

KEI Briefing Note 2020:2. The Federal Government’s Authority to Restrict or Eliminate Contractors’ Rights to Federally-Funded Inventions in “Exceptional Circumstances”

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Kathryn Ardizzone.¹

The exceptional circumstances clause is a provision of the Bayh-Dole Act, 35 U.S.C. §§ 200-212, that allows the government to restrict or eliminate a contractor’s² right to elect title to federally-funded inventions “in exceptional circumstances when it is determined by the Agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of [the statute].”³

Stated otherwise, the clause authorizes the federal government to exert greater ownership over intellectual property (IP) that was developed with federally-funded research, including by retaining title to the IP, if exceptional circumstances are present and doing so would better promote the objectives of the Bayh-Dole Act.

This memorandum explains the exceptional circumstances clause, discusses why it merits consideration as a policy tool for addressing the COVID-19 pandemic, and shares some examples of how agencies have utilized it.

The upshot is that the exceptional circumstances clause, like march-in rights, is an important safeguard to protect the public interest in federally-funded research and development (R&D). Unlike march-in rights, however, the exceptional circumstances clause:

- Has been utilized a number of times, by federal agencies such as the National Institutes of Health (NIH) and Department of Energy (DOE);
- Is not subject to an automatic stay pending appeal, if a contractor challenges it;
- Offers the government unlimited flexibility in how it exercises ownership of IP; and
- Is prospective, rather than retroactive, and must be implemented in a funding agreement.

¹ KEI thanks Laurel Boman, a J.D. candidate at NYU Law School for her assistance with this Note.

² A “Contractor” is defined as “any person, small business firm, or nonprofit organization that is a party to a funding agreement.” 35 U.S.C. § 202(c). The Bayh-Dole Act was extended to all businesses, regardless of size, by Executive Order 12591 (Apr. 22, 1987).

³ 35 U.S.C. § 202(a)(ii).

Background

Section 202 of the Bayh-Dole Act sets forth the default allocation of rights in federally-funded inventions: Generally, as long as contractors follow the requisite procedures, they may retain title to any subject invention.⁴ The federal government retains certain limited rights, including a royalty-free license to practice the invention throughout the world for or on behalf of the U.S. government,⁵ and the right to march in and issue a compulsory license if certain criteria are met.⁶ The funding agreement must include “Standard patent rights clauses”⁷ set forth at 37 C.F.R. § 401.14, including 37 C.F.R. § 401.14(b), which memorializes the contractor’s right to elect title and the government’s march-in rights and royalty-free license.

The exceptional circumstances clause is one of four exceptions to the contractor’s right to elect title. It authorizes the government to restrict or eliminate that right if two conditions are satisfied: (1) exceptional circumstances are present and (2) the modification of the contractor’s right to retain title will better promote the policy objectives of Bayh-Dole.

An agency seeking to make a determination of exceptional circumstances (DEC) must satisfy certain procedural requirements.⁸ The agency must deliver a copy of the determination of exceptional circumstances to the Secretary of Commerce within 30 days of awarding the funding agreement and must include an analysis justifying the determination.⁹ A contractor has the right to administrative review of an exceptional circumstances determination that “is either contrary to the policies and objectives of [the Bayh Dole Act] or constitutes an abuse of discretion by the agency.”¹⁰ The procedures for an appeal are set forth at 37 C.F.R. § 401.4(b) and include “a petition in the United States Claims Court, which shall have jurisdiction to determine the appeal on the record and to affirm, reverse, remand, or modify as appropriate, the determination of the Federal agency.”¹¹ Importantly, however, a contractor’s appeal “shall not be used as a basis for withholding or delaying the award of a funding agreement or for suspending performance under an award.”¹² While the claim is being resolved, “the contract may be issued with the patent rights provision proposed by the agency; however, should the final decision be in favor of the contractor, the funding agreement will be amended

⁴ 35 U.S.C. § 202(a). A “subject invention” is “any invention of the contractor conceived of or first actually reduced to practice in the performance of work under a funding agreement[.]” 35 U.S.C. § 201(e).

⁵ 35 U.S.C. § 202(c)(4).

⁶ 35 U.S.C. § 203.

⁷ 37 C.F.R. § 401.3(a).

⁸ 35 U.S.C. § 202(b).

⁹ *Id.*

¹⁰ 37 C.F.R. § 401.4(a).

¹¹ 37 C.F.R. § 401.4(b).

¹² 37 C.F.R. § 401.4(a).

accordingly and the amendment made retroactive to the effective date of the funding agreement.”¹³

Exceptional Circumstances and March-in Rights

A determination of exceptional circumstances differs in some important respects from march-in rights and the government’s royalty-free license, and may offer certain advantages as a policy tool, particularly in the context of a public health emergency that requires rapid and equitable dissemination of federally-funded diagnostics, treatments, and vaccines.

First, the exceptional circumstances clause operates prospectively rather than retroactively. To utilize the authority, a federal agency must include a determination of exceptional circumstances in the funding agreement, and agencies typically announce their intent to make a DEC for a particular project in presolicitation notices and Requests for Proposals (RFPs). Prospective contractors are thus aware of the limitation on the right to elect title at the outset of the funding relationship. By contrast, while contractors are advised of march-in rights in the funding agreement, the government exercises march-in after a contractor has retained title to a subject invention. By declaring exceptional circumstances *ex ante*, the government is arguably in a better position to exercise rights in a subject invention than it would be if title had already fully vested in a contractor.

Additionally, with respect to the royalty-free license, there is some debate as to whether the authority is limited to use by the government itself or it may extend to use by a third party on the government’s behalf. With the exceptional circumstances clause, the government need not take title to and practice the invention itself, but instead may allow the invention to enter the public domain so that it can be practiced by a third party, such as a manufacturer of generics.

Finally, the use of march-in authority is, in some circumstances not applicable to the exceptional circumstances clause,¹⁴ subject to an automatic stay pending appeal,¹⁵ a limitation that is especially problematic in case of a public health emergency, where swift action is required. In contrast, when the exceptional circumstances clause is invoked, an

¹³ *Id.*

¹⁴ 35 U.S.C. § 202(b), which pertains to determinations of exceptional circumstances, refers to 35 U.S.C. § 203(b)—the subsection of the Bayh-Dole Act addressing march-in appeals. Section 203(b) creates an automatic stay that does not extend to a DEC because the stay arises only when march-in authority is exercised under 35 U.S.C. § 203(a)(1)&(3), *i.e.*, when the government marches in because the contractor fails to achieve practical application of the invention or when “action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees.”

¹⁵ 35 U.S.C. § 203(b).

appeal “by the contractor shall not be used as a basis for withholding or delaying the award of a funding agreement or for suspending performance under an award.”¹⁶

Past Uses of the Exceptional Circumstances Clause

Below is a list of past agency programs or initiatives that involved a determination of exceptional circumstances.

National Cancer Institute (NCI) Full-Length cDNA Initiative

The NCI utilized DECAs in connection with the Full-Length cDNA Initiative, a program initiated by then-NIH Director Harold Varmus to enter sequenced cDNAs into the public domain. The goal of the Initiative was to create a “publicly accessible resource” that would become a “key platform for biomedical research.”¹⁷

As a condition of the grant awards, contractors/researchers were barred from filing patent applications on their inventions, and instead were required to rapidly contribute the resulting cDNA sequences to the public domain.¹⁸

Dr. Varmus said of the project: “The cDNA libraries, clones, and sequences generated as part of the NIH Full-Length cDNA Initiative will most effectively contribute to a resource for the research community if they are made publicly available without restriction and in a timely manner. The sharing of materials and data in a timely manner has been an essential element in the rapid progress that has been made in biomedical research.”¹⁹

NCI-Frederick

NCI-Frederick is a Federally Funded Research and Development Center (FFRDC) operated by an Operations and Technical Support Prime Contractor (OTS). NCI-Frederick’s contracts with its OTS include a determination of exceptional circumstances in which funded inventions are assigned to the government, with certain limited exceptions.

¹⁶ 37 C.F.R. § 401.4(a).

¹⁷ <https://www.genome.gov/10001047/fulllength-cdna-initiative>.

¹⁸ Kathy Hudson, *The Human Genome Project: A Public Good*, 12 Health Matrix 367, 373 (2002).

¹⁹ <https://web.archive.org/web/20041015182721/http://www.genome.gov/10001801>.

NCI-Frederick's current DEC, published on its website, states that "[t]he Contractor shall assign to the Government title throughout the world to each subject invention, except to the extent that rights are retained under paragraphs (b)(4) and (d) of this clause."²⁰

KEI located a model agreement between the current OTS contractor for NCI-Frederick, Leidos Biomedical Research, and subcontractors, which references the determination of exceptional circumstances. It states:

Entity acknowledges that as the OTS Contractor, Leidos Biomed is subject to a Determination of Exceptional Circumstances (35 U.S.C. § 202(a)(ii)), through which its rights in any inventions developed under this Agreement are assigned to the U.S. Government.²¹

NCI Molecular Targets Library

Another program involving a determination of exceptional circumstances is the Molecular Targets Library (MTL), an NCI project that "facilitates the discovery of compounds—synthetic as well as natural products—that may serve as bioprobes for functional genomics, proteomics and molecular target validation research, as well as candidates for drug development."²²

The NIH made a determination of exceptional circumstances with respect to MTL in order "to address the Government's present interest in the availability of the new technology developed under this Contract[.]"²³ The presolicitation notice for the project stated as follows:

R]espondents are advised that a Determination of Exceptional Circumstances (DEC) along with the associated deviated FAR clauses will be used for this Initiative.

[T]he DEC will enable the NCI to either elect title to inventions developed by the MTL under this Initiative, or to grant greater rights to such inventions to the MTL. The finalized version of the deviated FAR clauses will be available before final award of any potential contracts.²⁴

NCI Initiative for Chemical Genetics

The NCI has also issued a DEC with respect to its Initiative for Chemical Genetics, a

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<https://www.cancer.gov/about-nci/contracts/fnlcr-acquisitions/resources/current-determinations-of-exceptional-circumstances.pdf>.

²¹ <https://frederick.cancer.gov/sites/default/files/content/CollaborationAgreement.pdf>.

²² <https://irp.nih.gov/catalyst/v21i2/nci-campus-in-frederick>.

²³ Com. Bus. Daily, Feb. 24, 2000.

²⁴ *Id.*

project that was “designed to encourage the development of small molecular probes.”²⁵ Pursuant to the DEC, “[c]hemical probes, assays and screening directed at cancer targets [were made] available to the research community without IP constraints,” and there was an “[a]cknowledgment that inventions may be produced that would benefit from patent protection (i.e. potential therapeutics).”²⁶ “[T]he government returned Blanket Greater Rights to the contractor to operate as if [it were] under Bayh-Dole as long as the community resource goals are met.”²⁷

NIH Mouse Phenotyping

The NIH utilized DEC’s for a “mouse genetics research program that specifically focused on neurobiology and complex behavior.”²⁸

The NIH included a DEC in grants associated with the program in order to “ensure[] that the Government protects the public and the research community against nonuse or unreasonable use of [publicly-funded] inventions by making the mutant strains generated from the NIH mutagenesis initiatives rapidly and freely accessible to the scientific community for further research and development[.]”²⁹

Two of the RFAs associated, RFA-MH-99-007 and RFA-HD-99-007, included similarly-worded DEC’s. RFA-MH-99-007 stated as follows:

NIH expects to make a Determination of Exceptional Circumstances (DEC) to eliminate the potential for patents on mutant mice, embryos, and sperm. The application should include a proposed plan addressing if, or how, the PI and recipient institution will exercise their intellectual property rights regarding other patentable research resources not covered under the DEC, such as mutagenesis protocols, instrumentation, and phenotyping assays produced in projects funded under this RFA[.]

....

It is expected that the resources to be shared include all materials developed in projects funded under the RFA, including but not limited to, the following: mutant animals, preserved embryos and sperm, phenotypic and genetic data, phenotyping assays, instrumentation, and mutagenesis protocols. For this purpose, it is NIH’s opinion that dissemination of such data and materials via individual laboratories and Web sites is not sufficient, as it would force interested investigators to search several different data collections to make use of the results of this initiative. It is preferable that data, protocols, technologies, and biomaterials generated in grants funded under this RFA should be placed in

²⁵ <https://www.ncbi.nlm.nih.gov/pubmed/12690189>.

²⁶ Jeffrey W. Thomas, *Exceptional Circumstances to the Bayh-Dole Act: An NIH Perspective*, Address at the Federal Laboratory Consortium National Meeting (May 8, 2008).

²⁷ *Id.*

²⁸ Steven O. Moldin et al., *Trans-NIH Neuroscience Initiatives on Mouse Phenotyping and Mutagenesis*, 12 *Mammalian Genome* 575, 580 (2001).

²⁹ *Id.*

common, public repositories and databases that are widely accessible by investigators in the scientific community.³⁰

HD-99-007 contained similar language. Another, possibly related RFA, “Mouse Phenotyping: Development and Fertility Defects,” RFA-HD-01-020, contains the following DEC:

NIH has made a Determination of Exceptional Circumstances (DEC) to eliminate the potential for patents on new mutant strains that are generated by this project and on newly identified uses of existing mutant strains.³¹

DOE Energy Efficiency, Renewable Energy, and Advanced Energy Technologies

The Department of Energy (DOE) utilizes DEC’s in relation to contracts associated with energy efficiency, renewable energy, and advanced energy technologies. The DOE determined that it would better promote the policy objectives of the Bayh-Dole Act, which include promoting commercialization of inventions manufactured domestically, to require contractors to include U.S. Manufacturing Plans in their funding applications.³² The U.S. Manufacturing Plans are incorporated into funding agreements.³³ Under the DEC, if a contractor fails to honor its U.S. manufacturing obligations, it may be subject to remedies including forfeiture of rights to the subject inventions.³⁴

The DOE has used DEC’s in other contexts as well. A DOE contract with Savannah River Nuclear Solutions, LLC to operate the Savannah River Site contains a DEC clause that states as follows:

[T]he Contractor does not have a right to retain title to any exceptional circumstance subject inventions and agrees to assign to the Government the entire right, title, and interest, throughout the world, in and to any exceptional circumstance subject inventions.³⁵

“[E]xceptional circumstance subject inventions” are defined under the contract as inventions related to “uranium enrichment technology[,]” “storage and disposal of civilian

³⁰ <https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-99-007.html>.

³¹ <https://grants.nih.gov/grants/guide/rfa-files/RFA-HD-01-020.html>.

³² DOE, *Determination of Exceptional Circumstances under the Bayh-Dole Act for Energy Efficiency, Renewable Energy, and Advanced Energy Technologies*, September 9, 2013, available at

<https://www.energy.gov/sites/prod/files/2014/01/f6/DEC%20for%20Energy%20Efficiency%20Renewable%20Energy%20%26%20Advanced%20Energy.pdf>.

³³ *Id.*

³⁴ *Id.*

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<https://www.energy.gov/sites/prod/files/2019/09/f66/SRS-DE-AC09-08SR22470-SRNS-section-I.pdf>.

high-level nuclear waste and spent fuel technology[,]” and “national security technologies classified or sensitive under Section 148 of the Atomic Energy Act (42 U.S.C. 2168).”³⁶

NCATS BrIDGs

The NIH’s National Center for Advancing Translational Sciences (NCATS) utilizes DEC’s in relation to its Bridging Interventional Development Gaps (BrIDGs) program, which advances therapeutic candidates into clinical testing by generating preclinical data and creating clinical-grade material for use in Investigational New Drug (IND) applications.

While pre-existing intellectual property rights are retained by the owner, inventions created through BrIDGs participation may be subject to a DEC. As the program’s webpage states:

BrIDGs contractors or subcontractors are generally subject to a Determination of Exceptional Circumstances, through which their rights in subject inventions are assigned to the federal government.³⁷

NINDS Medicinal Chemistry for Neurotherapeutics Program

The National Institute of Neurological Disorders and Stroke (NINDS) proposed using a DEC for its Medicinal Chemistry for Neurotherapeutics Program, an initiative designed to “stimulate[] the development of new drugs for neurological diseases.”

The Request for Comments, which was incorporated into the solicitation,³⁸ modified the contractors’ right to elect title depending on the type of invention:

1) For Subject Inventions directed to analog compounds and their methods of use, the NINDS medicinal chemistry Contractors would be required to offer the first right of assignment to the Contributor. If the Contributor declines offer of assignment, then NINDS may dispose of the invention rights as NINDS determines would be in the best interests of the program and public health (e.g., allow Contractor to retain invention rights).

2) For Subject Inventions directed to the methods of manufacturing the analog compounds, the Contractor would retain all rights, but the DEC may require that

³⁶ *Id.*

³⁷ <https://ncats.nih.gov/bridgs/work/ip>; see also *Application Instructions* at 3, <https://ncats.nih.gov/sites/default/files/BrIDGs-app-instructions-2013.pdf>, (“Certain other contractors or subcontractors may be subject to a Determination of Exceptional Circumstances through which their rights in subject inventions may be assigned to the originating investigator institution.”).

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https://www.cov.com/-/media/files/corporate/publications/2013/01/hhs_proposes_to_amend_regulations_regarding_application_of_bayh-dole_act_and_data_rights.pdf.

the Contractor grant or agree to negotiate licenses so as to enable research use and commercialization of the compounds.³⁹

NCI Experimental Therapeutics Program (NExT)

The NCI has incorporated a DEC into a model Material Transfer Agreement (MTA) for the NExT program, an initiative designed to “bring improved therapies to patients with cancer by supporting the most promising new drug discovery and development projects.”

⁴⁰ Under the MTA:

Certain other NCI contractors or subcontractors may be subject to a Determination of Exceptional Circumstances (35 U.S.C. § 202(a)(ii)), through which their rights in inventions made using the Research Material may be assigned to the Government. Institution may then apply to NIH for a license to such inventions in accordance with 37 CFR Part 404.⁴¹

NCI PREVENT Clinical Preclinical Drug Development Program

The NCI also uses DEC with respect to the PREVENT program, an initiative designed to develop “cancer prevention interventions and biomarkers toward clinical applications.”

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The PREVENT program webpage notes that “[c]ertain . . . NCI contractors or subcontractors may be subject to a Determination of Exceptional Circumstances (35 U.S.C. § 202(a)(ii)), through which their rights in inventions made using the PREVENT Collaborator’s materials and/or data may be assigned to the Government.”

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) “Clinical Centers for the Osteoarthritis Initiative”

NIAMS’ “Clinical Centers for Osteoarthritis Initiative” was a “multi-center, longitudinal, prospective, population-based study of knee osteoarthritis (OA) to develop a public domain research resource.”⁴³

NIAMS issued a DEC with respect to the Initiative. It applied to “data, radiological images, DNA and biological specimens collected under the contract ‘to ensure [their] unrestricted availability.’”⁴⁴

³⁹ <https://grants.nih.gov/grants/guide/notice-files/NOT-NS-09-008.html>.

⁴⁰ <https://next.cancer.gov/about/mission.htm>.

⁴¹ https://next.cancer.gov/pipelineManagement/NEXT_MTA.pdf.

⁴² <https://prevention.cancer.gov/major-programs/prevent-cancer-preclinical>.

⁴³ <https://grants.nih.gov/grants/guide/notice-files/NOT-AR-01-009.html>.

⁴⁴ Mark L. Rohrbaugh, *Distribution of Data and Unique Material Resources Made with NIH Funding*, 11 J. of Com. Biotechnology 249, 258 (2005).

National Institute of Allergy and Infectious Diseases (NIAID) Therapies for Severe Viral Infections

NIAID has included DEC's in contracts related to programs designed to promote the development of therapies for severe viral infections, including the Antiviral Testing Program for *in vitro* screening, an *in vitro* testing program, an antiviral evaluation service, the Biodefense and Emerging Infectious Research Resources Repository (BEIR), preclinical research services, and clinical trials.⁴⁵

For all service contracts in this program which involved the use of third party material, NIAID included or proposed including a DEC stipulating that any inventions that use or incorporate the third party material were assigned to NIAID or "the provider as designated by NIAID."⁴⁶

Conclusion and Recommendations

The exceptional circumstances clause of the Bayh-Dole Act is an important legal authority that enables the federal government to assert ownership over federally-funded inventions where doing so would better promote the policy objectives of the Act, which include "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[.]"⁴⁷

With the rapidly escalating coronavirus pandemic threatening public health and our nation's fiscal future, the country undoubtedly faces exceptional circumstances, and policymakers need to ensure that federally-funded coronavirus tests, treatments, and vaccines are made available as rapidly and widely as possible, and undertake the following measures:

- The federal government should undertake the administrative measures necessary to issue a Determination of Exceptional Circumstances with respect to coronavirus funding agreements;
- Congress should require, in appropriations legislation, that agencies incorporate Determination of Exceptional Circumstances into funding agreements that award coronavirus stimulus funds; and
- Congress should request the Government Accountability Office to provide a report to Congress on the use of past uses of Determinations of Exceptional Circumstances by all federal agencies.

⁴⁵ Heather Greenstone et al., *NIAID Resources for Developing New Therapies for Severe Viral Infections*, 78 *Antiviral Research* 51 (2007).

⁴⁶ *Id.* at 55.

⁴⁷ 35 U.S.C. § 200.

