Proposed March-In Guidance Signals Funding Agencies to Actively Evaluate Government Rights Under the Bayh-Dole Act

The Bayh-Dole Act ("Bayh-Dole") governs the rights to inventions made with federal assistance. It offers ownership rights to federal award recipients ("Contractors") that "conceive or first actually reduce to practice" inventions utilising federal funding ("Subject Inventions"), but Bayh-Dole also comes with certain obligations that carry forward to licensees of government-funded technology. Bayh-Dole also provides rights to the U.S. government. Among these rights are two distinct but often conflated rights: the march-in and the request of title. Historically, the U.S. government has rarely exercised those rights. Indeed, in the nearly 45 years since the enactment of Bayh-Dole in 1980, no federal agency has exercised march-in rights (and the government has routinely declined to use march-in authority on request), and agencies have requested title only a handful of times.

On 8 December 2023, the Department of Commerce and the National Institute of Standards and Technology (NIST) published a Federal Register Notice titled "Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights" ("Draft Framework") detailing a new paradigm for the assessment of march-in rights. The Draft Framework reflects the current executive administration's effort to more aggressively monitor compliance by Contractors and encourage the exercise of government rights under Bayh-Dole.

March-In Threat Level Increases

The "March-in right" refers to a federal funding agency's right to require a Contractor, an assignee, or an exclusive licensee of a Subject Invention to grant a license to "a responsible applicant" (or applicants), or to grant a license itself, if certain conditions are met.[1]

The Draft Framework requests public comments on a proposed framework for the exercise of march-in. In view of President Biden's Executive Order of 28 July 2023 ("Executive Order 14014"), which invoked changes to utilisation reporting, the Draft Framework strongly signals that federal agencies will be more proactive in searching for effective opportunities to exercise march-in rights. Per the Executive Order and recently promulgated regulations by NIST, as of 1 October 2023, all agencies are required to collect annual utilisation reports for Subject Inventions, and NIST "strongly encourages" agencies not currently participating in iEdison to do the same. NIST has also provided standard utilisation questions, and answers to these utilisation questions will provide agencies with information to help assess whether exercising march-in is warranted and can be done effectively, according to the Draft Framework.

Executive Order 14014 places a clear emphasis on Bayh-Dole's domestic manufacturing requirement for exclusive licensees of Subject Inventions. This domestic manufacturing requirement is a statutory requirement and a major component of the Draft Framework. NIST's standard utilisation questions will help agencies assess whether this domestic manufacturing requirement is being met. In this light, it would not be surprising if the first product subject to march-in rights is a product that lacks compliance with Bayh-Dole's domestic manufacturing requirement.

Product Pricing in the Spotlight

In addition to the domestic manufacturing requirement, much attention has been directed at the Draft Framework's inclusion of the "reasonableness of price" of a product as a consideration for march-in. However, agencies were not previously precluded from reviewing product price as a consideration for march-in.[2] As such, the inclusion of "reasonableness of price" in the Draft Framework as a march-in consideration may not be surprising to some, but it is noteworthy that the Draft Framework places a clear emphasis on instances in which product price is increased in response to increased demand and/or a health or other disaster. Indeed, each exemplary scenario provided in the Draft Framework that discusses the "reasonableness of price" relates specifically to this context (Scenario 5 describes a 10,000% price increase for a product following a spike in demand; and Scenario 6 describes a 400% price increase for a product following a viral outbreak). It remains to be seen, but considerations of "reasonableness of price" may not weigh as heavily as feared outside of the context of a sudden product price increase.

While the Draft Framework reminds federal agencies that "march-in is an important tool for agencies," it also highlights various hurdles to the effective use of march-in. For example, many products are protected by multiple patents. If only a subset of the patents is subject to Bayh-Dole, the exercise of march-in rights alone would not provide a clear path for "a responsible applicant or applicants" to make and/or sell the product. Similarly, some products (e.g. drug products) are subject to regulatory approval, and the exercise of march-in rights does not negate the requirement that a similar product produced via march-in would also need regulatory approval. In light of these (and other) hurdles, it seems unlikely that march-in rights will be exercised against the vast majority of subject inventions.

Request for Title Remains a Major Danger for Bayh-Dole Noncompliance

In addition to the march in, Bayh-Dole describes circumstances when a federal agency can take title to a patent/patent application claiming a Subject Invention (i.e. to become the owner). Specifically, if a Contractor fails to timely disclose a subject invention to the funding agency or to timely elect title to a subject invention, the agency may exercise its right to take title. Typically, one must disclose the subject invention to the funding agency within two months after the inventor discloses it in writing to the Contractor's patent personnel, and one must elect title to the subject invention within two years of disclosure. Prior to 14 May 2018, Bayh-Dole regulations provided a 60-day window for a federal agency to take title if disclosure or election was not timely; in the absence of action by the federal agency title would remain with the Contractor or assignee. However, on 14 May 2018, this 60-day window was eliminated from the regulations, and as such, a funding federal agency may, in some instances, take title at any time, if disclosure or election is not timely.

For Contractors, assignees, and licensees of patents claiming Subject Inventions, the threat of loss of title is significantly greater than the threat of march-in. Indeed, and in contrast to march-in, if title is requested by the government for failure to timely disclose an invention, a Contractor, prior assignee or licensee may be sued for patent infringement for practicing the Subject Invention (absent a license from the federal agency). As such, it is very important that Contractors comply with Bayh-Dole requirements to avoid this risk.

Although not explicit, the Draft Framework also suggests that federal agencies may be more proactive in searching for opportunities to request title moving forward. Specifically, in the first step of the Draft Framework, an agency is asked to consider whether Bayh-Dole applies. In addition to considering whether the inventions were previously reported as Subject Inventions, the Draft Framework instructs agencies to actively review patents for "unreported subject invention[s]" (i.e. ones that were not properly disclosed). For example, the Draft Framework instructs funding agencies: to search for a publication(s) that relates to a patent to assess whether the publication acknowledges government funding, and to search for a funding agreement(s) that relates to a patent to assess whether the specific aims under the funding agreement are related to the claimed subject matter. Funding agencies would also be likely to review progress reports provided by the Contractor that correspond to any funding agreements identified as having potential relevance. With this information in hand, the Draft Framework instructs agencies to consider whether there is sufficient evidence to confirm whether a patent includes an invention that was "conceived or first actually reduced to practice under the performance of work under a funding agreement" (i.e. includes a Subject Invention).

While this discussion in the Draft Framework is within the context of march-in rights, it is important to remember that if a funding agency identifies "an unreported subject invention," its rights under Bayh-Dole are not limited to march-in rights. Instead, the funding agency has the option to take title to the patent claiming the Subject Invention, which would be extremely problematic for the Contractor, current assignee, or licensee.

Thus, the December 8th Draft Framework suggests that federal agencies may be more proactive in searching for opportunities to exercise their rights under Bayh-Dole moving forward, including march-in rights and the right to take title. To shield against the exercise of march-in rights, those that utilise federal funding to develop inventions should develop a strategy that would result in a fact pattern that would – according to the Draft Framework – weigh against the exercise of march-in. To shield against a potential loss of title to a funding agency, those that utilise federal funding to develop inventions should place a high emphasis on Bayh-Dole compliance, in particular on the timeliness of Subject Invention disclosure. Establishing strong internal protocols to formalise the disclosure of inventions will aid in these endeavors.

REFERENCES

1. 35 U.S.C. § 203
2. A proposed rule in 2021 (Federal Register vol. 86 No. 1, January 4), never adopted, stated that "March-in rights shall not be exercised *exclusively* on the business decisions of the contractor regarding the pricing of commercial goods and services arising from the practical application of the invention." It did not preclude pricing from being considered as a factor in combination with other factors.

Rob Sahr

Rob Sahr is a shareholder in Wolf Greenfield's Biotechnology Practice. Rob develops strategies for life science companies to maximize exclusivity for therapeutic and diagnostic products. He assists clients with building global patent portfolios aligned with product life cycle, and advises clients on regulatory exclusivities, patent term extensions, Orange Book listings, and biosimilars. In addition to pharma and biotech companies, Rob works with universities, research institutions, and venture capital investors, providing patentability and freedom-to-operate assessments, non-infringement and in-validity opinions, performing IP diligence, and preparing agreements. Rob also assists federal grant recipients and contractors with Bayh-Dole compliance, including use of iEdison.

Curtis Powell

Curtis Powell is an associate in Wolf Greenfield's Biotechnology Practice. Curtis focuses his practice on patent prosecution and counseling clients in the biotechnology and life sciences industries. In addition to advising clients on patent portfolio development and management, Curtis works with clients on: patentability, freedom-to-operate, infringement, and validity opinions; patent landscape studies; Bayh-Dole compliance; and due diligence. He has also worked with clients on contested matters before the USPTO and various foreign jurisdictions. Curtis's clients include start-ups, mid-size companies, large companies, and universities.