

## MMV and Intellectual Property Rights

The commercial market for new drugs to treat or prevent neglected diseases such as malaria, which primarily affect developing countries, is insignificant because people afflicted by these diseases have negligible purchasing power. The small size of this market means that private sector investment in R&D is also small. Coupled with minimal public-sector investment, this has resulted in only a handful of new medicines being developed for neglected diseases. A variety of approaches have been taken to address these gaps, with public-private product development partnerships (PDPs), such as Medicines for Malaria Venture (MMV), providing some of the more creative and effective solutions.

MMV's mission is to discover, develop, and deliver new antimalarial drugs through effective partnerships with academia, the pharmaceutical industry, public sector research organisations, and national and international policy makers. Through these partnerships, we ensure the sustainable and continuous generation of appropriate new malaria medicines and facilitate their access at the lowest prices practicable to those in need in developing countries.

MMV believes that with the effective management of resources for research, development, and delivery, the burden of malaria can be significantly reduced in the developing world.

### Management of Intellectual Property

Much of the technology and know-how that MMV needs to start researching new antimalarials is protected by the intellectual property (IP) of the public-sector academic research institutions or pharmaceutical companies with whom MMV works. Thus MMV needs to address IP rights (IPR) issues in nearly all of its research programmes.

When they work together in a given research programme, MMV and its partners decide on an appropriate strategy for managing existing and developed IPR. Such a strategy includes whether IP generated under the programme should be the subject of a patent application or should be dedicated to the public domain. This is not a simple exercise, and requires MMV and its partners to determine whether the IP has value as an incentive for the partners (or others in later-stage commercialization of the resulting products) to participate in the programme or has value in controlling how the product is distributed and used.

**The overarching goal, however, is whether rights to the IP will serve MMV's public health mission - IPR must serve MMV's mission and not vice versa.**

If IP *is* generated during a given research programme, it is not essential that MMV will take an ownership position in it to accomplish its mission. If, however, ownership of IP does not vest in MMV, MMV will insist on appropriate license rights to any compound(s) being developed under its portfolio. This is crucial in helping us achieve our public health mission, in that it:

- a) Enables us to ensure that promising compound(s) are developed through to completion with new partners if existing partners do not proceed with the research programme
- b) Facilitates the process of attracting a commercial partner for the development and commercialisation of the compound(s)

- c) Gives us the means to ensure that affordability is a critical element in the subsequent commercialisation of the drug, as this will help facilitate its widespread use in malaria-endemic countries
- d) Provides us and our partners an additional tool to control who manufactures and distributes the drug so as to ensure that safety and other public health goals are met.

Typically, MMV will work with a commercial partner through all the phases of the drug research and development (R&D) pipeline, from early discovery, through development and regulatory approvals, to delivery of the drug to the market. In the latter case, MMV will negotiate for delivery to the poor in developing countries to be on a “no profit, no loss” basis, with a right to audit the books to ensure these conditions are met. Other research projects may allow for many parties to manufacture a drug under license from MMV.

In either case, the goal is to deliver high-quality affordable drugs to the poor in malaria-endemic countries while maintaining the interest and involvement of partners in MMV-funded projects.

While MMV anticipates that its research programmes will succeed and its chosen partners will follow through on their commitments, we do build into our agreements clauses for occasions when partners do not or cannot follow through. In such cases, we require provisions that permit MMV to take ownership or appropriate licenses to both programme and background IPR to allow the project to be completed and the resultant drug to be launched in malaria-endemic countries.

**Exclusivity:** If MMV does not own the necessary IPR outright, it would insist on being granted an exclusive license to use the ‘programme IPR’ and any necessary ‘background IPR’ to develop a drug for malaria and bring it to market. That license should be **worldwide**, to ensure maximum flexibility for later-stage activities such as manufacturing and distribution.

**Royalty-free:** Any such licenses are preferably royalty-free, at least in malaria-endemic countries, to help keep costs to a minimum and ensure that the drug will be sold at the lowest price possible in these countries.

**Transferable:** Moreover, MMV does not conduct any R&D in-house or any manufacturing and, therefore, requires such rights to IP that can be transferred to other partners - especially manufacturing partners - if necessary.

MMV does not *normally* wish to retain any interest in IPR for use outside the field of malaria, or to constrain such use by its partners. The decision to retain IPR is made on a case-by-case basis.

MMV expects that income from sales of its products for the treatment of malaria in non-malaria-endemic countries, and income from sales of products for indications other than malaria, will contribute towards the reduction of prices in malaria-endemic countries, thus making these medicines readily accessible at the lowest feasible prices to the most vulnerable.

MMV recognizes the importance of disseminating its research information to the scientific community as rapidly as possible. It encourages, therefore, the publication of research results by partners in the form of press releases or scientific articles. The agreements MMV enters into typically provide for the mutual approval on content of the publication in

order to preserve IPR (especially any confidential information) and to allow, if appropriate, for patent protection to be sought. Such limits or delays in publication are, however, strictly limited to those necessary to preserve the possibility of IPR protection as necessary and appropriate to the pursuit of MMV's mission as discussed above.

## **Conclusion**

MMV has successfully negotiated contracts with over 60 cutting-edge research entities around the world including pharmaceutical and biotech companies, public and private research organisations, academic institutions, and contract research organisations (CROs) that wish to contribute to the shared goal of saving and improving lives in the developing world. When MMV enters into contractual relationships with its partners, its primary goal is to ensure that the malaria drugs it develops and launches will be accessible to those most in need in malaria-endemic countries, thus maximizing the public health impact. To facilitate this goal, MMV requires special treatment of the IP that is brought to and developed under a research programme.

MMV understands that Intellectual Property Rights alone are not a sufficient incentive for entities to boost the R&D of new medicines for neglected diseases, and concurs with the WHO that *'although intellectual property rights are an important incentive for the development of new health-care products ... this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain'*. Consistent with this view, the 60<sup>th</sup> World Health Assembly (May 2007) issued a resolution on malaria that Member States should *'provide, whenever necessary, in their legislation for use, to the full, of the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights in order to promote access to pharmaceutical products.'*

MMV has found that flexible, results-oriented approaches to dealing with IPR best serve their use as a tool to form and manage collaborations that can further MMV's public health mission: to develop effective and affordable antimalarials and make them accessible to our target population - children and the poor, those most at risk from malaria.