VitalTransformation
The impact of health technology made simple

PRESS RELEASE

New study finds 92% of new FDA approved medicines have no federally funded intellectual property or patents

The removal of congressionally mandated 'reasonable pricing clauses' in NIH grants led to a 500% increase in industry partnerships

November 30, 2023

New research released by Vital Transformation (VT) finds the pharmaceutical industry is the dominant source of innovation for funding new FDA approved medicines. By studying a cohort of 361 new FDA approved medicines and patents protecting the assets between 2011-2020, VT found that 92% of the medicines they researched were directly discovered by industry, and have no government interest statement (GIS), federally funded co-development, or federal partnership program associated with any patents core to the development of the medicine.

Patents that are created with government funding are required to include a government interest statement in the body of the document. However, until recently, searching for this specific statement was limited to manual searches or the NIH's own databases, often limited to the patent holders themselves. VT utilized The Lens database to more accurately determine how many approved medicines have patents funded by the US Government. This allowed VT, for the first time, to develop a more accurate understanding of the role that government funding, including NIH and other grant programs, plays in the actual commercialization of FDA approved medicines.

The ability for industry to license government funded research is the direct result of the Bayh-Dole Act. Passed in December of 1980, it allowed US academics to commercialize their inventions rather than handing their discoveries over to the federal government. The Wall Street Journal said that the Bayh-Dole Act, "gave professors and lab teams an enormous incentive to put to commercial use plans and ideas for inventions that they had long ago shelved in their minds and offices... the protection of intellectual property created a boom."[1]

The Use of March – in Rights

[1] https://www.wsj.com/articles/SB10001424052970203914304576628900383779840

VT's research provides valuable insights into recent requests by members of the US Congress and Senate to exercise 'march-in rights' under the provisions of the Bayh-Dole Act. March-in rights allow the government, in certain specific instances, to take back a patent when, "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."[2] There is a growing belief from many politicians that march-in rights can be interpreted to include it's use to control the prices of medicines.

According to Hans Sauer, Biotechnology Innovation Organization (BIO) Vice President of Intellectual Property, "NIH funding makes vast and critical contributions to the advancement of medicine by furthering our understanding of human disease and pointing in promising directions for applied drug research, but the weight of the evidence shows that in most cases the private sector invents the drugs that are based on that research and assumes the cost and risk of translating new scientific insights into practical new products. This study expands on previous research showing that NIH funding is responsible for only relatively few inventive contributions to new therapies. Moreover, in those rare instances where the federal government contributes directly to the development of new therapies, the monetary contribution is relatively small compared to the private sector spend. The present findings underscore the important complementary roles of public and private biomedical R&D funding."

In fact, VT's research found that less than 10% of all drugs in the study cohort had any inventive contribution from government funding, and only 5 of the 361 medicines included a government interest statement in their entire complement of composition of matter and mechanism of action patents. Practically, this means that less than 2% of the new therapies were invented entirely with federal funding support; another 8% have an inventive contribution from federal funding to only some aspect of the drug, and 92% were invented independently without federal support. Additionally, only one of the five medicines is a blockbuster, and is poised to go generic in 2027.

According to Duane Schulthess, VT's CEO, "Even if doing so were lawful, marching in on federally funded IP to only take back fewer than 2% of drugs from over 350 discoveries would have zero impact on national pharmaceutical spending, but would come at the cost of doing irreparable harm to the entire US public/private partnership ecosystem. It's a policy devoid of economic or scientific reality regarding how the private market will respond to such actions."

As a practical example, the removal of congressionally required 'reasonable pricing clauses' initially inserted into NIH CRADA grants led directly to a 5x increase in industry participation in NIH collaborations within 36 months. The NIH itself stated, "Eliminating the clause [promoted] research that can enhance health of the American people,"[3]

[2] https://www.govregs.com/uscode/35/203
[3] https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q&A%20Nov%202021%20FINAL.pdf

A previously published VT study found that, in 18 new FDA approved medicines, funding contributions from industry were 66 times higher than that found in their associated NIH grants. Using march-in rights to control prices would not only be inefficient and ineffective, but risks chilling the entire innovation ecosystem for little to no gain. It will create enormous uncertainties and risks for investors whom, as experiences with previous reasonable pricing clauses showed, will avoid partnerships with government funded research.

About Vital Transformation:
Vital Transformation understands the implications of new medical procedures, technologies and policies. We measure their impact on current clinical practices in close collaboration with health care professionals, researchers, and regulators. Through our web platform, client network, and Vital Health Podcast series, we are able to communicate our findings with international decision makers and stakeholders.

The full research pack and underlying data is available for download at www.vitaltransformation.com.

Contact: info@vitaltransformation.com