PRATT'S GOVERNMENT CONTRACTING LAW REPORT

VOLUME 9 **NUMBER 13** **January 2023**

LexisNexis®

QUESTIONS ABOUT THIS PUBLICATION?

For questions about the **Editorial Content** appearing in these volumes or reprint permission, please call:

Heidi A. Litman at 516-771-2169
Email: ..... heidi.a.litman@lexisnexis.com
Outside the United States and Canada, please call . . . . . (973) 820-2000

For assistance with replacement pages, shipments, billing or other customer service matters, please call:

Customer Services Department at . . . . . (800) 833-9844
Outside the United States and Canada, please call . . . . . (518) 487-3385
Fax Number . . . . . (800) 828-8341
Customer Service Website . . . . . http://www.lexisnexis.com/custserv/

For information on other Matthew Bender publications, please call

Your account manager or . . . . . (800) 223-1940
Outside the United States and Canada, please call . . . . . (937) 247-0293

Library of Congress Card Number:

ISBN: 978-1-6328-2705-0 (print)
ISSN: 2688-7290

Cite this publication as:

[author name], [article title], [vol. no.] PRATT'S GOVERNMENT CONTRACTING LAW REPORT [page number] (LexisNexis A.S. Pratt).
Michelle E. Litteken, GAO Holds NASA Exceeded Its Discretion in Protest of FSS Task Order, 1 PRATT'S GOVERNMENT CONTRACTING LAW REPORT 30 (LexisNexis A.S. Pratt)

Because the section you are citing may be revised in a later release, you may wish to photocopy or print out the section for convenient future reference.

Editorial Office
230 Park Ave., 7th Floor, New York, NY 10169 (800) 543-6862
www.lexisnexis.com

MATTHEW BENDER

(2023–Pub.4938)

Editor-in-Chief, Editor & Board of Editors

Pratt's Government Contracting Law Report is published 12 times a year by Matthew Bender & Company, Inc. For customer support, please contact LexisNexis Matthew Bender, 9443 Springboro Pike, Miamisburg, OH 45342 or call Customer Support at 1-800-833-9844. Direct any editorial inquiries and send any material for publication to Steven A. Meyerowitz, Editor-in-Chief, Meyerowitz Communications Inc., 26910 Grand Central Parkway Suite 18R, Floral Park, New York 11005, smeyerowitz@meyerowitzcommunications.com, 631.291.5541. Material for publication is welcomed—articles, decisions, or other items of interest to lawyers and law firms, in-house counsel, government lawyers, senior business executives, and anyone interested in privacy and cybersecurity related issues and legal developments. This publication is designed to be accurate and authoritative, but neither the publisher nor the authors are rendering legal, accounting, or other professional services in this publication. If legal or other expert advice is desired, retain the services of an appropriate professional. The articles and columns reflect only the present considerations and views of the authors and do not necessarily reflect those of the firms or organizations with which they are affiliated, any of the former or present clients of the authors or their firms or organizations, or the editors or publisher.

POSTMASTER: Send address changes to *Pratt's Government Contracting Law Report*, LexisNexis Matthew Bender, 230 Park Ave. 7th Floor, New York NY 10169.

March-in Rights: Implications from the COVID-19 Pandemic

By Nick Palmieri*

In this article, the author explains that "march-in rights" are unlikely to significantly change after the COVID-19 pandemic, thus remaining a limited remedy whose exact application has yet to be tested.

"March-in rights" were created as part of the Bayh-Dole Act of 1980[1] as a way to balance the need of small and non-profit entities to obtain government financing with the public's right to access certain innovation resulting from government funds.

In particular, march-in rights were created, at least in part, to further Congress's goal "to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions."[2]

Accordingly, under the provisions of 35 U.S.C. § 203, agencies of the federal government are empowered to require entities that receive federal funding to provide licenses in certain circumstances.

Yet in the more than 40 years since enactment, and despite several attempts, such march-in rights have yet to be exercised. Despite this lack of action, the rights remain in existence. The COVID-19 pandemic, and the world's response to develop a vaccine and treatment for the ravaging disease, renewed calls for the exercise of march-in rights have appeared.[3]

However, as will be discussed in more detail below, march-in rights are unlikely to significantly change after the COVID-19 pandemic.

SCOPE

Before delving into when and how march-in rights have been asserted, one must understand the limited circumstances in which the rights may even by applicable. As a preliminary matter, march-in rights only apply to inventions "in which a *small business* or *nonprofit organization* has acquired title."[4] The

---

* Nick Palmieri, an associate based in the New York office of Baker Botts L.L.P., serves in the firm's Intellectual Property Practice. He may be contacted at nick.palmieri@bakerbotts.com.

[1] Pub. L. 96-517.

[2] 35 U.S.C. § 200.

[3] Including a call by various Attorneys General for the National Institute of Health to exercise its march-in rights with respect to Gilead's remdesivir.

[4] 35 U.S.C. § 203(a) (emphasis added).

definitions of these entities is given separate from the meaning of "small" or "micro" entities used elsewhere in patent law.

A "small business" is defined by the U.S. Small Business Association (SBA) for each industry,[5] in a comprehensive document which outlines the revenue or number of employees that qualifies an entity as a "small business."[6]

"Nonprofit organizations" are defined as "universities and other institutions of higher education" or an organization exempt from taxation under 26 U.S.C. § 501(c)(3),[7] and thus applies to inventions generated by colleges and universities that take government funding.

So while the classification of entities to which march-in rights are limited, it is not as simple as applying the rights to "small entities," defined under 13 CFR § 121.802 as an entity "whose number of employees . . . does not exceed 500 persons" and "[w]hich has not assigned, granted, conveyed, or licensed . . . any rights in the invention" to a non-independent inventor or to any organizations that do not qualify as a "small business concern." Though these requirements certainly have some relation to one another, they are different and can impact the government's choice to exercise march-in rights.

March-in rights contain a further gatekeeping mechanism that must apply before the rights can even be considered: "subject inventions." Defined as "any invention of the contractor[8] conceived or first actually reduced to practice in the performance of work under a funding agreement,"[9] the law makes clear that march-in rights only apply where the invention was made as part of a "funding agreement."

Put another way, only those inventions which have been created with funding provided by one (or more) government agencies are even eligible for march-in rights. And the eligible agencies are broadly defined, including each "Executive agency" under 5 U.S.C. § 105 and all "Military departments" under 5 U.S.C. § 102.

---

[5] https://www.sba.gov/sites/default/files/2022-09/Table%20of%20Size%20Standards_NAICS%202022%20Final%20Rule_Effective%20October%201%2C%202022.pdf.

[6] 35 U.S.C. § 201(h); see 15 U.S.C. § 632 (empowering the SBA to define small businesses).

[7] This section covers "[c]orporations . . . operated exclusively for religious, charitable, scientific, testing for public safety, literary, or educational purposes, or to foster national or international amateur sports competition . . . , or for the prevention of cruelty to children or animals" which do not earn a profit.

[8] An individual, small business firm, or nonprofit organization who is party of a funding agreement with a federal government agency.

[9] 35 U.S.C. § 201(e).

This requirement serves as the backstop to the policy behind march-in rights. That policy is not to simply provide government agencies with the ability to license patents which may be pertinent to the public good. Rather, the purpose of march-in rights is specifically to balance the government's interest in funding innovations and research by smaller or non-profit entities with the public's interest in accessing innovations which have been funded by the public's taxes.

This interest in narrow and, to date, has not been sufficient to justify the government's intervention, though that need hardly count as a failure of the policy.

APPLICATION

Given a valid entity to which the Act applies, under the terms of a funding agreement by a Federal agency, there are two circumstances in which march-in rights can be applied to a subject patent, or imposed upon a "contractor": where the contractor is cooperative, and where it is not.

In the first circumstance, the contractor[10] may be required to grant "a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applications, upon terms that are reasonable under the circumstances."[11] The process for exercising these rights is set forth in the corresponding enabling regulations.[12]

Upon reception of information indicating that march-in rights may be warranted, the agency is required to coordinate with the contractor and investigate whether the circumstances warrant the exercise of march-in rights.[13] After providing written notice to the contractor, which includes the justification for march-in rights, the contractor is provided an opportunity to rebut or oppose the potential march-in.[14] If afterwards a "genuine dispute over the materials facts upon which the march-in is based" remains, the regulations require "fact-finding" to proceed, according to the specific procedures of each agency.[15]

These specific procedures are left specifically to the agency considering march-in rights, but the regulations note that procedures "shall be as informal

---

[10] Or an assignee or exclusive licensee.

[11] 35 U.S.C. § 203(a).

[12] 37 C.F.R. § 401.6. Individual agencies may also themselves have their own regulations which supplement the general regulations at Section 401.6. For example, the National Science Foundation sets forth enabling regulations in 45 C.F.R. § 650.13.

[13] 37 C.F.R. § 401.6(b).

[14] Id. § 401.6(d).

[15] Id. § 401.6(e).

as practicable and be consistent with principles of fundamental fairness."[16] The ultimate decision on whether to exercise march-in rights is left to the head of the relevant agency (or their designee) who will base their decision upon the facts found and arguments presented.[17] At any time, though, the agency, regardless of the facts in evidence or stage of the proceedings, may terminate the march-in proceeding if it determines that it "does not wish to exercise march-in rights."[18]

There is also a second scenario in which agencies may choose to exercise these rights: when the contractor "refuses" a request to grant a license. Where the relevant agency determines that the circumstances, and public policy, justify it, the law gives the agency the ability to direct grant licenses to use the subject invention, regardless of the contractor's cooperation. There are four circumstances in which the agency may directly grant a license under these circumstances (after the contractor's refusal):

(1) The contractor (or assignee) has not taken and is not expected to take effective steps to achieve "practical application" of the subject invention in the requested field of use;

(2) A license is necessary to "alleviate health or safety needs, which are not reasonably satisfied by the contractor";

(3) Federal regulations require public use of the subject invention, and the actions of the contractor are not sufficient to meet this requirement;

(4) An agreement under 35 U.S.C. § 204[19] has not been obtained, or is in breach of such an agreement.[20]

Where the relevant agency determines that at least one of these circumstances apply, they are empowered to grant a license, whether exclusive or not, to those deemed appropriate. Should a contractor disagree with this, or any determination, they may appeal the determination to the U.S. Court of Federal Claims, which is given jurisdiction over the exercise of these rights.[21]

---

[16] Id.

[17] Id. § 401.6(g).

[18] Id. § 401.6(h).

[19] The section, entitled "Preference for United States industry" requires that exclusive rights to a subject invention will only be granted to those who agree that the invention "will be manufactured substantially in the United States" subject to certain exceptions which may be granted by the relevant Federal agencies.

[20] 35 U.S.C. § 203(a)(1)–(4).

[21] While the Court of Federal Claims has jurisdiction in these cases, since no agency has

ATTEMPTS AT EXERCISE

As noted above, although march-in rights have been around for more than 40 years, they have yet to be successfully exercised, despite various calls to do so. To date, petitions have only asked the National Institutes of Health (NIH) to exercise these rights, in attempts to improve or better regulate the production of various pharmaceuticals. Ultimately, though, each of these petitions was denied.[22]

In 1997, the NIH received its first petition, from CellPro, Inc. after a competitor (Johns Hopkins) asserted that CellPro's Ceprate system infringed various patents. Finding ultimately that Johns Hopkins was taking steps to commercialize its own products and recognizing that Johns Hopkins had not sought to enjoin CellPro's conduct, but only sought a reasonable royalty rate, the NIH refused the petition.

In 2004, a diverse groups of patients, advocates, and even members of Congress asked the NIH to exercise its march-in rights in order to reduce the price of the HIV/AIDS treatment Norvir/ritonavir.[23] Here, the NIH denied the petition on that basis that the drug was sufficiently "available" to the public and that the "extraordinary" remedy of imputing the responsibility for controlling drugs prices to the NIH was "not an appropriate means" to justify the exercise of march-in rights.[24]

In a similar case in 2004, the NIH also refused to march-in against the manufacturer of Xalatan/latanoprost, finding that the drug had been practically applied, was actively being marketed and regularly prescribed, and it was not appropriate for the NIH to step in and regulate prices, even where the drug was being sold at a much higher price within the United States than elsewhere throughout the world.[25]

---

exercised march-in rights, there has never been a determination to appeal. Standing to make such an appeal is also limited to "any contractor, inventor, assignee, or exclusive licensee adversely affected" by the determination, so it does not provide an avenue of relief for those who might bring a petition to exercise march-in rights.

[22] See John R. Thomas, Cong. Rsch. Serv., R44597, March-In Rights Under the Bayh-Dole Act 8–9 (2016).

[23] Another petition was brought against this same drug in 2012 and denied for largely the same reasons, with the NIH taking the position that a disparity in prices does not fall within any of the defined criteria of Section 203.

[24] Elias A. Zerhouni, Director, NIH, In the Case of Norvir Manufactured by Abbott Laboratories, Inc., July 29, 2004, https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf.

[25] Elias A. Zerhouni, Director, NIH, In the Case of Xalatan, Manufacture by Pfizer, Inc.,

What these two petitions made clear, from the NIH's perspective at least, is that march-in rights are not, and should not be, a means of price control. The question of a particular drug having different prices across different country is, if it falls to anyone, an issue to be addressed by Congress, not one which the NIH should be responsible for regulating.

In 2010, in a petition to exercise march-in rights against the drug Fabrazyme/agalsidase beta, the NIH put forth a new reason to justify their decline. The manufacturer, Genzyme Corporation, faced certain manufacturing difficulties, and thus the petitioners desired an open license for the drug.

However, the NIH noted that (1) the manufacturing difficulties were actively being resolved and addressed, and (2) FDA approval for generic versions of the drug could not have been obtained before the manufacturing difficulties were resolved. As a result, the NIH's intervention at that time would not have alleviated any manufacturing difficulties or made the drug more readily accessible to the public (since Genzyme would have no difficulty meeting demand once it resolved the manufacturing difficulties), which is the entire purpose of march-in rights.

In 2016, the NIH received a petition to march-in against the drug Xtandi/enzalutamide, a prostate cancer drug. Again, though, the NIH denied the petition, noting again that it was "broadly available as a prescription drug" with increasing sales each year and no indication that the drug "will be in short supply," and it was not the NIH's role to regulate prices.[26]

The COVID-19 Pandemic also brought about new petitions, though similarly to no avail, despite the significant public interests inherent in effective treatments. One such petition sought the NIH to march-in against Remdesivir, an antiviral produced by Gildea Sciences, that showed promise as a treatment for COVID-19. So much promise, that the NIH funded a multi-stage clinical trial of the drug as treatment for COVID-19. Given the public's interest in resolution of this "unprecedented crisis" 34 Attorneys General submitted a petition to the NIH to exercise its march-in rights.[27]

But this petition ultimately proved unpersuasive as well, though for a different reason than many others. Despite the "unprecedented" public interest

---

September 17, 2004, https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-in-xalatan.pdf.

[26] Letter from Francis C. Collins, Director, NIH, to Andrew S. Goldman, June 20, 2016, https://www.keionline.org/sites/default/files/Final-Response-Goldman-6.20.2016.pdf.

[27] See Xavier Becerra, California Attorney General, et al., Letter to Alex M. Azar, Secretary, U.S. Dept. of Health & Human Services, August 4, 2020, https://www.oag.ca.gov/system/files/attachments/press-docs/Remdesivir%20Letter%2020200804.pdf.

in providing a treatment for COVID-19, march-in rights still require that the government agency's funding be directed to the invention itself. Remdesivir, though, was developed in 2009–2013, with NIH funding only coming during the clinical and testing phases of the drug.[28] As such, the NIH had no march-in rights to assert, as its funding was not used to develop the drug itself.

POST-COVID-19 MARCH-IN RIGHTS

Several lessons can be drawn from these petitions, and their subsequent rejection, the most notable of which is that the NIH, while recognizing that drug prices may be inconsistent across high-income nations, does not believe itself to be the appropriate body to regulate those prices, nor march-in rights the appropriate mechanism for redress.

In order to memorialize this understanding, the National Institute of Standards and Technology (NIST) published new "proposed rulemaking" in January 2021. The new regulation (which would be entered as 37 C.F.R. § 401.6(e)) notes that "[m]arch-in rights shall not be exercised exclusively based on the business decision of the contractor regarding the pricing of commercial goods and services arising from the practical application of the invention."[29]

While some call this a reduction in the scope of the provision, the proposed rule revision[30] clarifies the de facto policy which has already been practiced by the NIH. Whether other agencies would follow a similar rule is, as of yet, undetermined, but the rule would not preclude any agency from considering pricing as a factor in favor of exercising march-in rights, but merely precludes price as being the only consideration.

Such a policy is consistent with the overall purpose of march-in rights. The government's role, as far as march-in rights are concerned, is not to act as a price-setter, stepping in when competitors and purchasers believe a price is too high, but rather to monitor whether the public interest calls for access to an invention which cannot otherwise be provided to the public and which was created using public money.

While there may be legitimate concerns about the commercial availability of certain inventions, march-in rights remain a limited remedy whose exact application has yet to be tested.

---

[28] See U.S. Gov't Accountability Off. GAO-21-272, Biomedical Research: Information on Federal Contribution to Remdesivir 10 (2021), https://www.gao.gov/assets/gao-21-272.pdf.

[29] Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 85 Fed. Reg. 35, 37 (2021).

[30] Which has made it into President Biden's regulatory agenda, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202104&RIN=0693-AB66.