

Analysis of Current Issues

Intersection Between Biodefense and Patent Law: Federal Research Grants, Project Bioshield, and 28 USC §1498(a)

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THE PRESIDENT'S 2003 BUDGET for biodefense research at the National Institutes of Health (NIH) was \$1.75 billion, a greater than six-fold increase from the previous fiscal year, which constituted the largest single increase in resources for any discipline or any institute in the history of NIH.¹ Further, in June of 2004, President Bush signed Project Bioshield into law allocating \$5.6 billion over the next 10 years to develop new tools to improve the country's medical countermeasures against a chemical, biological, radiological, or nuclear attack.² Project Bioshield, still in its nascent stages, is designed to expedite NIH research and development on medical countermeasures and also to fund government contracts for the supply of vaccines and drugs to combat bioterrorism. Using both the NIH biodefense budget and Project Bioshield, the federal government will award new grants and contracts to academic researchers and corporations.

This influx of money for biodefense has the potential to force the courts to address an issue that has remained largely undeveloped in the case law, namely, can work performed pursuant to a federal research grant be considered work "by or for the government" within the meaning of 28 USC §1498(a)? This statutory provision shields government contractors and their agents from suit for patent infringement if the work is done "by or for" the federal government.³

Traditionally, 28 USC §1498(a) has been applied to government contracts, which may include explicit clauses whereby the government waives sovereign

immunity and consents to being sued for a contractor's infringement of a U.S. patent held by another.⁴ Such "authorization and consent" clauses shield a government contractor from suit by preventing a patent holder from enjoining the government-authorized activity. Rather than suing the contractor, the patent holder is required to seek compensatory relief from the federal government in the Court of Federal Claims.⁵ However, government contractors are not always completely shielded from liability. In some contracts, a "patent indemnity clause" is included, which requires the infringing contractor to reimburse the government should the government be found liable for damages to the patentee.⁶

The federal government established the Federal Acquisition Regulations System to provide uniform policies and procedures for acquisition of supplies and services by all executive agencies.⁷ This System consists primarily of one comprehensive document, the Federal Acquisition Regulation (FAR), which governs the acquisition process and provides specific contract language to be used in government contracts.⁸ The FAR applies only to acquisitions,

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² President George W. Bush, Address at the signing of Project Bioshield (June 21, 2004).

³ 28 USC §1498 (West 2004).

⁴ Lionel M. Lavenue, Patent infringement against the United States and government contractors under 28 U.S.C. section 1498 in the United States Court of Federal Claims, 2 J. Intell. Prop. L. 389 (1995).

⁵ See, e.g., FAR §52.227-1.

⁶ See, e.g., FAR §52.227-3.

⁷ See FAR §1.101.

⁸ *Id.*

which are defined as “the acquiring by contract of supplies or services” for use by the government.⁹ The FAR definition of a contract specifically excludes grants.¹⁰ Thus, absent some newly promulgated federal regulation, research grants awarded under either Project Bioshield or the NIH Biodefense Budget will not include authorization and consent clauses.

Legally, the courts have held that the government’s authorization and consent to be sued may be either express or implied.¹¹ Most often, express authorization and consent is given by including such a clause in a government contract.¹² However, the more interesting legal issue is the applicability of 28 USC §1498(a) when no such clause is present; for example, when the work is performed pursuant to a federal grant.

The issue of implied authorization and consent in the context of federal grants is a relatively undeveloped area of the law. In a case decided 36 years ago, *McMullen Associates Inc. v. State Board of Higher Education*,¹³ the Court of Appeals for the Ninth Circuit declined to make a rule that work performed under a federal research grant is *per se* “by or for the government.” However, the court did find, under the circumstances of that case, that a grantee performing research pursuant to National Science Foundation and Naval Research grants was shielded from patent liability by 28 USC §1498(a).¹⁴ The court’s decision was based on the following factors: (1) the work was of “vital importance to the government;” (2) the work was funded primarily through a National Science Foundation grant, which the court deemed a “funding device for work of special interest to the United States Navy;” and (3) the ship with the infringing devices was used only for research approved and financed by the government.

A more recent case, *Madey v. Duke University*,¹⁵ may provide further guidance concerning this issue. *Madey* is well known for the Court of Appeals for the Federal Circuit’s holding that the common-law experimental research exemption¹⁶ from patent infringement does not reach university-sponsored academic research.¹⁷ However, an ongoing second issue being addressed in *Madey* is whether the research, which was funded by a grant from the Office of Naval Research (ONR), was performed “by or for” the federal government.¹⁸ Like the Ninth Circuit in *McMullen*, the Court in *Madey* declined to create a bright-line rule. Instead, the Federal Circuit remanded the issue for further consideration by

the district court to “identify, discuss, or analyze the particular statements or aspects of the ONR grant that may have provided the government’s authorization or consent to be sued.”¹⁹ In the event that the district court finds that the grant provides such authorization and consent, the Federal Circuit further instructed the district court to determine which uses of the patented invention fell within the ONR grant and which uses are outside that scope.²⁰ On remand, the district court has asked the parties to brief these issues at trial.²¹ Thus, it remains uncertain whether the ONR grant in *Madey* will be deemed sufficient to invoke the protection of 28 USC §1498(a). Moreover, should the parties settle the litigation, the issue will remain unresolved.

In sum, both the Ninth Circuit in *McMullen* and the Federal Circuit in *Madey* have taken the position that the applicability of 28 USC §1498(a) to federal grants is a fact-intensive question that can be determined only after considering the wording of the grant, the degree of interest the federal government has in the research, and whether the research falls within the scope of the grant. Thus, because of the paucity of case law beyond *McMullen* and *Madey* and the lack of a bright-line rule, there remains a significant amount of uncertainty concerning what facts must be present to shield a grantee from patent liability. In the context of grants awarded to further biodefense research, an argument can be made that there is a high level of govern-

⁹ See FAR §2.101.

¹⁰ *Id.* (stating “contracts do not include grants and cooperative agreements covered by 31 U.S.C. 6301”).

¹¹ See generally Donald S. Chisum, *Chisum on Patents* §16.06[3][c] (1st Ed. 1998).

¹² *Stelma, Inc. v. Bridge Elec. Co.*, 300 F.2d 761 (3rd Cir. 1962); *Molinaro v. Watkins-Johnson CEI Div.*, 359 F. Supp. 467 (D. Md. 1973).

¹³ *McMullen Assocs. v. State Bd. of Higher Educ.*, 406 F.2d 497 (9th Cir. 1969).

¹⁴ 406 F.2d 497 (1969).

¹⁵ *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002), *remanded to 2004 U.S. Dist. Lexis 19182* (M.D. N.C. 2004).

¹⁶ The common-law research exemption originated in a district court opinion written by Justice Story in Massachusetts. *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).

¹⁷ Esmond, R.W. and Schwartzmann, R.A., *Intell. Prop. Strategist* 11:1 (2004).

¹⁸ 307 F.3d 1351.

¹⁹ *Id.* at 1359.

²⁰ *Id.* at 1360.

²¹ *Madey v. Duke Univ.*, 2004 U.S. Dist. Lexis 19182 at *37-28 (M.D. NC Sept. 20, 2004).

mental interest, given the overarching goal of defending the United States against bioterrorism. However, to increase the chances of avoiding patent liability, grantees would be well advised to seek affirmative statements in grants concerning the important governmental interest that is being served by the research. Further, the scope of grants should

be broad enough to encompass all of the grantee's activity because, even if 28 USC §1498(a) applies, activity falling outside a grant may infringe a patent held by another.

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