PDPs & IP Management Strategies for Improved Global Health

Biotechnology Industry Organization
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Carol Mimura, Ph.D.
Assistant Vice Chancellor for
Intellectual Property and Industry Research Alliances (IPIRA)
University of California, Berkeley
http://ipira.berkeley.edu

University Mission and Social Compact

Teaching, Research, Dissemination of Information, Public service

University of California's (UC's) economic impact is huge:

- 7% of all R&D activity in CA takes place at UC campuses*
- 1.3% of the growth in CA Gross St. Product* is due to productivity gains resulting from the research activities of the University of CA
- >$5B in federal funding (10 campuses)

As a research university we have a duty to ensure that basic research that has a practical application is transmitted and deployed to benefit society

*from *California's Future: It Starts Here (2004)* IBF consulting group

With Ownership Comes Responsibility

As owners of IP we must demonstrate good IP management and use our resources for public benefit to effect lasting societal change

- ✓ Most TT occurs in traditional ways (teaching, graduates, consulting, informing)
- ✓ Good stewards of IP think of broad implications when they make University property proprietary
  - ✓and don't impede public access to vital technologies for research, for cures (material transfer agreements)
- ✓ Faculty Service: reserve rights for research and education
- ✓ Maximization of research IMPACT, not licensing revenue

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Goals of the Socially Responsible Licensing Program (SRLP) at U.C. Berkeley

- ✓ Ensure widespread availability of technology & healthcare in the developing world
- ✓ Affordable pricing

- ✓ Attribution
- ✓ Revenue sharing

- ✓ Reservations of rights
- ✓ Expeditious sharing of research materials

- ✓ Expeditious publication of scientific results in accessible journals
- ✓ Diversity research funding sources

- ✓ IP management that provides commercial incentives, yet benefits the poor

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SRLP Examples

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Diagnostics Denge Fever, TB

Therapeutics

- Anti-viral
- Anti-malarial

Vaccines - STD

Agricultural Biotechnology

- Plant disease resistance
- Increased nutritional quality

Public Health - sanitation, water purity

Consumer Electronics and information technology

PDPs and PPPs

All examples rely on:

Product Development Partnerships (PDPs)

Public Private Partnerships (PPPs)

1) DIAGNOSTICS: Hand-held device Denge Fever, Nicaragua

The Sustainable Sciences Institute – a nonprofit.

	Licensee	University
Goal	Commercial license Proof of principle	Make an impact Stimulate funding for SSI
	Deploy at cost in LMC	Catalyze commercialization
	Need IP (copycats) Nontraditional license terms	Enable 2nd generation improvement Preserve additional licensing opportunities
Challenge	Lack of profit from LMC	Patent expenses, fair valuation
		Commercial license to nonprofit
Solution	Pay patent costs only and receive free IP license in non-profit territories	Define for-profit and non-profit territory, Grant free license in non-profit
	Remuneration to SSI via royalty sharing if Berkeley receives royalties from for-profit licenses	"informed consent" Retain right to license for-profit companies in for-profit territories

2) THERAPEUTIC: Antiviral Compound from Native Plant

Collaborative research agreement – Commonwealth of Samoa

	Collaborator	University
Goal	•Facilitate research to purify and characterize antiviral	•Obtain materials and engage in research
	•Benefit from success -credit national, local -royalties, use the drug	•If successful, achieve affordability and accessibility of therapy
Challenge	•Need collaborator with resources, equipment •Nothing invented yet	•Unknown future licensee •With unknown tolerance to SRLP terms
Solution	Facilitate access to botanical source, to local experts	Agree in research contract to give attribution (papers, talks plasmids), To associate Samoa with results
	Remuneration via royalty sharing	•Agree to share revenue with country, villages, indigenous experts •Agree to “exert reasonable efforts in licensing such IP for pb, mutual goal of providing therapy for free, at cost or minimal profit in the developing world”

3) Three licenses to big Pharma
THERAPEUTIC: Anticarcinogenic Combination Therapy

THERAPEUTIC: Neurodegenerative disease, spinal injury

VACCINE: STD

Exclusive patent licenses (and/or sublicenses)

No extraordinary contractual clauses but:

NO patents outside of Japan, Canada, U.S., EPO, Australia

Reservation of rights
Commercial diligence
- 2 include comprehensive commercialization

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4) AGRICULTURE / HUNGER: Plant disease resistance gene

Nonprofit Agbiotech Company license

	Licensee	University
Goal	•Commercialize disease resistant crops •Maximize use of trait for agriculture, rather than for profit •Manage gene use to preserve efficacy (disease resistance can be lost if commons)	•Enable the development of pesticide-free crops for public benefit •Support licensee's goal of trait management for long term agricultural benefits
	•Commercialize at cost in "least developed" countries	•If successful, achieve affordability and accessibility for poor
Challenge	•Need IP license but with accommodations for charitable aims	•Fair valuation, public benefit •commercial license to nonprofit
Solution	•Bifurcated business model Profit in Developed world, reinvest profits in further research	•Grant no-cost sublicenses in "least developed countries" emphasis on Africa. Receive royalty elsewhere. •"informed consent" • Exclusive license: diligence requirements incl. mandatory sublicensing

5) AGRICULTURE / HUNGER: Biofortified Sorghum

PDP with Africa Harvest Foundation Coupled with free, nonexclusive license

	Collaborator& Licensee	University
Goal	•Access experts and IP to complement existing R&D •Receive commercial license consistent with Global Access Strategy	•Participate in the PDP to produce and deploy improved sorghum in arid and semi-arid tropics with funding from Bill & Melinda Gates Foundation
	•If successful, achieve affordability and accessibility	•If research is successful, achieve affordability and accessibility, avoid conflicting obligations
Challenge	•Needs existing collaborator IP, And future IP from PDP research FTO from all participants, universities, Pioneer, Syngenta	•commercial license to nonprofit •NERF •some IP exists, additional IP will be developed with the funding under the PDP •other sponsors
Solution	Nonexclusive, royalty-free(NERF) license	•Define FOU, define Charitable Objective •NERF license to existing IP •“subject to legal ability to do so” a NERF to “project IP” to AHF

6) VACCINE: TB Vaccine Research For-profit biotech company

With Granting Agency "access" goals

	Collaborator	University
Goal	•Receive grant funding for company and university collaborator •If IP arises, receive assurance that license will be consistent with grant •Create business model to fund project	•Engage in collaborative/sponsored research, receive research funding •If successful, achieve affordability and accessibility in target areas
Challenge	•Need collaborator with expertise, equipment •Invention not reduced to practice	•avoid conflicting obligations •fair valuation
Solution	Letter of intent to license in the future	Agree in advance, that if successful, license to project IP will be royalty-free outside of JP, CA, EU"subject to legal ability" And NERF to US government if applicable

7) SANITATION: Water Purification Aquaya Institute (nonprofit)

	Collaborator	University
Goal	•Make clean drinking water accessible in ppor countries •Receive grant funding for company and university collaborator •At little or no cost •If IP arises, receive assurance that license will be consistent with grant •Allow international network to benefit	•Engage in collaborative/sponsored research on water treatment/sanitation •receive research funding •Develop a new class of household consumer products for disinfecting water (surface-bound cationic antimicrobial compounds) •If successful, achieve affordability and accessibility in target areas
Challenge	•need collaborators, expertise •deploy at cost in economically disadvantaged countries (EDC)	•avoid conflicting obligations •fair valuation •commercial license to nonprofit
Solution	Visiting Industrial fellow to Berkeley Receive NERF license in EDC for charitable purposes	Shall grant NERF license in EDCs Or nonassertion Sublicense to international network Retain right to license outside EDCs Informed consent

8) Electronics: Nokia – IP "Framework" Research Agreement

	Collaborator	University
Goal	•Sponsor research at cutting edge research university under a master agreement •Have a menu of choices of outcomes, within pre-negotiated framework (copyrights & pats)	•Engage in collaborative/sponsored research in areas of mutual interest •Provide opportunities for faculty and students •If commercially relevant inventions arise, achieve affordability and accessibility for poor
Challenge	•Deploy at cost/low cost in economically disadvantaged countries (EDC) •Segregate markets, differential pricing in countries with middle &upper class incomes •Protect markets in developed world	•avoid conflicting obligations •fair valuation, public benefit •SRLP terms in electronics industry •navigate antitrust concerns
Solution	•Deploy products for EDCs through charitable arm; •Ability to exercise convertible option •For-profit products as usual (currently sell for-profit products in EDCs)	Structure "conversion" option from humanitarian to commercial SRLP terms for "humanitarian products" in EDCs (for BK IP that cannot be commercialized through a Nokia business unit) Subject to third party rights Informed consent

SRLP Summary

And several research agreements from federal and foundation sources

Advance commitment from Berkeley to grant royalty-free licenses and/or requirement to provide licensed products for free or at cost for humanitarian use

MECHANISMS IN USE:

- royalty-free license
- no patent rights outside if JP, CA, EU, Australia, US
- 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 (application, and/or define humanitarian or charitable use)
- licensed territory
- royalty sharing, attribution
- diligence
- informed consent
- nonassertion

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Resources:

Socially Responsible Licensing at Berkeley

Humanitarian Use Clauses in Contracts

http://ipira.berkeley.edu then “Socially Responsible IP management”

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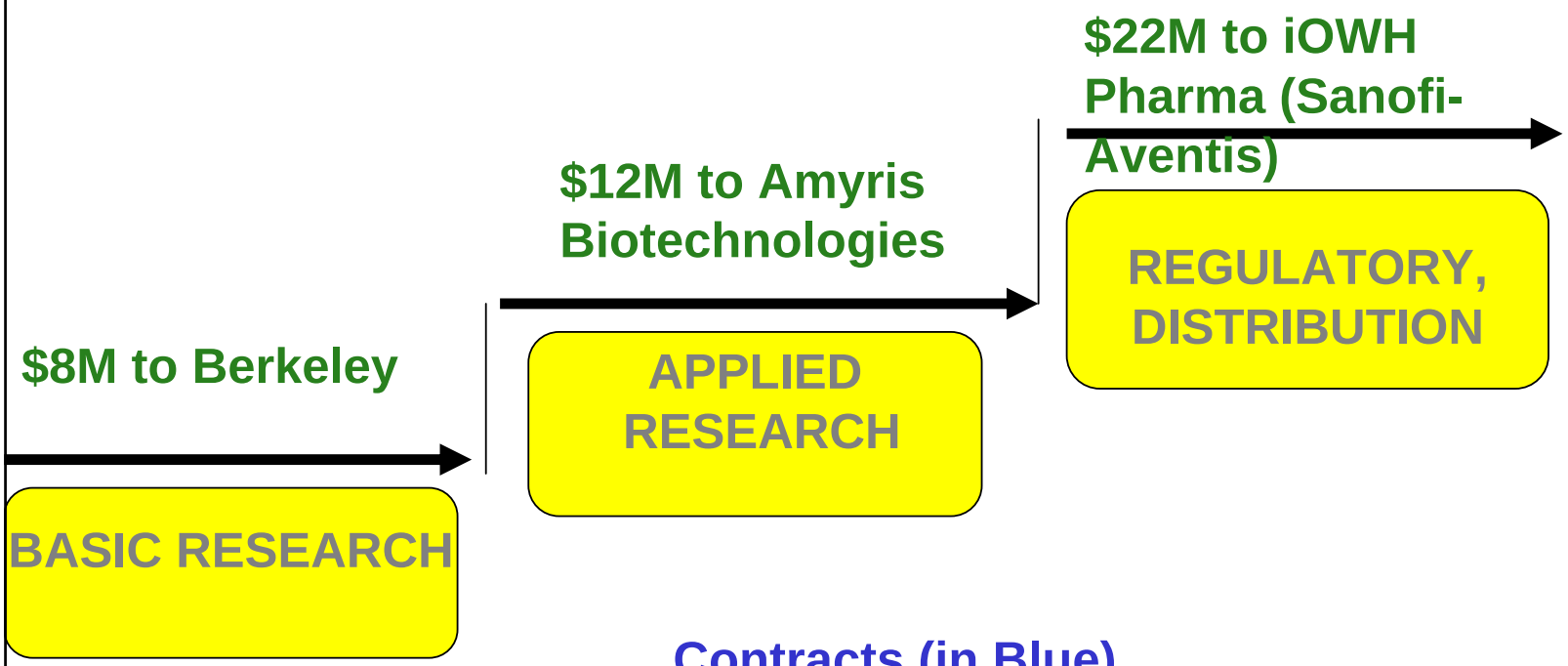
PDP: Malaria Drug Development Partnership

- Malaria afflicts up to 500M per year, kills 1-3M. Tropical disease, under resourced - profit margins low.
- Berkeley (Jay Keasling) has patented technology that allows terpene synthesis genes to engineered in *E. coli* and yeast. Overproduce artemisinin for ACT.
- Reduce reliance on natural product (extracted from wormwood)
- Berkeley's start-up Co., Amyris Biotechnologies, Inc. refine and scale up
- The Institute for One World Health (iOWH) is the world's first nonprofit pharmaceutical company and has expertise in clinical trials, FDA regulatory approvals. Mission: cure infectious diseases in developing world
- Gates Foundation, Berkeley, iOWH, Amyris have a mutual goal of making the existing malaria drug affordable ($2.40 per dose to ~24 cents).
- Neither Berkeley, iOWH, Amyris alone can see the project through to completion, Bill & Melinda Gates Foundation will fund if pricing and access goals are assured

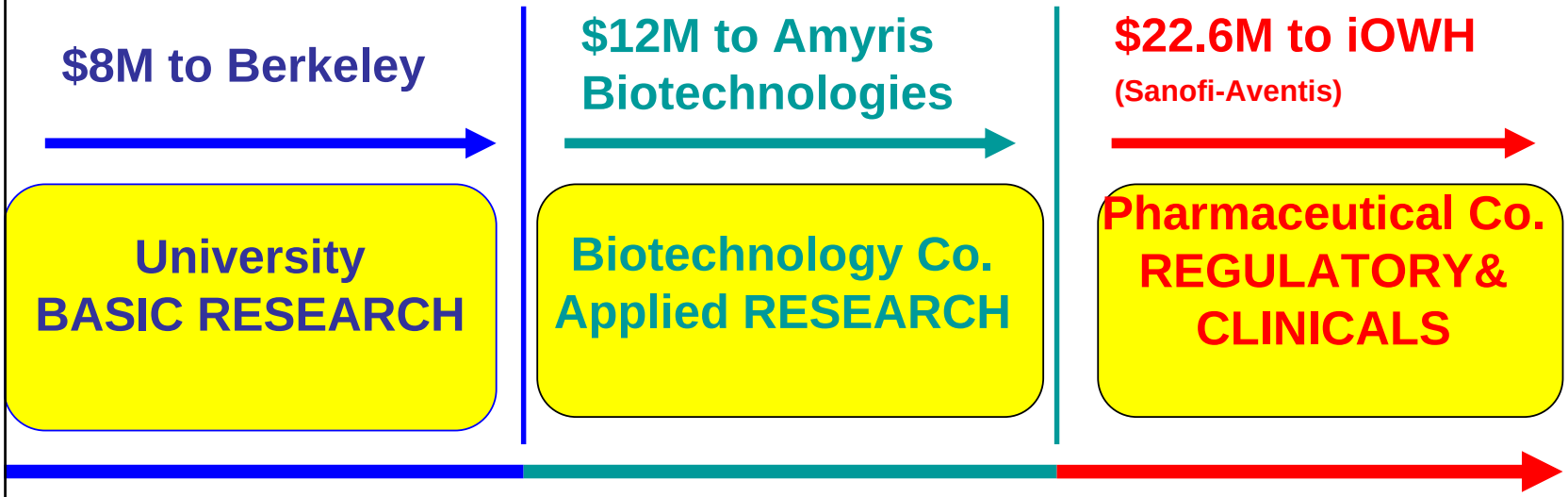
Low Cost Artemisinin Combination Therapy
$42.6M Bill & Melinda Gates Foundation
3-way collaboration agreement + 2 license agreements



Contracts (in Blue)

3- way research Collaboration Agreement	License #1 Berkeley to Amyris. Developed world. No profit for malaria drug. Profit for flavors & fragrances	License #2 Berkeley to iOWH. Sell drug at cost in developing world

A Single Grant to Expedite Translational Research
And Clinical/Regulatory Approvals



- Instead of a "relay race" a single donor makes one grant to fund basic research, translational research, clinical & regulatory activities
- No uncertainty in finding the next partner
- No uncertainty in future contract terms
- No gaps (time, expertise, additional transactions) between stages

This model: seamless transitions to accelerate & streamline translational research, commercialization & economic development

BASIC RESEARCH APPLIED RESEARCH CLINICAL/REGULATORY

- The model exemplifies “bench to bedside” translational research.

- Gates: hopes this structure will serve as a model for other Universities and calls it “An extraordinary public-private partnership that combines cutting edge science with a commitment to affordability and accessibility for those people in need.”

- William Haseltine: HGS founder: “The beginning of a new paradigm that could be transformational.”

- Tony Fauci, NIAID Director, “…Collaborations, coordination, and synergies between the private and public sectors are becoming increasingly essential.”

OUTCOME for Biotech Co. Amyris

Amyris spun out of University (start-up Co.)

- bootstrap philanthropy (faster start w/Gates funding)

For profit company

Dual commercial plan

- nonprofit model for malaria
- for profit model for all other applications

IP license gives incentive

- reduce to practice for malaria (short term)
- make a profit for all other applications (biofuels, long term)

OUTCOME for University

University research funding from foundation

- larger amount, broader scope

Spun out a biotech company

- faculty and postdocs as founders “make a difference”
- bridge translational research gap
- economic development in the region

Achieves impact

- drug accessibility, affordability in 88 target countries

Reputational gains - gifts

SRLP doesn’t harm university, compresses timelines

Demonstrates SRLP principles in action for Rx

OUTCOME for Pharma: iOWH & Sanofi-Aventis

1) iOWH a nonprofit pharmaceutical company

Achieves global health aims

- consistent with Gates Foundation global access goals

Demonstrates, through sublicense to Sanofi-Aventis, for profit

- licensee with commercial diligence requirements

doesn't itself, have to do it all

- uptake can be achieved by sublicensing a multinational pharma. (worldwide mfg, distribution) long term business model

2) Sanofi-Aventis: for profit, multinational

- ✓ U.S. FDA expedited review voucher
- ✓ Navigate drug regulatory systems in dev. World
- ✓ In-country presence for long term goals
- ✓ Goodwill, reputational gains