



1-1-2007

Government Contractor and Grant Researcher Affirmative Defenses Against Patent Infringement

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Recommended Citation

Danielle M. Conway, *Government Contractor and Grant Researcher Affirmative Defenses Against Patent Infringement Army Law*. 139 (2007).

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injunctions are generally unavailable.⁴² Thus, the remedies alone make recovery under 28 U.S.C. § 1498 different from that under 35 U.S.C. § 271.

Instead of being a case that clarifies a patentee's remedy for the government's unauthorized use of a patent, *Zoltek* creates more questions than answers.

Lieutenant Colonel Katherine E. White

Government Contractor and Grant Researcher Affirmative Defenses Against Patent Infringement

I. Introduction

Acquisition personnel are being tasked to keep pace with as well as innovate in the procurement and management of intellectual property assets for the benefit of the U.S. government. Along these lines, the U.S. government has increased federal spending for the development of research laboratories and research programs within private and public university settings. Practical and technical procurement and grant issues arise when the U.S. government undertakes research relationships with universities and private laboratories. These issues range from whether procurement regulations apply to agreements entered into between the federal government and contractors or grant recipients, to whether universities are performing research "on behalf of the government" in order to qualify for immunity from claims of infringement of intellectual property. The Federal District Court for the Middle District of North Carolina recently considered the latter issue in *Madey v. Duke University*.⁴³ This case represents protracted litigation which began in 1995 involving claimed patent rights of a university researcher and alleged patent infringement based on unauthorized use of patented inventions by Duke University.

The issues raised and addressed in the district court's decision in *Madey v. Duke University* are significant to the U.S. government, specifically the Department of Defense's research and technology innovation missions. Specifically, universities represent fertile ground for conducting cutting-edge basic and applied research. In fact, the research being done by university faculty and graduate students is often a major component in the federal government's race to remain ahead of foreign governments in the development of dual-use technologies. Accordingly, *Madey v. Duke University* is an important case for government attorneys, acquisition/grant professionals, and technical managers to consider so that the U.S. government can better ensure that universities and their talented personnel remain willing and able to perform research under government contracts or federal grants, absent the specter of potential claims of intellectual property infringement.

II. Background

In 1988, Duke University hired Dr. John M.J. Madey, a prominent scientist in the field of laser technology, as a professor in the physics department. Duke expected Dr. Madey to assist in establishing a Free Electron Laser Laboratory (FEL Lab) as well as assist the university to obtain federal research grants.⁴⁴ Dr. Madey in fact assisted Duke in obtaining federal research grants from the Office of Naval Research (ONR).⁴⁵ Dr. Madey's FEL Lab contained substantial equipment that required Duke to construct an extension onto its physics building in order to house the equipment. Several pieces of equipment contained in Dr. Madey's lab were covered by patents owned by Madey, i.e., U.S. Patent No. 4,641,103 covering a microwave electron gun, and U.S. Patent No. 5,130,994 covering a free-electron laser oscillator for simultaneous narrow spectral resolution and fast time resolution spectroscopy.⁴⁶

damages as beyond the reasonable and entire compensation damages permitted under 1498). See Lipson, *supra* note 32, at 253-54 (discussing the disfavored status of lost profits in § 1498 actions because they are based in an eminent domain theory that allows the United States to take a license and is at odds with an exclusive right).

⁴¹ *Lessona*, 36 Fed. Cl. at 208.

⁴² *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1282 (Fed. Cir. 1988) (stating: "In our view, the statute, 28 U.S.C. § 1498(a), which the injunction is said to contravene, assures it that right without interference from [alleged infringer].")

⁴³ 413 F. Supp. 2d 601 (M.D.N.C. 2006).

⁴⁴ *Id.* at 603.

⁴⁵ *Id.*

⁴⁶ *Id.*

Dr. Madey was employed at Duke for nearly a decade before resigning in 1998 following a dispute with Duke concerning his ability to manage the FEL Lab effectively. Specifically, Dr. Madey contended that as a result of this dispute, 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.⁴⁷ Despite Dr. Madey's resignation, Duke continued to use the lab's equipment, including the equipment covered by Dr. Madey's patents. Based on this unauthorized use of his patents, Dr. Madey sued Duke for patent infringement. In response, Duke contended that all uses of the FEL equipment were pursuant to the ONR grant or other government research grants or authorization.⁴⁸

III. Issues

Madey v. Duke University raises significant issues regarding affirmative defenses available to federal contractors and researchers performing under government contracts or federal research grants when private parties sue those contractors or researchers for infringement. Specifically, the case addresses the findings required to demonstrate what government statements or activities will qualify as government authorization and consent and the scope of such authorization and consent for contractors or researchers seeking immunity from patent infringement. In addition, the *Madey* case discusses the question regarding standing to raise the government license defense created by the Bayh-Dole Act in response to a claim of patent infringement between private parties.

IV. Section 1498 Immunity from Suit for Patent Infringement

Federal law immunizes government contractors and researchers from claims of patent infringement in certain circumstances. Section 1498 provides in part:

Whenever 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.⁴⁹

The Court of Appeals for the Federal Circuit described section 1498 as having two features: to relieve a third party from patent infringement liability and to waive sovereign immunity and consent to liability by the United States.⁵⁰ The courts cite the purpose of section 1498 as being a stimulant to contractors to furnish the government's needs for goods, services, or research without fear of becoming liable themselves for infringements to inventors or owners or assignees of patents.⁵¹ Accordingly, a contractor or researcher who demonstrates that it used a patented invention with the authorization and consent of the U.S. government as well as for the benefit of the government, cannot be held liable for patent infringement in a lawsuit between private parties.

A. Authorization and Consent to Infringe a Patent

As an initial matter, the section 1498 affirmative defense requires a party to establish authorization and consent. A use is with the authorization and consent of the government if the government either expressly or implicitly consents to the infringement.

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ 28 U.S.C. § 1498(a) (LEXIS 2006).

⁵⁰ *Madey*, 413 F. Supp. 2d at 606.

⁵¹ *See id.*

1. Express Authorization and Consent

In some circumstances, the government clearly and expressly authorizes and consents to infringement of a patented invention in the performance of a government contract or research grant. Such express consent is often contained in the language of the government contract or grant itself, or in other formal, written authorization from the government.⁵² Even though a formal writing is evidence of authorization and consent, it need not take a specific form.⁵³ Moreover, the authorization and consent can be broad or limited, depending on the intent of the parties.

a. Broad Authorization and Consent

If the parties intend an authorization and consent that is broad it could extend to any patented invention and any infringing use. For example, the *Federal Acquisition Regulation (FAR)* and contract clauses for federal research and development contracts provide an example of broad authorization and consent language. Specifically, *FAR part 52.227-1* provides:

The 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.⁵⁴

By choosing to negotiate a broad authorization and consent clause, the government ensures that its contractors or researchers have the freedom to use patented inventions to accomplish any work that is required to be performed under the government program or contract.

b. Limited Authorization and Consent

The government may choose to negotiate a more limited authorization and consent for patent infringement. A limited authorization and consent may restrict the contractor or researcher to using only certain patented inventions or to only those uses that are necessary for completing contract or research work. For example, *FAR part 52.227-1* also provides for a more narrow or limited authorization and consent. The clause states in pertinent part:

- (a) The 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 a 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.⁵⁵

By limiting the scope of the authorization and consent, the government controls the extent of patent infringement by its contractors or researchers and also controls the extent of its liability to inventors, owners, or assignees of patents.⁵⁶ Accordingly, limited authorization and consent operates as a limited, as opposed to a full, waiver of sovereign immunity.⁵⁷

2. Implied Authorization and Consent to Infringe a Patent

In other circumstances, the government might not expressly consent, either using broad or narrow language, to contractor/researcher use of patented inventions; instead, the government may be found to have provided implied consent.⁵⁸

⁵² See *id.* at 607-08.

⁵³ See *id.*

⁵⁴ 48 C.F.R. 52.227-1 (1984) (Authorization and Consent, Alternate I).

⁵⁵ 48 C.F.R. 52.227-1 (July 1995) (Authorization and Consent; see also 48 C.F.R. 27.201-2(a)).

⁵⁶ *Madey*, 413 F. Supp. 2d at 608.

⁵⁷ *Id.* at 609.

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.”⁵⁹

Because implied consent also operates as a waiver of sovereign immunity pursuant to section 1498, such authorization and consent must be narrowly construed.⁶⁰ The contractor or researcher carries the burden of proof that the government authorized and consented to its patent infringement because section 1498 is an affirmative defense that will immunize otherwise infringing conduct.⁶¹ In addition, the contractor or researcher must demonstrate that its infringing conduct falls within the scope of the government’s authorization and consent.⁶²

For the Benefit of the Government

The second prong of the section 1498 affirmative defense requires the contractor or researcher to show that its use of a patented invention was for the government. A use is for the government if it is in furtherance and fulfillment of a statement of government policy that serves the government’s interests.⁶³

Assertion of § 1498 Affirmative Defense in Private Party Litigation

Generally, when a patent holder asserts patent infringement against the government’s agent, either contractor or researcher, section 1498 provides an affirmative defense that applies only when an invention is used without a license. Thus, section 1498 provides an affirmative defense to contractors or researchers, acting without a license, who use a patented invention with the government’s authorization and consent for the benefit of the government without regard to the rights that the government may ultimately hold in the invention.⁶⁴ As a practical matter, section 1498 grants the government a compulsory, compensable license in the patent, which only requires the government to pay just compensation for a contractor’s or researcher’s use of the patented invention. Moreover, the section 1498 affirmative defense was meant to protect contractors or researchers who are required to use the patented inventions of others from patent infringement suits where the government is not a party to such litigation.

Duke University found itself party to such litigation. Importantly, Dr. Madey did not sue the government for patent infringement; rather, Dr. Madey only sued Duke University for its continued use of his patented inventions in the operation of the FEL Lab. In response to Dr. Madey’s claims of patent infringement, Duke University asserted the section 1498 affirmative defense. Specifically, Duke University contended that it remained a researcher for the Office of Naval Research and performed under ONR federal research grants that provided either express or implied authorization, and consent for the use of patented inventions for the benefit of the government. Furthermore, Duke University contended that all of its uses fell within the scope of the government’s authorization and consent because it was undertaking federally sponsored research.

The district court concluded, while a research grant in and of itself does not necessarily provide authorization and consent, a grant recipient may still avail itself of the section 1498 affirmative defense if the grantee demonstrates the necessary predicates. Accordingly, the district court stated that the statements or aspects of the particular governmental grant purportedly providing the government’s authorization and consent had to be analyzed. As such, the district court analyzed federal grant funding agreements, log books, and operating notebooks to determine whether the uses of the FEL Lab equipment were within the scope of the relevant federally funded programs.⁶⁵

⁵⁸ *Id.*

⁵⁹ *Id.* at 620.

⁶⁰ *Id.* at 609.

⁶¹ *Id.*

⁶² *Id.* at 610.

⁶³ *Id.* at 607.

⁶⁴ *Id.* at 614.

⁶⁵ *Id.* at 616.

With respect to two funding agreements with the Department of Defense and the Department of Energy, respectively, the District Court concluded that Duke University's uses of Dr. Madey's 103 and 994 patents fell within the scope of the federal grant programs and were protected by the section 1498 affirmative defense. The district court found that "the Office of Naval Research specifically amended the terms of the grant to include a 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 [the 103 patent] in the performance of work under this agreement or any subagreement at any tier.'"⁶⁶ The district court cited another provision of the funding agreement that stated: "In accordance with 28 U.S.C. § 1498, the use or manufacture of [the 103 patent] 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."⁶⁷ The district court cited similar language of authorization and consent in Department of Energy grant funding agreements with respect to [the 994 patent].

Based on these findings, the district court concluded that the specific grant provisions clearly provided express government authorization and consent for uses of the patents in the performance of the specific projects covered by the relevant funding agreements. The district court further concluded that there was no question that uses within the scope of the grants were for the government and with the authorization and consent of the government. For example, the district court noted that "research for the Army that was 'militarily relevant' to the 'warfighter' would be squarely within the original contemplation of Section 1498 as a use for the Government."⁶⁸ The district court explained that because of its holding regarding authorization and consent for uses that benefit the government, all Duke University would have to do in subsequent proceedings is present testimony and evidence that its research undertakings were within the scope of the DoD and DOE grants in order to assert successfully the § 1498 affirmative defense.⁶⁹

V. Government License Defense

The Government License Defense created by the Bayh-Dole Act⁷⁰ was meant to benefit and regulate the relationship between the government and its contractors or funding recipients.⁷¹ The Government License Defense cannot be invoked by a private party as a defense to a patent owner's claim of infringement because the defense only belongs to the Government. In order to take advantage of the Government License Defense, the government would actually have to be a party to the patent infringement litigation involving otherwise only private parties.

In *Madey*, Duke University contended that the government held a license to practice or have practiced on its behalf the 103 and 994 patents because the inventions described in these patents were originally developed as part of government sponsored research.⁷² Accordingly, Duke argued that the license extended at least to all uses that would be considered "for the United States."⁷³ Duke University's attempt to raise the Government License Defense was unsuccessful because Dr. Madey sued only Duke University for patent infringement, not the government. Accordingly, Duke University's motion for summary judgment as to the Government License Defense was denied because Duke could not, as a matter of law, raise that affirmative defense on behalf of federal agencies that were not party to Dr. Madey's patent infringement suit. Thus, the Government License Defense is best raised by the government as an affirmative defense, not by a private party in a patent infringement action against only itself.⁷⁴

⁶⁶ *Id.* at 617.

⁶⁷ *Id.*

⁶⁸ *Id.* at 618.

⁶⁹ *See id.*

⁷⁰ 35 U.S.C.S. § 200 - _____ (LEXIS 2006). The Act allows nonprofit organizations and small and large businesses to retain title to any subject inventions that result from federally funded projects. Congress passed the Act "to promote 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." *Id.* § 200. The Act also sought "to ensure that the Government obtains 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." *Id.*

⁷¹ *Madey*, 413 F. Supp. 2d at 613.

⁷² *See id.* at 605.

⁷³ *See id.*

⁷⁴ *See id.* at 613.

A. Statutory Government License

The Bayh-Dole Act creates a government license by statute. The statute retains for the federal funding agency a paid-up license. The Act states, in pertinent part:

With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.⁷⁵

As the statutory language indicates, the nonexclusive license that the government retains is not transferable. Accordingly, the statutory license right belongs only to the government and can be invoked only by the government. Thus, the government, if party to a patent infringement suit, is the only party able to raise the statutory Government License Defense. In order to establish that it is entitled to the Government License Defense, the government must proffer a funding agreement between itself and the patent holder; as well, the government must establish that the patented invention was conceived or first reduced to practice under that funding agreement.⁷⁶

In *Madey*, the district court concluded that Duke University could not avail itself of the statutory Government License Defense. The district court held that the statutory "Government License created by the Bayh-Dole Act [was] 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 or a private right of action or, [as in this case,] a private defense."⁷⁷

B. Contractual/Regulatory Government License

The Bayh-Dole Act creates a government license by reference to incorporated contract language. The Act requires that all federal funding agreements must include language that reserves for the government the license specified in 35 U.S.C. § 202(c)(4). As with the statutory Government License, the contractual Government License is not transferable and, therefore, remains a right only for the government. Moreover, the contractual Government License cannot be invoked as an affirmative defense to patent infringement by a private third party.

VI. Practical Implications of the Affirmative Defenses to Patent Infringement

Madey v. Duke University raised several implications for the drafting of government contracts and grant funding agreements. First, the government as well as its contractors and grant recipients must pay keen attention to the purpose and goals of the contract or research grant. The parties to the contract or grant must identify their intentions before executing contracts or funding agreements. In particular, the government and its contractors or grant recipients must ensure that agreements are unambiguous as to the scope and extent of authorization and consent for certain activity or conduct occurring under or pursuant to contracts or funding agreements.

Second, with respect to grant funding agreements in particular, the parties to such a grant cannot merely rely on the grant itself to establish the necessary predicates for invoking a section 1498 affirmative defense. For example, the government's mere approval of a research proposal, standing alone, is insufficient to show implied authorization and consent.⁷⁸ Instead, the government and its grant recipients should consider the more prudent course of including express language of authorization and consent and express statements regarding how grant activity will benefit the government in relevant funding agreements. By relying on express authorization and consent as opposed to implied authorization and consent, the government and its grant recipients can be confident of meeting the burden of proof for showing the applicability of section 1498 in a patent infringement suit between private parties.

Third, the government and its contractors or grant recipients should negotiate the proper type of authorization and consent based upon the contract work or federally supported research to be undertaken. The type of work or research to be performed will dictate whether the parties should contemplate broad or limited authorization and consent language in

⁷⁵ 35 U.S.C.S. § 202 (c)(4) (LEXIS 2006).

⁷⁶ *Madey*, 413 F. Supp. 2d at 612.

⁷⁷ *Id.* at 613.

⁷⁸ *Id.* at 620.

contracts or grant funding agreements. If broad authorization and consent language is intended and if such language is consistent with the work or research to be performed, it would be prudent to rely on express as opposed to implied authorization and consent.

Finally, a contractor or a grant recipient being sued for patent infringement where the government is not a party cannot rely on the Government License Defense. The Government License Defense is a right belonging only to the government and not to a private third party. Accordingly, a contractor or grant recipient must find its defense to patent infringement arising from private litigation in the application of section 1498.

Major Danielle M. Conway