International AIDS Vaccine Initiative

Promoting Innovation and Access through Effective Management of Intellectual Property

Background

IAVI's mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world. Because HIV vaccine science is very complex, it is imperative to encourage innovation in AIDS vaccine research and development. And because much of the expertise in the field resides in the private sector, it is vital to promote investment from private industry. To create an environment that fosters innovation and investment, it is important that intellectual property rights are recognized and protected. At the same time, because the AIDS epidemic disproportionately affects poorer countries, it is vital to guarantee the world's poor, in advance, widespread access to future vaccines. Therefore intellectual property rights, as they pertain to AIDS vaccines, should be managed with multiple goals in mind: the need to promote innovation and investment, as well as the need to ensure future vaccines are made available to poorer countries at affordable prices.

What is intellectual property and why is it important?

Intellectual property (IP) refers to products of creativity and knowledge such as books, artwork, designs and technologies. The rights to intellectual property are secured by such legal protections as patents, trademarks and copyrights. IP laws give the owner of a patent the right to exclude others from making products covered by their patent. These laws seek to balance the interest of rewarding the owner's enterprise with the interest of offering the larger community the benefit of the innovation.

The protection of intellectual property in the area of medicines and health technologies has spurred controversy, especially in the HIV/AIDS field. Some activists have characterized protection of IP as an obstacle to the development and affordability of drugs and vaccines. Others believe that protecting IP is crucial because it encourages new ideas and financial risk-taking among developers.

IAVI believes that this is not an either/ or debate. Rather, we believe that, if managed carefully, IP rights can both stimulate innovation and help guarantee wide access to future products. An environment that offers the possibility of a return to individuals and organizations for their investments in research and development is critical to encouraging innovation. The opportunity to develop, own and exercise IP rights can spur not only the private sector but also academic research institutions to invest in new technologies, medicines and vaccines. At the same time, IAVI believes IP rights can and should be managed to support widespread access to health technologies, particularly in the developing world. This can be done, for example, by segmenting markets to allow tiered (or differential) pricing for different countries, depending on their ability to pay, or by retaining licenses for use in developing countries. IAVI's own efforts, in R&D partnerships and in our advocacy work, support these dual objectives of encouraging innovation and ensuring access to products.

IAVI's approach to intellectual property management

IAVI uses different models of IP management and licensing arrangements in our partnerships with academic institutions and private companies in the biotechnology and pharmaceutical industries.

Patents: IAVI promotes the dissemination of findings from our research and development activities. We incorporate this philosophy into our partnership agreements. We encourage our staff and collaborators to present at conferences and publish relevant data or scientific developments. In certain cases, IAVI has elected to establish IP rights over discoveries and advances by filing patents, to secure our rights to develop a particular technology and to provide industrial partners who might further develop innovations with us the assurances they need that IP rights are secured. Patenting also allows IAVI

to stipulate that anyone who licenses the technology uses it in a manner consistent with our mission of providing poorer countries affordable access to health technologies.

Research consortia: IAVI has sponsored several joint research efforts. These include the Neutralizing Antibody Consortium, the Control of HIV Infection/Live Attenuated Consortium, and the Vector Consortium. These consortia comprise academic institutions and research institutes working collaboratively to address key challenges facing the AIDS vaccine field. Consortia members share information, data and materials, and work together to coordinate IP management. Each member contributing to an invention participates in the ownership of the resulting patents. What's more, members share revenues generated by technologies that emerge from the consortia that are used in the field of AIDS vaccines, which provides an added incentive for collaboration. IAVI retains licensing rights to further develop and commercialize those technologies so that we can ensure they are made accessible to poorer countries.

Exclusivity arrangements and access commitments: IAVI has allocated IP ownership and licensing rights with industrial partners in a variety of ways. In one transaction, a partner with proven capabilities in vaccine manufacturing and distribution was granted exclusive worldwide licensing rights to any product arising from the collaboration. Another partner was granted exclusive rights only for developed countries, while IAVI retained exclusive rights for developing countries. In a third case, IAVI retained exclusive global rights.

Whenever IAVI grants rights to industrial partners to develop and distribute vaccines arising out of IAVI-sponsored collaborations, those partners must agree to a set of "access commitments." These commitments provide that any vaccine will be promptly registered, manufactured in adequate quantities and distributed at reasonable prices in the developing world. Central to these commitments is the principle of differential pricing, i.e., that the vaccine may be made available in developed countries at market prices, but it must be made available in the developing world at an affordable price.

In cases where IAVI will rely on a partner to deliver a vaccine to the developing world, our licensing and partnership agreements ensure that the technology will be made available in those countries even if the partner fails to meet its commitment. These provisions, usually called "march-in rights," typically provide IAVI with guarantees that the technology, data, materials and licenses needed to manufacture and deliver the vaccine will be transferred to IAVI.

Conclusion

IAVI works with many diverse partners, from private sector pharmaceutical companies to academic researchers and public institutions. The goals common to each collaboration are the need to accelerate the development of safe, effective, preventive AIDS vaccines, and the need to ensure that they will be made available in developing countries rapidly after licensure, at reasonable prices, and in sufficient quantities. Having a wide range of partner organizations requires IAVI to approach IP management with flexibility, but based on these two clear needs.

IAVI also strives to share its model with other product development partnerships, academia and industry and to learn from the IP management of other organizations promoting new vaccines and drugs for the world's most pressing health problems. In this way, IAVI works to advance the AIDS vaccine field and hasten the research and development of a vaccine to help end the AIDS pandemic.

The International AIDS Vaccine Initiative (IAVI) is a global not-for-profit organization whose mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world. Founded in 1996 and operational in 24 countries, IAVI and its network of collaborators research and develop vaccine candidates. IAVI's financial and in-kind supporters include the Alfred P. Sloan Foundation, the Bill & Melinda Gates Foundation, the Foundation for the National Institutes of Health, The John D. Evans Foundation, The New York Community Trust, the James B. Pendleton Charitable Trust, The Rockefeller Foundation, The William and Flora Hewlett Foundation; the Governments of Canada, Denmark, Ireland, The Netherlands, Norway, Spain, Sweden, the United Kingdom, and the United States, the Basque Autonomous Government as well as the European Union; multilateral organizations such as The World Bank; corporate donors including BD (Becton, Dickinson & Co.), Continental Airlines, Google Inc., Henry Schein, Inc., Merck & Co., Inc. and Pfizer Inc; leading AIDS charities such as Broadway Cares/Equity Fights AIDS and Until There's A Cure Foundation; other private donors such as The Haas Trusts; and many generous individuals from around the world. For more information, see www.iavi.org.