

IP initiative takes aim at neglected diseases

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The World Intellectual Property Organisation (WIPO) has announced a collaborative initiative between pharmaceutical companies and the global health research community to share intellectual property (IP) assets and expertise. The aim is to encourage the development of new drugs, vaccines and diagnostics to treat malaria, TB and neglected tropical diseases.¹

The new initiative *WIPO Re:Search* will be managed by the non-profit organisation Bio-Ventures for Global Health (BVGH). Companies and research organisations will commit to making IP assets available under royalty-free licences to qualified researchers anywhere in the world. The assets are publicly available for view at www.wipo.int/research/en/search/ and include patents, lead compounds and associated data, unpublished results, regulatory data and dossiers, screening technologies and expertise and know-how in pharmaceutical research and development. The programme states that it will offer the opportunity for researchers to work directly with scientists at pharmaceutical companies to advance R&D on these diseases.²

Just as important as the database is the establishment of the "Partnership Hub" to be run by BVGH. This hub will aim to foster collaboration between the organisations while BVGH will provide licensing support to the collaborators. As WIPO Re:Search moves forward, it is hoped that offerings from current partners will continue to grow while new providers join and contribute further to the information, compounds, and services available.

Pharma industry leaders back initiative

The impressive list of industry backers means that there exists real potential to open up the research vaults of some of the big players to allow access by stakeholders not solely driven by the bottom line. Alnylam Pharmaceuticals, AstraZeneca, Eisai, GlaxoSmithKline, Merck Sharp & Dohme, Novartis, Pfizer, and Sanofi have signed up to collaborate with a number of research organisations including the U.S. National Institutes of Health (NIH), California Institute of Technology, the Center for World Health & Medicine, the Drugs for Neglected Diseases initiative, Fundação Oswaldo Cruz (Fiocruz), Massachusetts Institute of Technology, Medicines for Malaria Venture, PATH, the South African Medical Research Council, the Swiss Tropical and Public Health Institute, the University of California, Berkeley, and the University of Dundee (UK). It is hoped that the initiative will facilitate new partnerships to develop treatments for the diseases that are often prevalent in very poor populations.

WIPO Re:Search is open to all organisations that agree to allow a selection of their IP relating to neglected tropical diseases to be licensed on a royalty-free basis for research and development in any country. The IP assets must also be offered on a royalty-free basis for sale of neglected tropical

disease medicines in, or to, least developed countries.

Neglected tropical diseases

The development of treatments for malaria and tuberculosis is mentioned specifically but other diseases that are less well known are targeted under the banner of "neglected tropical diseases". This term is used by the World Health Organisation (WHO) to refer to less well known tropical diseases such as the parasite-borne diseases visceral leishmaniasis (VL), sleeping sickness (human African trypanosomiasis / HAT), and Chagas disease.

Although the collaborative effort to research and develop novel treatments for neglected tropical diseases is to be lauded, in many cases, high-tech solutions are not necessarily the answer. Many of the diseases already have effective treatments and the major problems are how to pay for and distribute the medicines, and how to educate the population about effective prophylactic measures. As stated in the First WHO Report on Neglected Tropical Disease³: *Control of neglected tropical diseases today relies on two pillars: access to treatment with safe and effective medicines available free of charge to affected populations, and judicious use of pesticides for vector control.*

Interventions by the WHO that embody these two pillars have in many cases been phenomenally successful in reducing morbidity and mortality caused by neglected tropical diseases. For example systematic screening and treatment of at-risk populations have reduced cases of sleeping sickness to their lowest level in 50 years. In 2010, there were 7139 new cases, compared with 9878 cases in 2009, a decrease of 28% in just one year. This intervention was partially made possible by the donation of eflornithine, melarsoprol and pentamidine from Sanofi, which is also contributing US\$25 million from 2011-2016 to support WHO's human African trypanosomiasis control programme. Similarly, Bayer, GSK, Johnson & Johnson, Novartis, Pfizer and Merck have made significant contributions of medicines and cash to support treatment programmes for a number of neglected tropical diseases.

A criticism that has been levelled at a number of big players in the Pharma industry is that the vast majority of their research dollars and expertise are used to develop high value treatments for diseases that afflict relatively rich populations. Whether true or not, the expensive, high quality research and trials that are carried out by big pharma are a vital part of validating products before they are brought to market. The high price of patented medicines means access by the world's poorer populations is often initially severely limited. Despite this, many tried and tested treatments are eventually made available to all but the poorest populations as a result of the indispensable competition provided by generic manufacturers.

This is not to say that pharmaceutical companies could not do more and Bio-Ventures for Global Health (BVGH) aims to persuade them to do so. BVGH was set up in 2004 with a start-up grant from the Bill & Melinda Gates Foundation, and the support of the Biotechnology Industry Association (BIO) of the USA and the Rockefeller Foundation. BVGH develops financial incentives to engage biopharmaceutical companies in global health research and development as well as delivering information on how they can apply their expertise and technologies to global health problems.

Evolution of the pharma industry

The provision of free medicines to poorer populations appears to be a growing facet of pharma company behaviour, possibly driven by the public pressure for positive corporate social responsibility strategies. The WIPO Re:Search programme fits well with these strategies as well as potentially providing a new perspective on shelved research programmes. There also exists the possibility of new IP being developed as a result of the programme that is not subject to the royalty-free agreements for use of existing IP.

A further aspect of the initiative that is suggestive of the future strategy of pharmaceutical companies is the collaborative approach sought with academic and governmental research institutions. The decline in success rates for new drugs⁴ and the expiry of a number of patents on yesterday's blockbusters⁵ is leading the industry away from the traditional "closed" model of big in-house R&D spend, towards a more open, collaborative model. As part of this transition, pharmaceutical companies are forming partnerships with biotech start-ups and academia to boost early-stage discoveries and secure IP rights to tomorrow's blockbusters. The

collaborative approach to tackling global health issues and the open-sourcing of even a small portion of the knowledge held by pharma can only be a good thing and we look forward to the prospective treatments coming to fruition.

If you have any queries regarding intellectual property related matters (including patents, trademarks, copyright or licensing), please contact:

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References

1. Conditions covered by the WIPO Re:Search initiative include Buruli ulcer, Chagas disease (American trypanosomiasis), cysticercosis, dengue/dengue hemorrhagic fever, dracunculiasis (guinea-worm disease), echinococcosis, endemic treponematoses (yaws), foodborne trematode infections (clonorchiasis, opisthorchiasis, fascioliasis, and paragonimiasis), human African trypanosomiasis (African sleeping sickness), leishmaniasis, leprosy, lymphatic filariasis, malaria, onchocerciasis, rabies, schistosomiasis, soil transmitted helminths, trachoma, tuberculosis, podoconiosis, and snakebite.
2. WIPO Re:Search Brochure/Flyer (October 2011) http://www.wipo.int/export/sites/www/research/en/docs/flyer2011_10_20.pdf Accessed 29 November 2011.
3. First WHO report on neglected tropical diseases http://whqlibdoc.who.int/publications/2010/9789241564090_eng.pdf Accessed 29 November 2011
4. Press Release on the 2010 Pharmaceutical R&D Factbook compiled by CMR International. http://thomsonreuters.com/content/press_room/science/RandD-rodutivity-Declines Accessed 29 November 2011.
5. Pharmaceuticals & Biotech Industry Global Report 2011. http://www.imap.com/imap/media/resources/IMAP_PharmaReport_8_272B8752E0FB3.pdf Accessed 29 November 2011.



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