Broad's licensing principles and how they were applied in the CRISPR case

September 15, 2017

BROAD INSTITUTE

The Broad Institute

A partnership with MIT, Harvard, and the Harvard hospitals

Extending the research capacity of leading universities and medical institutions

A collaborative scientific community

Bringing together thought leaders contributing to multidisciplinary and integrated programs

Intellectual 'free trade' zone

An operating agreement prescribes and guides ways for institutions to work together

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Principles for Disseminating Scientific Innovation

Guiding principle

The Broad's mission is to accelerate the understanding and treatment of disease. To do so, we must ensure that others can build on scientific advances made by the Broad community.

In disseminating our work, our primary aim is to maximize the benefit for human health.

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Principles for Disseminating Scientific Innovation

Foundational data sets

Tracing back to the Human Genome Project, Broad scientists have been involved in systematic efforts to create large datasets intended to serve as a foundation for biological and medical studies in thousands of laboratories around the world.

To maximize their impact, the data from such projects is made widely available to the entire scientific community through publicly available databases.

Principles for Disseminating Scientific Innovation

Sharing with academic institutions

As an academic non-profit research institute, Broad recognizes the unique role that such institutions play in propelling the biomedical ecosystem by exploring fundamental questions and working on risky, early-stage projects that often lack clear economic return.

To maximize its impact, our work (including discoveries, data, tools, technologies, knowledge, and intellectual property) is made readily available for use, at no cost, by other academic and non-profit research institutions.

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Principles for Disseminating Scientific Innovation

Interactions with industry

Industry plays an essential role in creating products to speed research and to directly benefit patients. Industry is often able to undertake efforts that cannot be readily undertaken in academia — because, for example, they require funding at a scale that can typically be obtained only from private investment; or the ability and infrastructure to run large clinical trials.

To ensure that our work ultimately benefits patients, we must interact with industry. We do so through (i) engaging in scientific collaborations with industrial partners who share our vision around a scientific area, and (ii) licensing our innovations to industry.

Principles for Disseminating Scientific Innovation

Licensing

With respect to commercial licensing, our most important consideration is maximizing public benefit.

In most cases, we believe that this goal is best accomplished through non-exclusive licensing, which allows many companies to use innovations and thus compete to bring to market products.

In some cases, we recognize that an exclusive license may be necessary to justify the level of private investment required to develop a product.

- An example is therapeutics - without an exclusive license, a company would be reluctant to invest hundreds of millions of dollars in clinical trials, because competitors could subsequently 'free-ride' on their results)

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Principles for Disseminating Scientific Innovation

Policy considerations

To ensure that scientific innovation benefits human health, scientists must also try to ensure that cutting-edge technologies are used in a socially responsible way.

We may place policy restrictions on certain licenses to prohibit uses that would be socially irresponsible based on current scientific knowledge and societal consensus. For example:

- Our licenses for biomedical applications of CRISPR do not permit their use for human germline editing.
- Our licenses for agricultural applications of CRISPR do not permit such purposes as ‘gene drives,’ ‘sterile seeds,’ and increasing tobacco consumption.

BROAD INSTITUTE

Licensing CRISPR

We make CRISPR tools, knowledge, methods and other IP for genome-editing freely available to the academic and non-profit community.

Since February 2013, we shared more than 40,000 plasmids and reagents with more than 2,000 institutions across 59 countries to help accelerate research into virtually every aspect of human health—including cancer, schizophrenia, diabetes, HIV and other infectious diseases.

BROAD INSTITUTE

Licensing CRISPR

We license CRISPR IP non-exclusively to companies to use in their own commercial research.

We license CRISPR IP non-exclusively to companies wishing to sell tools and reagents for genome editing.

We license CRISPR IP non-exclusively to companies wishing to develop and sell products in various fields such as agricultural and materials.

To date we have executed over 60 non-exclusive licenses!

BROAD INSTITUTE

Licensing CRISPR

For human therapeutics, we concluded that certain exclusivity is necessary to drive the level of investment and strategic focus needed to develop the technology as well as the complementary technologies to the point that it is safe, effective, and capable of precise editing in specific cell types.

However, to ensure the broadest possible development of the technology Broad Institute, Harvard, and MIT limited the exclusivity through an approach that we call “inclusive innovation” model.

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Licensing CRISPR

Inclusive Innovation

Under this model, Broad, Harvard, and MIT have licensed CRISPR to a primary licensee, Editas Medicine. Editas has a right to exclusively use the technology on targets of its choosing for the development of genomic medicines. However, after an initial period of two years, other companies may apply to license CRISPR for use against genes of interest not being pursued by Editas.

Licensing CRISPR

Inclusive Innovation

(i) a third party interested in an individual gene target would provide a development plan to Broad/Harvard,

(ii) Editas then has a pre-defined period to decide whether it intends to pursue the specific gene of interest and to commit the necessary funding and launch a program, and;

(iii) if Editas is not already working on the gene of interest and chooses not to fund and launch a new program of its own within this period, the IP is available for licensing by Broad, Harvard, and MIT to the third party.

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Licensing CRISPR

The goal of our inclusive innovation model is to enable Editas to access sufficient capital and devote the necessary investment to develop CRISPR and complementary technologies to treat human diseases, while supporting broad development of medicines to reach many patients.

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