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Patent 'March-In' Policy Shift Will Likely Drive Uncertainty More Than Price Drops

by Brenda Sandburg

Biden administration's new framework will consider whether a product's price is reasonable in deciding whether to exercise march-in rights. Numerous other factors could limit provision's impact, but industry is concerned it will discourage firms from licensing government-funded inventions.

While the Biden Administration is advising federal agencies to consider product pricing in determining whether to invoke march-in rights to license a company's patents, the directive may not change the status quo given all the other factors to be considered in taking such action. But industry is concerned that the new policy will be detrimental to government collaboration and product development.

The Department of Commerce's National Institute of Standards and Technology issued a *draft framework* that describes the factors an agency may consider when deciding to implement the march-in provision of the Bayh-Dole Act. The framework, which will be published in the Federal Register tomorrow, was announced on 7 December, the same day the Department of Health and Human Services issued an analysis of competition in various segments of the pharmaceutical industry. (*See box for related stories.*)

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The framework includes a host of questions for agencies to address. The issue of whether to consider pricing has been contentious and the new guidance affirms that product pricing will be a factor in responding to march-in requests.

"If the contractor or licensee has commercialized the product, but the price or other terms at which the product is currently offered to the public are not reasonable, agencies may need to

further assess whether march-in is warranted," the framework states. "Whether action may be needed to meet the needs of the Government or protect the public against nonuse or unreasonable use of the subject invention may include consideration of factors that unreasonably limit availability of the invention to the public, including the reasonableness of the price and other terms at which the product is made available to end-users."

The framework does not address how an agency will determine whether a price is reasonable.

The Bayh-Dole Act governs inventions made with government assistance. It gives the funding agency the right to require the contractor, an assignee, or exclusive licensee of a subject invention to grant a license to a responsible applicant on reasonable terms. If its request is refused, the agency may march-in and grant a license itself. To date, no government agency has done so.

Industry expressed concern about the potential impact of the new policy.

"Using the Bayh-Dole Act's march-in process as a mechanism to control prices is a dangerous precedent to set. The move would create yet another element of uncertainty within the biotech industry at a time when policy makers have been increasingly adding obstacles to innovation," Nick Shipley, chief advocacy officer at the Biotechnology Innovation Organization, said in a statement. "This type of policy would discourage the exact type of private-public sector partnerships that the Bayh-Dole Act was designed to encourage, and it would undermine a valuable piece of the drug discovery process."

Megan Van Etten, a spokesperson for the Pharmaceutical Research and Manufacturers of America, said in a statement that the framework "would be yet another loss for American patients who rely on public-private sector collaboration to advance new treatments and cures. The Administration is sending us back to a time when government research sat on a shelf, not benefitting anyone."

Outside observers were more sanguine. "We see little direct or meaningful impact for biopharmaceutical manufacturers from the White House announcement," John Leppard wrote in a Washington Analysis research note. "The core consideration for March In remains the steps a manufacturer takes to facilitate access to government-funded products, and therapeutics that are available as on-formulary options for millions of Americans – 84% of whom have prescription drug coverage – would still seem to fall well short" of the new licensing criteria released in the draft guidance.

Policy Shift

The framework marks a shift in policy by the government. In 2019, NIST issued a draft paper stating that march-in rights should not be used as a mechanism to control or regulate the market

price of goods and services. A final green paper did not include this statement and cited stakeholder concerns about using march-in rights as a price control. (Also see "*End Of The 'March-In' Pricing Petitions?* " - Pink Sheet, 24 Apr, 2019.)

In January 2021, NIST issued a notice of proposed rulemaking on rights to federally funded inventions and licensing of government owned inventions with a provision stating that march-in rights "shall not be exercised exclusively based on the business decisions of the contractors regarding the pricing of commercial goods and services arising from the practical application of the invention."

In March, the NIST issued a final rule that removed the proposed language that would have prohibited the government's use of march-in solely on the basis of product pricing. At the same time, HHS and the Department of Commerce announced that an interagency working group would develop a framework for implementation of the march-in provision.

Development of the framework was announced the same day the National Institutes of Health denied a request for the government to grant march-in rights on patents on *Astellas Pharma, Inc.* and *Pfizer Inc.*'s prostate cancer drug Xtandi (enzalutamide). (Also see "*After Xtandi, Will Government Ever Seek March-In Rights Over Drug Pricing?*" - Pink Sheet, 22 Mar, 2023.)

Will March-In Increase Accessibility?

The framework directs agencies to assess three overarching questions:

- Whether Bayh-Dole applies to the inventions at issue;
- Whether any of the statutory criteria for exercising march-in applies under the circumstances; and
- Whether the exercise of march-in rights would support the policy and objectives of Bayh-Dole.

NIST said the last question helps the agency assess the practical value of exercising march-in, specifically in terms of increasing accessibility of the invention.

The agency should consider how long it would take another licensee to start producing and marketing the covered product and to satisfy the existing demand for the product, and at what price the licensee would be able to make the product available to the public.

"What intellectual property, in total, is needed to make the product in question? Does making the product or performing the service also require use of intellectual property that was not

government funded and is not subject to Bayh-Dole?" the framework states.

"For example, if only one of several patents necessary to produce a product is subject to march-in, that likely weighs against march-in, since other licensees would need separate permission to use several other patents before they could make the product," the framework says.

"On the other hand, if all the intellectual property needed to produce the product is a subject invention(s), that might result in a different licensee being able to produce product quickly or efficiently."

Potential March-In Situations

The document provides seven hypothetical scenarios where march-in could emerge. In one scenario a biotech company partners with a government-funded university to develop treatments for autoimmune skin diseases and obtains an exclusive license to a government-funded patent owned by the university. Once the company receives approval by the US Food and Drug Administration for its own product it apparently stops all work on the compound invented by the university.

In another scenario, a small pharmaceutical startup that receives extensive government funding develops a monoclonal antibody that is the only treatment for a rare disease. Its patents on the antibody each contain a clause acknowledging the government funding. After flooding halts production at its manufacturing plant, a rare disease patient group asks the government to march-in and issue licenses to all the patents necessary to make and use the antibody.

The guidance says the agency would likely focus on whether there are other responsible applicants interested in manufacturing the product or practicing the subject invention. It would also look at the remaining term of the relevant patents, time required for regulatory approvals of new products or manufacturing facilities, and the potential length of a march-in proceeding and any appeals.

The scenario is similar to a situation that Genzyme Corp. faced when manufacturing problems led to a supply shortage of Fabrazyme (agalsidase beta). Fabry's disease patients asked NIH to exercise its march-in rights to grant an open license to patents Mount Sinai School of Medicine licensed to Genzyme.

NIH denied the request in 2010 saying a license was unlikely to increase the supply. (Also see "*Fabrazyme Patients Ask FDA To Retool Genzyme's Product Distribution Plan*" - Pink Sheet, 15 Feb, 2011.)

Policy Does Not Go Far Enough, Advocates Say

The framework did not appease organizations who have petitioned the federal government to

pursue march-in rights.

“Today’s announcement by the White House merely kicks the can further down the road, offering only feint hope that NIH might someday take action to ensure that taxpayer funded inventions are made ‘available to the public on reasonable terms’ as required by the 1980 Bayh-Dole Act,” Robert Sachs, a member of the board of trustees of the Dana Farber Cancer Institute, said in a statement. “Meanwhile, American consumers will continue to be charged exorbitant prices for potentially life-saving drugs available for a fraction of the U.S. price in other highly developed countries.”

Sachs, a prostate cancer patient, submitted a petition to HHS with Clare Love in 2021 asking it to grant march-in rights for patents on Xtandi to ensure US residents have access to the drug on reasonable terms. (Also see "*Xtandi Petition Will Give Biden Administration Chance To Weigh In On Pricing, March-In Rights*" - Pink Sheet, 15 Dec, 2021.)

Public Citizen’s Access to Medicines director Peter Maybarduk said in a statement that the proposed framework is far too restrictive. He said the examples it provides evade the main use case where drug corporations abuse their monopoly power to charge exorbitant prices, ignore the government contributions to R&D and charge consumers more than people in other countries.

Sen. Bernie Sanders, I-Vt., chairman of the Senate Health, Education, Labor and Pensions Committee, said the framework is a step in the right direction but needs to go further. He said the administration should reinstate and expand the reasonable pricing clause to require the pharmaceutical industry to charge affordable prices for new prescription drugs developed with taxpayer support and should move to substantially lower the price for Xtandi by allowing companies to make generic versions of the drug.

Sen. Elizabeth Warren, D-Mass., issued a statement saying she was committed to working with the Biden-Harris administration to strengthen and finalize the framework.

The comment period on the draft framework closes on 6 February. NIST will review and make comments publicly available before issuing a final rule.

Editor's note: *The story was updated to correct the attribution of the quote by Robert Sachs.*