2022-2248

In The
United States Court of Appeals
For The Federal Circuit

UNIVERSITY OF SOUTH FLORIDA BOARD OF TRUSTEES,

Plaintiff – Appellant,

v.

UNITED STATES,

Defendant – Appellee.

APPEAL FROM THE UNITED STATES COURT OF FEDERAL CLAIMS IN NO. 1:15-cv-01549-PEC, JUDGE PATRICIA E. CAMPBELL-SMITH.

APPELLANT'S PETITION FOR REHEARING OR REHEARING *EN BANC*

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2022-2248

Short Case Caption University of South Florida Board of Trustees v. United States

Filing Party/Entity University of South Florida Board of Trustees

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 09/27/2022

Signature: /s/ Steven Kelber

Name: Steven Kelber

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☑ None/Not Applicable
University of South Florida Board of Trustees		

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☐ Additional pages attached

The Kelber Laws Group, LLC	Steven Kelber	
Greenberg & Traurig	Jerry Stouck	

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

☑ None/Not Applicable ☐ Additional pages attached

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

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STATEMENT OF COUNSEL, RULE 35(b)

Based on my professional judgment, I believe the Panel decision is contrary to the following decision(s) of the Supreme Court of the United States or the precedent(s) of this court: *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc*., 563 U.S. 776 (2011) *and Campbell Plastics Engineering & MFG., Inc. v. Brownlee*, 389 F.3d 1243 (Fed. Cir. 2004).

Based on my professional judgment, I believe this appeal requires an answer to the following precedent-setting questions of exceptional importance:

1. May a Government License, 35 U.S.C. § 202(c)(4), in an invention *ever* be granted where no government funds of any type were ever provided in the making of the invention?
2. Can an invention first reduced to practice months prior to any federal funding agreement be treated as a "subject invention" as defined in 35 U.S.C. § 201(e) for the purposes of awarding the Government a license pursuant to 35 U.S.C. § 202(c)(4)?

/s/ Steven B. Kelber
Steven B. Kelber
ATTORNEY OF RECORD FOR THE
UNIVERSITY OF SOUTH
FLORIDA BOARD OF TRUSTEES

ARGUMENT

POINTS OF FACT AND LAW MISAPPREHENDED BY THE PANEL DECISION

I. THE PANEL DECISION RESTS ON NON-EXISTENT FACTS - USF DID NOT RECEIVE MONEY FROM MAYO AT ANY TIME FOR THE COSTS INCURRED IN INVENTING AND REDUCING TO PRACTICE THE MICE OF THE '094 PATENT

The Panel's decision affirms the decision of the Court of Claims after rejecting its analysis and facts, finding that the Government is entitled to a license in the '094 Patent even though no government funds were ever used in making the invention of that patent. At no time did USF ever receive funds under any Government funding agreement for conceiving, reducing to practice or any other effort with respect to the invention of that patent. The Panel's decision rests on non-existent, made-up facts – there is simply no evidence whatsoever that USF ***ever*** received funds to make that invention.

At the core of the Panel Decision of February 9, 2024, is the assertion, at page 13, that "USF in fact accepted payment from Mayo, using funds from the NIH grant, for the April 1997 work at issue. (Referring to work to reduce the mice of the '094 Patent to practice.) *See, e.g., Claims Court Decision, 162 Fed. Cl. at 64.* On appeal, USF presents no substantial challenge to any of those findings of fact." The Panel is completely wrong – that assertion is not supported by any

evidence of any kind, testamentary or documentary, and is **contrary to the evidence of record**.

The record demonstrates that funds received by USF from Mayo under their funding agreement were for work that had nothing to do with the mice of the '094 Patent. Testimony from the Government's own expert, Steven Snyder, as well as fact witnesses including Karen Duff, David Morgan and Marcia Gordon all confirm that USF was not and could not have been paid with NIH funds for the work involved in reducing the mice to practice.

In 1995, a Federal Grant application advanced by John Hardy, then a professor at USF, was submitted to the National Institute on Aging. That grant application described five different projects, all related to developing methods of treating Alzheimer's disease. Two of the projects are relevant – Project IV, directed to the development of transgenic mice, naming Karen Duff as leader; and Project V, directed to the study of rodent brains employing new immunostaining procedures, naming Marcia Gordon and David Morgan as co-leaders. Duff, Gordon and Morgan were all faculty at USF together with Hardy when the Grant Application was submitted. Those Projects were clearly delineated in the Grant Application. The Grant Application appears at Appx1793 – 2050, with Project IV at Appx1971-1999 and Project V at Appx2000 – 2044. There is no overlap between the work to be done described in Project IV and that described in Project V.

Work on the development of the transgenic mice began before August 1996, well before the award of the Grant Application to Mayo, where John Hardy had moved following submission of that Grant Application. That work on the mice *was done* at USF, and *paid for by* USF. The transgenic mice were developed and monitored by USF personnel – it takes months after birth for the transgenic mice to develop and exhibit properties referred to in the '094 Patent as "accelerated exhibition of Alzheimer's disease." An actual reduction to practice of those mice was confirmed in writing on April 25, 1997, by Karen Duff, who asked USF to proceed with patenting those mice.

At no time before the conception of the transgenic mice, during the creation of the transgenic mice and up to and through the actual reduction to practice of the mice, or at any time thereafter, did Mayo or any other party pay, or offer to pay, USF for the costs incurred in inventing the subject matter of the '094 Patent. There is simply no evidence that anyone other than USF paid for any costs or actions associated with the mice themselves, their actual reduction to practice or the '094 Patent. The patented mice were so valuable that USF licensed them to third parties long before the patent on the mice had issued – before creation of any "funding agreement" i.e., the "Consortium Agreement" between Mayo and USF, was signed. That Agreement was effective September 1, 1997, many months *after* the mice were reduced to practice and made the subject of a patent application.

No party at any time presented any evidence that Mayo paid for, or reimbursed USF's costs and expenses associated with, the transgenic mice. The Panel simply made that up. The Panel concluded that "USF in fact accepted payment from Mayo, using funds from the NIH grant, for the April 1997 work at issue." Decision, 14. While the Panel asserts "USF presents no substantial challenge to any of those findings of fact" Panel decision, p. 13, ***no such findings were ever advanced or even suggested by any party.*** USF could not deny what had not been asserted. Similarly, the Panel decision asserts wrongly that "[W]e accept that USF received money from Mayo – including money for the April 1997 work – when the November 1997 express subcontract was in place and not earlier." p. 14. There is no evidence of record or any factual basis for this proposition, and it is flatly wrong. There is simply NO evidence that USF received money from Mayo for the April 1997 work at ANY TIME. Indeed, had USF received money under the Consortium Agreement effective September 1, 1997, for work outside of the specific tasks set forth in the Agreement, it would have had to be provided for expressly in the subcontract – it was not. It is unclear what the Panel concluded USF was paid for under the Consortium Agreement. The funds that were provided under that subcontract were for work on Project V, the immunohistochemistry work. THAT work continued in Year 2, unlike the work on the mice of Project IV,

which ended with the reduction to practice before May of 1997, months in advance of the Consortium Agreement.

In fact, the Consortium Agreement the Panel wrongly concludes was used to repay USF for its work on the transgenic mice is expressly limited to funds for **year 2** of the NIA Grant 14633, expressed as AG 14633-2. The express language of that subcontract is limited to funds for work in year 2 of the Grant – something confirmed by Dr. Duff, see Trial Transcript (TT) p. 72, Day 1 of the Trial. David Morgan also testified that the funds he sought by way of an advance, and provided for under the Subcontract, were limited to funds for work on Year 2. TT, p. 504, l. 14 – 506, l. 10. The mice of the '094 Patent were reduced to practice in April 1997, months prior to year 2 – neither Mayo nor USF could use funds set aside for year 2 of Grant 14633 to pay the expenses incurred in reducing the mice to practice, all of which was completed well before year 2 of the Grant.

What those funds could have been used for, and undoubtedly were used for, was to pay for the costs of Project V of the Grant – which had nothing to do with the transgenic mice. This was confirmed by Karen Duff, TT p. 102, who testified that Project IV of the Grant did not pay for the development of the transgenic mice. TT p. 101, l. 7 – 20. David Morgan testified that he would have requested an advance for year 2 of the Grant, and it would have been for Project V, TT 506, l. 2 – l. 10. Project V had nothing to do with the transgenic mice of the '094 Patent.

See, e.g., David Morgan at TT p. 514, l. 5 – 8 and Marcia Gordon's testimony, TT page 529, l. 4 – 15.

The Panel's blatantly wrong assertion that Mayo paid USF for the work on the transgenic mice out of government funds made available pursuant to the Consortium Agreement is contrary to the very agreement itself. The funding agreement, Appx1265-1270, requires invoices to Mayo before USF can be paid, in order to identify work done and costs incurred which may only arise from work beginning after September 1, 1997, Article 4 Appx1268. No such invoices are in the trial record because no such invoices exist. It is important to keep in mind that aspects of Alzheimer's disease research at USF had other sources of funding. Indeed, Dr. Gordon testified that her work before and after the Grant was awarded to Mayo was funded from a variety of other sources. TT 506, l. 14 – 20 and 563, l. 2 – 10.

Bluntly – there is no evidence, no record, no document and no testimony of any kind that supports, in any way, the fiction asserted and relied on by the Panel that USF received money from Mayo after September 1, 1997, to pay for USF's costs or expenses incurred developing the mice of the '094 Patent. It simply never happened. Because that non-existent "fact" is the linchpin of the Panel decision, the matter should be reheard. **The Panel made a fundamental error of law by**

awarding the Government a license even though no government funds ever supported work on the mice of the '094 Patent.

The Panel did not refer to or identify whatever source of information it was relying on for its erroneous assertion that Mayo paid USF for the work on the mice at any time. There is no witness or document that supports that misstatement. No one ever offered any testimony as to what Mayo paid for under the 1997 funding agreement. No one from Mayo ever testified at trial. No documents or evidence from Mayo were ever introduced at trial. No one from USF ever testified that USF received money from Mayo under the 1997 Consortium Agreement for work done months earlier. The subcontract between Mayo and USF at Appx1265-1270 is very clear – to receive funds, USF would have to have conducted work within the scope of the grant for year 2, track its costs, and present an invoice to Mayo for work done only *after the contract began.* See Article 4, Appx1266. None of that happened, which is why no evidence of any of that is in the record.

The only witness offering any testimony with respect to payments under the subcontract from Mayo to USF was Stephen Snyder, former head of NIA. Snyder testified that money under the subcontract would have been paid to USF for work ***done after the subcontract began*** provided that work was still viable. As the work specific to Project IV, Duff's project, had already been completed, there would be

no further funding with respect to it – in Snyder's own words, "it was no longer viable." Appx2607-2608

USF would not have turned to Mayo for retroactive payment of funding concerning the reduction to practice of the mice. By the time Mayo and USF entered into their "funding agreement" USF was actively licensing the mice to third parties. USF was receiving payments from research institutions, and six figure license fee payments from corporate licensees. Why, at that point in time, would USF then turn to Mayo and ask it for compensation for the work involved in reducing the mice to practice up to 18 months earlier? It would not and did not.

The Panel observed that its basis for decision was not one advanced by either party, or in any way considered by the Claims Court, but that it was "accepting USF's position on the timing-of-payment issue." Panel at 14. NO IT DID NOT. USF never offered any argument, evidence or opinion that it received money from Mayo for its efforts in reducing the mice to practice. USF had no need to take a position 'on the timing-of-payment issue' – establishing a basis for entitlement to a license was the burden of the Government, not USF. The Government did not support that burden.

The Panel made the decision to reject the opinion from U.S. Court of Federal Claims. The Panel was correct in that respect – as noted, there was simply no evidence to support the trial court's determination that there was an implied-in-fact

agreement between USF and Mayo regarding the reduction to practice of the mice.

The Panel then 'invented' findings of fact that are simply wrong. The Panel's "determination" that Mayo repaid USF's cost of reducing the mice of the '094 Patent through the subcontract is, as noted above, contrary to the testimony of Steven Snyder, Karen Duff, David Morgon and Marcia Gordon. All four testified that the money for which an advance *was requested* was for the second year of Project V – addressing immunohistochemistry but having nothing to do with the mice of the '094 Patent. The mice were reduced to practice long before Mayo and USF ever arrived at a "funding agreement" and long before any opportunity for Mayo to "repay" USF for its costs could ever arise. Given that the Panel decision awards a Bayh-Dole license to the Government based on facts that are wrong and contrary to the record, when in fact no government funds were ever used to support the work on the mice of the '094 Patent, reconsideration by the Panel or *en banc* is requested.

II. THE PANEL'S DECISION IS CONTRARY TO PRECEDENT

The Panel's decision acknowledges that there was no funding agreement, no written express agreement and no implied-in-fact agreement, up to and through the time the mice of the '094 Patent were reduced to practice. It asserts instead that Mayo and USF agreed, *before the mice of the '094 Patent were reduced to practice*, that Mayo would repay USF's costs incurred in making that invention so

that the Government could nonetheless retroactively "claw back" a license under the patent directed to that invention. Not only is the Panel's "resolution" contrary to the facts, but it is also contrary to law and precedent.

The Panel expressly found that the term "subject invention" as set forth in the Bayh-Dole Act, 25 U.S.C. 201(e), is not limited "temporally". Panel, p. 17. That is, even if there is no extant funding agreement at the time an invention is reduced to practice, that invention may subsequently BECOME a subject invention if a funding agreement is later arrived at and leads to later payment. That is contrary to the plain language of the statute, which specifically indicates a subject invention is one made "in the performance of work under a funding agreement." The Panel Decision alters the language of the Statute, changing the definition of "subject invention" in 35 U.S.C. 201(e) to read "a subject invention means any invention of a contactor, conceived or first actually reduced to practice *before or* during the performance of work related to a funding agreement." That is contrary to law.

At the time the mice of the '094 Patent were reduced to practice, USF had no agreement with Mayo, and USF was not a contractor under *any* definition of the terms of the Bayh-Dole Act. At the time the mice of the '094 Patent were reduced to practice, no individual at USF was working with Mayo, and no one at USF was acting pursuant to any agreement of any type with Mayo. The Panel's decision to

make a wholesale change in the law, without briefing or factual basis, is simply beyond jurisprudence.

Not only does the Panel mangle the plain language of the statute, indicating that work done months before any funding agreement was ever considered may nonetheless somehow become a "subject invention" over a year later in time, it runs contrary to case law. In *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc*, 563 U.S. 776 (2011) the Supreme Court accepted the plain language meaning of the words "made in the performance of work under a funding agreement." The Supreme Court specifically observed that the work in question was conducted while there was a federally funded agreement in place at Stanford, and THAT work, not earlier work, conferred a license on the Government in the work then actually reduced to practice. ("Some of Stanford's research related to the HIV measurement technique was funded by the National Institutes of Health (NIH), thereby subjecting the invention to the Bayh–Dole Act." 131 S. Ct. at 2193).

The District Court in *Madey v. Duke University*, 413 F. Supp. 601, 612 (N.C. 2006), *affd. in part*, 307 F.3d 1351(Fed. Cir. 2002) found a government license to exist only as to inventions made while there was a funding agreement in place, on identical reasoning. (Pursuant to this provision, the Government keeps a "Government License" in subject inventions that result from federally sponsored

research.). The mice of the '094 Patent – without any question – DID NOT result from efforts supported by federally sponsored research. In *Campbell Plastics Engineering & MFG., Inc v Brownlee,* 389 F. 3d 1243, 1247 (Fed. Cir. 2004) this Court again enforced the same "plain language" understanding that to be a subject invention, the work in question must be performed *pursuant to* a federally funded agreement. ("the Act allows nonprofit organizations and small business firms to elect to retain title to any invention by the contractor developed pursuant to a government contract. For purposes of the Act, Congress has termed these inventions "subject inventions.").

In *Collins v. Western Digital Technologies, Inc.,* 2011 WL 3848631*3 (ED Tx 2011) the Court also demonstrated it understood the term "subject invention" to be that "developed using research funded by multiple Navy research contracts." Quite simply, in every case undersigned counsel was able to identify, the term "subject invention" was used to refer to inventions made after a funding agreement had been executed.

In *Trinity Industries v. Road Systems, Inc.,* 235 F.Supp.2d 536, 539 (ED Tx 2002) the District Court concluded that an invention reduced to practice *after the contractor began receiving funds* pursuant to a federal funding agreement, would create a license in favor of the Government – if made before that funding agreement began – no license would be created. In case after case, the Courts have

concluded that AFTER a "funding agreement" is entered into, the conception or reduction to practice of an invention may give rise to a license in favor of the Government; if the invention is reduced to practice before the funding agreement is executed – there is no license in favor of the Government. This is the first case, in any Federal Court anywhere, which has found a license pursuant to the Bayh Dole Act to lie in favor of the Government when the invention was first reduced to practice long before any "funding agreement" existed.

The Panel's decision, altering the statutory element "subject invention" to apply to inventions *made in the absence of a funding agreement* is contrary to law and precedent. In formulating an entirely new definition for the meaning of the statutory provision "made in the performance of work under a funding agreement" the Panel violates essential rules of statutory construction and creates uncertainty and vagueness in this critical funding provision.

The Panel decision posits, falsely, that USF received money from Mayo for USF's work on the mice of the '094 Patent long AFTER the inventive mice were reduced to practice. It then concludes wrongly that because Mayo used government funds to pay USF that money later on, the Government can, long after that payment was made, acquire a license in the previously made invention. The facts asserted by the Panel decision are **wrong** – no such money was ever paid by Mayo to USF for that work at any time. Even if they were correct, however, that does not

support the Court's alteration of the statute. As noted in *Stanford* and the other cases cited, you cannot step outside of time, and base rights on developments *after* the actual reduction to practice of an invention. Either the actions giving rise to the license occurred at the time of performance under the Federal grant – or they did not. The actions involved in reducing the mice of the '094 Patent to practice did not.

USF further notes that the Panel's position would render the phrase "in the performance of work" unnecessary and superfluous. Petitioner submits this Court should honor the long history of "reluctan[ce] to treat statutory terms as surplusage" *Duncan v. Walker*, 533 U.S. 167, 174, (2001) and adopt a less strained interpretation of "in the performance of work under a funding agreement" that recognizes, as the Supreme Court did in *Stanford,* that subject inventions are those conceived or actually reduced to practice during the funding agreement, not at some point in time months earlier.

The Supreme Court expressly rejected a statutory construction under the Bayh-Dole Act shockingly similar to that adopted by the Panel here. In *Stanford,* the Court rejected a construction of the Bayh-Dole Act advanced that would confer title outside the period "of performance under the contract" conveying federal funding. The Supreme Court noted:

> Under Stanford's construction of the Act, title to one of its employee's inventions could vest in the University even if the invention was conceived before the inventor became a University employee, so long as the invention's reduction to practice was supported by federal funding.

The Supreme Court rejected such a reading of the statute, observing the use of such unusual terms would be truly surprising.

> We are confident that if Congress had intended such a sea change in intellectual property rights it would have said so clearly—not obliquely through an ambiguous definition of "subject invention" and an idiosyncratic use of the word "retain." Cf. *Whitman v. American Trucking Assns., Inc.,* 531 U.S. 457, 468 (2001) ("Congress ... does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions").

Rehearing or rehearing *en banc*, to provide an opportunity to resolve this matter in the fashion required by law and statute, is respectfully requested.

Respectfully submitted,

/s/ Steven B. Kelber

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CERTIFICATE OF FILING AND SERVICE

I hereby certify that on this 20th day of March, 2024, I caused this Appellant's Petition for Rehearing and Rehearing *en banc* to be filed electronically with the Clerk of the Court using the CM/ECF System, which will send notice of such filing to the following registered CM/ECF users:

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Counsel for Appellee

/s/ Steven B. Kelber
Counsel for Appellant

CERTIFICATE OF COMPLIANCE

1. This petition complies with type-volume limits because, excluding the parts of the document exempted by Fed. R. App. R. 32(f) (cover page, disclosure statement, table of contents, table of citations, statement regarding oral argument, signature block, certificates of counsel, addendum, attachments):

   [X] this petition contains [*3,803*] words.

   [ ] this petition uses a monospaced type and contains [*state the number of*] lines of text.

2. This petition complies with the typeface and type style requirements because:

   [X] this petition has been prepared in a proportionally spaced typeface using [*Microsoft Word 365*] in [*14pt Times New Roman*]; *or*

   [ ] this petition has been prepared in a monospaced typeface using [*state name and version of word processing program*] with [*state number of characters per inch and name of type style*].

Dated: March 20, 2024

/s/ Steven B. Kelber
Counsel for Appellant

ADDENDUM

United States Court of Appeals for the Federal Circuit

UNIVERSITY OF SOUTH FLORIDA BOARD OF TRUSTEES,
Plaintiff-Appellant

v.

UNITED STATES,
Defendant-Appellee

2022-2248

Appeal from the United States Court of Federal Claims in No. 1:15-cv-01549-PEC, Judge Patricia E. Campbell-Smith.

Decided: February 9, 2024

STEVEN B. KELBER, The Kelber Law Group, Bethesda, MD, argued for plaintiff-appellant. Also represented by JERRY STOUCK, North Bethesda, MD.

WALTER W. BROWN, Commercial Litigation Branch, Civil Division, United States Department of Justice, Washington, DC, argued for defendant-appellee. Also represented by BRIAN M. BOYNTON, GARY LEE HAUSKEN, KAVYASRI NAGUMOTU, CARRIE ROSATO.

Before REYNA, TARANTO, and STOLL, *Circuit Judges*.

TARANTO, *Circuit Judge*.

University of South Florida Board of Trustees (USF) owns now-expired United States Patent No. 5,898,094, which was issued in 1999 and is titled "Transgenic Mice Expressing APPK670N,M671L and a Mutant Presenilin Transgenes." In 2015, USF sued the United States in the Court of Federal Claims (Claims Court) under 28 U.S.C. § 1498(a), alleging that the United States was liable for infringement of the '094 patent because, as is undisputed before us, The Jackson Laboratory, with the government's authorization and consent, had been producing and using mice covered by the patent for the government. As a defense, the government argued that the United States had a license to practice the patent, and have the patent practiced on its behalf, under 35 U.S.C. § 202(c)(4), a provision of the Bayh-Dole Act, Pub. L. No. 96-517, § 6(a), 94 Stat. 3019–28 (1980) (codified as amended at 35 U.S.C. §§ 200–12), which addresses patent rights in work funded by the federal government. After summary-judgment proceedings and a trial, the Claims Court agreed with the government and entered final judgment of noninfringement. *University of South Florida, Board of Trustees v. United States*, 162 Fed. Cl. 59 (2022) (*Claims Court Decision*).

USF timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(3). There is no dispute that the judgment must be affirmed if § 202(c)(4) applies. We conclude that the provision does apply. We therefore affirm.

I

A

The '094 patent describes and claims doubly transgenic mice with accelerated pathology for Alzheimer's Disease, produced by the mice's expression of both a mutant Swedish amyloid precursor protein transgene and a

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mutant presenilin transgene. *See* '094 patent, Abstract and col. 14, line 26 through col. 16, line 59. Claim 1 states:

> 1. A transgenic mouse with enhanced Alzheimer's Disease related amyloid accumulation in its brain produced by:
>
> producing an F_1 generation mouse by crossing a first transgenic mouse whose genome comprises at least one transgene comprising a DNA sequence encoding mutant presenilin M146L operably linked to a promoter with a second transgenic mouse whose genome comprises at least one transgene comprising a DNA sequence encoding APP K670N,M671L operably linked to a promoter, wherein the first transgenic mouse expresses the DNA sequence encoding the mutant presenilin and wherein the second transgenic mouse expresses the DNA sequence encoding the APP; and
>
> selecting from the offspring of the cross, those transgenic mice whose genome comprises at least one DNA sequence encoding mutant presenilin M146L operably linked to a promoter and at least one transgene comprising a DNA sequence encoding APP K670N,M671L operably linked to a promoter, and identifying an F_1 mouse which express both transgenes such that the F_1 mouse develops *accelerated deposition of Aβ* in its brain as compared to non-transgenic mice or either parental mouse.

Id., col. 14, lines 26–49 (emphasis added).

The application that issued as the '094 patent was filed on July 30, 1997, but it claims priority to a provisional application filed on October 21, 1996. Drs. Karen Duff and

John Hardy are the inventors named on the '094 patent. In October 1996, just before the filing of the October 21, 1996 provisional application, the two inventors assigned to USF the patent rights for inventions described in that provisional application.

B

The invention of the '094 patent involves doubly transgenic mice having a particular property of developing an identified symptom of Alzheimer's Disease on an "accelerated" basis. The invention was conceived by Drs. Duff and Hardy while both were professors employed by USF. J.A. 3762. At USF, Drs. Duff and Hardy worked with Dr. David Morgan and Dr. Marcia Gordon, both of whom were also professors at USF. The role of the latter two scientists, as relevant here, was to conduct (with assistance within their laboratory) the tissue analysis needed to determine, for mice resulting from two gene modifications, when in their aging process the mice developed the claimed symptom.

The first litter of mice expressing both of the two transgenes at issue—a mutant Swedish amyloid precursor protein transgene and a mutant presenilin transgene—was born at USF on August 21, 1996. J.A. 631–32, 3890–91. But time was needed to determine if those mice would actually develop Alzheimer's Disease pathology at an accelerated rate.

During that period of mouse aging, Dr. Hardy changed his employer from USF to Mayo, and Dr. Duff did the same, in December 1996, shortly after Dr. Hardy. The doubly transgenic mice remained at USF after Drs. Duff and Hardy moved to Mayo. While at Mayo, Dr. Duff continued to oversee the doubly transgenic mouse project. J.A. 152–54. The day-to-day work of caring for the mice, however, became the responsibility of Dr. Gordon in Dr. Morgan's laboratory. J.A. 529. Additionally, Dr. Gordon, at her USF lab, performed immunohistochemistry, or tissue-examination, work on the brains of sacrificed doubly transgenic

mice to identify whether and when the mice developed Alzheimer's Disease pathology. J.A. 152–54, 148–50.

An actual reduction to practice of the invention claimed the '094 patent required construction of an embodiment and recognition that the embodiment worked for its intended purpose. *See Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998); *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 594–95 (Fed. Cir. 1997); *Hahn v. Wong*, 892 F.2d 1028, 1032 (Fed. Cir. 1989); *Scott v. Finney*, 34 F.3d 1058, 1062 (Fed. Cir. 1994); *Knorr v. Pearson*, 671 F.2d 1368, 1375 (CCPA 1982). Here, the first document recording the actual reduction to practice of the doubly transgenic mice—the fact and recognition of the sooner-than-otherwise development of the specified Alzheimer's Disease pathology in those mice—is a facsimile sent on April 25, 1997, by Dr. Duff, then at Mayo, to William Coppola, at USF's office for technology transfer. J.A. 1271–74, 142–45, 148. The parties accept, for present purposes, that the first actual reduction to practice occurred shortly before that promptly sent communication. *Claims Court Decision*, 162 Fed. Cl. at 64 ("The parties agree, and the evidence demonstrates, that the invention described in the '094 patent was first reduced to practice in April 1997."). We therefore refer to the first actual reduction to practice as occurring in April 1997.

Dr. Duff marked the facsimile "urgent" because "[t]his was the first time we [the researchers] had seen . . . this pathology developing so rapidly in these mice." J.A. 148. To show the pathology developing, the facsimile included two figures demonstrating that the doubly transgenic mice had amyloid plaques, which play a role in Alzheimer's Disease, at an age lower than the age at which previously identified mice had such plaques. J.A. 1272–74, 143–44. Dr. Duff noted on the figures in the facsimile: "N.B. [nota bene] work performed by D[avid] Morgan at USF, in collaboration." J.A. 1273, 4233–34. The tissue analysis (immunohistochemistry testing) that identified the premature

development of amyloid plaques was performed within the Morgan-Gordon laboratory at USF. J.A. 151–54, 1273, 4233–34; *see* USF's Opening Br. at 6–7, 21.

In July 1997, Dr. Duff, along with Dr. Hardy, Dr. Morgan, Dr. Gordon, and others, submitted a paper to *Nature Medicine*, describing the doubly transgenic mice and their accelerated development of the Alzheimer's Disease-related property. The paper was accepted in November 1997 and published in January 1998. Leigh Holcomb et al., *Accelerated Alzheimer-type phenotype in transgenic mice carrying both mutant* amyloid precursor protein *and* presenilin 1 *transgenes*, 4 Nature Medicine 97 (1998) (*Nature Medicine Article*). The article notes that "[t]his work was supported by the Mayo/USF Program Project on the presenilins," *Nature Medicine Article*, at 100, citing, though with a typographical error, the government grant described next.

C

In September 1995, Dr. Hardy, while still employed by USF, submitted a grant application to the National Institute of Aging, one of the institutes within the National Institutes of Health (NIH). The application, titled "The Role of the Presenilins in Alzheimer's Disease," proposed "five[] mutually interlinking projects aimed at elucidating the role of the presenilins in Alzheimer's [D]isease." J.A. 1793, 1795; *see* J.A. 1793–2044. Key personnel on the project, as stated in the grant application, included Dr. Hardy, Dr. Duff, Dr. Morgan, and Dr. Gordon, then all employed by USF. J.A. 1795, 2001–04 (addressing tissue-analysis work involving presenilins). The proposed period of government support ran from July 1, 1996, to June 30, 2001. J.A. 1793.

The scientists' already-begun research continued during the year that consideration of the grant application was underway. Just as the 1996 fiscal year was ending, NIH awarded the applied-for grant, which had a project start date of September 30, 1996. J.A. 3237; *see also* J.A. 2089,

3235–44. The findings and record before us make clear that the grant-covered project included the specific doubly transgenic mice that were the subject of what became the '094 patent (for which the provisional patent application was in preparation, J.A. 1162–63). *See* J.A. 2631–36, 2645–50 (Stephen Snyder, the relevant NIH administrator, testifying that the creation and study of the doubly transgenic mice expressing both a mutant Swedish amyloid precursor protein transgene and a mutant presenilin transgene were within the program project grant); *see also* J.A. 4080. Just before the award was made, the grantee designated in the application was changed from USF to Mayo, to which Dr. Hardy was in process of switching his employment. J.A. 3237; *see also* J.A. 2089. The grant therefore was made to Mayo, and funds from the NIH grant were available to Mayo as of October 1, 1996. J.A. 2603–04.

Because Mayo was the grantee, but some grant-covered work was to take place at USF, government policies implementing the Bayh-Dole Act required that Mayo and USF would in due course enter into a subcontract with each other in order for grant money received by Mayo to be paid to USF for the grant-covered work of individuals remaining there, such as Drs. Morgan and Gordon. *See* J.A. 2607–11 (NIH official Stephen Snyder); J.A. 567 (Dr. Morgan); *see also* U.S. Department of Health and Human Services, *Revised NIH Grant Policies and Procedures*, 14 NIH Guide for Grants and Contracts, No. 7, June 21, 1985, at 23 (attached document *4820—Establishing and Operating Consortium Grants*, at 2–3) (*NIH Grant Policies*).

In November 1997, more than a year after the NIH grant was awarded, Mayo and USF executed a written subcontract ("Consortium Agreement"), J.A. 1265–70, which states that the agreement was executed to comply with the just cited NIH Guidelines, J.A. 1265. The November 1997 agreement states that the start of its "effective period"—when its obligations took effect—was September 1, 1997.

J.A. 1266. And it expressly provides for treatment of patents and inventions in accordance with the Bayh-Dole Act (and implementing regulations, 45 C.F.R. chs. VI, VIII (1997)), thus supplying USF's agreement to the Act's government-license provision. J.A. 1268.

II

In the present action by USF, the Claims Court granted judgment for the government on the ground that it had a license, under the Bayh-Dole Act, 35 U.S.C. § 202(c)(4), to have The Jackson Laboratory practice the patent by creating and using patent-covered mice (with the two transgenes and accelerated plaque development required by the '094 patent). As relevant here, it is not disputed that The Jackson Laboratory was so practicing the patent and that it was doing so for the government and with the government's authorization and consent. The dispute that is before us is whether the invention was a "subject invention" within § 202(c)(4), which gives the government a license (to practice or have practiced for it) certain federally funded inventions.

A

Before 1980, federal agencies followed a variety of policies, implemented in provisions of grants or contracts for the furnishing of government funding for research, to address the disposition of patent rights in inventions resulting from the government-funded research. *See*, *e.g.*, H.R. Rep. No. 96-1307, pt. 1, at 3, 5 (1980); S. Rep. No. 96-480, at 2–3 (1979); *Technical Development Corp. v. United States*, 597 F.2d 733, 745–46 (Ct. Cl. 1979); *Mine Safety Appliances Co. v. United States*, 364 F.2d 385, 387–93 (Ct. Cl. 1966). Some of the government patent policies required government-fund recipients to allow the government to own these patent rights. *See, e.g.*, S. Rep. No. 96-480, at 2 (1979). In the Bayh-Dole Act, with a particular focus on government-funded research by universities and small businesses, Congress sought to reduce the disuniformity of

government policies and also to strengthen the patent rights of government-fund recipients, under conditions that protected government interests, in order to incentivize commercial development of patentable inventions into useful products. *See* H.R. Rep. No. 96-1307, pt. 1, at 3; S. REP. NO. 96-480, at 2–3, 15–30. The Act itself declares its "policy and objective." 35 U.S.C. § 200. The Supreme Court noted key purposes: "In 1980, Congress passed the Bayh-Dole Act to 'promote the utilization of inventions arising from federally supported research,' 'promote collaboration between commercial concerns and nonprofit organizations,' and 'ensure that the Government obtains sufficient rights in federally supported inventions.'" *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc.*, 563 U.S. 776, 782 (2011) (quoting 35 U.S.C. § 200) (*Stanford v. Roche*).

"To achieve these aims, the Act allocates rights in federally funded 'subject invention[s]' between the Federal Government and federal contractors." *Id.* (alteration by *Stanford v. Roche* Court) (quoting § 201(e)). The Act "provides that contractors may 'elect to retain title to any subject invention.'" *Id.* (quoting § 202(a)). A "contractor" is "any person, small business firm, or nonprofit organization that is a party to a funding agreement." § 201(c). A "funding agreement" is

> any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government. Such term includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as herein defined.

§ 201(b). And an "invention" includes "any invention or discovery which is or may be patentable or otherwise protectable under this title," and a "subject invention" is "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement." § 201(d), (e).[1]

In light of all of those definitions set out, the key provision of the Bayh-Dole Act for this case states:

> (c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following: . . .
>
> (4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world[.]

§ 202(c)(4).

B

In this case, on the § 202(c)(4) issue in dispute before us, the Claims Court, before trial, denied USF's motion for summary judgment that § 202(c)(4) was inapplicable. *University of South Florida, Board of Trustees v. United States*, 146 Fed. Cl. 274, 285–89 (2019) (*Summary Judgment Ruling*). The Claims Court subsequently denied USF's motion in limine to exclude testimony of Drs. Gordon and Morgan on that issue. *University of South Florida, Board of Trustees v. United States*, 154 Fed. Cl. 145, 147–48 (2021). The Claims Court then held a trial, which addressed several

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[1] The definitions of "invention" and "subject invention" also address plant varieties that may be protected by the Plant Variety Protection Act, 7 U.S.C. § 2321 *et seq*. That language is not applicable here.

issues, including the license issue. After trial, the Claims Court determined that § 202(c)(4) applied, giving the government a license, and on that basis the court entered judgment for the government. *Claims Court Decision*, 162 Fed. Cl. at 60.

The Claims Court made findings of fact confirming the events and actions described *supra*. *See id.* at 60–63. The Claims Court also described certain documents indicating that USF set up internal accounts associated with the NIH grant project and expected money from that grant partially to fund at least Dr. Gordon's salary. *Id.* at 62–63; *see*, *e.g.*, J.A. 2050–58, 2086, 3860. Relatedly, the Claims Court recited testimony from Dr. Morgan and Dr. Gordon about when USF actually received grant money, which included testimony about the difficulty of recalling precisely what occurred two decades earlier and testimony about the system of USF "'underwriting'" salary and other expenses and getting reimbursed for the "'advance'" once grant money covering the earlier work eventually arrived. *Claims Court Decision*, 162 Fed. Cl. at 62–63; *see*, *e.g.*, J.A. 521–26, 545–54, 565–69, 592–98 (Dr. Morgan); J.A. 623–29 (Dr. Gordon).

With respect to USF's receipt of grant money from Mayo, the Claims Court clearly found that Mayo "paid for the work done by Dr. Gordon at USF with the NIH grant funds," including (what is crucial here) the April 1997 work. *Claims Court Decision*, 162 Fed. Cl. at 65. USF nowhere disputes that finding on appeal to the extent it means that grant funds *eventually* went from Mayo to USF to pay for the April 1997 work, though not necessarily at the time of the work or, indeed, before Mayo and USF entered into the formal contract later that year. Given the evidence recited thereafter in support, the Claims Court's finding may mean no more than that. *Id.* The Claims Court went on to say that "[t]he greater weight of the trial testimony also established that [USF] was *using NIH funds by December 1996* to pay for costs associated with

conducting the immunohistochemistry work that was a key part of the research that led to the '094 patent." *Id.* (emphasis added). That statement suggests a finding that USF received money from Mayo by December 1996, but the correctness of that interpretation of the statement is less than clear, at least because of the two citations immediately following it—which suggest the scenario in which USF was "using NIH funds" in an accounting sense, *i.e.*, itself paying for the work in the expectation of being reimbursed eventually by NIH money from Mayo, which in fact occurred. *Id.*

Timing of funds transfer aside, the Claims Court's key finding was that "beginning in October 1996, [USF] operated [in the relevant work on the invention] pursuant to an implied contract with the Mayo Clinic for grant funds under the" NIH grant. *Id.* The Claims Court found that the evidence established an implied-in-fact contract (a meeting of the minds inferred from the surrounding circumstances), stating: "Regardless of whether [USF] underwrote those funds for a time before money flowed from the Mayo Clinic, it is clear in the record that [USF] had a 'tacit understanding' with Mayo that the funds would eventually arrive." *Id.* at 66 (quoting *Atlas Corp. v. United States*, 895 F.2d 745, 754 (Fed. Cir. 1990)). Although the government argued in the alternative that there was an implied-in-*law* contract between Mayo and USF, *see Summary Judgment Ruling*, 146 Fed. Cl. at 287 (noting the government's argument); Def.'s Post-Trial Br. at 10–11, *Claims Court Decision* (March 31, 2022), ECF No. 279, the Claims Court had no need to address, and did not address, that argument (which the government has not renewed on appeal).

Based on its findings, the Claims Court determined that USF was a "contractor" having an implied-in-fact subcontract that was a "funding agreement"; the invention was an "invention of the contractor," given the assignment to USF; and the invention was a "subject invention" in that it was "first actually reduced to practice" in April 1997 "in

the performance of" the funding agreement. *Claims Court Decision*, 162 Fed. Cl. at 66–67. The government therefore had a license under § 202(c)(4) to practice the '094 patent, or have the patent practiced for or on behalf of it by The Jackson Laboratory, as asserted by USF. *Id.* at 67. That conclusion required judgment for the government against the claim under 28 U.S.C. § 1498(a).

III

We decide legal issues presented by the Claims Court decision de novo, and we review its factual findings for clear error. *Gaylord v. United States*, 777 F.3d 1363, 1367 (Fed. Cir. 2015). "A finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948); *see Anderson v. City of Bessemer City*, 470 U.S. 564, 573–74 (1985); *Bitmanagement Software GmBH v. United States*, 989 F.3d 938, 948 (Fed. Cir. 2021); *Oliveira v. United States*, 827 F.2d 735, 742 (Fed. Cir. 1987).

A

We proceed on the basis of the following facts, reflected in findings of fact by the Claims Court that are not clearly erroneous based on the record. The April 1997 work that first actually reduced the '094 patent invention to practice was covered by the NIH grant. Mayo and USF entered into an express subcontract in November 1997 whereby Mayo would pay USF money received from NIH under the grant for work covered by the grant. USF in fact accepted payment from Mayo, using funds from the NIH grant, for the April 1997 work at issue. *See*, *e.g.*, *Claims Court Decision*, 162 Fed. Cl. at 64. On appeal, USF presents no substantial challenge to any of those findings of fact.

USF does present a factual challenge regarding when Mayo paid NIH money to USF for the April 1997 work.

USF argues that the record makes it clear that USF did not receive such money from Mayo at the time of the April 1997 work, or at any time before Mayo and USF entered into the express subcontract in November 1997. The government insists that the Claims Court found otherwise and had adequate evidentiary support to do so.

We do not resolve this dispute. Specifically, we do not decide whether the Claims Court even made such a finding—or whether, instead, it is best understood as having found only (what is not disputed on appeal) that the April 1997 work was paid for by Mayo with NIH funds at some time, *e.g.*, after Mayo and USF signed the November 1997 subcontract. Nor do we decide whether any such finding would be sustainable under the clear-error standard of review applied to the record as a whole—or whether, instead, the record must be read as showing simply that USF advanced the funding at issue (*e.g.*, for salaries) and only later received what amounted to reimbursement for those advances when it received NIH money from Mayo upon the signing of the November 1997 express subcontract.

Besides accepting the above-identified facts clearly established in the trial court, we proceed by accepting, for purposes of this appeal, USF's position on the timing-of-payment issue. That is, we accept that USF received NIH money from Mayo—including money for the April 1997 work—when the November 1997 express subcontract was in place and not earlier.

B

The question to be decided, on that basis, is whether the April 1997 work (the first actual reduction to practice)—for which USF in fact received government funds supplied, through Mayo, by the NIH grant—was "in the performance of work under a funding agreement." 35 U.S.C. § 201(e). If so, the government had the license, under § 202(c)(4), that defeats USF's infringement claim here.

The Claims Court answered the question in the affirmative.

USF's argument for reversal of the Claims Court's judgment has two necessary premises. The first is that any "funding agreement" adequate to trigger § 202(c)(4) must be in place at the time of the relevant work (here, a first actual reduction to practice in April 1997), so that the November 1997 subcontract (whose execution and effective date were later than April 1997) does not suffice to trigger § 202(c)(4). The second is that there was no legally adequate *implied* agreement at the time of the April 1997 work (indeed, at all), and the Claims Court's contrary determination must be reversed.

We conclude that USF's first premise is legally incorrect in the circumstances presented here, so the November 1997 subcontract is adequate to give the government a § 202(c)(4) license. Although the Claims Court decided the case on the implied-contract ground, and the parties have accordingly focused their arguments on that ground, the underlying premise of a requirement of a contract in effect at the time of the relevant work is logically necessary to the bottom-line result of no license that USF urges. The validity of this premise presents a legal issue requiring determination of no facts in this case other than the ones identified above that are beyond reasonable dispute here. In these circumstances, we may address this legal premise, the rejection of which is a ground for affirmance, without further examining the extent to which the government has briefed the issue. *See*, *e.g.*, *United States National Bank of Oregon v. Independent Insurance Agents of America, Inc.*, 508 U.S. 439, 447 (1993); *Arcadia v. Ohio Power Co.*, 498 U.S. 73, 77 (1990); *United States v. New York Telephone Co.*, 434 U.S. 159, 166 n.8 (1977); *In re Seagate Technology, LLC*, 497 F.3d 1360, 1371–72 (Fed. Cir. 2007) (en banc), *abrogated in a different respect by Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 579 U.S. 93, 104–10 (2016); *Granite*

Management Corp. v. United States, 416 F.3d 1373, 1378 (Fed. Cir. 2005).

On the factual premises stated above, USF accepted (received) NIH funds from Mayo, pursuant to the November 1997 subcontract to the NIH grant, to pay for the April 1997 work, as well as ongoing work. We conclude that the April 1997 work, *i.e.*, the first actual reduction to practice, was "in the performance of work under a funding agreement," § 201(e)—a subcontract between Mayo and USF to the NIH grant (the latter a funding agreement of NIH with Mayo). The statutory terms are broad enough to cover the facts on which we decide this appeal.

The November 1997 agreement between Mayo and USF was a "funding agreement," § 201(b). The original NIH grant awarded to Mayo was itself a funding agreement because it was a grant entered into between NIH and Mayo for the performance of experimental, developmental, or research work funded in whole or in part by the federal government, *id.* The November 1997 agreement, then, was a funding agreement because it was an express "subcontract" entered into for the performance of experimental, developmental, or research work under the 1996 NIH grant, *id.*

The work of tissue analysis (constituting the first actual reduction to practice in April 1997) was covered by the 1996 NIH grant. The November 1997 agreement signed by USF and Mayo did not limit the scope of the NIH grant. *See* J.A. 1265–70. The April 1997 work was in "the performance of work under [those] funding agreement[s]" pursuant to a recognized meaning of "under" applicable to the statutory phrase, § 201(e): It was substantively covered by both, and (on the facts we accept) both provided money to pay for it. *See Random House Webster's Unabridged Dictionary* 2059 (2d ed. 2001) (defining "under" as "14. in accordance with"); Bryan A. Garner, *Garner's Dictionary of Legal Usage* 910, 737–38 (3d ed. 2011) (stating that "under

is preferable to **pursuant to* when the noun that follows refers to a . . . contractual provision," and defining "pursuant to" as "(1) in accordance with; (2) under; (3) as authorized by; or (4) in carrying out").

USF opposes this conclusion on the basis of a time-based limitation it urges is present in the Bayh-Dole Act provisions. USF argues that the November 1997 agreement is legally insufficient, even if it provided funds to pay for the pre-agreement, April 1997 work, because it was entered into in November 1997 and had an effective date in September 1997, after the April 1997 work. We reject this suggested temporal limitation on the scope of the relevant Bayh-Dole Act language.

The Act says that "funding agreement" includes "any . . . subcontract of any type" for the performance of work under a funding agreement. § 201(b). That breadth-indicating language supports inclusion within the provision of a subcontract that provides for, among other things, payment for work already performed before the subcontract is executed or its "effective" date (when its obligations take effect, *see Date*, Black's Law Dictionary (11th ed. 2019) (defining "effective date")). A contract may provide for payment for work previously done at least where, as here, the contract also pays for work yet to be done. Restatement (Second) of Contracts § 80 (American Law Institute 1981) ("(1) There is consideration for a set of promises if what is bargained for and given in exchange would have been consideration for each promise in the set if exchanged for that promise alone. (2) The fact that part of what is bargained for would not have been consideration if that part alone had been bargained for does not prevent the whole from being consideration."); 17 C.J.S. *Contracts* § 174 (2023) ("A promise founded on consideration which is partly past and partly present or executory is enforceable, although in a sense no resort to the past consideration need be had as the new or executory consideration is conceptually adequate to support enforceability of the contract."); 17A Am. Jur. 2d

Contracts § 147 (2023) ("Where the consideration is partly past and partly future, a single promise as to both will be sustained."); *see also Hackin v. Pioneer Plumbing Supply Co.*, 457 P.2d 312, 318 (Ariz. Ct. App. 1969); *Jim Murphy & Associates, Inc. v. LeBleu*, 511 So. 2d 886, 891 (Miss. 1987); *Johnson v. Hazaleus*, 338 P.2d 345, 347 (Okla. 1959); *Kahn v. Lischner*, 275 P.2d 539, 543 (Cal. Dist. Ct. App. 1954); *W. T. Rawleigh Co. v. Miller*, 73 P.2d 552, 554 (Mont. 1937).

USF's own position that Mayo paid for the April 1997 work with the relevant NIH grant funds after the November 1997 contract was executed or took effect confirms that such backward-reaching payment is a recognized contract practice. And it confirms that the November 1997 contract included Mayo's promise to pay for the April 1997 work with the NIH funds. USF nowhere suggests that Mayo did or properly could pay for that work with the NIH grant funds outside a subcontract, as Mayo was obligated to enter into subcontracts for funded work with its consortium partners.

This understanding of the November 1997 agreement, and of its meaning for the Bayh-Dole Act, is consistent with the agreement's provision stating that the "effective period of this Agreement shall be from September 1, 1997, through August 31, 1998, unless otherwise provided for by modification in this Agreement." J.A. 1266. The "effective period" merely identifies when the obligations (specified elsewhere in the contract) are binding. *See*, *e.g.*, 17A Am. Jur. 2d *Contracts* § 323 (2023) (equating "effective date" with the date on which "a written contract becomes binding"); 1 Albert H. Kritzer et al., *International Contract Manual* § 19:23 (2023) ("[T]he effective date of the contract will ordinarily be the date on which the contract first creates a legal obligation on both parties."); *cf. Hamilton v. Lanning*, 560 U.S. 505, 518 (2010) (explaining that "effective date" of plan of reorganization is when plan is adopted "and becomes binding"). When one party's work performed

before the contract took effect is included in what the other party agrees to pay for (along with yet-to-be-performed work from the first party), that recognized type of contract does not turn already-completed pre-effective-date work into work the first party was obligated to perform, when there had been no obligation to perform it when it was performed—as USF insists is the case for the April 1997 work. Of course, such a contract does create an obligation relating to that work—at least the second party's voluntarily undertaken obligation to pay for that work (or do other things because of that work)—but the already-completed performance of the first party's work remains not obligatory. Thus, the start of the "effective period" on September 1, 1997—for a one-year period to align with NIH's designation of the second year of the NIH grant—does not exclude the April 1997 work from being under the formal agreement, in that it was part of what Mayo undertook to pay for and did pay for with the NIH grant funds through the formal contract.

Understanding the Bayh-Dole Act language to embrace such past-work funding fits the statutory context. To begin with, consistent with the Act, our understanding respects, rather than overrides, the patent owner's choice whether to enter into a subcontract and on what terms, including what work will be paid for under it. Here, on the facts that are the basis for our decision, and against the well-known background of the Bayh-Dole Act regime, USF entered into the November 1997 agreement (which expressly provides for application of the Act) and accepted the NIH funding from Mayo for the April 1997 work under that agreement.

The statutory interpretation we adopt fits the statutory context more generally. It reflects the stated statutory policy to "ensure that the Government obtains sufficient rights in federally supported inventions," § 200, where the patent owner accepts federal funds under an agreement that invokes the Act. Even before enactment of the Bayh-Dole Act, this court's predecessor had given a "liberal

construction" to "the general phrase 'in the performance of'" used in some government funding contracts, explaining that the construction ensures that, in such circumstances, the public, having paid for an invention, would "'not again be taxed for its use, nor excluded from its use[,] nor permitted to use it upon restrictive conditions advantageous to no one but the patent owner.'" *Technical Development*, 597 F.2d at 745 (quoting *Mine Safety Appliances*, 364 F.2d at 392). This policy applies even when the agreement provides for payment of government funds for pre-agreement work having the defined relationship to the invention (here, that the government-funded work includes the first actual reduction to practice of the invention).

This conclusion is strongly bolstered by the record in this case, which suggests that what occurred here is not an uncommon fact pattern in government funding of research conducted in part by non-grantee members of a consortium called for in a government grant. Specifically, the record makes clear that subcontracts are commonly not executed until sometime after the grant is awarded, yet the grant-covered work proceeds without waiting for the inking of a subcontract. The commonplace nature of this scenario suggests that, if USF's time-restrictive view of the Act were adopted, one or more policies of the Act might be impaired—*e.g.*, by the government insisting, in order to protect its rights, that research by a consortium member be postponed until a subcontract was executed. Our understanding of the statute avoids such impairment by focusing on the facts of agreement, coverage, and actual funding, whether forward-looking or backward-looking.

Several witnesses testified, without contradiction, that it was common for there to be a delay in subcontracting after award of a government grant. J.A. 136 (Dr. Duff, stating that subcontracts are "very often delayed"); J.A. 523 (Dr. Morgan, stating that subcontracting "usually does not occur immediately upon the award of the grant itself"); *see also* J.A. 624–25 (Dr. Gordon stating "[u]niversity

bureaucracy" slowed down the agreement between USF and Mayo); J.A. 2607–11 (Mr. Snyder discussing post-award subcontracting); *NIH Grant Policies*, *supra* (contemplating the same). Other aspects of the record—*e.g.*, the absence in the record of any written subcontract for more than a year after the NIH grant award, Dr. Morgan's own uncertainty about when money actually flowed from Mayo to USF, the evident expectation by USF that it would receive grant funds—tend to confirm that, in practice, grantees and their consortium institutions often do not place high priority on speedily getting a formal subcontract executed after a grant is awarded.

At the same time, it is of great significance for the advancement of useful knowledge (here, in medicine) and for many particular grant projects that research continue without interruption, suggesting that all persons concerned, including the government, would expect the grant-covered work to proceed immediately upon award of the grant, without awaiting a formal subcontract. Notably, the record in this case indicates that it was clear from the outset of the NIH grant project that the USF work that was part of it would have to proceed without delay. The first litter of the doubly transgenic mice was born in August 1996, just before the late-September NIH award. The responsibility for the colony remained at USF, even after Dr. Duff moved to Mayo in December. J.A. 529. Dr. Gordon and her USF colleagues could not have waited to complete the work of caring for the mice. Dr. Gordon was also responsible for the immunohistochemistry work on the brains of sacrificed mice in the colony to identify the development of Alzheimer's Disease pathology. J.A. 152–54, 148–50. This work was highly time sensitive: A core objective was to determine the timing of such development, and the immunohistochemistry testing therefore had to begin, and it did begin, no more than a few months after the birth of the mice. *See Nature Medicine Article* at 97–98; J.A. 3231–32 (comparing deposits in the brains of sacrificed 13-

to 16-week-old singly transgenic mice, which express only a presenilin transgene, with those in the brains of sacrificed 13- to 16-week-old doubly transgenic mice and comparing deposits in the brains of sacrificed 24- to 32-week-old singly transgenic mice with those in the brains of sacrificed 24- to 32-week-old doubly transgenic mice). Such immediate performance of the work, beyond being necessary as a scientific matter, was also important for grant administration, as NIH had to decide each year whether to renew the funding of the grant, requiring an evaluation of progress in the project. *See* J.A. 2616.

For all of the foregoing reasons, we reject USF's reliance on the November 1997 agreement's effective date and execution date as a basis for not recognizing it as a funding agreement sufficient to give rise to the license rights of the government under § 202(c)(4). The Claims Court's judgment of non-infringement is correct on this ground. Given this conclusion, it is not necessary that we address whether the Claims Court's finding of an implied-in-fact contract was correct.

IV

The judgment of no liability for infringement by reason of a license is affirmed.

The parties shall bear their own costs.

AFFIRMED