# 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

#### **CRISPR-CAS9 licensing agreements**

Exclusive licenses to surrogates for human therapeutics limit access to CRISPR as a platform technology.

INSTITUTIONS/PATENT HOLDERS	SURROGATES		OTHER LICENSEES
MASSACHUSETTSHuman therapeut	tics_ EDITAS	Chimeric antigen receptor T cells	→ JUNO
GENERAL HOSPITAL	MEDICINE	Research tools	
DUKE UNIVERSITY -		Research products and services	- CLONTECH
		Research and drug discovery	→ ATCC
BROAD INSTITUTE - (HARVARD & MIT)		Agriculture	→ TRANSPOSAGEN
		Drug target assessment	→ MONSANTO
		Research applications	→ AMRI
		Research applications	GE HEALTHCARE
		Research and drug discovery	→ SIGMA-ALDRICH
— Exclusive		Research and animal models	EVOTEC
─► Non exclusive		Translational research models	→ TACONIC → CHARLES RIVER
		Research tools and reagents	- CHARLES RIVER
		Animal models and reagents	<b>⇒</b> HORIZON
		Genetically engineered rats	<b>⇒</b> SAGE LABS
HO DEDVELEY		Agriculture-major row crops	
JC BERKELEY All fields	CARIBOU	Livestock	► DUPONT
UNIVERSITY	BIOSCIENCES	Genetically engineered mice	→ GENUS → THE JACKSON
OF VIENNA		Reagents for research	LABORATORY
	Human nerapeutics	Drug screening and validation	→ IDT
U	rerapeutics	Chimeric antigen receptor T cells	NOVARTIS
	INTELLIA - THERAPEUTICS	Theraeutic products for the liver	1
		Tools for drug development	REGENERON
All fields except		Research tools amd reagents	
EMMANUELLE human therapeutic	EKS _	Industrial applications	→ EVOLVA
	GENOMICS	Cross-divisional applications	→ BAYER
		Engineered model organisms	→ KNUDRA
Human therapeut	tics CRISPR	Blood, eye, and heart disease	
	THERAPEUTICS	Cystic fibrosis and sickle cell diseas	CASEBIA Ses VERTEX

## 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