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Trump’s march-in rights threat: Why pharma is rethinking collaborations

Federal oversight, funding cuts, and patent uncertainties are forcing universities, startups, and pharma companies to reassess partnership models, finds Marisa Woutersen.

US life sciences innovation could be on shaky ground—and universities across the country are in the crosshairs.

The government's threat to force institutions to license federally funded patents has pharma on edge, stoking fears that march-in rights could stall drug discoveries and diminish the talent pipeline.

The Bayh-Dole Act gave universities the freedom to patent inventions funded by federal research, fuelling many partnerships with the industry.

Now, that balance is under scrutiny, with Harvard University's patents becoming a flashpoint in concerns over the government's authority to exercise 'march-in rights'.

Recently, Commerce Secretary Howard Lutnick warned that the government may seize or license parts of Harvard's lucrative patent portfolio—worth hundreds of millions.

The dispute comes against the backdrop of a sweeping federal funding freeze that has hit the university's research programmes hard.

The university's $2.2 billion multi-year grants and $60 million in research contracts were suspended—a move that has now been overturned by Judge Allison Burroughs who found the government violated Harvard's free speech rights.

Harvard is far from the only target. Several other universities including the University of Pennsylvania, Columbia, Brown, and the University of California system, have faced similar funding threats.

John Covert, director at Sterne Kessler, notes that "the political climate of the past two administrations have posed potential challenges to the development and commercialisation of government-funding inventions".

Still, Jon Stone, partner at Quarles & Brady, finds the administration's threat to be "more symbolic than indicative" of a broader policy shift—given ongoing tensions between the administration and Harvard.

"This move seems more like a strategic message than a concrete effort to redefine how march-in rights are applied," he explains.

Even so, the situation has all eyes on it as it could have "widespread application for universities and startups," says Katherine Rubino, partner at Wiggin and Dana.

The stakes are especially high in life sciences, where so much innovation begins at universities.

March-in rights threat unsettles pharma

If the government forced Harvard, or any university, to license its patents, it would mark “a significant shift in how the Bayh-Dole Act is enforced,” says Stone.

Although march-in rights have existed since 1980, they’ve almost never been used. Stone warns that invoking them now could “send a chilling message to the innovation ecosystem,” making pharma companies less willing to partner with federally funded institutions if there’s a risk that IP could be later handed to competitors.

Alfonso Chan, partner at Cahill Gordon & Reindel, notes that mandating licensing of federally funded patents can “significantly affect the value of such patents and diminish the exclusivity they afford to university research partners”.

This can “substantially affect the economics” of drug development and the role universities play.

Covert agrees, adding that using march-in rights beyond their intended purpose is “not helpful to developing and commercialising inventions in a complicated technology area that requires the inter-dependence of many actors, including inventors, universities, investors, small business startups and big pharma”.

The long timelines and large investments in this space need as much predictability as possible regarding IP rights.

The government’s intervention may create hesitation or caution, according to Rubino, around university spin-outs where the core IP is generated and owned by the university.

“For these companies, it will also cause investors to hesitate to fund these startups if the IP rights aren’t secured or there is uncertainty about government ownership of the IP,” she says.

Licensees may also push for lower royalty rates, knowing the government could intervene.

Fall out from funding squeeze and scrutiny

The National Institutes of Health has also announced it will cut $4 billion annually by reducing “indirect” funding that supports universities, hospitals, and other institutions.

The White House’s 2026 budget proposal goes further, seeking $18 billion in NIH cuts—a 40% reduction.

Funding cuts, combined with stricter government oversight will most likely slow or halt new drug discoveries, Rubino explains, since much of the early-stage research behind new drugs begins at university labs.

She says the result could be fewer breakthroughs at the early stage discoveries.

Covert agrees, cautioning that the impact may take five to ten years to become clear. The long-term consequences, he says, could include “less patentable inventions, but also a reluctance for industries to exclusively license (and develop) government-funded inventions if the rights can be abrogated by the government”.

Stone adds that shrinking funding cuts and tighter patent scrutiny could “seriously disrupt the future of drug discovery in the US,” and biotech startups are “especially vulnerable”.

He explains: “Pulling back support risks slowing the pace of new therapies and increased patent oversight could also make pharmaceutical companies more cautious about partnering with universities and startups, potentially chilling collaboration at a time when it could be needed the most.”

The damage could go beyond discoveries themselves, as Covert notes that it could result in less opportunities to train the next generation of scientists.

Much of the research under these funding grants is carried out by graduate students.

Chan points out that many university labs and hospitals are already cutting staff and scaling back research budgets and activities.

The combined effect could ultimately weaken the “talent pipeline”, adds Stone.

Pressures drive new models of collaboration

The current climate is reshaping how pharma companies structure partnerships with universities.

Rubino predicts pharma is already reworking agreements to include clauses around government rights, pricing obligations, audit mechanisms, US manufacturing requirements, and indemnification.

“Pharma may also turn to earlier start-up partnering or creation of their own R&D initiatives that minimise university involvement,” she adds.

Stone agrees, noting that universities may lean more on forming startups to advance early-stage therapies and attract private investment through collaborative, risk-sharing models.

At the same time, he believes funding pressures could push academia and industry closer together.

“An increase in sponsored research agreements is likely, as companies step in to help bridge funding gaps left by NIH cuts,” he says.

These shifts may also affect licensing dynamics. Larger companies, in particular, may gain greater leverage, pushing universities into less favourable terms—including stringent representations and warranties around Bayh-Dole compliance.

Covert highlights that the current situation is already creating caution around licensing government funded inventions.

“The basic Bayh-Dole contract clauses are mandated by statute and rules. There is little a company can do to restructure these aspects of the licensing agreement,” he explains.

Chain echoes that concern, warning that pharma companies that work with universities will have to review the benefits of collaborating with academics.

“Such companies might not be afforded the exclusivity needed to make university collaboration economically viable. Creative licensing might not be an effective work-around if the federal government can unilaterally eliminate exclusivity,” he says.

What can pharma companies do?

In this uncertain climate, experts urge pharma companies to be more vigilant when negotiating licences with universities.

Rubino advises pharma companies to carefully assess what funding sources were used to develop inventions and to include audit provisions that monitor where research funds are sourced from.

She also recommends adding pricing carve-outs and strong indemnity clauses to protect against potential government intervention.

Covert stresses the importance of strong contractual protections. He suggests including representatives and warranties to ensure universities are meeting Bayh-Dole reporting requirements, as well as obligations to keep companies updated on compliance steps.

He also stresses that “any company negotiating a licence to a government-funded invention should perform due diligence and confirm that reporting and other requirements were timely done”.

“Companies thinking about licensing also need to keep in mind the preference for substantial domestic manufacturing, as this requirement is unlikely to be waived by the current administration,” he notes.

Stone echoes these points, stressing that due diligence is key.

“Companies should assess whether the university has a strong track record of Bayh-Dole compliance, including timely invention disclosures, proper election of title, and robust internal procedures,” he says.

He also recommends licensing agreements should clearly outline obligations around commercialisation timelines, public accessibility, and compliance with Bayh-Dole requirements—while building in flexibility to address government concerns without jeopardising the licence.

Chan suggests companies go even further by “conducting patent licence audits as soon as practicable to assess the extent of your risk posed by Bayh-Dole march-in rights”.

He also advises the industry to engage directly in policy discussions: “Lobby the administration and your legislators to persuade them not to exercise march-in rights, or at the very least, not exercise them with respect to your particular technological field or university collaborator”.

Overall, Rubino notes that “pharma companies should think about IP diversification”, encouraging firms to analyse gaps in their portfolios, strengthen their own IP and even consider collaborations with other pharma companies rather than relying solely on universities.

Despite the risks, Covert cautions companies not to “shy away from licensing government-funded inventions”.

“Understand the potential risks of non-compliance and march-in—they are different. Perform diligence to check for compliance to date, and communicate with the licensing officer to ensure continued compliance,” he says.

Many of today’s healthcare innovations were born from federally funded research, and, as he notes, “there will continue to be opportunities to license patent applications to promising healthcare inventions”.

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