

# Collaborative Innovation: Partnerships & IP Management Strategies in Global Health



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<http://ipira.berkeley.edu>

## 2004: Restructured IP Management at U.C. Berkeley

- Redefined TT: ongoing relationship continuum
  - bi-directional, long-term
  - relationship model: partnerships and collaborations are key
- Goals:
  - maximize impact of research – social, economic
  - **diversify funding sources** – more applied research
  - new ways of working with corporations, foundations, non-profits

*innovate faster, better, creatively, catalyze commercial uptake & investment*
- New business models

### Open Innovation Principles: innovation as an open system

- Full spectrum of IP management strategies, from strong to weak\*
- Including Socially Responsible: access and affordability in developing countries
- Metrics: use, collaboration, diversified funding, social benefit, **translational efficiency, innovation acceleration, global outreach, collaboration, uptake, sharing, gifts, reputational gains, affiliation, PDPs, PPPs**

\*Nuanced Management of IP Rights: Shaping Industry-University Relationships to Promote Social Impact [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1434545](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1434545)

## **Interface with Industry is Multifaceted**

Corporate sponsored research

Corporate collaborations

Material and knowledge transfer

Consulting and other public service

IP creation and licensing

Gifts: cash, endowed chairs, in-kind, sponsorship of graduate programs

Graduate fellowships

Industry consortia – memberships, gifts

Exchange of personnel, sharing of resources

Investment in startups

Networks of service providers

Private capital investors: entrepreneurship and startups

Venture philanthropy

# Evolution of IPIRA's Industry – University Relationship Models

## Three “Pivots” to date

**1<sup>st</sup> generation traditional - push**

“want to license?”

**2<sup>nd</sup> generation – pull, industry sponsored**

**Research “help us invent the improvement”**

**3<sup>rd</sup> generation – collaboration is everything**

- industry affiliate programs “join our club”

- “tablets” “help us to be relevant to CA’s innovation economy”

- on-campus, dedicated

Industry-sponsored institutes – grand challenges

“let’s invent the future”

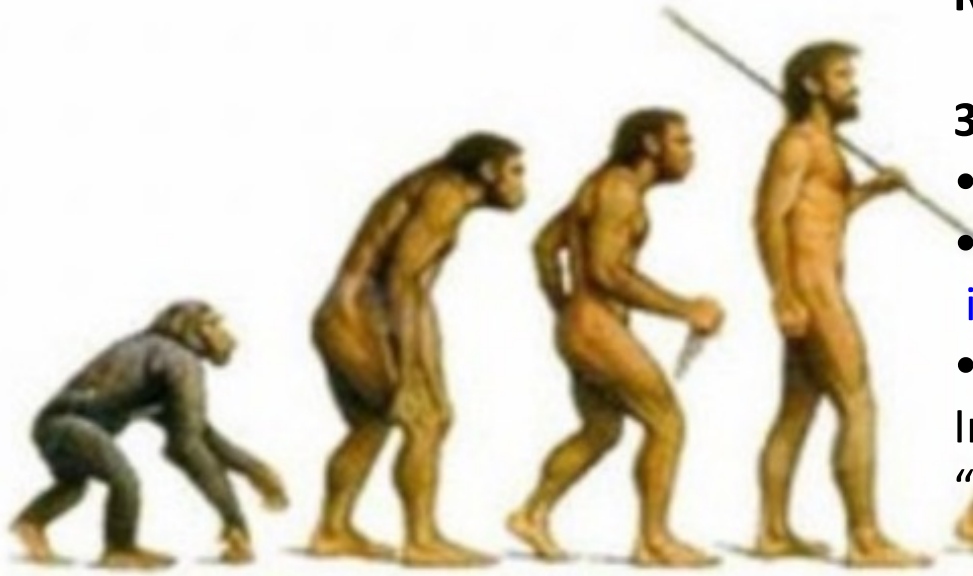
**4<sup>th</sup> generation – entrepreneurship & startups**

Local innovation ecosystem, SBIR/STTRs,

“it’s all about support for entrepreneurs, startups”

**5<sup>th</sup> generation – regional econ development**

Connect multidisciplinary research to regional econ development – UC’s value prop to state



Service unit has to continually adapt

3rd generation: the art of collaboration

# Public-Private Partnerships to Advance Global Health

~2003 translation can be expedited through innovative **Public-Private Partnerships**



Eva Harris – Denge diagnostic



Jay Keasling malaria ACTs

Access and affordability can be addressed through innovative **Humanitarian use clauses in research and license agreements**

Research Patently in the Public Interest

[http://www.berkeley.edu/news/berkeleyan/2005/12/02\\_licensing.shtml](http://www.berkeley.edu/news/berkeleyan/2005/12/02_licensing.shtml)

Launch of antimalarial drug a triumph for uc berkeley, synthetic biology

<http://newscenter.berkeley.edu/2013/04/11/launch-of-antimalarial-drug-a-triumph-for-uc-berkeley-synthetic-biology/>

## Global PPPs and PDPs - Berkeley's SRLP

- different motivations, intended outcomes, approaches
- **access and affordability** in developing countries
- “humanitarian use” research agreements, collaborations, license agreements
- **Agriculture, sanitation, diagnostics, therapeutics, vaccines, research tools**

Some examples (and see handout):

- **Two Blades Foundation**: durable and pesticide-free crops
- **Cell-Scope** : cell phone microscope
- **Silicon Biodevices**: hand-held diagnostic
- **Commonwealth of Samoa**: antiviral from mamala tree
- **Sustainable Sciences Institute**: portable dengue fever diagnostic
- **iOWH, Amyris, Sanofi-aventis**: low cost malaria therapeutic
- **Africa Harvest**: more digestible and nutritious sorghum
- **Aquaya Institute**: low cost treatment for clean water

For more examples & info see: <https://ipira.berkeley.edu/socially-responsible-licensing#>

## NTDs Market Failure

### Need is Great, Ability to Pay is Low

Developing countries bear a disproportionate burden of diseases for which commercial investment in R&D is lacking

Treatments, diagnostics, are needed

Drug **development is expensive and risky**

Corporations don't have an incentive to invest in projects that don't produce a profit

The Risk:Reward proposition is skewed

**Market failure** - doesn't address the gap between tremendous need and the cost of developing therapies, health solutions

# The Fundamental Problem

For conditions of poverty:  
neglected disease, neglected  
populations  
Unmet needs: hunger,  
sanitation

Tension, balance

- profit, market forces
- non-market societal  
needs
- risk/reward ratio



Commercial  
Incentives

Social  
Welfare



# Finding the Exquisite Balance

IP licensing is but one aspect

SRLP challenge

Retain commercial incentives

Outside of “market economy”  
countries



Commercial  
Incentives

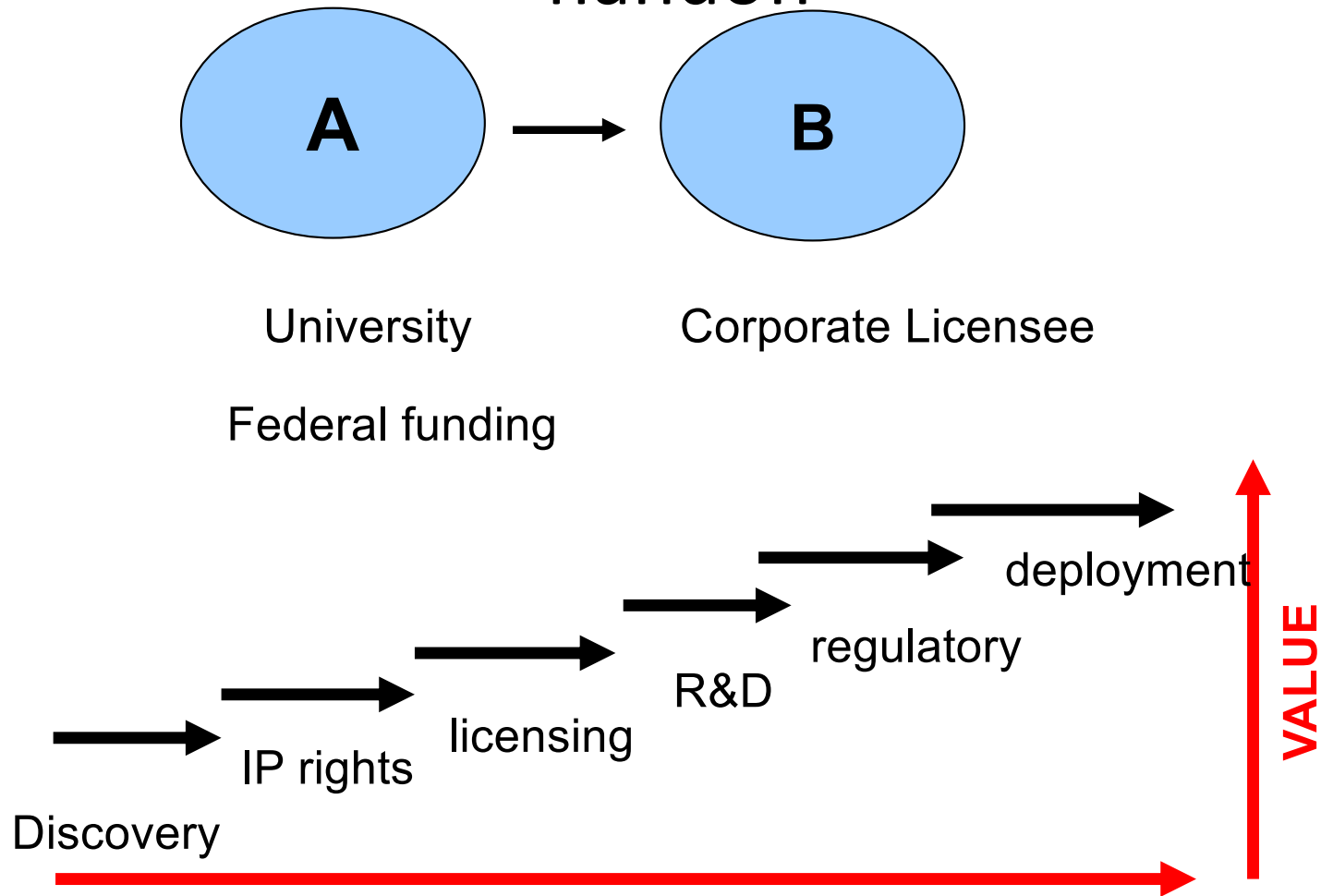
Profit  
Shareholders

Social  
Welfare

Access  
Affordability

# SRLP: Deal structures, Models

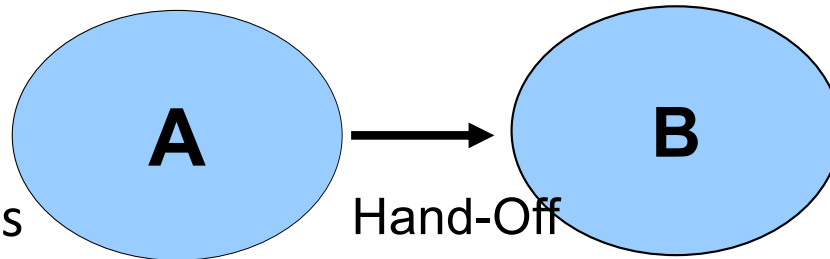
Traditional, linear innovation  
handoff



# Traditional, Linear Innovation

## IP License Not Enough

- Value Proposition
- No profit incentive DCs



University

Corporate Licensee

- Royalty free in EDCs
- Provide at cost or free
- Royalty bearing
- Third party challenge
- Enforcement

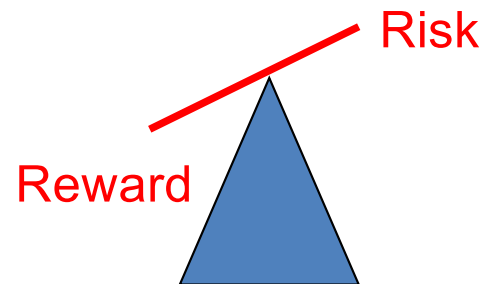
Federal funding

Expensive R&D  
Regulatory risks



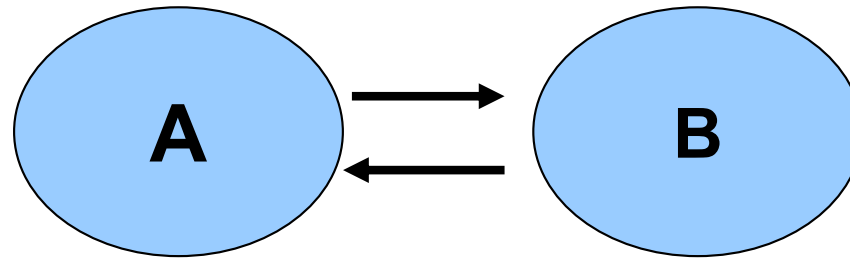
Discovery R&D Clinical Regulatory Deploy

>\$B's and 12+ years



# License + Research Collaboration: Partnering, Sharing, Parallel Innovation, De-Risking

- Non linear
- Overlapping & loopbacks
- Value Proposition better
- Compressed timeline
- Shared funding
- Gap funding
- Shared tools, expertise, data
- **Lower risk**, more mature
- Feedback: adjustments
  - Scale -up considerations
  - Proprietary components

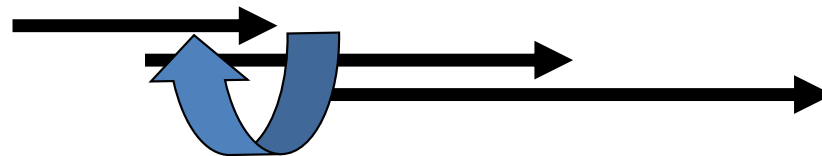


University

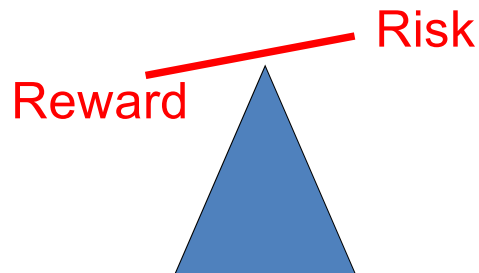
Corporate Licensee

Shared funding  
Tools, data

Expensive R&D  
Regulatory risks



Discovery, Translation, Commercialization



R:R balance better. Both parties perform in parallel, innovation acceleration, extend Univ. role further into value chain  
**Goal alignment:** translational research, improvements

# Partnering: PDPs Play a Central Role

Product Development Partnerships (PDPs)

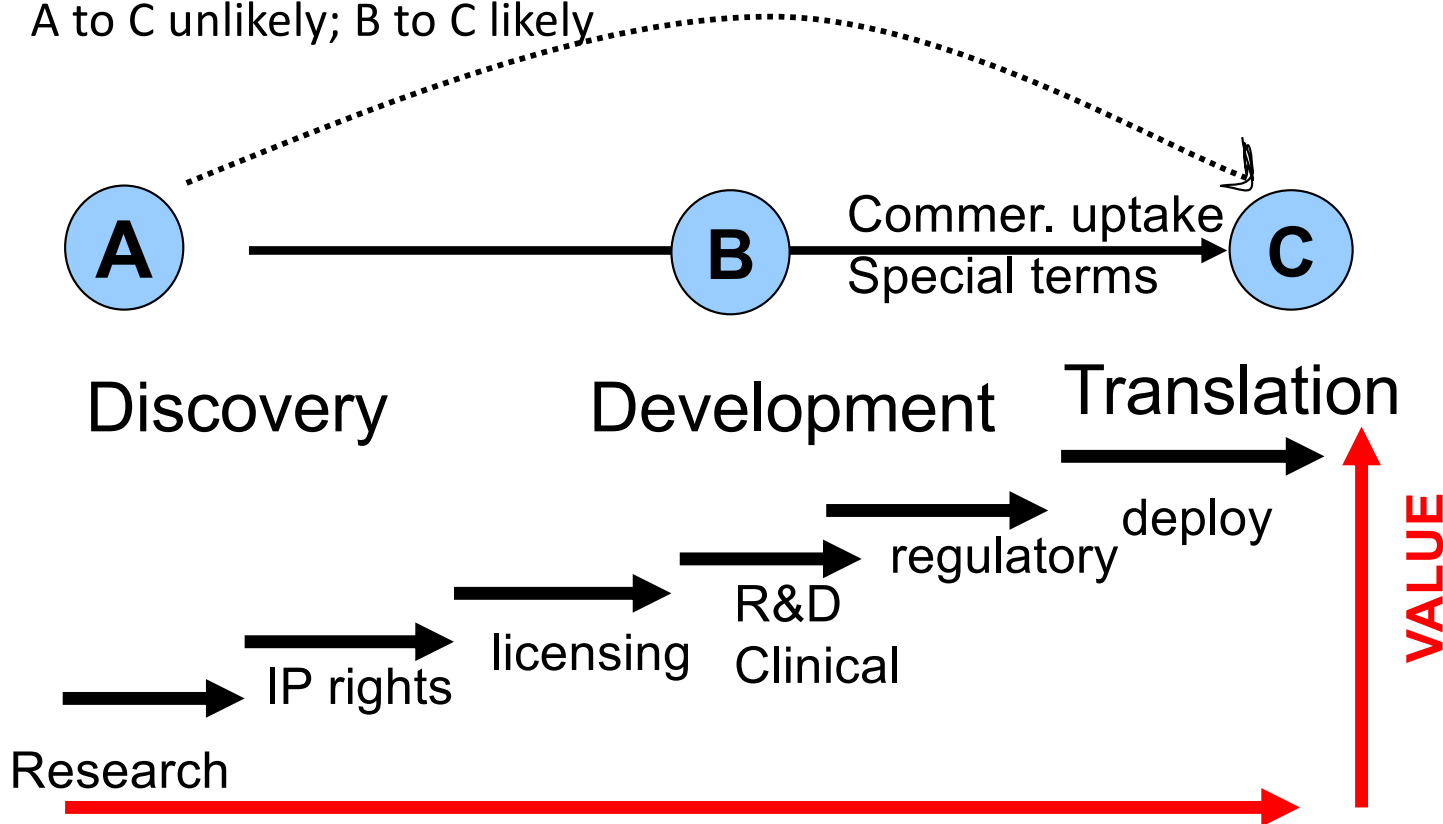
- nonprofits, funded by foundations, others

Partner up and down the value chain & leverage mutual resources, capabilities, relationships

Operate in the crucial, middle area

Add value, decrease risk, increase uptake under SRL terms

A to C unlikely; B to C likely



# Multiple Licensees: NonProfit, ForProfit & Hybrid

Still no profit incentive DCs for both

- Value proposition good
- Different incentives

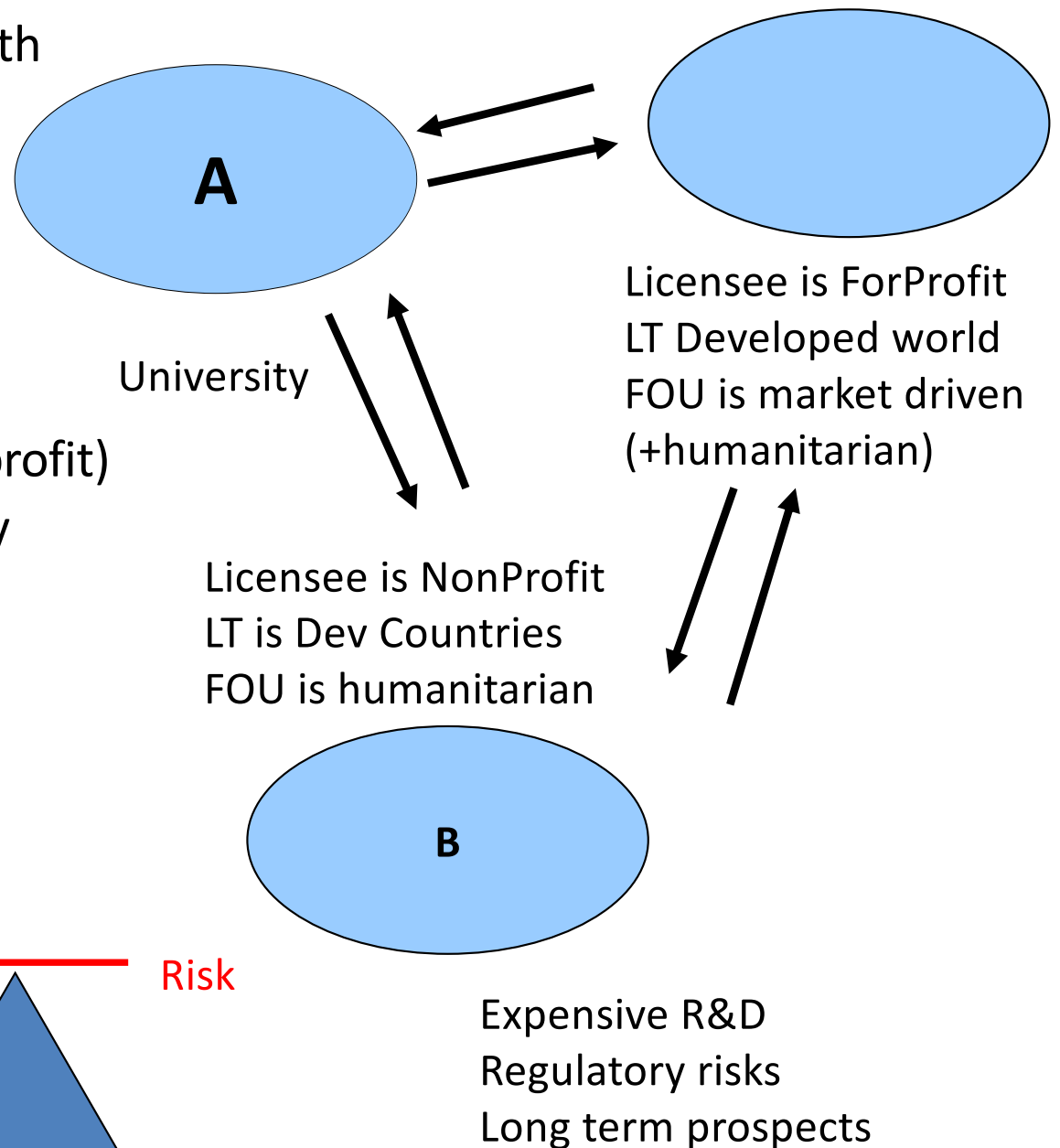
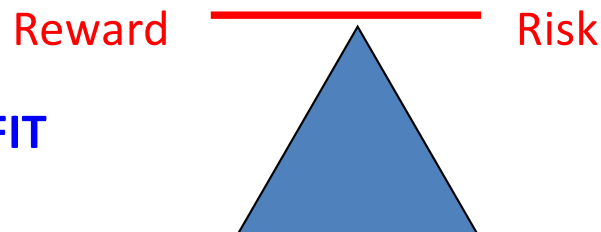
For-profit

- Profit goal
- Dual commercialization plan
- Dual market (short term, nonprofit)
- Corporate Social Responsibility
- Bootstrap philanthropy

Non-profit:

- Funding from Charitable orgs
- Shared grants
- Charitable aims as goal for NP
- Partnering

**Ultimate Goal:**  
**DERISK for FOR PROFIT**



# SRLP Examples at Berkeley

- **Diagnostics** - portable
- **Therapeutics**
  - Malaria (ACTs), anti-viral, oncology
- **Vaccines**
  - STD
- **Agricultural Biotechnology**
  - Plant disease resistance
  - Increased nutritional quality
- **Public Health** - sanitation, water purity
- **Consumer Electronics\*** and information technology



# SRLP Summary

Licenses, collaboration agmts, sponsored research agreements, IP management strategies

## **MECHANISMS IN USE\***

- royalty-free license
- humanitarian reservation of rights
- no patent rights outside of JP, CA, EU, Australia, US (but consider long term strategy)
- mandatory sublicensing to address unmet needs and/or achieve target price
- separate treatment of for-profit markets from non-profit markets
  - tiered pricing within a given country
  - define target countries for free or at-cost distribution
  - conversion option
- field of use licensing (define “humanitarian” or “charitable use”)
- royalty sharing, attribution
- march in (diligence)
- informed consent
- non-assertion

Other IP management strategies: Open Collaboration. Open Source Licensing - BSD

Patent Pools – but consider effects of the commons vs. stewardship

\*see SRLP Guidance and Clauses at:

[https://ipira.berkeley.edu/sites/default/files/shared/docs/SRLP\\_Guidance\\_%26\\_Clauses\\_v100817.pdf](https://ipira.berkeley.edu/sites/default/files/shared/docs/SRLP_Guidance_%26_Clauses_v100817.pdf)

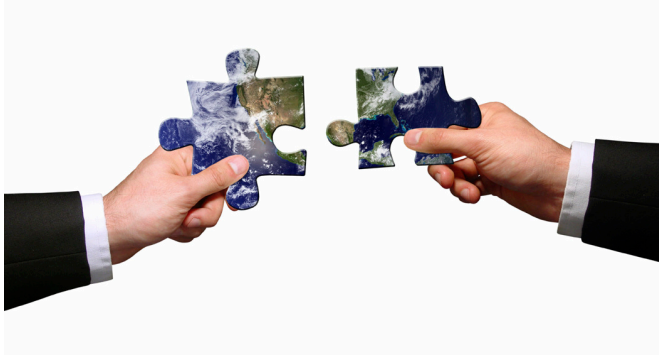


# Anatomy of PPPs and PDPs

- business models, partnership structure, IP management strategy
  - who are the parties – for-, non-profit, hybrid
  - find and preserve incentives, deliver ROI
  - maintain mission and goals of each participant
  - how are property rights, including IP, treated?
  - and tangible properties (data, materials)
  - timing of entrances and exits, and how
  
  - what are the parties roles, milestones, which are distinct, overlapping?
  - how is it financed? Kinds of financing, and timing
  - how many and what kinds of contracts are needed?
  - how are results delivered, measured and put to USE?
- successful partnerships
  - flexible and nimble IP management strategies coupled to new business models
  - push and pull mechanisms
  - creative, motivated negotiators, drafters – goal is collaboration
  - change the culture of collaboration

# “Bento Box” Solution

Humanitarian clauses + IP Strategies + Business Models



## Contract Levers

A	<input type="checkbox"/>
B	<input checked="" type="checkbox"/>
C	<input type="checkbox"/>

## IP strategy

1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input checked="" type="checkbox"/>

## Business Model

X	<input checked="" type="checkbox"/>
Y	<input type="checkbox"/>
Z	<input type="checkbox"/>

Permutations, Combinations: mix & match to create incentives, alignment

Contract Lever	IP Strategy	Business Model
Parties (govt, univ, foundt'n, industry) status (licensee, sub, collaborator)	Nonassertion	Dual commercialization
Licensed territory	Patent/no patent and where	For-, non-profit entity
Humanitarian Field-of-use	Open license	PDP, collaboration, Timing, co-dev, co-mkt
Exclusive, co-, non-exclusive	Open source	Funding, self, sources OPM
Royalty-free in DW Royalty bearing, non-Roy. sharing, -non	Research Commons	Alliance, sponsorship
Price restrictions -target -tiered (conversion option)	Patent Pool	Incentives Timing (PRV) End user govt, individ, HMOs
Humanitarian reservation of rights	Monetize	Corporate responsibility
Mandatory sublicensing	Social impact	Monetary ROI Non-monetary ROI
Ownership	Sole, joint	Short term, long term ROI

No particular order, no associations horizontally

# Case Studies\*

1) Goals

2) Strategies: IP management & deployment

3) Business Model

- Collaboration Structure
  - who does what, when, how, where, why
- Funding
- Benefits, when, how

\*See: Brochure at

[http://ipira.berkeley.edu/sites/default/files/shared/3-Panel\\_Brochure\\_Final.pdf.pdf](http://ipira.berkeley.edu/sites/default/files/shared/3-Panel_Brochure_Final.pdf.pdf)

## Denge Fever - Diagnostics

The Sustainable Sciences Institute – a nonprofit.

	Licensee	University
<b>Goal</b>	Commercial license Funding for proof of principle Hand-held diagnostic device	Make an <b>impact</b> Stimulate funding for SSI – Acumen Fund & from SSI to Berkeley
	<b>Deploy at cost in LMC</b>	Catalyze commercialization
	Need IP (copycats) Need funding Nontraditional license term	Enable 2nd generation improvement Preserve additional licensing opportunities
<b>Challenge</b>	Lack of profit from LMC	<b>Patent expenses</b> , fair valuation
		Commercial license to nonprofit
<b>Solution</b>	Pay <b>patent costs only</b> and <b>receive free IP license</b> in non-profit territories	Define <b>for-profit and non-profit territory</b> , <b>Grant free license in non-profit</b> Diligence in license (sublicensing)
	Remuneration to SSI via <b>royalty sharing</b> if Berkeley receives royalties from for-profit licenses	<b>“informed consent”</b> <b>Retain right</b> to license for-profit companies in for-profit territories

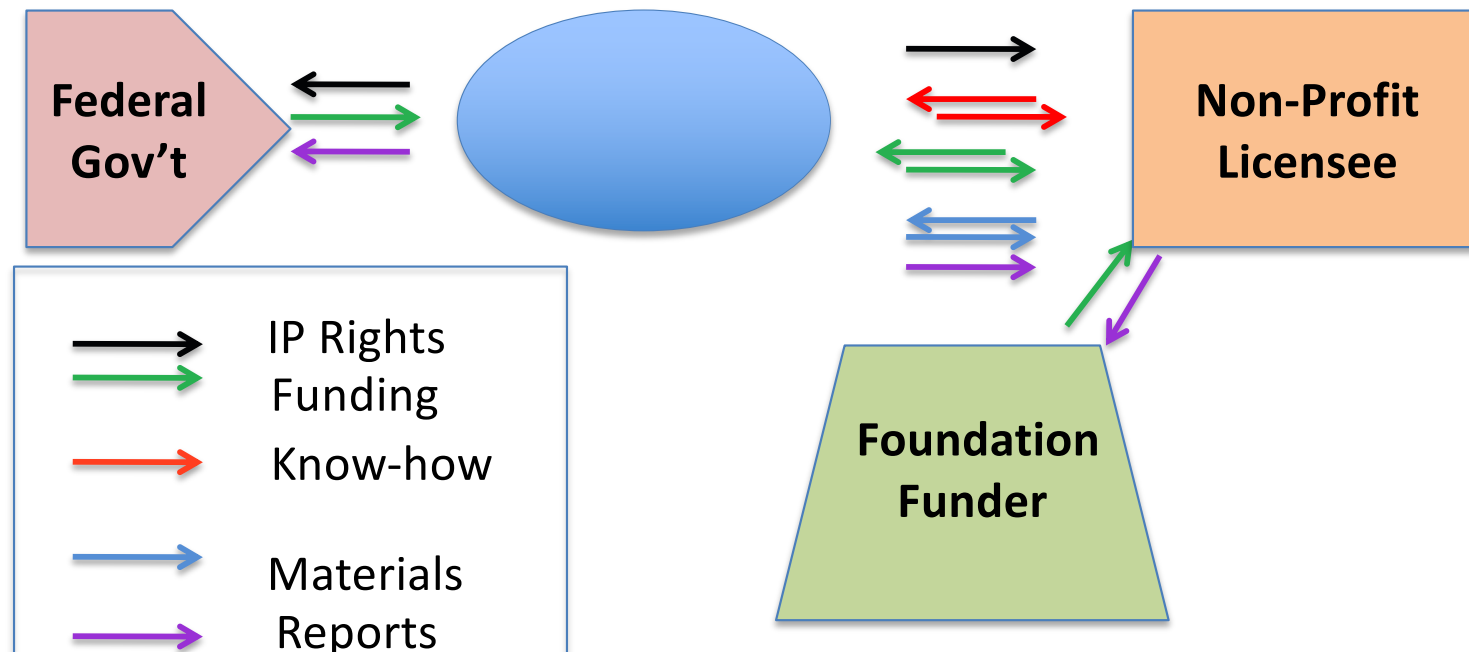
# Denge Fever - Diagnostics

The Sustainable Sciences Institute – a nonprofit

Mutual Goals: low-cost, durable, portable diagnostic for tropics

Berkeley files patents, SSI reimburses  
IP license is free in nonprofit territories

Inducement of funding for SSI and for research laboratory at Berkeley



## AGRICULTURE HUNGER: Biofortified Sorghum

**PDP with** Africa Harvest Foundation Coupled with free, nonexclusive license

	Collaborator& Licensee	University
<b>Goal</b>	<ul style="list-style-type: none"> <li>• <b>Access experts and IP</b> to complement existing R&amp;D</li> <li>• Commercial license consistent with Global Access Strategy</li> <li>• Achieve <b>affordability and accessibility</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>participate in PDP</b> -produce &amp; deploy improved sorghum in tropics</li> <li>• <b>Research funding</b> through Africa Harvest (Bill &amp; Melinda Gates Foundation)</li> <li>• Achieve <b>affordability and accessibility &amp; avoid</b> conflicting obligations</li> </ul>
<b>Challenge</b>	<ul style="list-style-type: none"> <li>• Needs existing collaborator IP, And future IP from PDP research FTO from all participants, universities, <b>Pioneer, Syngenta</b></li> </ul>	<ul style="list-style-type: none"> <li>• commercial license <b>to nonprofit</b></li> <li>• <b>Non-excl. royalty-free license</b> (in FOU, CO)</li> <li>• certain IP exists, additional IP will be developed with the funding under the PDP</li> <li>• <b>other sponsors</b></li> </ul>
<b>Solution</b>	<p>Nonexclusive, royalty-free(NERF) license</p>	<ul style="list-style-type: none"> <li>• <b>Define FOU, define Charitable Objective</b></li> <li>• NERF license to existing IP</li> <li>• “subject to legal ability to do so” a NERF to “project IP” to AHF</li> <li>• subject to gov’t rights</li> </ul>

# Agriculture, Hunger – Super Sorghum

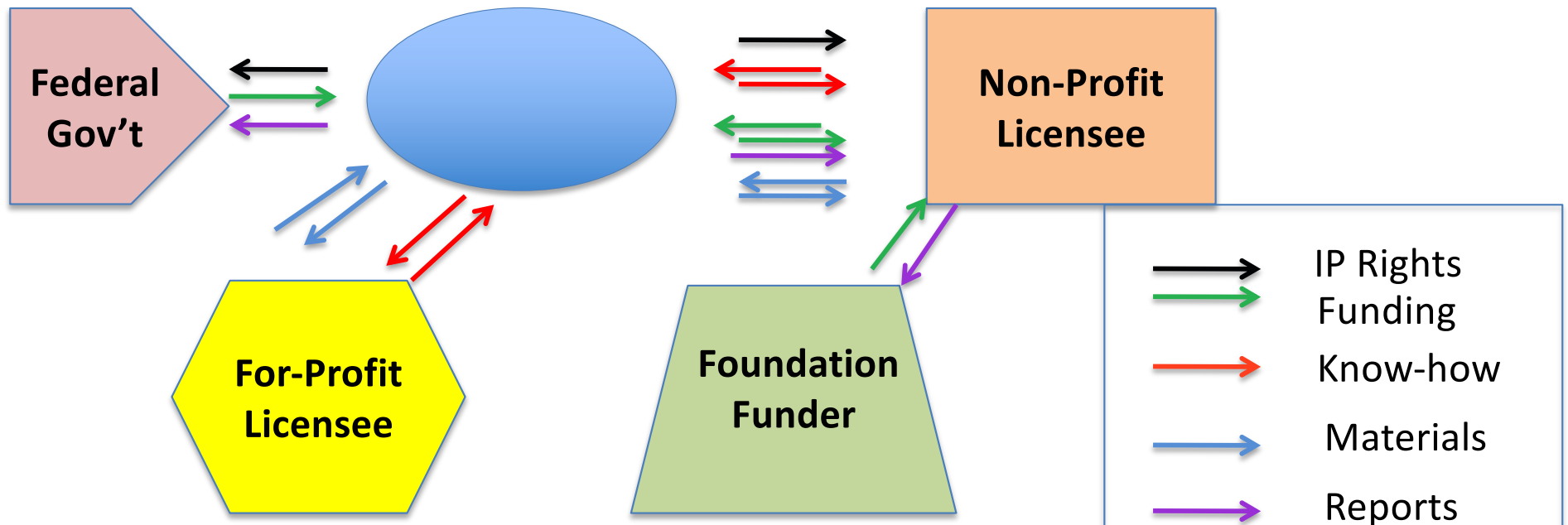
Africa Harvest Foundation – a nonprofit funded by Bill & Melinda Gates Foundation  
Product Development Partnership (PDP) with Syngenta, Pioneer Hi-Bred

Mutual Goals: nutritional sorghum for semi-arid and arid tropics

IP management strategy: Berkeley files patents, AHF reimburses

IP license is free

Inducement of funding for research laboratory at Berkeley





## Therapeutic: Anti-Malarial Drug ACT

Institute for One World Health, Amyris, Inc., Sanofi-Aventis, Bill and Melinda Gates Found.

	Initial Licensees	University
<b>Goal</b>	<ul style="list-style-type: none"><li>•affordable malaria drug in LMI countries</li><li>•stabilize supply of drug</li></ul>	<ul style="list-style-type: none"><li>•Enable research for public benefit</li><li>• Research funding and collaboration</li><li>•Support licensees' and foundation goals</li></ul>
	<ul style="list-style-type: none"><li>•sublicense, enable commercialization</li></ul>	<ul style="list-style-type: none"><li>•affordability and accessibility in developing world</li></ul>
<b>Challenge</b>	<ul style="list-style-type: none"><li>•Need IP and know-how licenses but with accommodations for charitable aims, no profit for tropical diseases</li></ul>	<ul style="list-style-type: none"><li>•Fair valuation, public benefit</li><li>•commercial license to nonprofit</li></ul>
<b>Solution</b>	<ul style="list-style-type: none"><li>•Bifurcated business model Profit in Developed world, None in developing</li><li>•de-risk the project through non-profit collaboration</li><li>• sublicense to for-profit pharma</li></ul>	<ul style="list-style-type: none"><li>•Grant no-cost licenses to each of biotech and PDP</li><li>•“informed consent”</li><li>• Exclusive license: diligence requirements incl. mandatory sublicensing, “at cost” requirement</li></ul>

# Low-Cost Malaria Therapeutic: Artemisinin Combination Therapy

Mutual Goals: low cost ACTs, stable, synthetic alternative to plant-based extraction

Package of 4 contracts: 3-way collaboration, 2 IP licenses  
+ later, sublicense to Pharma

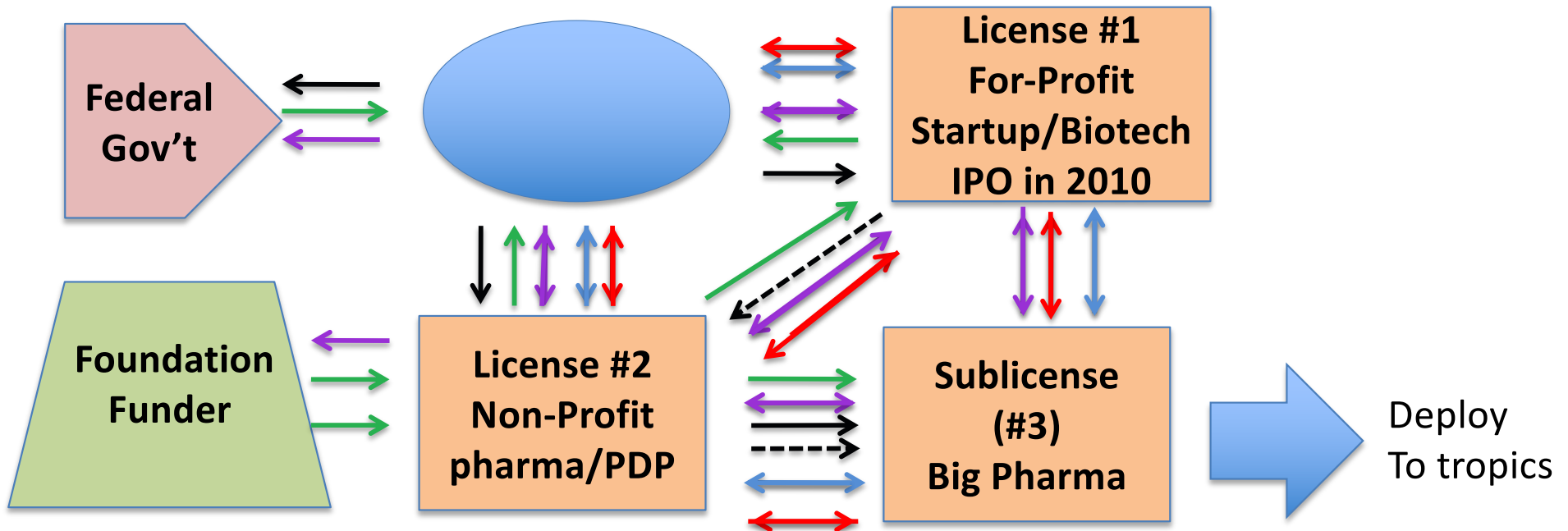
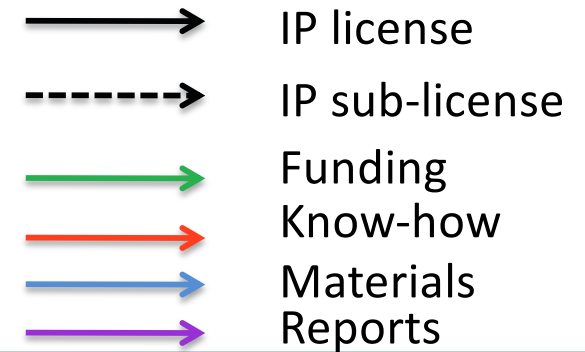
Separate FOU licenses, separate licensed territories

Biotech/startup company DUAL commercialization plan

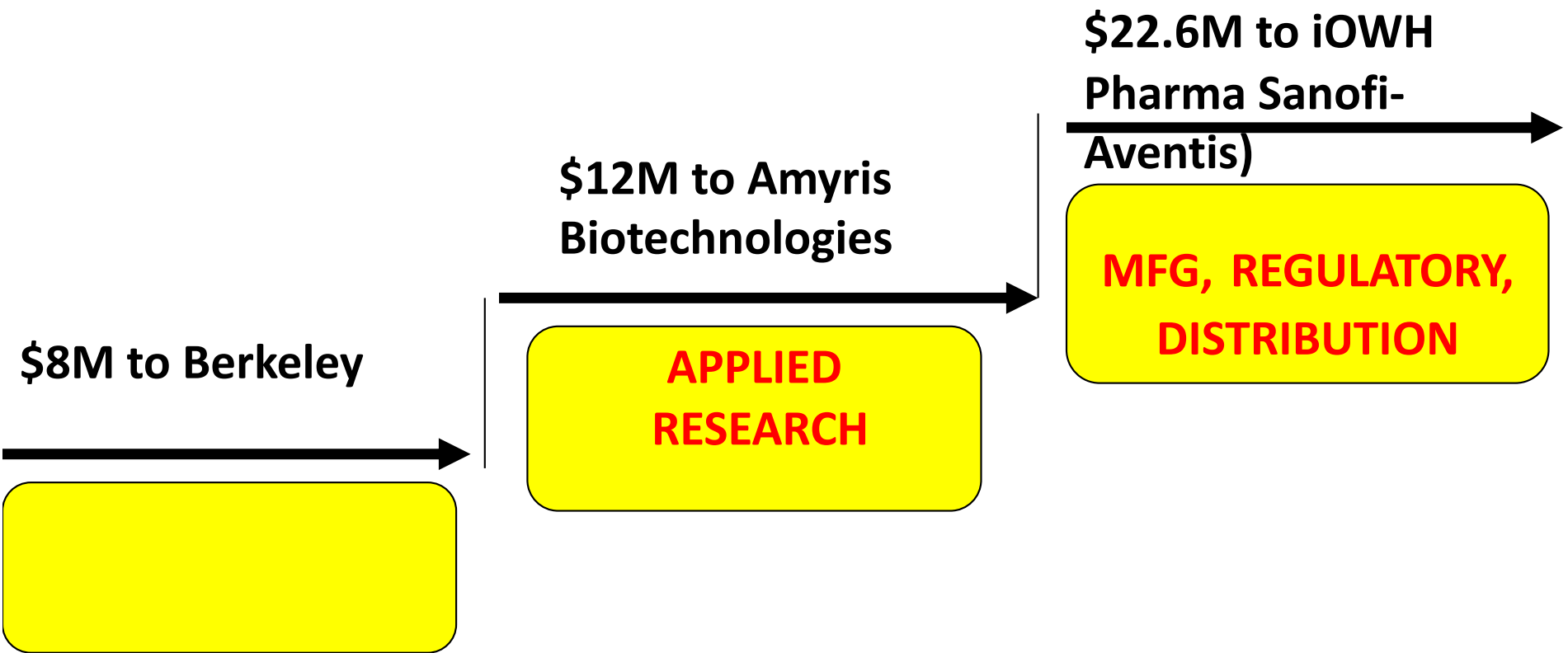
Malaria as a nonprofit, biofuels as for-profit

Royalty-bearing in developed countries

TRAVERSE translational research gaps



Low Cost Artemisinin Malaria Combination Therapy  
 \$42.6M Bill & Melinda Gates Foundation (+ \$10.7M in phase II)  
 3-way collaboration agreement + 2 license agreements + sublicense to Big Pharma



<p><b>3- way research Collaboration Agreement</b></p>	<p><b>License #1 Berkeley to Amyris. Developed world.</b>                  No profit for malaria drug.                  Profit for flavors &amp; fragrances</p>	<p><b>License #2 Berkeley to iOWH.</b>                  Developing world low cost  <b>SUBLICENSE to Big Pharma</b></p>
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# BVGH Pool for Open Innovation meets GX Open Innovation

2009 GSK drugs for global poor

Price reductions in LDCs, reinvestment into LDC infrastructure

Made hundreds of patents (and know-how) available in a pool

License elements of research program on neglected, tropical diseases

Alnylam also joined, donated

Pool managed by BioVentures for Global Health (BVGH)\*

Berkeley posted 4 TB patents

GreenXchange collaboration founded by 10 companies including Creative Commons

Vision: sustainability, business models through better collaboration, sharing

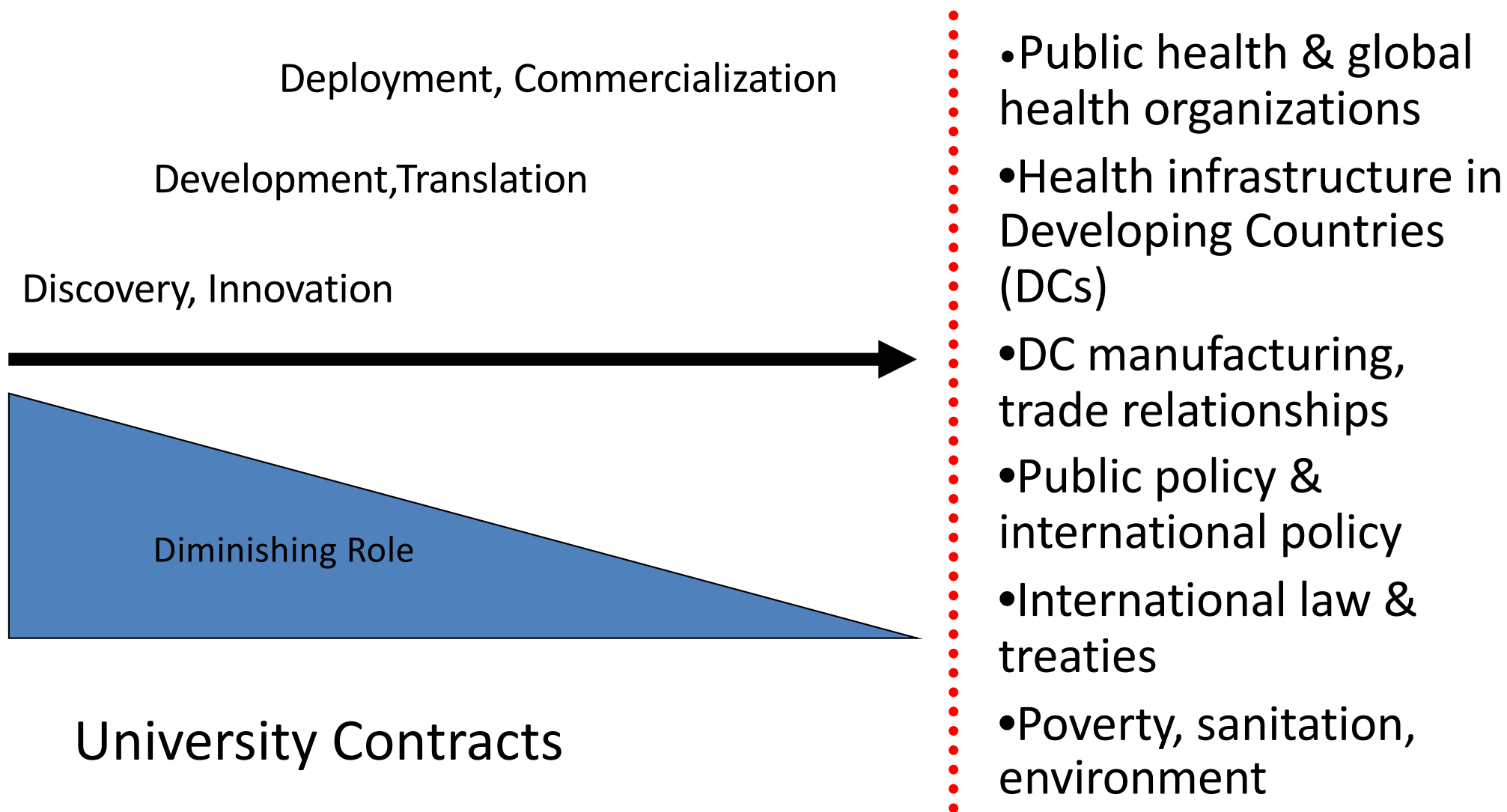
Berkeley became 1<sup>st</sup> univ. to use the CC-developed GX Public License

For licensing of BVGH-posted IP rights Invariant, standardized

Seekers can inspect the patents and the corresponding license

See: <http://greenxchange.cc/>

# Universities are upstream in the value chain



Thank you!

<https://ipira.berkeley.edu/socially-responsible-licensing#>