

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

JOHN M. J. MADEY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	1:97CV01170
	)	
DUKE UNIVERSITY,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION

Beaty, District Judge.

This matter is presently before the Court on Defendant's renewed Motion for Summary Judgment [Document #149], Plaintiff's Motion for Leave to File a Sur-Reply [Document #175], and Plaintiff's Motion for Leave to File Documents Under Seal [Document #177] related to documents filed with the proposed Sur-Reply. For the reasons discussed below, Defendant's Motion for Summary Judgment [Document #149] is DENIED, Plaintiff's Motion for Leave to File a Sur-Reply [Document #175] is DENIED, and Plaintiff's additional Motion [Document #177] related to documents filed with the proposed Sur-Reply is DENIED as moot.<sup>1</sup>

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<sup>1</sup> The Court notes that Plaintiff has subsequently filed a Motion to Disclose Certain Documents [Document #180]. The Court will issue a separate Order addressing that Motion.

## I. FACTUAL AND PROCEDURAL BACKGROUND

The facts of this case have previously been discussed extensively by the Court in prior Orders and Opinions dated December 1, 1999, June 15, 2001, and September 20, 2004. Therefore, the relevant facts will be summarized here only briefly. Dr. Madey is a scientist in the field of electromagnetic radiation, and was hired by Duke in 1989 as a professor to assist Duke in establishing a Free Electron Laser Laboratory ("FEL Lab") and research program. Dr. Madey claims patent rights in two patents that he contends are being used in Duke's FEL Lab: United States Patent Number 4,641,103 ("the '103 Patent"), and United States Patent Number 5,130,994 ("the '994 Patent").

Following Dr. Madey's arrival at Duke, Dr. Madey assisted Duke in obtaining a federal research grant from the Office of Naval Research (the "ONR grant"). Dr. Madey contends that as a result of a dispute that later arose, Duke conspired to take control of the FEL Lab and his patented technology, removed him from his position as Director of the Lab, and petitioned the Office of Naval Research to remove him from his position as Principal Investigator on the ONR grant. Dr. Madey submitted his resignation effective on August 31, 1998, and Dr. Madey contends that Duke continued to make use of his patented inventions even after his departure. In response, Duke contends that all uses of the FEL equipment were pursuant to the ONR grant or other Government research grants or authorization.<sup>2</sup>

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<sup>2</sup> Duke also contends that it owns the '994 Patent, not Dr. Madey, and that it did not infringe Dr. Madey's patent. However, for purposes of the summary judgment motion only, Duke assumes that Dr. Madey's patents were infringed, and contends that it is nevertheless

On November 5, 1997, Dr. Madey filed a lawsuit in this Court, claiming, inter alia, infringement of the '103 Patent and infringement of the '994 Patent, as well as state law claims for conversion of property, constructive fraud, and breach of contract. In a Memorandum Opinion and Order and Judgment dated December 1, 1999 (the "1999 Dismissal Opinion"), the Court found that, under 28 U.S.C. § 1498, it lacked jurisdiction over Dr. Madey's infringement claims with respect to Duke's uses of the '103 Patent that came under the authority of the ONR Government research grant. Dr. Madey appealed that decision to the Federal Circuit. On October 3, 2002, the Federal Circuit issued an Opinion affirming in part and reversing in part this Court's decision, and remanding the matter to this Court for further proceedings. See Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002). With respect to the 1999 Dismissal Opinion, the Federal Circuit held that 28 U.S.C. § 1498 was not jurisdictional in suits between private parties, and instead provided an affirmative defense in such cases. Therefore, the Federal Circuit reversed this Court's dismissal pursuant to Rule 12(b)(1), and remanded for further proceedings before this Court. The Federal Circuit noted that in applying the § 1498 affirmative defense, this Court should make specific findings as to what Government authorization had been given to Duke, as well as what uses by Duke were covered by that Government authorization. See Madey, 307 F.3d at 1359-60.

Dr. Madey's appeal to the Federal Circuit also included an appeal of this Court's June 15, 2001 Order and Judgment ("the 2001 Summary Judgment Opinion"), which granted Duke's

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entitled to certain affirmative defenses.

Motion for Partial Summary Judgment. In the 2001 Summary Judgment Opinion, this Court held that the “experimental use defense” barred Dr. Madey’s patent-infringement claims against Duke. With respect to this 2001 Summary Judgment Opinion, the Federal Circuit reversed this Court’s decision, finding that this Court’s application of the experimental use defense was too broad. The Federal Circuit held that on remand, this Court should reconsider this issue and apply the more narrow experimental use defense as outlined in the Federal Circuit decision.

Finally, in the appeal to the Federal Circuit, Duke also attempted to raise the “Government License” defense, based on the Bayh-Dole Act at 35 U.S.C. §§ 202-212, as a basis for judgment in its favor. However, because the Government License defense had not been fully considered by this Court and was not a basis for the 2001 Summary Judgment Opinion,<sup>3</sup> the Federal Circuit declined to consider the availability of such a defense as an initial matter, and instead remanded to this Court for consideration of Duke’s contentions.<sup>4</sup> As a result, on remand, this Court was directed to consider three separate affirmative defenses asserted by Duke: (1) experimental use, (2) Government License, and (3) 28 U.S.C. § 1498. See Madey, 307 F.3d

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<sup>3</sup> As noted above, this Court granted Duke’s Motion for Summary Judgment based on the experimental use defense. Therefore, this Court did not reach Duke’s contentions with respect to the Government License defense.

<sup>4</sup> Specifically, the Federal Circuit held that “the government license issue needs further development before the district court,” and remanded “for the parties to litigate Duke’s asserted government license defense.” Madey, 307 F.3d at 1364. The Federal Circuit specifically refused to make any determination with respect to the “government license issue.” Therefore, it appears to this Court that the Federal Circuit’s mandate was not to proceed directly to trial on this defense, but rather for this Court to consider as an initial matter the application and availability of the asserted Government License defense to Duke in this case.

at 1360, 1364.

On September 20, 2004, this Court entered an Order and Opinion (“the 2004 Order”) addressing the pending matters following the remand from the Federal Circuit. In the 2004 Order, the Court applied the experimental use defense outlined by the Federal Circuit and held that Duke’s Motion for Summary Judgment would be denied as to the experimental use defense. The Court also denied Duke’s Motion for Summary Judgment as to Dr. Madey’s state law claims. However, the Court concluded that the record was incomplete with respect to Duke’s contentions regarding the Government License defense and the applicability of 28 U.S.C. § 1498, and the Court therefore denied the Motion for Summary Judgment but allowed Duke the opportunity to file a subsequent summary judgment motion only as to those issues, specifically addressing the relationship between § 1498 and the Government License defense. In response to the Court’s ruling, Duke subsequently filed the present Motion for Summary Judgment [Document # 149] based on its contention that Plaintiff’s patent infringement claims are barred by the Government License defense contained in the Bayh-Dole Act and by the affirmative defense in 28 U.S.C. § 1498.

In its present Motion for Summary Judgment, Duke contends first that § 1498(a) bars Dr. Madey’s claim because Duke is using the ’103 and ’994 Patents “for the Government” and pursuant to “authorization and consent” by the Government based on various Government research grants. Duke contends that log books and operating notebooks from the FEL lab show that all uses of the equipment were for Government-sponsored research “for the United States”

and that it is entitled to summary judgment on that basis. Duke next contends that the Government has a license to practice or have practiced on its behalf the '103 and '994 Patents under the Bayh-Dole Act, 35 U.S.C. § 200, et seq., because the inventions described in the '103 and '994 Patents were originally developed as part of Government-sponsored research. Duke contends that this license extends at least to all uses that would be considered "for the United States" and provides an additional defense beyond § 1498 for Duke's uses of the equipment under Government research grants.

In response, Dr. Madey contends that the Government research grants presented by Duke do not provide sufficient evidence of Government authorization and consent to use the '103 and '994 Patents so as to provide Duke with a § 1498 affirmative defense. Dr. Madey also contends that Duke has failed to establish what uses of the FEL equipment by Duke fell within the scope of a particular Government authorization or consent. In addition, Dr. Madey raises various other arguments in opposition, including his contentions that use by Duke could not be "for the United States" since Duke contributed some of its own funding for the FEL Lab, that the Government had other reasonable alternatives and therefore could not authorize Duke to use Dr. Madey's patented inventions, that there was no "direct benefit" to the Government, and that a federal grant for general University research is not "for the United States" and does not establish authorization and consent of the United States. Finally, Dr. Madey contends that the Government License created by the Bayh-Dole Act belongs to the Government, not Duke, and may not be raised by Duke in a patent infringement suit between private parties.

Before considering these contentions, the Court notes that after the briefing was completed with respect to the Motion for Summary Judgment, Dr. Madey filed a Motion for Leave to File a Sur-Reply [Document #175]. However, Sur-Replies are not permitted by the Local Rules of this district. See Local Rules 7.3, 56.1. Moreover, no basis exists in the present case to allow the Motion or consider the proposed Sur-Reply. Therefore, Plaintiff's Motion for Leave to File a Sur-Reply [Document #175] will be DENIED, and Plaintiff's additional Motion [Document #177] related to documents filed with the proposed Sur-Reply will be DENIED as moot. Therefore, in evaluating Defendant's Motion for Summary Judgment, the Court will consider the parties' contentions and evidence based on the briefings properly before the Court, and will not consider Plaintiff's proposed Sur-Reply.

In evaluating the contentions and evidence presented by the parties, the Court will first outline the relevant statutory scheme in 28 U.S.C. § 1498. The Court will then separately consider the applicability of the Government License provisions of the Bayh-Dole Act at 35 U.S.C. § 202(c)(4). After determining the applicable legal rules, the Court will then evaluate the evidence presented to determine what issues in the present case can be decided as a matter of law, and what issues involve disputed factual questions to be reserved for trial.

## II. STATUTORY PROVISIONS

### A. 28 U.S.C. § 1498

Title 28 United States Code, Section 1498(a) provides that

“[w]henever an invention described in and covered by a patent

of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. . . . For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States."

28 U.S.C. § 1498(a). The Federal Circuit has held that § 1498(a) has two important features: "[i]t relieves a third party from patent infringement liability, and it acts as a waiver of sovereign immunity and consent to liability by the United States." Madey, 307 F.3d at 1359. This scheme allows the Government to obtain what it needs from third parties, whether goods, services, or research, regardless of potential patent infringement, with compensation provided later to patent holders in a suit against the Government in the Court of Federal Claims for any patents infringed in the process. The original purpose of § 1498 was "to stimulate contractors to furnish what was needed for the War, without fear of becoming liable themselves for infringements to inventors or the owners or assignees of patents." Richmond Screw Anchor Co. v. United States, 275 U.S. 331, 345, 48 S. Ct. 194, 197, 72 L. Ed. 303 (1928). The Federal Circuit has noted that, in order to further this purpose, "[t]he coverage of § 1498 should be broad so as not to limit the Government's freedom in procurement by considerations of private patent infringement." TVI Energy Corp. v. Blane, 806 F.2d 1057, 1060 (Fed. Cir. 1986) (noting that Congress' intent was

“to allow the Government to procure whatever it wished regardless of possible patent infringement.”).

In a lawsuit between private parties, § 1498(a) operates as an affirmative defense, and where a private party’s use of a patented invention is “for the Government” and with the “authorization and consent of the Government,” that private party cannot be held liable for patent infringement. See Madey, 307 F.3d at 1359; see also Crater Corp. v. Lucent Techs., Inc., 255 F.3d 1361, 1364 (Fed. Cir. 2001) (“If a patented invention is used or manufactured for the government by a private party, that private party cannot be held liable for patent infringement.”); W.L. Gore & Assocs., Inc. v. Garlock, Inc., 842 F.2d 1275, 1282-83 (Fed. Cir. 1988) (“In short, use or manufacture for the United States is immune from suit for patent infringement in the district courts against the user or manufacturer.”). In order to claim the protection of the affirmative defense provided by § 1498, the private party must establish that its use is (1) “for the Government”; and (2) “with the authorization or consent of the Government.” A use is “for the Government” if it is “in furtherance and fulfillment of a stated Government policy” which serves the Government’s interests and which is “for the Government’s benefit.” Riles v. Amerada Hess Corp., 999 F. Supp. 938, 940 (S.D. Tex. 1998); see also Hughes Aircraft Co. v. United States, 534 F.2d 889, 897 (Ct. Cl. 1976) (holding that the use must be “for the Government’s benefit”). A use is with the “authorization and consent of the Government” where the Government either expressly or impliedly consents to the infringement. See Parker Beach Restoration, Inc. v. United States, 58 Fed. Cl. 126, 132 (2003)

(noting that “authorization and consent can be either express or implied”); Applera Corp. v. MJ Research Inc., 311 F. Supp. 2d 293, 299 (D. Conn. 2004).

In applying these provisions, courts generally consider whether a use is “for the Government with its authorization and consent,” relying primarily on either the existence of clear, express Government authorization and consent as part of a Government program or contract, or a clear Government purpose and implicit authorization and consent. See, e.g., Carrier Corp. v. United States, 534 F.2d 244, 247 (Ct. Cl. 1976) (analyzing whether a use was “for the Government with its authorization and consent”); Bereslavsky v. Esso Standard Oil Co., 175 F.2d 148, 149 (4th Cir. 1949) (finding implied authorization and consent based on the Government’s direction and a clear Government purpose); Roberts v. Herbert Cooper Co., 236 F. Supp. 428 (M.D. Pa. 1959) (focusing on express authorization and consent clause in Government contract). Thus, § 1498 requires that a contractor’s use be both “for the Government” and “with the authorization or consent of the Government,” but these provisions must be considered together and applied on a case-by-case basis to determine whether a use meets the articulated statutory requirements, particularly in light of the purpose of § 1498 and Congress’ intent “to allow the Government to procure whatever it wished regardless of possible patent infringement.” TVI Energy Corp., 806 F.2d at 1060.

In some circumstances, the Government clearly and expressly authorizes and consents to the infringement of a patented invention in the performance of a Government contract. Such express consent is often contained in the language of the Government contract itself, or in other

formal, written authorization from the Government, although § 1498 does not require the authorization to take any specific form. See Parker Beach Restoration, 58 Fed. Cl. at 132 (“Although not required by § 1498 itself, the Government generally consents and authorizes the use of a particular device by inserting an authorization and consent clause into its contracts.”); Hughes Aircraft Co., 534 F.2d at 901 (recognizing that an authorization and consent clause may be contained in a contract or in a subsequent letter authorization from the Government, and that such an express authorization and consent clause “comports with the broad purpose and policy of § 1498(a)”).

When the Government provides express consent, that consent may be very broad, extending to any patented invention and any infringing use, or may be limited to only certain patented inventions or to only those uses that are necessary or are specifically consented to by the Government. See Carrier Corp. v. United States, 534 F.2d 244, 249 (Ct. Cl. 1976) (“Since Section 1498(a) expressly provides that any use of a patented invention for the Government must be authorized or consented to, it is plain that the Government can limit its authorization and consent.”). The federal procurement regulations recognize the varying types of consent that may be included in certain Government contracts.<sup>5</sup> For example, the federal procurement regulations at 48 CFR § 27.201-2(b) and 48 CFR § 52.227-1 for federal research and development contracts provide an example of a “broad” authorization and consent clause using the following language:

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<sup>5</sup> The Court notes, however, that these provisions are simply illustrative, since § 1498 by its language is not limited to just federal procurement contracts, and, as noted above, § 1498 does not require that authorization and consent take a specific form.

“[t]he Government authorizes and consents to all use and manufacture of any invention described in and covered by a United States patent in the performance of this contract or any subcontract at any tier.” 48 CFR § 52.227-1; see also Roberts v. Herbert Cooper Co., 236 F. Supp. 428, 430 (D. Pa. 1959) (holding that where a broad authorization and consent clause is included in a contract, “[n]o extended discussion is required on the question whether this action falls within the provisions of 28 U.S.C. 1498 [because] Defendant’s contracts are with the United States and the authorization and consent of the Government provided for in the statute is present”). In contrast, 48 CFR § 27.201-2(a) and 48 CFR § 52.227-1 provide in other instances for inclusion of a narrower or “limited” authorization and consent clause, based on the use of language which grants the Government’s authorization and consent, but only where (i) the patented invention is embodied in the structure or composition of an article accepted by the Government, or (ii) the patented invention is used in tools or methods which necessarily results from compliance with specifications in the contract or specific written instructions from the contracting officer.

By choosing the scope of its consent in its selection of the contract language, the Government may control the extent of patent infringement it chooses to authorize, and the corresponding liability it chooses to accept. As noted above, given the purposes of § 1498, this authority should be broadly construed to allow the Government to consent to patent infringement in order to obtain desired goods, services, or research for the United States, with appropriate royalties paid to the patent holder in a suit against the Government in the Court of

Federal Claims for this taking. See TVI Energy Corp., 806 F.2d at 1060. When the Government chooses to provide such express authorization and consent as part of a Government program or contract, a contractor or sub-contractor is entitled to rely on that authorization, and is entitled to the affirmative defense provided by § 1498 for uses of patented inventions within the scope of the consent. See Crater Corp. v. Lucent Techs., Inc., 255 F.3d at 1364. However, where the Government limits its consent, as contemplated by use of language providing a narrower or “limited” authorization and consent, that limited consent operates as a limited waiver of sovereign immunity and should be narrowly construed so as not to find consent and impose potential liability on the Government where the terms of the consent clause are not fully met. See Carrier Corp., 534 F.2d at 247 (finding no authorization or consent by the Government where the relevant contract included a limited authorization and consent clause, since non-infringing alternatives were available and no specification or written instructions required the use of any certain equipment).<sup>6</sup>

In other circumstances, the Government might not expressly consent to use of patented inventions, in either the “broad” or “narrow” sense discussed above, but may nevertheless be found to have provided implied consent. See TVI Energy Corp., 806 F.2d at 1060 (“In proper

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<sup>6</sup>The Court notes that in the present case, Dr. Madey contends that the Government may never authorize or consent to infringement if other non-infringing alternatives exist. However, § 1498 does not require that “no infringing alternatives exist.” Instead, as noted above, the existence of alternatives may be relevant where the Government provides only narrow, “limited” consent or where consent is implied. Contrary to Dr. Madey’s assertions, however, the existence of non-infringing alternatives does not limit the Government’s broad authority to expressly authorize and consent to the use of any patented inventions for the United States.

circumstances, Government authorization can be implied.”). In such instances, implied consent may be found, for example, “by contracting officer instructions, by specifications or drawings which impliedly sanction and necessitate infringement, [or] by post hoc intervention of the Government in pending infringement litigation against individual contractors.” Hughes, 534 F.2d at 901 (noting that there is no requirement “that authorization or consent necessarily appear on the face of a particular contract”). This includes situations where “(1) the government expressly contracted for work to meet certain specifications; (2) the specifications cannot be met without infringing on a patent; and (3) the government had some knowledge of the infringement.” Larson v. United States, 26 Cl. Ct. 365, 370 (1992) (citing Bereslavsky v. Esso Standard Oil Co., 175 F.2d 148, 150 (4th Cir. 1949)). Implied authorization and consent will also be found where the government requires the private contractor to use or manufacture the allegedly infringing device. See Hughes Aircraft Co. v. United States, 29 Fed. Cl. 197, 223 (1993) (citing TVI Energy Corp., 806 F.2d at 1060). Because implied consent operates as a waiver of sovereign immunity pursuant to § 1498, it is clear that any implied consent should be narrowly construed. See, e.g., Parker Beach, 58 Fed. Cl. at 132-34 (noting that if non-infringing alternatives exist, then Government specifications alone will not “impliedly sanction or necessitate infringement”).

Because § 1498 is an affirmative defense in suits between private parties, the burden is on the party asserting the defense to show the existence and extent of any Government authorization and consent, either express or implied. If a contractor establishes that the

Government provided it with express or implied consent to infringe the patent, the contractor must then establish that its uses of the patented invention fall within the scope of that consent. Thus, when the Government provides the requisite authorization and consent, either express or implied, in relation to a Government contract or grant, the issue is “which uses fall within the scope of the . . . grant and which uses are outside that scope.” Madey, 307 F.3d at 1360; see also Carrier Corp., 534 F.2d at 247 n.4 (Ct. Cl. 1976) (noting that where a Government contract contains a broad authorization and consent clause consenting to “all use and manufacture of any invention described in and covered by a patent of the United States in the performance of this contract,” the “alleged use need only be in the performance of the contract”). Therefore, as part of the analysis of the § 1498 defense, courts must consider the specific uses made of the patented inventions and whether those uses are within the scope of a particular authorization and consent by the Government.

Having thus reviewed the various rules that courts have used in interpreting § 1498, the Court will apply those rules to the evidence presented by Duke in this case to determine whether Duke is entitled to the § 1498 affirmative defense as a matter of law. However, before undertaking that analysis, the Court will first turn to a consideration of the statutory provisions of the other defense raised by Duke, that is, the “Government License” defense pursuant to the Bayh-Dole Act, 35 U.S.C. § 202(c)(4). As part of this determination, the Court will analyze the relevant statutory provisions of the Bayh-Dole Act, and will then consider whether the Bayh-Dole Act creates a separate defense for Duke from that which may be provided by § 1498.

B. The "Government License defense" and the Bayh-Dole Act

The Bayh-Dole Act, 35 U.S.C. §§ 200 - 212, "allows nonprofit organizations and small business firms to elect to retain title to any invention by the contractor developed pursuant to a government contract." Campbell Plastics Eng'g & Mfg., Inc. v. Brownlee, 389 F.3d 1243, 1247 (Fed. Cir. 2004). The Act was passed by Congress in 1980 "to promote the commercialization and public availability of inventions made in the United States by United States industry and labor," and "to encourage maximum participation of small business firms in federally supported research and development efforts." 35 U.S.C. § 200. Before passage of the Bayh-Dole Act, the Government retained title to any inventions resulting from federally-funded research, unless specific provisions in the funding grant provided otherwise. However, the Bayh-Dole Act changed this system and created a uniform rule that allowed private contractors and inventors to retain title to their own inventions that were developed with the assistance of federal funding. Although the Bayh-Dole Act by its terms was applicable only to non-profit organizations and small business firms, its effect has been extended to large businesses by the Memorandum on Government Patent Policy of 1983 and by Executive Order 12591. See 52 Fed. Reg. 13,414 (Apr. 10, 1987). As a result, federal funding agreements for large businesses, small businesses and non-profit organizations include provisions allowing the funding recipient to retain title to any subject inventions that result from the federally-funded research.

However, the Bayh-Dole Act also sought to "ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government" and to

ensure that inventions could be used “without unduly encumbering future research and discovery.” 35 U.S.C. § 200. To meet these goals, the Government retains a paid-up license in any subject inventions conceived or reduced to practice in the performance of federally-funded research:

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.

35 U.S.C. § 202(c)(4). Pursuant to this provision, the Government keeps a “Government License” in subject inventions that result from federally-sponsored research. In addition, under the Bayh-Dole Act, “all funding agreements, including those with other than small business firms and nonprofit organizations, shall include the requirements established in section 202(c)(4) and section 203 of this title” which establish the irrevocable, paid-up Government License. 35 U.S.C. § 210(c). Thus, the Bayh-Dole Act creates a Government License in two ways. First, as to non-profit organizations and small businesses, the statute itself retains for the federal funding agency a paid-up license pursuant to 35 U.S.C. § 202(c)(4), creating a statutory Government License. Second, all federal funding agreements, including those with large businesses, small businesses, and non-profit organizations, must include language which reserves for the Government the license specified in 35 U.S.C. § 202(c)(4). These contractual provisions in the federal funding agreements therefore create a contractual Government License pursuant to the

Bayh-Dole Act.<sup>7</sup>

The theory behind the Government License is to protect the needs of the Government:

“Inventions made under a Government contract are the product of expenditures from the public treasury in the course of a governmental function; the public, having in a sense ordered and paid for the invention through its representatives, should 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 Dev. Corp. v. United States, 597 F.2d 733, 745 (Ct. Cl. 1979) (quoting Mine Safety Appliances Co. v. United States, 364 F.2d 385, 392 (Ct. Cl. 1966)); see also Kersavage v. United States, 36 Fed. Cl. 441, 448 (Fed. Cl. 1996) (“The government finances research contracts to earn the benefit of the research without paying further royalties to the inventor.”). This Government License is not transferrable, but covers any uses of the invention by the Government or its contractors for or on behalf of the United States. 35 U.S.C. § 202(c)(4).

Although the terms of the Bayh-Dole Act and the provisions incorporated into federal funding agreements do not specify how the Government License may be raised, courts have recognized that the license may be raised by the Government as an affirmative defense when the Government is sued for patent infringement in the Court of Federal Claims. See, e.g., Technical Dev. Corp., 597 F.2d at 745-46; Technitrol, Inc. v. United States, 440 F.2d 1362 (Ct. Cl. 1971).

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<sup>7</sup> Even before passage of the Bayh-Dole Act, Government funding agreements often provided that “any inventions conceived of or first actually reduced to practice in the performance of the contract may be used by the Government on a royalty-free, non-exclusive basis.” Technical Dev. Corp. v. United States, 597 F.2d 733, 745 (Ct. Cl. 1979).

Thus, when a patent holder sues the Government in the Court of Federal Claims pursuant to 28 U.S.C. § 1498 for patent infringement by the Government or a Government contractor, the Government may raise the Government License created by the Bayh-Dole Act and the terms of the federal funding agreement as an affirmative defense. See, e.g., Kersavage, 36 Fed. Cl. at 448. In order to establish that it is entitled to the Government License defense, the Government must point to a funding agreement between itself and the original patent holder and must establish that the patented invention was conceived or first reduced to practice under that funding agreement. See Technical Dev. Corp., 597 F.2d at 746. If the Government meets this burden, the Government is not liable for royalties for any uses of that invention within the scope of the Government License.

However, the terms of the Bayh-Dole Act and the provisions incorporated into federal funding agreements do not specify any means for allowing a private party itself to raise the Government License defense as a defense in a patent infringement suit. In the present case, Duke seeks to raise for itself such a "Government License defense" as an affirmative defense, based on its contention that the inventions described in and covered by the '103 Patent and '994 Patent are "subject inventions" conceived or reduced to practice under federal funding agreements.<sup>8</sup>

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<sup>8</sup> Specifically, Duke contends that the invention described in the '103 Patent is a "subject invention" developed by Dr. Madey while he was working at Stanford University, under contract ONR-0403 awarded by the Office of Naval Research to Stanford, and that the terms of the Bayh-Dole Act were incorporated by mutual agreement into the terms of the ONR-0403 contract. Duke further contends that the invention described in the '994 Patent is a "subject invention" under contract ARO-0109 awarded by the U.S. Army Research Office to Duke in 1988.

However, Duke does not point to any authority for the proposition that the Government License defense may be raised by a party other than the Government. Therefore, this Court must first consider whether and how the Government License defense may be raised in a patent infringement suit between private parties, if at all.

In making this determination, the Court notes first that neither Duke nor Dr. Madey have cited to any authority regarding use of the Government License defense by private parties. However, district courts considering other portions of the Bayh-Dole Act have concluded that no private right of action was intended or included in 35 U.S.C. § 202. See, e.g., Platzer v. Sloan-Kettering Inst. for Cancer Research, 787 F. Supp. 360, 364-65 (S.D.N.Y. 1992) (holding that there is no private right of action under 35 U.S.C. § 202(c)(7)(B) regarding the sharing of royalties between an inventor and a federal funding recipient), aff'd, 983 F.2d 1086 (Fed. Cir. 1992). In Platzer, the court held that “the intended beneficiaries of the Bayh-Dole Act are the institutions themselves [who may retain title to their subject inventions] and the government.” Id. In addition, the Platzer court noted that the statute “serves as a directive to organizations that receive federal funding” and because “the legislative history is completely silent with regard to a private cause of action . . . it is safe to assume that Congress did not intend for a private right of action to exist.” Id. at 365; see also Gen-Probe, Inc. v. Center for Neurologic Study, 853 F. Supp. 1215, 1217-18 (S.D. Cal. 1993) (holding that a researcher lacked standing to bring claims for alleged violations of § 202 or alleged breach of federal funding agreements, because there is no private right of action under 35 U.S.C. § 202, and the researcher could not assert the claims

of the federal agencies either directly or as third party beneficiary); Fenn v. Yale Univ., 393 F. Supp. 2d 133, 141-42 (D. Conn. 2004) (holding that “the primary purpose of the Bayh-Dole Act is to regulate relationships of small business and nonprofit grantees with the Government” and that the Bayh-Dole Act did not control or preempt the issue of patent ownership between a University and its former faculty member under state law). Thus, under existing case law, there is no private right of action under the Bayh-Dole Act, because the purpose of the Bayh-Dole Act is to regulate the relationship between the Government and its funding recipients, not the relationships between private third parties. Therefore, these cases would support the conclusion by this Court that the Government License created by the Bayh-Dole Act is designed to regulate the relationship between the Government and its funding recipients, but it would not be available to a private third party as the basis for a private right of action or private defense.

In addition, the Court notes that the evaluation of the existence and scope of a Government License is not suited to cases where the Government is not a party to an action. While the patent itself may reflect that “the Government has certain rights in this invention,” the scope of those rights requires reference to the language of the funding agreement between the Government and the patent holder. In Ciba-Geigy Corp. v. Alza Corp., 804 F. Supp. 614, 627-28 (D.N.J. 1992), although not specifically related to the Government License defense, the court attempted to make a determination as to whether certain patents included “subject inventions” under the Bayh-Dole Act. However, the funding agencies were not parties to the litigation, and the court did not have the funding agreements before it. See id. Moreover, the

court could not determine whether the inventions were conceived or first reduced to practice under the grants, and the court noted that neither of the funding agencies had made any claim to the patented inventions. *Id.* at 628. Thus, the Ciba-Geigy case illustrates the practical difficulties involved in attempting to determine whether an invention was conceived or first reduced to practice under a federal funding agreement when the Government is not a party to the action to assert the existence or scope of its license. Ultimately, the court in Ciba-Geigy concluded that even if the patent did include a “subject invention,” the rights under the Bayh-Dole Act belonged to the agency, and “no private right of action exists.” *Id.* at 629. That case, and the difficulties encountered by that court in attempting to make such a determination without the Government as a party to assert the existence and scope of its license, further supports this Court’s conclusion that the Government License defense is best raised by the Government as an affirmative defense, not by a private third party in a patent infringement action against it.

Moreover, the Court notes that there is nothing in the terms of the Bayh-Dole Act or the provisions incorporated into the federal funding agreements that reserves or retains a license for any private third party. Under the terms of the Bayh-Dole Act, “the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license,” and all federal funding agreements must include that same requirement. 35 U.S.C. § 202(c)(4), § 210(c). Thus, the license created by the Bayh-Dole Act and by the terms incorporated into federal funding agreements belongs to the funding agency, not to a private party that subsequently infringes the patent. The license

is retained by the Government and is not transferrable. Therefore, the statutory provisions create a statutory and/or contractual affirmative defense for the Government, as discussed above, but there is no provision in the statutory language that reserves or retains the license for private third parties.

Finally, the Court notes that any application of the Government License defense between private parties must be considered in light of the affirmative defense provided by 28 U.S.C. § 1498. As discussed in the previous section, in a lawsuit between private parties, § 1498(a) operates as an affirmative defense where a private party's use of a patented invention is "for the United States," which includes any use "for the Government" and with the "authorization or consent of the Government." See Madey, 307 F.3d at 1359. The statutory language of the Bayh-Dole Act at 35 U.S.C. § 202(c)(4) uses similar language to create a Government License for practice of a subject invention "for or on behalf of the United States." Thus, both defenses would apply to uses of an invention "for the United States." Although § 1498 applies only where an invention is used "without license of the owner thereof," it has been interpreted to provide an affirmative defense to Government contractors, acting without a license, who use a patented invention "for the Government with its authorization and consent," without regard to what rights the Government may ultimately hold in the invention. See Crater Corp., 255 F.3d at 1364; W.L. Gore & Assocs., 842 F.2d at 1282-83. Thus, § 1498 already provides a defense to private parties where the use of the patented invention is "for the United States," regardless of whether the Government holds a license or other contractual or statutory right in the

invention. In this Court's view, there is no basis to infer a duplicative Government License defense in suits between private parties, where both defenses would require the private party to establish a use "for the United States."<sup>9</sup>

This Court further concludes that this reading of the statutes is consistent with the principle that, pursuant to § 1498, the Government "takes" a "compulsory compensable license in the patent" and the Government is then liable for "just compensation," usually based on a reasonable royalty for the license taken. See Leesona Corp. v. United States, 599 F.2d 958, 968 (Ct. Cl. 1979); see also Motorola, Inc. v. United States, 729 F.2d 765, 768 n.3 (Fed. Cir. 1984) (noting that "[a]s a compulsory, nonexclusive licensee, the Government is treated as . . . [a] voluntary licensee, and not as . . . [a] private, unlicensed infringer"). However, to the extent that the Government may already hold a royalty-free license pursuant to the Bayh-Dole Act or the terms of a funding agreement, the Government would not be liable for additional royalties for uses within the scope of that royalty-free license. To the extent that a patent holder contends that the Government does not hold a royalty-free license or exceeded the scope of its royalty-free license, those issues may be resolved between the patent holder and the Government in a suit for reasonable compensation pursuant to § 1498. In this Court's view, that determination is more appropriately made by the Court of Federal Claims in a suit brought pursuant to § 1498

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<sup>9</sup> Contrary to Duke's contentions, the existence of a Government License would not automatically sanction the use of a subject invention in any Government-funded research without specific direction or assent from the funding agency. Thus, the Government License defense, if it could be raised by a private party, would require a showing, like the § 1498 defense, that the use was "for the United States" and with the assent or direction of the Government.

in which the Government is a party asserting the defense on its own behalf.

In this regard, the Court also notes that the Court of Federal Claims' interpretation of the Government's Bayh-Dole Act defenses should not be defined or confined by the interpretation and construction of § 1498. Instead, § 1498 and the provisions of the Bayh-Dole Act at 35 U.S.C. § 202(c)(4) should be read in tandem as part of an overall scheme that: (1) allows the Government to authorize patent infringement to obtain what it needs, (2) protects private Government contractors or grant recipients who use a patented invention for the Government with the Government's authorization and consent, (3) protects patent holders by allowing suits against the Government for reasonable royalties where the Government or an authorized contractor uses a patented invention, and also (4) provides the Government with a defense where the use of a patented invention is within the scope of the Government's royalty-free license for inventions originally developed with Government funding.

For all of these reasons, the Court concludes that the Government License defense may not be asserted by a private party in a patent infringement suit. Instead, in this Court's view, it is § 1498 which provides a defense in suits between private parties when the private party's use of a patented invention is "for the Government with its authorization and consent," as discussed in detail above.

Having determined the rules that will apply in this case, the Court will now turn to a consideration of Duke's Motion for Summary Judgment in light of these rules. In this regard, the Court notes that given the analysis above, Duke's Motion for Summary Judgment as to the

Government License defense will be denied, since the Court has determined as a matter of law that the Government License defense belongs to the Government as a statutory and contractual affirmative defense, and Duke may not raise that defense on behalf of federal agencies that are not a party to this suit. However, Duke is nevertheless entitled to claim the defense of § 1498 for any use that is “for the Government with its authorization and consent,” and the Court will therefore consider Duke’s Motion for Summary Judgment on the basis of that § 1498 affirmative defense.

### III. ANALYSIS OF MOTION FOR SUMMARY JUDGMENT AS TO § 1498 DEFENSE

#### A. Summary Judgment Standard

Pursuant to Federal Rule of Civil Procedure 56, summary judgment “shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c); see also Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S. Ct. 2548, 2552, 91 L. Ed. 2d 265 (1986). “The burden is initially upon the movant to establish the absence of any genuine issue of material fact and entitlement to judgment as a matter of law.” Crater Corp. v. Lucent Techs., 255 F.3d 1361, 1366 (Fed. Cir. 2001) (citing Celotex, 477 U.S. at 323-34, 106 S. Ct. at 2553). “Once a properly supported motion for summary judgment is made, the adverse party ‘must set forth specific facts showing that there is a genuine issue for trial.’” Id. (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250, 106 S. Ct. 2505, 2511, 91 L. Ed. 2d 202 (1986)). In making this determination,

the Court must “draw all reasonable factual inferences in favor of the nonmovant.” Id. (citing Anderson, 477 U.S. at 255, 106 S. Ct. at 2513).

B. Scope of Government Authorization to Use Patented Inventions

In the present case, Duke contends that its use of the FEL equipment is protected by the § 1498 affirmative defense because all of its uses of the patented inventions were undertaken pursuant to federally-sponsored research, and were “for the United States.” Duke further contends that the Government’s authorization and consent, either express or implied, can be found in the various research funding agreements from the Government to Duke. In response, Dr. Madey appears to contend that a federal research grant to a private party such as Duke cannot be “for the Government.” Dr. Madey further contends that such a research grant cannot provide authorization and consent to infringe patents. However, the Federal Circuit has specifically rejected Dr. Madey’s propositions. See Madey, 307 F.3d at 1359. Therefore, it is clear that a research grant could be “for the Government” and could provide the requisite authorization and consent. See id. at 1359-60; John J. McMullen Assocs., Inc. v. State Board of Higher Education, 406 F.2d 497, 498 (9th Cir. 1969) (holding that § 1498 applied where the Government gave implied consent to infringement as part of a Government research grant involving “work of vital importance to the government”). However, it is also clear that a research grant in and of itself does not necessarily provide authorization and consent. See Madey, 307 F.3d at 1359-60. Therefore, to determine whether § 1498(a) provides an affirmative defense to the recipient of a Government research grant, the Court must, as with other

Government contracts, determine whether the Government research grants “authorize the necessary predicates for § 1498(a),” as discussed above. Madey, 307 F.3d at 1360; Applera Corp. v. MJ Research, Inc., 311 F. Supp. 2d 293, 299 (D. Conn. 2004) (holding that determining whether § 1498 provides an affirmative defense in the context of Government research grants “requires analysis of the particular statements or aspects of the particular governmental grant or contract purportedly providing the Government’s authorization or consent to be sued.”). The Court must then determine “which uses fall within the scope of the . . . grant and which uses are outside that scope.” Madey, 307 F.3d at 1360.

Duke has presented multiple federal funding agreements in an effort to establish that its uses of the patented inventions pursuant to those federally-funded programs were “for the Government with its authorization and consent.” Duke has also presented log books and operating notebooks from the FEL Lab to establish that all of its uses of the FEL equipment were within the scope of these federally-funded programs. Therefore, the Court will first undertake an analysis of each of these federal funding agreements to determine whether the agreement meets the requirements of § 1498 as “for the Government” and “with the authorization and consent” of the Government. After reviewing and addressing each of the federal research agreements presented by Duke, the Court will then address the evidence presented by Duke as to which uses of the FEL equipment were within the scope of which particular federally-funded program.

1. Department of Defense/Office of Naval Research Medical Free Electron Laser Grants

The first federally-funded research grant presented by Duke involves funding from the Office of Naval Research/Department of Defense. According to Duke, the majority of its uses of the FEL Lab were pursuant to Medical Free Electron Laser Grants from the Department of Defense, originally administered by the Office of Naval Research, and currently administered by the Air Force Office of Scientific Research. The Medical Free Electron Laser program was initially funded by Grant # N0014-94-1-0818, which covered the period June 1, 1994 through May 31, 1997, and was extended incrementally through August 31, 2000. (Mueller Decl. [Document # 151, 160] Ex. A.) This Grant was awarded by the Office of Naval Research of the Department of Defense to support specific medical and biomedical research. The Medical Free Electron Laser program was later funded through Grant #F49620-00-1-0370 from the Air Force Office of Scientific Research, which provided funding from September 15, 2000 through June 30, 2004, and Grant #FA9550-04-1-0086 from the Air Force Office of Scientific Research, which provided funding from February 1, 2004 through January 31, 2005. (Dillon Decl. [Document # 155, 158] Ex. C, D.) Specific aspects of this program were also funded by the Office of Naval Research through Grant # N00014-97-1-0911 for the period July 1, 1997 through September 30, 1999 and Grant # N0014-94-1-0927 for the period July 1, 1997 through April 30, 2000. (Dillon Decl. [Document # 155, 158] Ex. G.)

With respect to this program, the Court notes first that the Office of Naval Research

specifically amended the terms of the grant to include a specific clause from the Department of Defense providing that the “work under this agreement is of vital interest to the U.S. Government” and that “the U.S. Government authorizes and consents to all past and future use and manufacture of the invention described in and covered by United States Patent Number 4,641,103 [the ’103 Patent] in the performance of work under this agreement or any subagreement at any tier.” (Mueller Decl. [Document # 151, 160] Ex. A, #DU017006.) The funding agreement further provided that “[i]n accordance with 28 U.S.C. § 1498, the use or manufacture of United States Patent Number 4,641,103 by the recipient under this agreement or by any person, firm or corporation under any subagreement is construed as use or manufacture for the United States.” (Mueller Decl. [Document # 151, 160] Ex. A, #DU017006.) This specific clause requires Duke to report to the Grants officer any infringement claim as to the ’103 Patent, and to provide any requested information if the Government is sued on account of any alleged infringement of the ’103 Patent. (Mueller Decl. [Document # 151, 160] Ex. A, #DU017006.) In addition, the Court further notes that with respect to this project, the Department of the Army subsequently indicated that it was “pleased to collaborate” with Duke on the Mark III FEL project because it involved “excellent application of infrared imaging technology in medicine and is relevant to the warfighter.” (Dillon Decl. [Document # 155, 158] Ex. F, #DS000874.) The Army specifically indicated to Duke that it was “committed to providing you and your organization the technical support you need to successfully complete your research on this important and militarily relevant topic.” (Dillon Decl. [Document # 155,

158] Ex. F, #DS000874.)

After reviewing these provisions and the detailed proposals regarding the research undertaken by Duke pursuant to these specific grants, the Court concludes that these provisions clearly provide express authorization and consent by the Government for uses of the '103 Patent in the performance of the specific projects covered by these funding agreements. Particularly given the explicit language quoted above, there is no question that uses within the scope of this grant were "for the Government" and "with the authorization and consent of the Government." In this regard, the Court notes that research for the Army that is "militarily relevant" to the "warfighter" would be squarely within the original contemplation of § 1498 as a use "for the Government." The Department of Defense's findings and authorization provide the exact protection to Duke contemplated by § 1498, and to hold otherwise would thwart the purpose of § 1498. Specifically, to not find § 1498 applicable here would expose contractors to infringement suits even where direct authorization was provided, and would therefore undermine the Government's ability to obtain goods, services, and research it needed regardless of patent infringement issues.<sup>10</sup> Therefore, in the present case, the Court concludes that any uses

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<sup>10</sup> To the extent that Dr. Madey contends that this authorization was invalid because it was granted at Duke's request, the Court notes that Dr. Madey has not filed any administrative challenge to the agency's action in this regard, and the Court concludes that Duke followed the appropriate procedure in this situation. Specifically, Duke determined that it might infringe on a patented invention for which the Government held a license, and Duke therefore requested the Government's authorization and consent to use the patented invention for the United States. This process is exactly the procedure contractors should follow if their performance of a Government contract involves potential patent infringement, since obtaining the required authorization and consent provides the contractor (Duke in this case) with the affirmative

of the '103 Patent that Duke can establish were within the scope of the Department of Defense grants for the Medical Free Electron Laser program,<sup>11</sup> including maintenance and testing of the equipment, will be protected by the § 1498 affirmative defense.<sup>12</sup>

## 2. Department of Energy Grants

Duke also claims the availability of the § 1498 defense by pointing to an authorization and consent clause provided in a Department of Energy Grant, #DE-FG02-97ER41033, for the Triangle Universities Nuclear Laboratory (TUNL) program covering the period April 1, 1997 through March 31, 2006. (Dillon Decl. [Document # 155, 158] Ex. F.) This program involved a cooperative study between Duke, certain other universities, and the Department of Energy to conduct nuclear astrophysics research involving, *inter alia*, development of polarized ion beams, studies of nuclear structure using neutrons and charged particles, and portions of the Kamioka

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defense in § 1498.

<sup>11</sup> From the Court's review of the evidence, it appears that the authorization and consent was given for the Department of Defense Medical Free Electron Laser program, and that the authorization and consent did not change when the funding was administered by the Air Force Office of Scientific Research. However, the Court will, as part of the trial in this case, allow the parties to address the scope of the program that is covered or not covered by the authorization and consent clause in this specific grant.

<sup>12</sup> Dr. Madey contends that the scope of the § 1498 affirmative defense is somehow contingent on the percentage of funding provided by the Government. However, nothing in § 1498 requires a specific percentage of Government funds to qualify as "for the United States" or with "authorization and consent" of the Government. In this Court's determination, if a Government research grant explicitly authorizes research as "for the Government" and with express authorization and consent of the Government to use patented inventions under the grant, § 1498 would provide an affirmative defense for any use within the scope of that grant, even if other entities also provided funding for the research.

Liquid-scintillator Anti-Neutrino Detector ("KamLAND") experiment in conjunction with Japanese researchers related to the "search for the oscillation of anti-neutrons emitted by several nuclear power plants." (Dillon Decl. [Document # 155, 158] Ex. F, TUNL-KamLAND Proposal.) The grant included a broad authorization and consent clause providing that "[t]he Government hereby gives its authorization and consent for all use and manufacture of any invention described in and covered by a patent of the United States in the performance of this grant or any part hereof or any amendment hereto or any contract hereunder (including all lower-tier contracts hereunder)." (Dillon Decl. [Document # 155, 158] Ex. F, #GUS-1293.) A later Amendment to the grant similarly provided that "[t]he Government authorizes and consents to all use and manufacture of any invention described in and covered by a United States patent in the performance of this contract or any subcontract at any tier." (Dillon Decl. [Document # 155, 158] Ex. F, Amendment No. A001 p.1.) Based on the subject and purposes of the grant and the express authorization and consent included in the funding agreements, this Court concludes that any uses of the '103 or '994 Patents within the scope of this program, including maintenance and testing, would be "for the Government" and "with the authorization and consent" of the Government. Therefore, Duke is entitled to an affirmative defense with respect to any alleged infringement within the scope of this Department of Energy TUNL program involving nuclear astrophysics research.

As part of its assertion of the § 1498 affirmative defense, Duke also points to the authorization and consent provided in a separate Department of Energy Grant, #DE-FG02-

01ER41175, for the period from July 1, 2001 through October 31, 2005. (Dillon Decl. [Document # 155, 158] Ex. E.) This program involved development and utilization of a high-intensity gamma ray source for nuclear physics research (the "HIGS" program). However, this grant contained a more limited authorization and consent clause, providing that "[t]he Government authorizes and consents to all use and manufacture in performing this contract or any subcontract at any tier of any invention described in and covered by a United States patent (1) embodied in the structure or composition of any article the delivery of which is accepted by the Government under this contract or (2) used in machinery, tools, or methods whose use necessarily results from compliance by the Contractor or subcontractor with (i) specifications or written provisions forming a part of this contract or (ii) specific written instructions given by the Contracting Officer directing the manner of performance." (Dillon Decl. [Document # 155, 158] Ex. E, #DS000243.)

With regard to this particular limited authorization and consent clause, Duke contends that its alleged uses of the patented inventions resulted from the "Government's instructions" because Duke's research proposal should be viewed as Government "instructions" which necessarily required the alleged infringement. However, Dr. Madey contends that Duke's use did not necessarily result from any specific Government instruction. With respect to this issue, the Court concludes that Duke's research proposal for the HIGS program was specifically incorporated into the terms of the agreement and therefore became "written provisions forming a part of this contract." (Dillon Decl. [Document # 155, 158] Ex. E, #DS000233 (incorporating

Duke's proposal as a term and condition of the agreement).) However, the Court is unable to determine from the evidence presently before it whether any alleged use of the patented inventions as part of the HIGS program "necessarily resulted" from compliance with the terms of the research proposal. Therefore, the Court finds that testimony on this issue would be necessary to make such a determination. In addition, the Court notes that documents submitted with respect to this HIGS program indicate that a 2003 Amendment to the HIGS grant in fact removed the authorization and consent clause that was previously given for this project. (Dillon Decl. [Document # 155, 158] Ex. F, Amendment 12.) Therefore, the Court cannot make a summary determination with respect to this program at this time, and this issue must be resolved at trial. As a result, Defendant's motion for a summary determination as to this HIGS program will be denied.

### 3. Additional Government Contracts

As part of its assertion of a § 1498 affirmative defense, Duke also points to three other Government funding agreements to establish that Duke's uses of the equipment were "for the Government" and with the "authorization and consent of the Government" so as to provide an affirmative defense under § 1498. Specifically, Duke notes that the National Institutes of Health provided funding through Grant #R01-HL067111 for the period May 2, 2001 through April 30, 2005 for research involving the development of new systems for the diagnosis and therapy of cardiovascular disease. (Dillon Decl. [Document # 155, 158] Ex. B.) In addition, Duke notes that the Environmental Protection Agency provided funding through Grant #R-82901201 for the

period September 20, 2001 through August 19, 2005 for research into potential methods for treating drinking water, specifically "UV irradiation for pathogen inactivation in surface waters." (Dillon Decl. [Document # 155, 158] Ex. H.) Finally, Duke notes that the Army Research Office provided funding through Grant #DAAH04-96-1-0246 for the period June 1, 1996 through May 31, 2000 for Duke's high energy laser defense research program in collaboration with the Boeing Defense and Space Group. (Dillon Decl. [Document # 155, 158] Ex. I.)

After reviewing these agreements, the Court notes first that the purpose and scope of these agreements could certainly involve research "for the Government." However, none of these funding agreements include an express authorization and consent clause, nor has Duke presented any other written authorization and consent from the Government for use of patented inventions as part of these programs. As discussed above, the existence of Government funding for a particular research program is alone insufficient to establish authorization and consent. See Madey, 307 F.3d at 1359-60. Similarly, a Government agency's approval of a research proposal, standing alone, is insufficient to show implied authorization and consent, unless there is a clear indication that the Government agency was specifically aware of and approved of the infringement in its specifications, directions, or other communications with the contractor. As previously noted, implied authorization and consent may be found in situations where "(1) the government expressly contracted for work to meet certain specifications; (2) the specifications cannot be met without infringing on a patent; and (3) the government had some knowledge of the infringement," or where the government requires the private contractor to use or

manufacture the allegedly infringing device. Larson, 26 Cl. Ct. at 370; see also Hughes Aircraft Co., 29 Fed. Cl. at 223. Authorization and consent will not be implied lightly, however, and this Court concludes that there is insufficient evidence to establish that these general funding agreements provided the requisite authorization and consent to be “for the United States” as a matter of law. However, the Court will allow Duke to present evidence on this issue at trial in an effort to establish a sufficient factual basis on which to find either express or implied consent as to each of these three programs in light of the legal standards outlined herein.

#### 4. Uses of the Equipment By Outside Researchers

Finally, Duke contends generally that all use of the FEL Lab by other, outside researchers was also pursuant to Government funding agreements. To the extent that the outside users were federal researchers from the Los Alamos National Laboratory or Thomas Jefferson National Laboratory, there would not appear to be any question that such uses were by or for the United States. However, as to other outside researchers from other universities or organizations, Duke has not presented copies of any federal funding agreements providing authorization and consent from the Government to those outside researchers for specific programs “for the United States.” In addition, the evidence is presently unclear as to what uses were made of the equipment by those outside researchers and whether those uses fell within the scope of any of Duke’s specific programs outlined above. Thus, on the basis of the evidence presently before it, the Court cannot determine what outside uses were made of the FEL Lab and what Government authorization may have been provided for those uses. Therefore, Duke may present evidence

at trial to establish entitlement to the § 1498 defense for these uses, but there is insufficient basis for a summary determination on this issue at this time, and Duke's Motion for Summary Judgment with respect to these outside researchers will be denied.

C. Analysis of Log Books, Operating Notebooks and Specific Uses by Duke

Having considered the various federally-funded programs that Duke contends were "for the United States," the Court must turn to the next step in determining the applicability of § 1498, specifically, a determination of which of Duke's alleged uses of the patented invention fall within the scope of which federal programs. As noted above, where a Government contract or research grant is "for the Government" and provides the requisite "authorization and consent," the next issue for the Court is "which uses fall within the scope of the . . . grant and which uses are outside that scope." Madey, 307 F.3d at 1360.

With respect to this issue, Duke has presented extensive log books and operations notebooks to establish that all of its uses of the Mark III FEL and the storage ring FEL were part of the federally-sponsored programs outlined above. Specifically, Duke contends that from June 1, 1997 through April 30, 1999, all research use of the "Mark III FEL" and "storage ring FEL" occurred under Government research grants, based on the entries in the FEL Operations notebooks. Duke also contends that from May 1, 1999 to the present, all research use of the FEL was supported by Government research grants, although some of the uses were also supported by Duke. In support of this contention, Duke has submitted the FEL Lab Mark III Operations Notebook for the period February 3, 1997 through February 6, 2004, the FEL Lab Storage Ring

Operations Notebook for the period June 2, 1997 through February 2, 2004, and the Storage Ring User's Time Log Sheet for the period from January 13, 1998 through February 7, 2004. (Mueller Decl. [Document # 151, 160] Ex. B, C, D; Edwards Decl. [Document # 153, 157] Ex. A, B, C.)

The Storage Ring User's Time Log Sheet is a date and time log showing the date and time for each use of the equipment, and a brief description of the experiment conducted. For example, an entry on April 27, 1999 shows a log-in time of 10:25 and a log-out time of 12:08 for "TUNL/HIGS," apparently referring to an experiment conducted as part of the TUNL or HIGS research funded by the Department of Energy. (Edwards Decl. [Document # 153, 157] Ex. C.) The Operating Notebooks, in contrast, are not simply sign-in logs, but actually contain research notes and scientific and technical data. (Edwards Decl. [Document # 153, 157] Ex. A, B.) According to Duke, this information can be used to verify that all uses of the Mark III FEL and Storage Ring FEL were within the scope of Government-funded research programs or involved equipment maintenance, diagnostic testing, and equipment upgrades in support of Government-sponsored research. (Mueller Decl. [Document # 151, 160]; Edwards Decl. [Document # 153, 157].)

However, the Court has reviewed the log books and operating notebooks, and cannot make a summary determination as to which uses of the equipment were specifically within the scope of which Government-funded program that was undertaken at Duke. Thus, even for those Government-funded programs that had express authorization and consent and are clearly "for

the United States” for purposes of § 1498, the Court cannot make a summary determination based upon the log books and operations notebooks as to which uses of the equipment by Duke fell within the scope of those programs. The Court therefore concludes that testimony and factual determinations will be required to determine which uses of the equipment fell within the scope of which specific federally-funded program.<sup>13</sup> Therefore, the Court concludes that genuine issues of material fact exist that must be resolved at trial, and Duke’s Motion for Summary Judgment on their assertion of a § 1498 affirmative defense will be denied.

D. Procedural Posture of the Case

Having determined that factual issues remain for trial, the Court intends to schedule this case for trial before this Court during the July 2006 Civil Trial Session. The parties have indicated that a hearing may be required in advance of trial to determine patent construction issues, and the Court anticipates that, if necessary, such a hearing would be held in May 2006. In light of these dates, the Court requests that the parties submit within 10 days of the date of this Order and Memorandum Opinion a proposed schedule, jointly if possible, addressing any supplemental discovery that may be needed, as well as any briefing that may be necessary with respect to the claim construction issues.

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<sup>13</sup> In addition, as discussed above, there are also genuine issues of fact with respect to whether some of the federally-funded programs were “for the Government” and with the “authorization and consent” of the Government to satisfy the requirements of § 1498.

IV. CONCLUSION

For the reasons discussed above, Plaintiff's Motion for Leave to File a Sur-Reply [Document #175] is DENIED, and Plaintiff's additional Motion [Document #177] related to documents filed with the proposed Sur-Reply is DENIED as moot. In addition, as discussed in detail above, Defendant's Motion for Summary Judgment [Document #149] is DENIED, but the Court will follow the legal principles outlined herein in considering the relevant factual issues at trial. As noted above, the Court intends to schedule this case for trial during the July 2006 Civil Trial Session, with any necessary hearing on claim construction issues held in May 2006. In light of these dates, the parties are to submit, within 10 days of the date of this Order and Memorandum Opinion, a proposed schedule, jointly if possible, addressing (1) any supplemental discovery that may be needed, and (2) any briefing that may be necessary with respect to the claim construction issues.

This, the 31<sup>st</sup> day of January, 2006.

  
United States District Judge

