,
 - attract new biotechnology R&D resources,
 - obtain returns on public investment.
- It might also stimulate economic and social development in the U.S. developing countries and emerging economies.

PPPs

PPS

- Global Alliance for TB www.tballiance.org
- MVI www.mvi.org
- MMV www.mmv.org
- DNDi www.dndi.org
- GAVI www.gavi.org
- IAVI www.iavi.org

Partnerships for Global Health

