Bayh-Dole March-In

James Love

February 24, 2017

35 USC §200. Policy and objective

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development . . .

. . . in a manner to promote free competition and enterprise without unduly encumbering future research and discovery . . .

. . to ensure that the Government obtains sufficient rights in federally supported inventions **to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions;** and to minimize the costs of administering policies in this area.

35 USC §203. March-in rights

(a) With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right. . .to grant [a license] upon terms that are reasonable under the circumstances...if...

(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

(3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

How is “practical application” defined?

35 U.S.C. §201. Definitions

(f) The term “practical application” means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations **available to the public on reasonable terms.**

Bayh-Dole march-in cases

Past Cases under 35 USC 203

- Cellpro, 1997
- Ritonavir, 2004
- Latanoprost (Xalatan), 2004
- Ritonavir (and other drugs), 2012
- Xtandi, 2016

Cases where march-in or royalty free right played a helpful role

- CDC, reverse genetics patents
- NIH/WARF stem cell patents

Mark Rohrbaugh
Senior Advisor for Technology Transfer and Innovation at NIH

“We’re not preoccupied with financial value,” Dr. Rohrbaugh said. “Our mission is treatment of people and improving public health.”

U.C.L.A. made more than $500 million by selling its royalty rights to the drug. But the N.I.H. declined to exercise its march-in rights on Xtandi, arguing that it was not qualified to judge whether a drug’s price is reasonable and that a high price does not mean a drug is not being made available to the public.

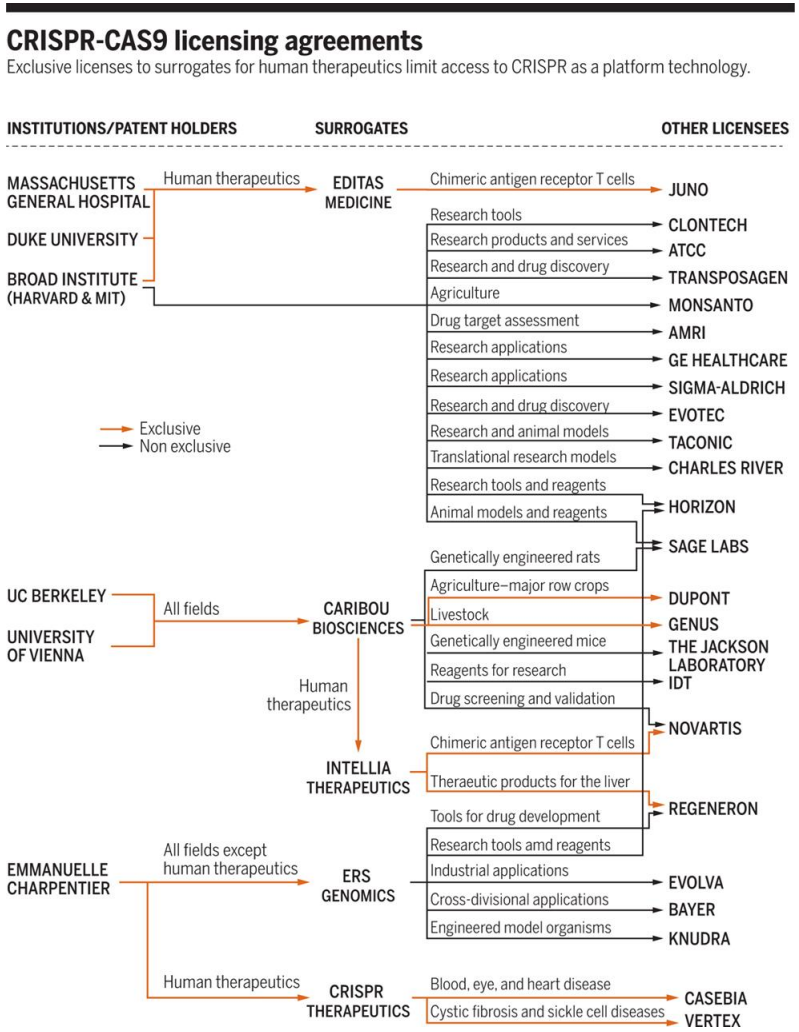
“N.I.H. has made it clear that its job is not to decide prices of drugs, period,” Dr. Rohrbaugh said.

Matt Richtel and Andree Pollack, Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits, New York Times, December 19, 2016

Contreras and Sherkow on CRISPR

CRISPR is a broadly applicable, enabling technology platform, similar in many respects to “research tools”: equipment, reagents, and methods that enable a broad range of downstream research (9). Exclusive rights in research tools are generally unnecessary for commercialization of downstream products developed using them. . . exclusive licenses granted to the institutions' surrogates for human therapeutics limit access to CRISPR as a platform technology, potentially hindering competition and creating innovation bottlenecks.

CRISPR, surrogate licensing, and scientific discovery, Jorge L. Contreras Jacob S. Sherkow, Science 17 Feb 2017: Vol. 355, Issue 6326, pp. 698-700 DOI: 10.1126/science.aal4222



Some suggested reforms

NIH has is biased, and does not protect the public's rights. DHHS should have ask some other entity to evaluate the march-in requests.

Amend 35 USC 203(b), which reads in part: "in cases described in paragraphs (1) and (3) of subsection (a), the agency's determination shall be held in abeyance pending the exhaustion of appeals or petitions filed under the preceding sentence."

Develop standards for licensing and pricing of licensed products that reduce uncertainty over practices that trigger the march-in

Consider extending march-in to all medical products regulated by the FDA, regardless of role of federal funding, and to test data rights