Intellectual Property Management
Medicines for Malaria Venture

Life Sciences Symposium
WIPO – 15 December 2008

Structure of the presentation

• 1. MMV at a glance - PPP model

• 2. MMV and Intellectual Property Management

• 3. Issues and challenges
1. **MMV at a glance – our mission**

- MMV is a non-profit organization with a mission to **Discover, Develop and Deliver** safe and effective antimalarial drugs through public-private partnerships

- Malaria is a disease of the poor. Huge demand for drugs but the people affected have no purchasing power. MMV was created in 1999 at a time when the pipeline for new antimalarials was virtually empty

- Our vision is a world in which new medicines will help eradicate this terrible disease

1. **MMV at a glance - Operating Principles**

- Operating model: Public-private partnership for Product Development
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- Operating model: Public-private partnership for Product Development
- Raise funds (very diverse funding base)

1. MMV at a glance - Support from Private Sector and 7 Governmental Agencies

Total Received/Pledged $330 Million

- Bill & Melinda Gates Foundation 61.3%
- U.K. DFID 8.8%
- Rockefeller Foundation 1.7%
- Netherlands Minister Devt. Co-operation 5.2%
- World Bank 1.4%
- WHO/PRBC 1.1%
- Swiss Government S.D.C. 1.9%
- Welcome Trust 6.3%
- Exxon Mobil Foundation 0.9%
- BHP Billiton 0.2%
- USAID 4.9%
- Irish Aid 3.3%
- NIH 1.6%
- Spanish Agency for International Development 1.5%
- Irish Aid 3.3%
- USAID 4.9%
- BHP Billiton 0.2%
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1. MMV at a glance - Operating Principles

• Operating model: Public-private partnership for Product Development
  • Raise funds (very diverse funding base)
  • Fund projects in our portfolio

• Play an active role in portfolio management (MMV Science Team and ESAC)
1. MMV at a glance - Operating Principles

- Operating model: Public-private partnership for Product Development
  - Raise funds (very diverse funding base)
  - Fund projects in our portfolio
  - Play an active role in portfolio management (MMV Science Team and ESAC)
  - But, we keep in mind our public health mission (cost of end product)

2. Intellectual Property Management

- Drug Development PPPs, such as MMV, will, by design, create new IP or further develop existing technologies
- We have today the largest antimalarial portfolio in the world, with projects at every stage of drug development:
  - Exploratory
  - Discovery
  - Preclinical
  - Development
  - Regulatory
## 2. IP Management - Portfolio Q3 2008

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<th>Research</th>
<th>Translational</th>
<th>Development</th>
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<td>Preclinical</td>
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<td>Lead Opt</td>
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<td>Others</td>
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1 with stringent international regulatory authority

## 2. IP Management at each stage

- Our portfolio is populated with new projects
  - either coming into our pipeline at various stages
  - or progressing through the pipeline, if successful

- Any product developed within a project will typically include:
  - Background technologies
  - Technologies acquired or licensed from third parties
  - Program or Foreground technologies

- Necessity to decide on a strategy for managing existing or future IP at each stage of the product development
2. IP Management - Securing IP

- Is IP protection essential for MMV? Why?
  - Not for financial returns
  - But, for further development of the project (ensuring development of promising compounds, attracting partners)

- Is it essential for MMV to own IP Rights?
  - Not always preferred option
  - But appropriate license rights are vital

2. IP Management - Securing Background IP

- Background IP
  - Remains the property of the Party owning them
    - Unencumbered compounds
    - Owned (and protected) by the other party
    - Licensed to the other party
  - Each party grants to the other(s) a license to its Background IP
    - Non-exclusive
    - Worldwide
    - Paid up
    - Royalty free
    - Sub-licensable (restrictions)
2. IP Management - Securing Program IP

- Program IP
  - Vests in the party at which the invention took place
  - Decisions to file, prosecute and maintain patents taken by a joint committee or by the pharma partner (possible sharing of costs)
  - MMV will seek the appropriate license rights to Program IP:
    - Exclusive (in the field of malaria)
    - Worldwide
    - Paid up
    - Royalty free
    - Sub-licensable

2. IP Management - Acquired IP

- In-licensing of compounds
  - MMV will seek the appropriate license rights:
    - Exclusive in the field of malaria
    - Worldwide
    - Paid up
    - Royalty free
    - Sub-licensable
2. Securing IP - MMV’s perspective - Summary

• From MMV’s perspective:
  • To ensure that promising compounds are developed in the field of malaria (early stages) – but at the exploratory stage, it may be decided to publish early
  • To facilitate the process of attracting a commercial partner (clinical phases)
  • To control the manufacturing and distribution of the drug (late stages)

2. Commercial partner’s perspective

• From the commercial partner’s perspective:
  • Rights in the premium private sector of malaria endemic countries
  • Rights in the developed countries (treatment and prophylaxis)
  • When IP has broad applicability, rights outside the field of malaria
3. Issues and challenges - Universities

- Dealing with “tech transfer” offices in universities. We need to:
  - Explain our public health mission
  - Secure license rights to Background IP
  - Secure license rights to Program IP
  - Insist on getting those rights without paying for patent costs

- Dealing with scientists. We need to:
  - Protect the IP and prevent early publications

3. Issues and challenges - Pharmas

- Pharmas may wish to keep the right to withdraw compounds if potential for development and commercialization exists outside the field
  - MMV will not allow this after candidate selection
  - Compounds will have to be reinstated if the pharma no longer wishes to develop them outside the field
  - If compounds are developed outside the field MMV may seek compensation (royalties on net sales)
3. New Developments

• Addition of new section 524 to the Federal Food, Drug, and Cosmetic Act: the FDA will be able to award Priority Review Vouchers to entities that have obtained FDA approval for tropical diseases drug products.

• This is an enormous incentive and will encourage drug development for tropical diseases.

• It will help MMV negotiate partnerships and leverage pharmas involvement in our projects

In conclusion

• MMV uses IP as a tool to achieve our public health goals: to promote access to life saving medicines

• The Priority Review Voucher is a new tool at our disposal to attract pharmaceutical partners. It will encourage R&D in the field of tropical diseases, such as malaria.
Thank you
7 Governmental Agencies: $88 Million

MMV - Medicines for Malaria Venture
funding from Foundation to 2010 (Oct 2008)

(7 Government Agencies: $88 Million)

- U.K. DFID: 32.5%
- Netherlands Minister Devt. Co-operation: 19.1%
- Swiss Government S.D.C.: 7.2%
- USAID: 18.0%
- NIH National Institutes of Health: 5.6%
- Spanish Agency for International Development: 5.3%
- Irish Aid: 12.2%

Back-up slide – Win/Win situation

**MMV and Partners Inputs**
- $$
- Drug Profile
- Partner Management
- Link to WHO/GMP/Policy
- Malaria Expertise
- Evaluation / Monitoring

**MMV and Partners Gets**
- Rights in DEC
- IPR in ‘Field’
- Drug Supply
- Return on non DEC Sales

**Industry Inputs**
- Chemistry IPR
- Toxicology
- Assets in Kind
- Liability Insurance
- Know how
- Expertise

**Industry Gets**
- Rights in non DEC
- IPR outside ‘Field’
- Validation of Technology
- PR Benefit Corporate Citizenship and Responsibility
- HR Benefit Staff Satisfaction

Public + Private = leveraged cost
Curing Malaria Together

MMV’s partners across the world