Cyclofem® Contraceptive: Upjohn, WHO, and the Concept Foundation

The case study of the development and distribution of Cyclofem® contraceptive as a project of Upjohn and the World Health Organization (WHO) is an example of innovative intellectual property (IP) management in which a collaboration between a public sector institution and a private pharmaceutical company led to the establishment of a new nonprofit organization that brought the product to developing country markets. The venture described in this case study was also new type of undertaking for WHO.

Upjohn pharmaceutical company developed the once-a-month injectable contraceptive Cyclofem®. Despite successful Phase III trials undertaken jointly by WHO and Upjohn, the drug company decided there was an insufficient market for the contraceptive and donated the clinical trial data to WHO. When no U.S. or European commercial partner could be found to take the product forward, WHO invited the nonprofit organization PATH (to which it licensed the clinical data rights) to come up with a viable solution.

PATH proposed establishing a new nonprofit organization, the Concept Foundation, which would focus on developing countries. Intellectual property and know-how was transferred via PATH to the Foundation, which licensed developing country producers on an exclusive basis in defined private sector markets and on a nonexclusive basis for public sector markets to ensure competition. A royalty stream of 4% was paid to the Foundation to support continued production and distribution. Manufacturers were expected to meet national and international (current good manufacturing practices, or cGMP) regulations. Milestones were an important part of the package, and were linked to territories, regulatory matters, and market penetration.

Production was established in Mexico and Indonesia, supplying private and public sectors with an affordable quality product that had been dropped by its developer. This was the first pharmaceutical product to result from successful WHO product R&D. The Concept Foundation is now self-sufficient and provides valuable technical assistance and introduction support, alongside economic development and technology transfer.

EXTERNAL FACTORS THAT AFFECTED DECISION MAKING

Establishing a nonprofit organization in a developing country was an appropriate option because WHO could not own, manufacture, distribute, or manage the product. PATH did not want to jeopardize its own neutral role in improving public health. Another consideration was liability. PATH, with assets in the United States, could not afford to risk its well being. Ultimately, after much discussion it was realized that the liability risk should rest in a jurisdiction that reflected the environments in which the product would be used.

The Foundation's aim was to on-license to producers and distributors in developing countries. If a government wanted to buy the product, it could go to any of the manufacturers and ask for a bid on cost prices. As time passed, the Concept Foundation identified the need to update the regulatory dossier for Cyclofem®. It carried out this updating and made the new dossiers available to current and prospective licensees.

Mahoney R. 2007. Cyclofem Contraceptive: Upjohn, WHO, and the Concept Foundation. In *Executive Guide to Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

Editors' Note: An earlier version of this case study was presented at the MIHR conference Using Intellectual Property for Improved Health in Developing Countries: An Evidence-Based Approach to Good Practice, Bellagio, Italy, June 14–18, 2004..

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LESSONS LEARNED AND HEALTH-ACCESS ISSUES

This case study is an example of innovative IP management where collaboration between WHO and Upjohn led to the establishment of a new nonprofit organization with the purpose of bringing the Cyclofem® contraceptive to developing country markets. This case demonstrates that clinical trial data can be important IP that can help ensure availability of products in developing countries. Putting it simply, without clinical trial data, the product can not be marketed; thus the data are of great value. The goal of the Concept Foundation and similar ventures is to ensure availability of products to the poorest of the poor. It is not enough to ensure that the private market helps public sector distribution. As this case study shows, investing time in updating a dossier to meet the requirements of other countries and therefore helping to encourage producers to go into markets that have not been served is important. Similarly, having solid and enforceable milestones is not an indication of lack of trust; it is rather being serious about business and wanting to succeed. ■

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