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

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1. MMV at a glance - Operating Principles

- Operating model: Public-private partnership for Product Development

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  - Raise funds (very diverse funding base)

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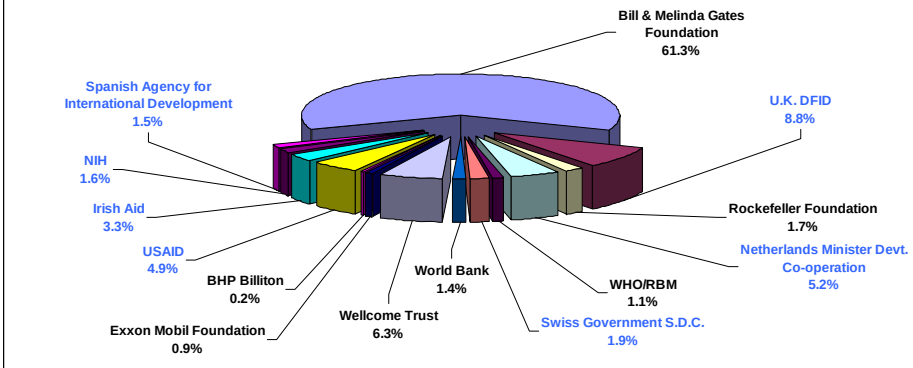
1. MMV at a glance - Support from Private Sector and 7 Governmental Agencies



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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)
  - But, we keep in mind our public health mission (cost of end product)

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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

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2. IP Management - Portfolio Q3 2008

Research		Translational			Development	
Lead Gen	Lead Opt	Preclinical	Phase I	Phase II	Phase III	Registration[1]
Novartis 9 projects	DHFR BIOTEC/ Monash/LSHTM	OZ 439 Monash/UNMC/STI	Isoquine GSK	IV artesunate University of Tübingen	Eurartesim™ Sigma Tau	Coartem®-*D* Novartis
GSK 3 projects	DHFR Novartis	GSK 932121 GSK	Tafenoquine GSK		Pyramax® ShinPoong/ University of Iowa	
Broad/Genzyme 5 projects	Pyridones GSK					
Others 6 projects	Macrolides GSK					
	DHODH UTSW/UW/Monash					
	Nat Product Novartis					
	Ozonides Monash/UNMC/STI					

[1] with stringent international regulatory authority

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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

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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

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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)

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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

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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

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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)

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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

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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

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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)

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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

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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.

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Thank you

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Discover Develop Deliver

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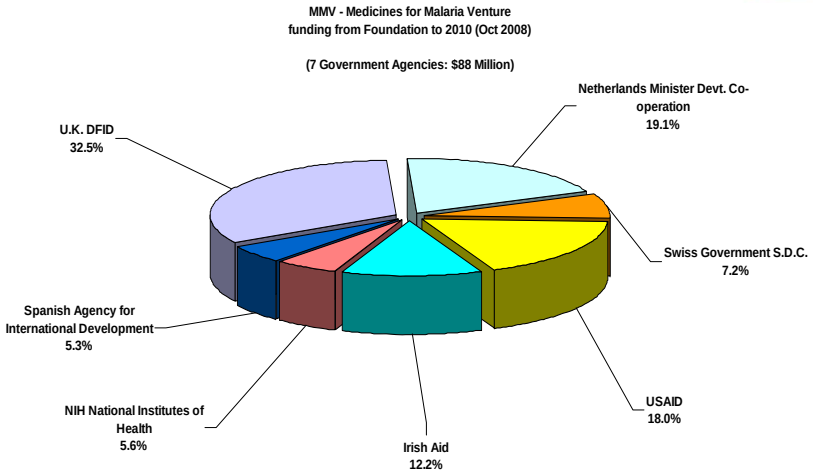
7 Governmental Agencies: $88 Million



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Back-up slide – Win/Win situation

MMV and Partners Inputs

- $$$
- Drug Profile
- Partner Management
- Link to WHO/GMP/Policy
- Malaria Expertise
- Evaluation / Monitoring

Industry Inputs

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

Public

R&D

For the 'Public Good'

Private

MMV and Partners Gets

- Rights in DEC
- IPR in 'Field'
- Drug Supply
- Return on non DEC Sales

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

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MMV's partners across the world