Product Development and IP Strategies for Global Health Product Development Partnerships

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ABSTRACT

The mission of global health product development partnerships (PDPs) is to develop effective, affordable health products and make them available and affordable to those in need. The not-for-profit product development partnerships (PDPs) often seek for-profit partners to access essential technology, expertise, and resources. These may be early-stage companies, leveraging philanthropic and government resources to develop a platform technology or established companies building out from existing markets or testing new technologies. Such not-for-profit/for-profit partnerships require unique product development and IP (intellectual property) strategies that both recognize the company's need for commercial benefit and deliver important health products to developing countries.

1. INTRODUCTION

"*Thus we come to the conclusion that patents are neither inherently bad nor inherently good for this purpose, but—like most tools—must be used wisely.*"[1] Lita Nelson's words are particularly appropriate for thinking about global health product development partnerships (PDPs), which today are harnessing the power of both the private sector—especially its intellectual property (IP)—and the IP system itself to help deliver public sector goods.

The mission of a PDP is to develop, manufacture, and deliver affordable and accessible health-care products that treat the diseases of the developing world. PDPs seek to serve underserved and disadvantaged markets where there is little or no competition from other pharmaceutical companies. In some instances, their products also will reach private, profitable markets in developed countries, but it is not their main goal to serve these markets.

The efforts of PDPs have significantly increased the number of products currently being developed for diseases that affect developing countries.[2] Products under development include drugs, vaccines, and diagnostics for diseases such as AIDS, tuberculosis (TB), malaria, meningitis, dengue fever, shigella, and cholera, among others.[3]

2. CHARACTERISTICS OF PDPS

Although they are not-for-profit organizations, PDPs have similarities with both for-profit companies and research institutions. For one thing, the IP (intellectual property) goals of PDPs are similar to those of other types of organizations: to respect valid third-party patents; to ensure their own freedom to operate (FTO)—in other words, to use their own IP without constraint and to use patents to leverage investment, partnerships, and political goodwill.

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Research institutions usually have neither the funding nor the expertise to take products to the marketplace. Therefore, they rely on corporate partners to develop their technologies into products for public use. They use patents to attract corporate interest in their projects, seeking patent protection in countries where corporate partners will want a competitive advantage.

Like research institutions, PDPs have nonprofit missions, rely largely on philanthropic and government support, and do not plan to manufacture and market the products that reach customers.[4] PDPs prefer to partner with for-profit companies so that they can draw on their manufacturing expertise, production facilities, market channels, and sometimes their R&D expertise, as well.

For-profit companies try to gain advantages over their competitors in order to maximize their market share and profits. They reduce the risk of developing new products by assiduously protecting their intellectual property. PDPs also work to protect the intellectual property produced through their partnerships, but their goal is, like research institutions, to leverage their intellectual property for access to other intellectual property or for other uses that will contribute to their mission.

Like for-profit companies, PDPs develop products that will someday be introduced to the marketplace. They manage portfolios of products that are at various stages of development, project and establish markets, and work to overcome logistical and social barriers to product adoption. However, their IP strategies are different from those of for-profit companies, for several reasons. They have no need to protect their market share or profits. In fact, they aim to achieve the lowest, rather than the highest, possible product pricing. They welcome the presence of other organizations that are developing products for the same market. They are open to sharing knowledge, resources, and projects. Thus, there IP strategy does not include the for-profit motive of keeping competitors out of their market or increasing market share.

In spite of these differences, most PDPs are evolving product development and IP strategies that are very similar to those of for-profit companies. In pursuit of their humanitarian goals, PDPs may license their own intellectual property or access the intellectual property of their corporate partners. In fact, if a company has already developed a product that is ready for immediate use, there may be no need for a PDP to get involved at all. This situation can occur, for example, when companies are directly engaged to provide anti-AIDS drugs at greatly reduced cost.[5]

3. PDP PARTNERSHIPS WITH FOR-PROFIT COMPANIES

In order to attract the interest and investment of for-profit partners, PDPs must protect their own intellectual property. It can be expensive and time consuming to obtain patents in developing countries, and the markets tend to be small, but the existence of an enforceable patent is often a strong inducement to potential industrial partners.

PDPs follow a wide range of business models: virtual pharmaceutical-development organizations (such as TB Alliance[6]), in-house research capabilities (such as the International AIDS Vaccine Initiative[7]), the inclusion of manufacturing capabilities (such as Aeras Global TB Vaccine Foundation[8]), and nonprofit pharmaceutical companies (such as Institute for OneWorld Health, iOWH[9]). All PDP business models draw heavily on public and philanthropic support (such as the Bill and Melinda Gates Foundation [BMGF]), as well as on extensive partnering with not-for-profit, government, philanthropic, and for-profit partners.

Examples of the many partnerships PDPs develop with companies are presented in the case studies in the *Handbook Executive Guide*.[10] The product development and IP strategies vary considerably based on the technology, the stage of development, and the nature of the market. Most products developed by PDPs fall into one of two broad categories: those that incidentally have large, profitable markets in developed countries (such as those that treat AIDS or TB) and those that do not. Examples of how the

PDP strategies differ in these two situations are shown below.

3.1 *Producing healthcare products with profitable markets*

TB affects both the developed and the developing world. One PDP, the TB Alliance, seeks to develop more affordable, more effective products with shorter dosing regimens that increase the likelihood that patients will complete their courses of medication.[11] A major component of the TB Alliance's product-development strategy is the formation of partnerships with companies that own the rights to approved, IP-protected drugs that could be repurposed to treat TB. It has therefore partnered with Bayer Healthcare AG to perform clinical studies on Bayer's drug moxifloxacin; it is hoped that this drug will be effective in three or four months rather than the standard six months. The agreement states that Bayer donates the drug and covers regulatory costs; the TB Alliance will coordinate and help cover the cost of the trials, and seek to leverage support from corporate partners.

In 2006, another PDP, AERAS, exclusively licensed patent rights to a vaccine technology from Vanderbilt University so that it could develop a TB vaccine; the university retained the right to license the technology to other partners engaged in non-TB development. The exclusive license gives AERAS access to the technology and university expertise, as well as freedom to operate; if the organization is able to develop a TB vaccine (or even to make some improvements on the existing technology), it will be able to use its knowledge to attract for-profit partners.

3.2 Producing healthcare products without profitable markets

Different strategies are needed when developing products for markets with low (or no) profit potential. It may be difficult to find a for-profit corporate partner that is already working to develop such products. However, there are companies with relevant expertise, technology, and products, and they can be encouraged to partner with PDPs to their mutual benefit.

Malaria is found disproportionately in developing countries, though for-profit markets are growing in such places as India and among travelers and military personnel from developed nations.[12] There is currently no approved malaria vaccine. The PDP Malaria Vaccine Institute partners with universities, government labs, and both early-stage and established companies in order to advance malaria vaccine candidates. It is currently working with the for-profit company GSK Biologicals to test its vaccine in African children. The vaccine has proven to be effective for at least 18 months, reducing clinical malaria by 35% and severe malaria by 49%. *Time* magazine declared this project to be one of the most important accomplishments in the field of healthcare in 2005.

The PDP iOWH has licensed a technology based on technology developed at the University of California at Berkeley. This technology is useful for producing a precursor to artemisinin, a natural product in short supply that is used in malaria treatment. The PDP iOWH teamed up with a spinout company, Amyris Biotechnologies, in late 2004. With support from the BMGF, the three-way agreement benefited all parties: the university's technology was advanced, Amyris fine-tuned its production processes, and iOWH developed a malaria drug candidate.

4. CONCLUSIONS

The developed world has a growing commitment to meeting the healthcare needs of the developing world. Successful product development and IP strategies are just two of the many issues involved in the commitment to developing products for underserved markets. The engagement of various regulatory jurisdictions, local political and legal issues, the management of liability, the delivery of products to areas with limited infrastructure or security, and cultural acceptance of new products—all of these issues need to be addressed and managed in order for PDPs to achieve their goals. ■

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1 See, also in this *Handbook*, chapter 1.4 by L Nelsen and A Krattiger.

2 Moran M, A Ropars, J Guzman, J Diaz and C Garrison. 2005. The New Landscape of Neglected Disease Drug Development. LSE Pharmaceutical R&D Policy Project. The Wellcome Trust: London. www.lse.ac.uk/collections/LSEHealthAndSocialCare/documents/PRPP/Thenew-landscapeofneglecteddiseasedrugdevelopment.pdf.

3 See, for example, www.mihr.org, www.tmgh.org, and www.gatesfoundation.org for information about PDPs and their projects.

4 A notable exception is the Aeras Global TB Vaccine Foundation, which setup an in-house manufacturing facility for producing rDNA vaccines.

5 www.bms.com/sr/philanthropy/data/introx.html.

6 www.tballiance.org.

7 www.iavi.org.

8 www.aeras.org.

9 www.iOWH.org.

10 Krattiger A, RT Mahoney, L Nelsen, JA Thomson, AB Bennett, K Satyanarayana, GD Graff, C Fernandez and SP Kowalski. 2007. *Intellectual Property Management in Health and Agricultural Innovation: Executive Guide to Best Practices*. MIHR: Oxford, U.K., and PIPRA: Davis, California, U.S.A.

11 "Working with the best in both the public and private sectors, we collaborate formally with leading university laboratories, large pharmaceutical companies, biotechnology companies, and government agencies. Our work is also informed by constant dialogue with other organizations working to develop TB treatments." TB Alliance. 2006. Next Steps Now. Annual Report 2005/06. TB Alliance: New York. p. 14. www.tballiance.org/downloads/publications/TBA_Annual_2005-2006.pdf.

12 www.malariavaccine.org/files/Market-Assessment-18Jan05-LB-BOS.pdf.