Biotechnology Innovation Organization
1201 Maryland Avenue SW
Washington DC 20024

National Institute of Standards and Technology
U.S. Department of Commerce
100 Bureau Drive
Gaithersburg, MD 20899

April 5, 2021

Re: Docket No.: 201207-0327, RIN 0693–AB66; Proposed Rule: Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 86 FR 35 (Jan. 4, 2021).

Dear Sir or Madam:

The Biotechnology Innovation Organization (BIO) submits these comments in response to the National Institute of Standards and Technology (NIST) request for comments on proposed revisions to regulations that would further the Return on Investment (ROI) Initiative for Unleashing American Innovation. The notice proposes revisions to "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms under Government Grants, Contracts, and Cooperative Agreements" and "Licensing of Government-Owned Inventions."[1]

Summary

BIO supports the proposed revisions. As explained in greater detail below, BIO recommends the following clarifications to the proposed rules:

- Proposed new CFR §401.6.(a)(2) should make clear that the initiation of march-in proceedings will be based specifically and exclusively on one or more of the four enumerated grounds under 35 USC §203(a)(1)-(4).
- The proposed rule should make clear that the requisite agency determination under one or more of paragraphs (1)-(4) of 35 USC §203(a) shall include factfindings

[1] 86 FR 35 (Jan. 4, 2021).

sufficient to establish that a third-party license is necessary to achieve the objective of the applicable paragraph.

- Proposed new CFR §401.6.(a)(1) should clarify that the new initial agency consultation is not for enforcement purposes, but is intended to be informal, informative, and constructive.
- The proposed rule should make clear that a march-in determination under 35 USC §203(a)(1) may be based only on conduct that is attributable to the contractor or assignee, whereas a determination under 35 USC §203(a)(2)-(3) may additionally be based on conduct that is attributable to the licensee.

Introduction

NIST's proposed revisions would reaffirm the government's longstanding understanding of "march-in rights" under the Bayh-Dole Act[2], which has been the key to this country's global leadership in innovation. BIO believes that deviation from the plain language of the statute and the clear intent of Congress would threaten this country's successful public-private partnership in numerous technical fields including the life sciences. The Bayh-Dole Act has been called "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century."[3] The proposed regulations must continue that record of success.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members operate at the intersection of biology and technology to cure patients, protect our climate, and nourish humanity. As BIO looks to the future, we seek to advance disruptive innovation by 1) being a voice of science and for science; 2) uniting and empowering biotech innovators and their ecosystem to improve lives; 3) removing barriers to innovation; 4) championing broad access to biotech breakthroughs and scientific equality; and 5) catalyzing resilient and sustainable biobased economies.

BIO's members have invested billions of dollars developing important discoveries into the vaccines, cures, diagnostics, crops, biofuels, and other new products that are saving and enriching lives every day. Their success is proof that the policy embodied in the Bayh-Dole

[2] 35 U.S.C. §§ 200–212, Pub.L.No. 96-517, 94 Stat. 3015 (Dec. 12, 1980).

[3] The Economist (Dec. 14, 2002). Available at: https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose

Act delivers an excellent return to the taxpayers on their investment. In the response to the COVID-19 pandemic alone, of the more than 840 unique active compounds currently in development today, approximately half are being developed by companies based here in the United Sates.[4]

The success of the Bayh-Dole Act is clear. In 1980, prior to the enactment of the Bayh-Dole Act, less than 5% of the federal government's nearly 30,000 patents had been licensed for commercial development.[5] By empowering federally-supported universities and small businesses to hold and license patents, the Bayh-Dole Act fueled a vibrant innovation sector that, between 1996 and 2017, led to the development of more than 200 new drugs and vaccines, 13,000 startups, $865 billion in added GDP, 5.9 million jobs, and more than 13,000 startups.[6]

Clear and enforceable patent rights are the key to this success. Investors evaluate the strength of intellectual property rights before investing in a pre-revenue company proposing to do important but costly and high-risk research. This investment is critical to the nation because these small biotechnology companies produce a majority of the innovation. Seventy percent of the current clinical pipeline programs originate from small emerging bioharma companies.[7] Our review of FDA data indicate that more than 60% of new FDA approved drugs now originate from small emerging biopharma companies. As a result, biopharmaceutical companies invested nearly $165 billion in research and development compared with the NIH budget of just $33 billion.[8] This robust investment would not be possible without secure intellectual property rights.

Proposed revision to existing 37 CFR §401.6.

BIO supports the proposed revisions to CFR §401.6. and in particular agrees that new subsection (e) should clearly reaffirm that an agency shall not exercise march-in rights on

[4] BIO COVID-19 Therapeutic Tracker. Available at: https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker

[5] Government Accountability Office, Administration of the Bayh-Dole Act by Research Universities, GAO/RCED-98-126 at 3 (May 1998).

[6] AUTM, Driving the Innovation Economy (2018). Available at: https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM_FY2018_Infographic.pdf

[7] Emerging Therapeutic Company Investment and Deal Trends 2009-2018 (2019) Available at: https://www.bio.org/emerging-therapeutic-company-investment-and-deal-trends

[8] BIO Industry Analysis (October 2018).

the basis of business decisions of a contractor regarding the pricing of commercial goods arising from the practical application of the invention.

We believe this to be no more than an affirmation of current and longstanding policy that has been adopted consistently by agencies throughout the federal government for the past 40 years. BIO would, however, recommend several clarifications to be included in the proposed new CFR §401.6.

First, the proposed rule at new CFR §401.6.(a)(2) should make clear that the initiation of march-in proceedings will be based specifically and exclusively on one or more of the four enumerated grounds under 35 USC §203(a)(1)-(4). In this way, the agency notice required by new CFR §401.6.(a)(2) would provide clarity not just with respect to facts on which the proceeding will be based, but also with respect to which of the four statutory triggers is/are being invoked – or, in other words, which of the four agency determinations under 35 USC §203(a)(1)-(4) the agency is pursuing. Doing so will help define and limit the legal scope of the ensuing proceeding at its inception, and guard against the possibility that agencies might use shifting justifications for exercising march-in as proceedings unfold and evidence is taken.

Second, the proposed rule should make clear that the requisite agency determination under one or more of paragraphs (1)-(4) of 35 USC §203(a) shall include factfindings sufficient to establish that a third-party license is necessary to achieve the objective of the applicable paragraph. For example, if the proceeding is based on the alleged failure of the contractor to comply with the "public use" provision under 35 USC §203(a)(3), the agency's march-in determination should include findings that the relevant requirements for public use specified by Federal regulations cannot reasonably be met *without* issuing a third-party license.

Doing so would more clearly give effect to the statutory mandate that requires agency action to be "necessary" under the circumstances. By including the words "action is necessary" in each of the enumerated circumstances of 35 USC §203(a)(1)-(4), Congress clearly intended march-in to be used for *remedial* purposes, and not automatically, or for punitive reasons. Thus, in the above example, under the plain terms of the statute the agency would not just have to find that the contractor failed to reasonably satisfy public use requirements, but also that the grant of a third-party license would more likely than not

cause these public use requirements to be met and that there is no way that these public use requirements could reasonably be met other than through the award of a third-party license. Requiring such findings would ensure against the pointless exercise of march-in rights for mere contractor noncompliance that could be remedied in other ways, and would reserve march-in proceedings only for circumstances where problems cannot otherwise be resolved.

Relatedly, BIO recommends a clarification to the proposed initial informal consultation between the agency and the contractor under new CFR §401.6.(a)(1). There has been some confusion about what is meant by the consideration of "possible actions other than march-in rights," and some concern whether this would entail other, new and as yet unknown forms of agency enforcement. In order to emphasize that this initial meeting is not for enforcement purposes, but is intended to be informal, informative, and constructive, BIO recommends that the first sentence of new CFR §401.6.(a)(1) be amended to read:

> "(1) Whenever an agency receives information that it believes might warrant the exercise of march-in rights, […] it shall […] request an informal consultation and information relevant to the matter with the contractor to understand the nature of the issue and consider possible steps that could be taken by or in conjunction with the contractor in order to resolve the issue and render the initiation of a march-in proceeding unnecessary. "

Third, the proposed rule should make clear that a march-in determination under 35 USC §203(a)(1) may be based only on conduct that is attributable to the contractor or assignee, whereas a determination under 35 USC §203(a)(2)-(3) may additionally be based on conduct that is attributable to the licensee. Doing so would more clearly give effect to the explicit language of the statute. Compare: 35 USC §203(a)(1) ("*[…] because the **contractor or assignee** has not taken […] effective steps…")* with 35 USC §203(a)(2) and (3) (health or safety needs or public use requirements are "*not reasonably satisfied by the **contractor, assignee, or licensees**.*").

By in this way juxtaposing different groups of actors – "contractor or assignee" and "contractor, assignee, or licensees" - in closely-related and neighboring provisions,

Congress could not have been more clear that it intended paragraph (1) of section 203(a) to have a narrower scope than paragraphs (2) and (3).

In each case, the proposed rule should also confirm that third-party conduct that is not attributable to a contractor, assignee, or licensee – or, in the case of a determination under 35 USC §203(a)(1), to the contractor or assignee - will not be used as grounds for a march-in proceeding.[9] This should be self-evident, but unfortunately there have been public policy discussions over the past years that, in an effort to force government market intervention by way of march-in, would attribute to contractors or licensees any ostensibly undesirable aspect of how products are deployed in the marketplace. Such discussions fail to acknowledge that the reach of 35 USC §203 is necessarily limited to only a few actors at the top of a long chain that stretches from federally-supported inventors to consumers with products in hand. In many instances, contractors, assignees, or licensees will have little control over how products will be manufactured, used, sold, or made available in the future by others down the production and distribution chain.

Moreover, critics who object to the way products embodying Bayh-Dole covered inventions have been priced have failed to understand that such products are subject to the same market forces that affect any other kind of product. There is no magic imbuing these products that requires them to be marketed, branded, priced, or sold differently from comparable products against which they must compete on their merits, price, quality, profitability, brand recognition, efficiency, etc. Those who seek government intervention because they believe markets should operate differently are free to invoke other, more suitable laws designed to protect the interests of consumers or competitors, or that regulate products or markets for such products. The Bayh-Dole Act's march-in provisions, on the other hand, are designed to cure specific instances of noncompliance or omissions by specific actors, not to regulate markets or to set the commercial terms under which products are marketed, priced, or sold.

[9] To illustrate, assume a contractor exclusively licensed a subject invention to a licensee. The licensee manufactures products embodying the subject invention and sells them to multiple wholesalers, who in turn sell the product to regional distributors, who sell it to retail chains. Assume further that through actions of distributors or buying decisions by retail chains, the product is effectively not being made available to end-purchasers in several regions of the country. Even though such non-utilization frustrates the goal of the Hatch-Waxman Act, it should be evident that no march-in proceeding would be warranted because 35 USC §203 does not apply to independent distributors or retailers whose conduct is not under the direction or control of a contractor, assignee, or licensee.

Conclusion

As NIST has accurately noted, no petition for the exercise of march-in rights has ever been granted, and that of the 12 to have been filed, 10 specifically sought march-in on the basis of price. "NIH determined that the use of march-in to control drug prices was not within the scope and intent of its authority."[10]

This conclusion is consistent with the understanding of the main sponsors:

> Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research.[11]

The Government Accountability Office has noted the "chilling effect" exercise of march-in rights could have:

> Some agency, university, and industry officials we contacted said the march-in authority could have a "chilling effect" on the willingness of venture capital firms and other investors to provide funding for the further commercial development of federally funded inventions . . . . The march-in authority would also have a chilling effect if researchers, particularly private-sector researchers, were unwilling to apply for federally funded projects because the potential for an agency to march in creates uncertainty with regard to ownership of an invention.[12]

This chilling effect is not hypothetical. When the National Institutes of Health imposed a "reasonable pricing clause" on its Cooperative Research and Development Agreements, interest in such agreements declined so precipitously that NIH withdrew the requirement. NIH Director, Dr. Harold Varmus, observed,

> An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS scientists without providing an offsetting benefit to the public . . . Eliminating the clause will promote research that can enhance the health of the

[10] Return on Investment Initiative to Advance the President's Management Agenda: Final Green Paper (April 2019) at 29. Available at: https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf

[11] Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," Washington Post (April 11, 2002) Available at: https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/

[12] Government Accountability Office, Federal Research: Information on the Government's Right to Assert Ownership Control over Federally Funded Inventions, GAO-09-742 at 14 – 15 (July 2009).

> American people…. The clause attempts to address the rare breakthrough product at the expense of a more open research environment and more vigorous scientific collaboration . . . . One has to have a product to price before one can worry about how to price it, and this clause is a restraint on the new product development that the public identified as an important return on their research investment.[13]

These concerns comport with the experience of our members.

Thank you for the opportunity to provide comments on this draft proposal. Please feel free to contact me directly if you have any questions about our comments.

Respectfully submitted,

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[13] NIH News (April 11, 1995).