Malaria Vaccine Initiative
Intellectual Property Rights and Vaccines in Developing Countries
WHO Meeting
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Malaria Vaccine Initiative

Accelerating the development of promising malaria vaccines and ensuring their availability and accessibility in the developing world.
Why is intervention critical?

**Barrier 1:**
Existing market forces are insufficient to drive malaria vaccine development

**Barrier 2:**
Malaria vaccines are not perceived to be technically feasible
Scientific Complexity

Market Attractiveness
(Based on Developed Country Markets)

High

Low

Orphan Zone
High Risk-Low Return

Probable Orphans
Low Risk-Low Return

Market Product
Low Risk-High Return

Possible Product
High Risk-High Return

Mening A/C

Rotavirus
Pneumo

Hookworm,
Schisto

Cancer
Therapeutic

Malaria

TB, AIDS

Probable Orphans
Low Risk-Low Return

Possible Product
High Risk-High Return

Market Product
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Rotavirus
Pneumo

Hookworm,
Schisto

Cancer
Therapeutic

Malaria

TB, AIDS
Challenges impacting the malaria vaccine IP environment

• Industry willingness to develop and supply
  – Bringing new players to the field
  – Survival for small companies with malaria as a lead product
• Challenging environment for malaria-specific IP
• Need for non-malaria technologies
MVI’s IP Principles

• MVI’s practice is not to own IP
• IP rights are generally held by partners
• MVI acts as a safety net for public sector investment
  – No/low-cost technology transfer (PATH, third party) if IP holder chooses not to develop or manufacture
MVI’s IP Principles

• Malaria-specific IP should be easily accessible by the field
  – Public domain or patent pool?
  – Goal: Prevent ‘lock up’ by the private sector

• MVI believes IP is necessary
  – For innovation
  – Fiscally important to biotech and pharmaceutical industry
## Vaccine Candidate Portfolio

### Institutes and Their Candidates

- **ICGEB**
  - PvRII

- **WRAIR**
  - FMP-1

- **MVDB**
  - MSP1:3D7
  - MSP1:FVO
  - AMA1:3D7
  - AMA1:FVO

- **LaTrobe**
  - MSP2:3D7
  - MSP2:FVO

- **QIMR**
  - RAP-2

- **Monash**
  - MSP4
  - MSP5

- **SMMU**
  - CP2.9

### Collaborating Organizations and Their Candidates

- **Oxford**
  - MVA:CSO
  - FP9:CSO

- **Apovia**
  - ICC-1132:S
  - ICC-1132:A
  - ICC-1132:M

- **GSK**
  - RTS,S

- **Genvec**
  - AMA1:MSP1
  - CSP:SSP2:LSA1

- **CDC**
  - FALVAC1A

- **GSK**
  - LSA3,S

- **SMMU**
  - CSP
  - AMA1

- **SMMU**
  - CSP:LSA1
  - AMA1:MSP1
IP issues vary by partner

- Biotech companies
- Multinational vaccine manufacturer
- Government (e.g., NIH, DoD)
- Academia
- Contract manufacturer
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<th>Gov’t Partner</th>
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What will it take?

Delivery Platform

A1

A2

A3

A4

A5

Processes

Adj.
Combination vaccines

Delivery Platform

A1
A2
A3
A4
A5

Processes
Adj.
Royalty stream

30%

10%

8%

1%

2%

2%

1%

2%

2%
IP landscape for malaria vaccines

*Malaria-specific IP*

- Unlikely to be of great commercial value
- Impedes development and testing of antigens
  - High transaction costs (time and money) for access to IP
  - Unrealistic sense of value
  - Confusing IP landscape leads to avoidance
- IP holders unlikely to see return on investment?

*We could not give our malaria technologies away.*  - M. Freire
MSP-1: A case in point...
MSP-1 complexities

• Conflicting claims?
  – overlapping claims, different inventors

• Little IP heritage
  – limited backward or forward citations
  – uncertain relationships

• Qualitative questions about validity and enforceability of MSP-1 patent “families”
IP landscape for malaria vaccines

Non-Malaria Technologies

• Non-malaria-specific technologies are critical to the portfolio
  – Likely to contribute to a more effective vaccine
  – Increase industry participation in the field
• …but this complicates the IP environment for a malaria vaccine
  – IP ownership is critical for commercialization/investment
  – IP can prevent access for neglected diseases
  – But, developers may use malaria to advance their technology without a long-term commitment to MVI’s market
IP landscape for malaria vaccines

Non-Malaria Technologies

• Adjuvant supply commitments are especially important
  – Guarantees of pre-clinical, clinical, and commercial access
MVI’s IP initiatives

Patent pool study (Q2/Q3 2004)

• Guiding principles:
  • Ensure recognition for the inventors and their institutions
  • Ensure that if others profit from a malaria vaccine that the inventor will in some way also profit
  • Ensure that the organizational responsibilities for commercialization of government-funded research can be met
MVI’s IP initiatives

• Guiding principles (cont’d…):
  • Decrease the transaction time and costs for licensing IP
  • License IP on a non-exclusive basis to prevent monopolies
  • Not pay patent costs for marginal patents (reward inventors for letting their marginal patents lapse)

• Adjuvant access commercial strategy (Q2 2004)
The Vision