



Institute for OneWorld Health

A Nonprofit Pharmaceutical Company



Case Studies in Technology Transfer & IP Management

Julie J.L. Cheng, Esq.

General Counsel and VP Business Development

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iO^{WH} Mission

The Institute for OneWorld Health Develops
Safe, Effective, and Affordable
New Medicines for People with Infectious Diseases
in the Developing World



Malaria Case Study

Background:

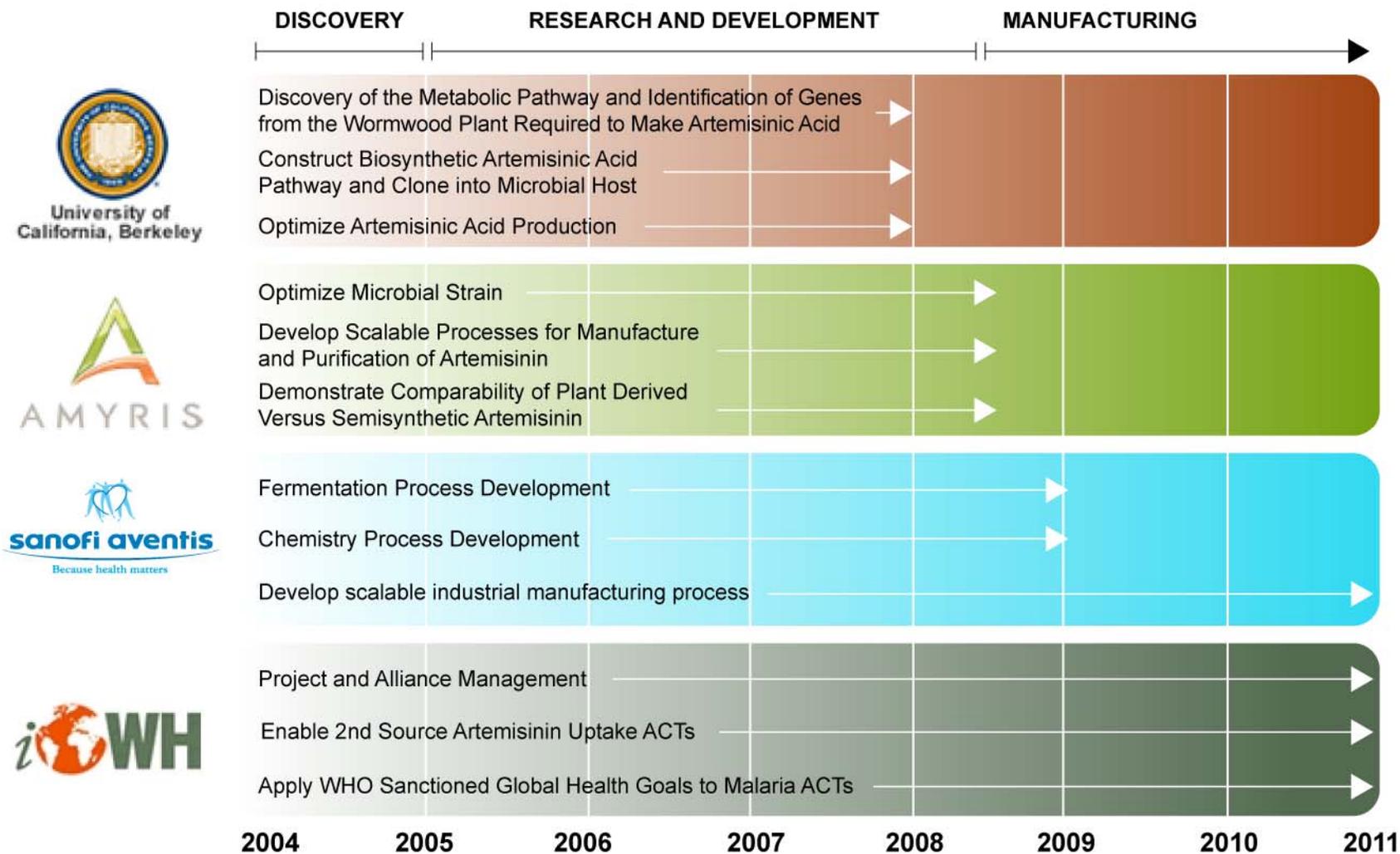
- In 2001, the World Health Organization (WHO) recommended **artemisinin-based combination therapy (ACT)** for uncomplicated malaria in areas experiencing drug resistance
- Malaria control requires multi-prong approach, with **drug therapy** being key component
- While many countries have adopted the WHO recommendation, **access** remains a barrier to use in many developing countries
- The artemisinin **supply chain is volatile** and may not be able to meet projected demand

Malaria Partnership Goals

- Create a complementary source of non-seasonal, high-quality and affordable artemisinin to supplement the current plant-derived supply
- Stabilize the price of botanical artemisinin and reduce risk in the event of a supply disruption
- Ensure semi-synthetic artemisinin is available to all eligible manufacturers
- Enable millions of people infected with malaria to gain consistent access to affordable, high-quality, life-saving ACTs



The Partners



Artemisinin Intellectual Property

- Pre-project IP developed by UC Berkeley was licensed on a royalty-free basis to iOWH
- During development, IP was created by UC Berkeley, Amyris and sanofi-aventis
- Ownership and licensing of project IP are tied to subject matter rather than inventorship, with iOWH holding licenses for use in malaria
- Separate rules apply for non-project IP that are contributed to the collaboration

Roche Case Study

Background:

- Diarrheal disease is the leading cause of death of children under the age of five in developing countries, killing approximately 2 million children each year.
- The pediatric death toll due to diarrheal illnesses exceeds that of AIDS, tuberculosis, and malaria combined
- Diarrheal disease is caused by multiple agents; no single treatment will address all causes of diarrhea
- iOWH is developing anti-secretory agents to be used in conjunction with ORS



The Research Program

- The program allowed iOWH to screen ~780,000 compounds from the Roche library to identify new drug candidates for the treatment of diarrheal diseases
- Based on the results of the screening campaign, Roche provided structural identification and characterization data of the hits to iOWH
- iOWH intends to use this information to further its overall diarrheal disease program



Diarrheal Disease Intellectual Property

- Inventions made in the course of the program are jointly owned.
- Roche provides a non-exclusive, royalty-free license to iOWH in the field of diarrheal diseases and in the iOWH territories with respect to the Roche compounds selected by iOWH
- Roche has options to rights of first negotiation for any compound that iOWH decides to out-license.
- Both parties have freedom to operate with respect to each others patents that arise after the conclusion of the program but relate back to the activities of the parties in the conduct of the program.

Other Considerations in PDP Licensing

- **Royalties:** royalty-free, running royalty or flat fee royalty
- **Territory:** the world, developing countries, endemic country focus, public sector sales
- **Patent Prosecution & Maintenance Costs:** who bears what portion and for which territories
- **Trade Secrets:** can they be appropriately maintained with PDPs

Thank You

