Case study

Development and use of the Uniject® device

Administration of medical injections has been problematic in many lower-income countries. Many areas have also lacked health care workers with the necessary skills. Health care workers have needed a way to safely and easily administer injectable drugs and vaccines—both within health facilities and out in homes and communities where they are often needed most.

In the 1980s, PATH began developing technology to address the need for safe injection in low-resource settings. We first collaborated with Merck, which had developed, but then shelved, a promising integrated needle/package prototype. After obtaining related intellectual property from Merck and funding from the US Agency for International Development, PATH created a new design featuring a collapsible blister, and the Uniject device was born. After additional development and testing, PATH licensed the technology in 1996 to Becton, Dickinson & Co. (BD), the world’s largest syringe manufacturer. BD invested at least US$25 million to establish a manufacturing facility in Singapore and another $10 million to launch the product globally.

Collaboration between PATH and BD

Today, PATH and BD are working with companies around the world to manufacture and market an expanding array of vaccines, injectable contraceptives, uterotonic drugs, neonatal antibiotics, and other medicines packaged in the Uniject device. As part of the license agreement, BD supplies Uniject devices to vaccine and pharmaceutical producers at preferential prices for use in lower-income country public health programs. Because neither PATH nor BD can directly control the price of vaccines and drugs delivered in a Uniject device, PATH negotiated specific terms to ensure supply and encourage competition, including:

- BD must expand capacity promptly to meet public-sector demand or the license becomes nonexclusive.
- BD must not provide any producer with exclusive access to the device for key global health products without consulting PATH.

Despite PATH’s ownership of key intellectual property, BD is not required to pay ongoing royalties on sales to PATH. Instead, BD donates 500,000 units each year for PATH’s targeted use in public health programs.

Unique drivers of partnership diversity

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<tr>
<th>More certain</th>
<th>Factor</th>
<th>Less certain</th>
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<tr>
<td>Intellectual property already controlled and/or ownership structure is simple</td>
<td>Intellectual property status unclear and/or ownership structure complex</td>
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<td>Introduction straightforward and success is highly likely</td>
<td>Distribution system readiness</td>
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Uniject is a registered trademark of Becton, Dickinson & Co.
Drivers of a unique partnership
Key factors shaping development of PATH’s partnership with BD included:

- **Intellectual property:** Because PATH had clear control of key intellectual property, we were in a strong position to negotiate an agreement obligating BD to make needed investments to have a significant global impact.

- **Distribution system readiness:** The Uniject device introduced a new type of single-dose, prefilled syringe not previously used in lower-income countries, so new policies were needed to incorporate the device into health systems. BD recognized that PATH plays a critical role in helping innovate across global health programs and could help advocate for policies to accelerate product uptake.