

IN THE NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY

In re:
Rights to Federally Funded Inventions and
Licensing of Government Owned
Inventions

Docket No. 201207-0327
86 Fed. Reg. 35

COMMENTS OF THE R STREET INSTITUTE

The following comments are respectfully submitted in response to the Notice of Proposed Rulemaking dated Jan. 4, 2021. The commenter is a nonprofit research organization based in Washington, D.C., and has regularly commented on matters of intellectual property, competition policy and innovation.

Briefly, the commenter opposes the proposed amendment to 37 C.F.R. § 401.6 that provides that march-in rights under the Bayh–Dole Act “shall not be exercised exclusively based on the business decisions of the contractor regarding the pricing of commercial goods and services arising from the practical application of the invention.” March-in rights serve an important, ongoing purpose of ensuring competition and avoiding market failures, by setting background expectations for critical negotiations over technologies of public importance. The current administration’s efforts with regard to COVID-19 vaccination have made that purpose especially clear.

In light of this important purpose of march-in rights, the value of the proposed amendment is unclear at best and harmful at worst. Tying the hands of government agencies from exercising statutory march-in rights potentially slows the government’s emergency response capabilities at the times it is needed most, creates confusion over the interpretation of untested regulatory language, and upsets expectations for both federal agencies and private contractors.

March-in rights serve an important, ongoing purpose of correcting market failures resulting from patents.

March-in rights under the Bayh–Dole Act serve an important role of setting background expectations that overcome market failures and promote the benefits of competition especially in times of urgent need. Recent events relating to COVID-19 vaccination have shown this background role to be especially important, such that undermining march-in rights could substantially impede future responses to pandemics and other national crises.

The Bayh–Dole Act provides that a federal agency that provides funding resulting in a patented invention “shall have the right” to require its grantee “to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants” under certain conditions laid out in the statute.¹ In particular, the agency may march in when the contractor fails to take effective steps toward “practical application” of the patented invention, to make the benefits of that invention “available to the public on reasonable terms.”²

This provision serves essentially as a safety valve to correct market failures that arise out of patent licensing otherwise enabled by the Bayh–Dole Act. A patent is, by nature, an intervention in ordinary free-market dynamics, prohibiting ordinary market competition over a particular range of products covered by the patent. Generally, this intervention is thought to be tolerable in view of the long-term dynamic competition benefits: By offering a temporary monopoly over an invention, the patent grant encourages the development and commercialization of new inventions.

But at times, such as during national crises when rapid supply of technologies is critical, the static inefficiencies of patent protection can outweigh the long-term dynamic benefits. Transaction costs or other impediments may prevent private industry from reaching the sorts of licensing deals needed to ensure supply in these sorts of situations, and powers like march-in rights give the government a foothold to resolve such difficulties in a timely, effective manner.

¹35 U.S.C. § 203(a).

²35 U.S.C. § 203(a)(1); 35 U.S.C. § 201(f).

While march-in rights have not been explicitly invoked to date, that does not mean they have been ineffective. Their mere presence, along with other government powers to reorder patent interests,³ is often sufficient to grease the wheels of private and public negotiation. Historically, private patent holders have been willing to ramp up supply or cut prices in negotiations with the government, not because of direct invocations of these government powers over patents but in the shadow of those powers.⁴

Recent events relating to the COVID-19 pandemic have made especially clear the importance of this background effect of government powers like march-in rights. The current administration recently brokered a “historic” deal in which Merck would assist in manufacturing a vaccine developed by Johnson & Johnson.⁵ As several news reports noted, the two companies had previously been engaged in negotiations on the topic, but they were not progressing rapidly due to a lack of strong interest on behalf of either company.⁶ That changed when administration officials began to encourage the companies to work together, raising the possibility of invoking the Defense Production Act. That law, which also allows for the reordering of intellectual property interests, was never invoked directly with respect to the companies themselves, but administration officials acknowledged using it as “implicit” incentive for cooperation.⁷

Although one might hope that patent-holding firms would strike the sorts of deals to supply the needs of a pandemic, the evidence shows otherwise: Companies will not open the door to

³These powers include 28 U.S.C. § 1498 and the Defense Production Act, 50 U.S.C. §§ 4501–4568.

⁴See Christopher J. Morten and Charles Duan, “Who’s Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises,” *Yale Journal of Law and Technology* 23 (2020), pp. 13–33, https://yjolt.org/sites/default/files/23_yale_j.l._tech._1_section_1498_0.pdf.

⁵See “Biden Administration Announces Historic Manufacturing Collaboration Between Merck and Johnson & Johnson to Expand Production of COVID-19 Vaccines,” United States Department of Health and Human Services, March 2, 2021, <https://www.hhs.gov/about/news/2021/03/02/biden-administration-announces-historic-manufacturing-collaboration-between-merck-johnson-johnson-expand-production-covid-19-vaccines.html>.

⁶See Jeremy Diamond, “‘They just were not all in’: How the White House convinced two pharmaceutical giants to collaborate on a vaccine,” *CNN Politics*, March 3, 2021, <https://www.cnn.com/2021/03/03/politics/biden-merck-johnson--johnson-dpa/index.html>.

⁷Tamara Keith, “How the White House Got 2 Pharma Rivals to Work Together on COVID-19 Vaccine,” *National Public Radio*, March 3, 2021, <https://www.npr.org/2021/03/03/973117712/how-the-white-house-got-2-pharma-foes-to-work-together-on-covid-19-vaccine>.

competitive markets even in times of greatest need.⁸ Provisions such as march-in rights under the Bayh–Dole Act are necessary parts of the government’s toolbox to encourage collaboration and competition during these present times and others.⁹

The value of constraining march-in rights is uncertain at best.

Despite this important background role that march-in rights serve, the Notice of Proposed Rulemaking would amend the regulatory framework for march-in rights to prevent them from being invoked in certain circumstances. Doing so is of uncertain value at best and harmful to the public interest at worst. By preventing federal agencies from using march-in rights, the proposed rule potentially cuts off one tool that federal agencies can use to overcome situations where patent holders are unable to negotiate a private licensing deal even in the most pressing circumstances.

More concerningly, the proposed amendment creates uncertainty among multiple dimensions for both patent holders and the public. The proposed amendment limits the exercise of march-in rights where it is “exclusively based on the business decisions of the contractor regarding the pricing of commercial goods and services.” Since basic economics teaches that supply is intimately tied to price, the provision raises a difficult question of whether insufficient supply is an adequate basis for the exercise of march-in rights. That uncertainty will potentially stymie future licensing negotiations until it is possibly resolved by the courts, years down the road. Furthermore, the diminishing of march-in rights may channel the government toward using other means of reordering intellectual property rights, such as 28 U.S.C. § 1498, the Defense Production Act or assertion of federally owned patents against private firms. This is not to say that these other means are undesirable; it is to say that the proposed amendment may have unintended consequences that ought to be considered.

⁸See Morten and Duan, p. 37, https://yjolt.org/sites/default/files/23_yale_j.l._tech._1_section_1498_0.pdf.

⁹See *id.* pp. 37–39.

The intention of the proposed amendment is to avoid “uncertainties in the U.S. innovation system.”¹⁰ But it is not clear that the proposed amendment actually avoids uncertainties. Patent holders face uncertainty in the value of their patents all the time, in view of potential invalidity or noninfringement findings, unchallengeable foreign activity, unexpected appearance of blocking patents or new prior art, exercise of other government patent use authorities or changes in patent law doctrine. Removing a small range of potential uses of march-in rights will likely have little effect on that much broader uncertainty. Compounded with the new uncertainties that the proposed amendment creates, it is not clear that the game is worth the candle.

Conclusion

For the foregoing reasons, the commenter opposes the proposed amendment to 37 C.F.R. § 401.6.

The commenter thanks the National Institute of Standards and Technology for providing the opportunity to submit these comments. If there are any remaining questions relating to the matters presented herein, the undersigned would be happy to provide further information as necessary.

Respectfully submitted,

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¹⁰National Institute of Standards and Technology, *Return on Investment Initiative to Advance the President’s Management Agenda: Unleashing American Innovation*, U.S. Department of Commerce, April 2019, p. 31, <https://www.nist.gov/unleashing-american-innovation/green-paper>.