

Bayh-Dole and March-In

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Note: My participation in this panel is from the perspective of a former leader of AUTM. Opinions expressed are my own and not those of NYU Langone Health or New York University.



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Four Circumstances for March-in Rights

- (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 [domestic manufacture requirement for exclusive licensees sold in the U.S.] 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

Bayh-Dole Act Requirements by Contractor Include...

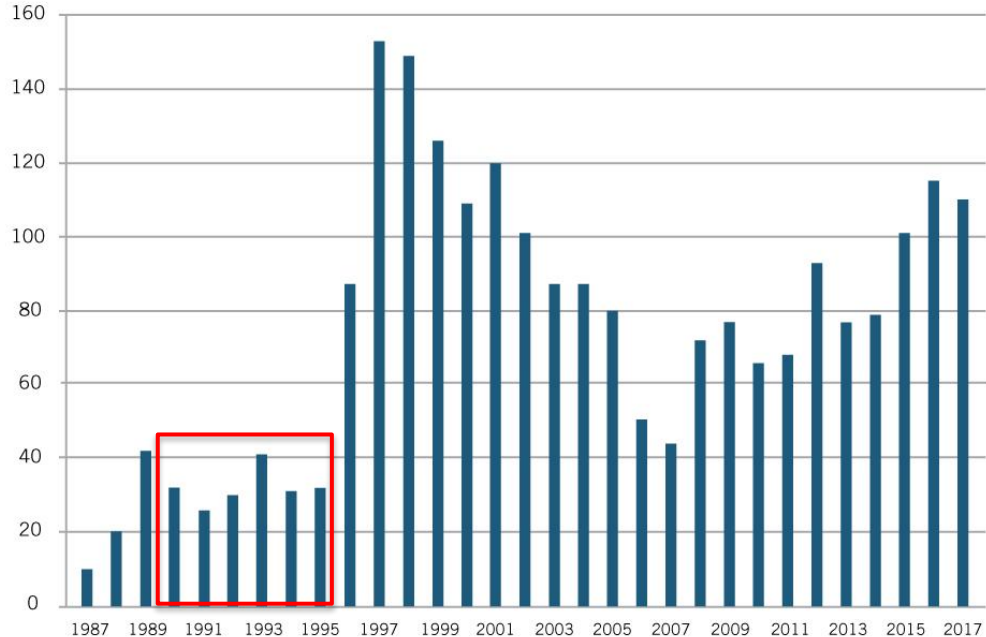
- Complying with administrative components of the law (educating employees, reporting to the Government, filing patent applications, etc.);
- Granting the Government a nonexclusive, irrevocable, paid-up license to use the subject invention throughout the world;
- Requiring substantial manufacture in the U.S. for any exclusive licensee; and
- Allowing the U.S. Government to exercise March-in Rights (requiring contractor to license to another party – or the Government will) under certain limited circumstances.

“Reasonable Pricing” Clause Stunted Innovation

NIH imposed “reasonable price” requirements on CRADAs in 1990; NIH repealed then in 1995.

Varmus: “The pricing clause has driven industry away from potentially beneficial scientific collaborations.”

NIH New CRADAs Per Fiscal Year, 1987-2017



Source: NIH Annual Reports; Joseph Allen, “Compulsory Licensing for Medicare Drugs– Another Bad Idea from Capitol Hill”