IP Asset Sale Involving an Intra-Uterine Device: Population Council

The Population Council, a nonprofit, nongovernmental, international research organization that focuses on reproductive health, was faced with patent expiration on its intra-uterine device (IUD). The Council wanted to continue the product's availability while maintaining growth of the public and private sector markets and providing a reasonable financial return. Intellectual property (IP) relating to the IUD included patents and the regulatory dossier, known as a new drug application (NDA). By the end of 2002, the IUD patents had expired, but the proprietary information contained in the NDA remained a viable asset.

In deciding on an appropriate IP management strategy for achieving its objectives, the Council decided to "think outside the box" and took innovative steps that included using the services of outside consultants. Also, the Council took a new approach, which was to sell the NDA in a bidding process rather than to grant license rights to the NDA. Because the IUD had been marketed for many years, the Council knew what could be expected in sales revenues and had a good basis from which to estimate a reasonable sale price for the NDA. The Council conducted an IP sale bidding process from which it selected the manufacturer of the IUD as the transferee. The manufacturer was a single-product company that produced 2.5 million IUD units per year and sold 2.3 million of these units annually to the U.S. Agency for International Development (USAID) at deep discounts for supply to less-developed countries.

The purchase agreement included annual minimum sales and annual sales growth requirements. It also provided for a guaranteed supply of the product to indigent women in the U.S., free-of-charge through a charitable foundation. Also, selling the dossier to the manufacturer guaranteed that the IUD would continue to be supplied to USAID. Deciding to sell the dossier was a result of the Council thinking strategically about how to handle its NDAs, recognizing that NDAs have traditional and unique values that could be leveraged to meet the Council's goals.

An interesting aspect of this case study is how intellectual property owned by a nonprofit organization was sold using commercial strategies of IP management (for example engaging the services of outside consultants and selling the asset through a bidding process). Essential was understanding the rights associated with the intellectual property and the business environment in which the Council was operating. In this example, the dossier had a viable role beyond patent expiration and was used to help the organization continue to provide the public with access to a mature product. Creative thinking helped design new frameworks and models through which access could be promoted. Intellectual property does not have to be licensed: it can be sold, assigned, and handled in many different ways depending on the goals of the IP owner.

TYPES OF AGREEMENTS

The Population Council entered into an asset purchase agreement with the U.S. manufacturer of the IUD.

Vaughan P. 2007. IP Asset Sale Involving an Intra-Uterine Device: Population Council. 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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IP RIGHTS DECISIONS AND IP MANAGEMENT

The Population Council had to decide to whom ownership of the NDA should be transferred in order to ensure that:

- the product would continue to be made available for use by women
- private and public sector markets would continue to grow and supply needs would be satisfied
- the Population Council would receive a reasonable financial return in exchange for the transfer of its ownership of the asset

The Council engaged in number of activities important with respect to strategic IP management:

- choosing outside consultants
- assigning value to the intellectual property
- conducting the IP asset sale
- marketing the intellectual property
- managing the due diligence process
- conducting negotiations with multiple bidders
- maintaining confidentiality
- selecting a transferee
- negotiating an agreement
- handling post-transfer matters

POLICY IMPLEMENTATION

This project implemented the Population Council's policy to commercialize all Council-developed reproductive health products, so that they could be made available to users in the private and public sectors in developed and developing countries.

EXTERNAL FACTORS THAT AFFECTED DECISION MAKING

A number of external considerations affected the Council's decisions, including:

- nature of the market for intra-uterine devices
- advice of outside consultants
- available bidders
- U.S. government regulations
- law

LESSONS LEARNED AND HEALTH-ACCESS ISSUES

The following items represent key lessons learned through the IP asset sale. The lessons may be applicable with respect to other projects involving intellectual property:

- Think outside the box.
- Understand the long- and longer-term competitive edge that your intellectual property provides or does not provide.
- Use outside expertise as needed.
- Conduct due diligence.
- Exercise creativity and flexibility in negotiations to obtain win-win outcomes.
- Build relationships. ■

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