2010-1499 (Serial No. 10/924,633)

United States Court of Appeals

for the

Federal Circuit

IN RE JEFF LOVIN, ROBERT ADAMS, and DAN KURUZAR

Appeal from the United States Patent and Trademark Office, Board of Patent Appeals and Interferences.

BRIEF OF AMICUS CURIAE REGULATORY CHECKBOOK IN SUPPORT OF NEITHER PARTY ON THE MERITS AND IN SUPPORT OF APPELLANTS' PETITION FOR REHEARING EN BANC

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SEPTEMBER 20, 2011

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* Regulatory Checkbook certifies the following to the best of their current knowledge:

- 1. The full name of the *Amicus* represented is Regulatory Checkbook.
- 2. There are no real parties in interest associated with the *Amicus*.
- 3. There are no parent corporations or any publicly held companies that own ten percent (10%) or more of the stock of Regulatory Checkbook.
- 4. Regulatory Checkbook did not appear in the trial court. Expected to appear on behalf of Regulatory Checkbook before the Court of Appeals for the Federal Circuit is William P. Atkins of Pillsbury Winthrop Shaw Pittman LLP.

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STATEMENT OF AMICUS CURIAE

Regulatory Checkbook is a non-profit Virginia Corporation engaged in regulatory review and oversight in the public interest, including compliance by federal agencies such as the U.S. Patent and Trademark Office ("PTO") with the Paperwork Reduction Act (44 U.S.C. § 3501 *et seq.*, "PRA"). Regulatory Checkbook believes that full enforcement of 44 U.S.C. § 3512, the PRA's public protection provisions, is essential to achieve the purposes of the law.

Regulatory Checkbook's principal, Dr. Richard B. Belzer, earned a Ph.D. from Harvard in 1989. From 1988 to 1998, he was a staff economist in the Office of Information and Regulatory Affairs ("OIRA") in the Office of Management and Budget ("OMB"). OIRA was established in 1981 to implement the PRA.¹

PRELIMINARY STATEMENT

A. Legal Background: Procedural Requirements for Agency Rulemaking Arising Under the Paperwork Reduction Act

The PRA and implementing regulations² promulgated by OMB are intended to protect the public from burdensome paperwork. Whenever an agency plans to collect information from the public, the agency must prepare objectively supported

¹ Pursuant to Federal Circuit Rule 29(c)(5), no party's counsel authored the brief in whole or in part, no party or party's counsel contributed money that was intended to fund preparing or submitting the brief, and no person other than the amici or their counsel contributed money that was intended to fund preparing or submitting the brief.

² 44 U.S.C. §§ 3501–3520, especially §§ 3506, 3507 and 3512, and 5 C.F.R. Part 1320 (often called the Information Collection Rule), especially §§ 1320.5, 1320.8, 1320.9, and 1320.11. Relevant portions are set forth in the Addendum to this brief.

estimates of burden, seek public comment, and secure prior OMB approval. 44 U.S.C. §§ 3503, 3507; 5 C.F.R. §§ 1320.3, 1320.5, and 1320.8 to 1320.12. On approval, OMB issues a "control number," which must be "displayed" before the agency may collect the information. 5 C.F.R. § 1320.3(f).

Section 3512 says "no person shall be subject to any penalty for failing to comply with a collection of information" that does not display a valid OMB control number, or that lacks a statement "that such person is not required to respond to the collection of information unless it displays a valid control number." 44 U.S.C. § 3512. The definition of *penalty* includes "denial of a license, privilege, right, grant, or benefit." 44 U.S.C. § 3502(14); 5 C.F.R. § 1320.3(j). The PRA allows any affected person to cite the absence of a valid OMB control number as a complete defense "at any time during the agency administrative process or judicial action applicable thereto." 44 U.S.C. § 3512(b); 5 C.F.R. § 1320.6. Failure to obtain a control number renders an agency's request to collect information unenforceable. Center for Auto Safety v. National Highway Traffic Safety Admin., 244 F.3d 144, 148 (D.C. Cir. 2001) ("If [the agency] fails to obtain prior approval from OMB, the request for information can be ignored without penalty."). Indeed, Congress acted in 1995 to strengthen and extend the PRA's public protections in ways directly relevant to the PTO, the Board, and this case.³

³ Floor statement of Sen. Nunn, in support of S. 244, the Paperwork Reduction Act of 1995, Pub. L. 104-13, 109 Stat. 163, at Cong. Rec. S3506, *available at* http://www.gpo.gov/fdsys/pkg/CREC-1995-03-06/html/CREC-1995-03-06-pt1-PgS3504-2.htm.

B. Statement of Facts

During the entire pendency of Appellants' patent application, the PTO lacked OMB approval for information it seeks to collect in its *ex parte* appeal rules in 37 C.F.R. Part 41, except for a pair of routine forms each estimated by the PTO to take 12 minutes to complete. The first time the PTO secured a valid OMB control number permitting the PTO to collect the information it seeks in appeal briefs was December 22, 2009.⁴ Appellants filed their brief on August 4, 2008.

SUMMARY OF ARGUMENT

Because the PTO did not have a valid OMB control number for Appellants' August 4, 2008 Appeal Brief, the PTO has no authority to enforce the information collections contained in 37 C.F.R. § 41.37. Thus, the PTO may not impose any penalty for the alleged failure to include particular information in the Brief.

Appellants' failure to raise the Section 3512 defense earlier is not a bar to raising it now because the PRA expressly allows it to be raised "at *any* time during the agency administrative process or judicial action applicable thereto." 44 U.S.C.

Although the act's public protection provisions explicitly shield the public from the imposition of any formal agency penalty for failing to comply with such an unapproved, or bootleg, paperwork requirement, individuals often feel compelled to comply. This is especially true when the individual has an ongoing relationship with the agency and that relationship accords the agency substantial discretion that could be used to redefine their future dealings. In other words, leverage. Under S. 244, a member of the public can blow the whistle on such a bootleg paperwork requirement and be accorded the protection of anonymity.

⁴ http://www.reginfo.gov/public/do/PRAOMBHistory? ombControlNumber=0651-0063.

§ 3512(b) (emphasis added). Appellants' Request for Rehearing *en banc* is an applicable judicial action, and the PTO's systematic noncompliance with the PRA and persistent lack of transparency would argue for the Court's indulgence even if Appellants did not have this unambiguous statutory right.

Appellant's failure to raise the Section 3512 defense earlier can be explained by how the PTO misinformed the public about the Office's PRA responsibilities and its refusal to acknowledge having failed to comply, discussed in Sec. II below. In its Federal Register notices for the Board's 2003-04 and 2007-08 rulemakings, the PTO falsely stated that the information collections contained therein had been approved by OMB. Applicants cannot be expected to look past an agency's false statements to ascertain their true legal rights.

ARGUMENT

I. By Statute, the "Public Protection" Provision of the Paperwork Reduction Act May Be Raised at Any Time, Including Anew on Appeal

The PRA's public protection provisions are worded with extraordinary breadth and comprehensiveness. They apply "notwithstanding any other provision of law" and they "may be raised in the form of a complete defense, bar, or otherwise at any time during the agency administrative process *or judicial action* applicable thereto." 44 U.S.C. § 3512(a), (b) (emphasis added); *Center for Auto Safety v. NHTSA*, 244 F.3d 144, 150 (D.C. Cir. 2001) ("[B]y explicitly allowing parties to raise a Paperwork Reduction Act claim at any time during ongoing proceedings, the [PRA] 'prevents an agency or court from refusing to consider a [PRA] argument on the ground that it is untimely." (quoting *Saco River Cellular*,

Inc. v. FCC, 133 F.3d 25, 31 (D.C. Cir. 1998)). This powerful remedy shows Congress was serious about protecting the public from agency misconduct.

II. The PTO Cannot Enforce 37 C.F.R. Part 41 Against Appellants

A. The PTO Lacked a Valid OMB Control Number for Appeal Briefs Filed Before December 22, 2009

The PRA and the OMB's implementing regulations require agencies to include in every Notice of Proposed Rulemaking ("NPRM") an identification of the specific information it proposes to collect, allow no less than 60 days' public comment, and submit an approval request to OMB for review. 5 C.F.R. § 1320.11(a)-(c). The PRA and OMB's implementing regulations also require the PTO to submit Final Rules and revised approval requests to OMB on or before the date of promulgation "explain[ing] how any collection of information contained in the final rule responds to any comments received from OMB or the public." 5 C.F.R. § 1320.11(h), (f).

The accessible public record shows that at no time before December 22, 2009 could the PTO *ever* have had a valid OMB control number for *any* material collection of information contained in 37 C.F.R. Part 41, nor for the pre-2004 appeal rules §§ 1.192 and 1.193, because <u>before December 2009</u> the *PTO never obtained OMB approval*. ⁵ On that date, OMB issued a control number expressly

⁵ For appeals, the PTO had a valid OMB approval only for Form SB/31 (notice of appeal) and SB/32 (request for oral hearing). Each form is purely clerical, and is estimated by the PTO to take 12 minutes to complete.

limited to *only* collections of information contained in the Board's *2004* rules.⁶ Thus, when Appellants filed their appeal brief in August 2008, the Board did not have a valid OMB control number and *knew* it had no valid OMB control number, having implicitly confessed as much in a June 9, 2008 *Federal Register* notice.⁷ The Board also failed to provide notice to Appellants that they were "not required to respond to the collection of information" because it lacked a valid OMB control number. 44 U.S.C. § 3506(c)(1)(B)(iii)(V); 5 C.F.R. § 1320.5(b)(2)(i).

In February and May 2010, the Board affirmed a rejection *solely because Appellants failed to make a particular argument in their Appeal Brief* (A025-26, A004-05). This is a "bootleg" attempt to collect information without OMB approval. *See* note 3 above. The Board's refusal to consider patentability is a penalty that it cannot impose because the Board lacked (and *knew* that it lacked) a valid OMB control number and failed to inform Appellants that they had no obligation to comply.

B. The PTO Failed to Request OMB Clearance for the Modification Implied in the Board's Decision

When an agency proposes to modify its interpretation of an existing rule, the agency must request approval for the paperwork burden imposed by that new interpretation. 5 C.F.R. § 1320.11, 1320.12. This requirement applies to any non-trivial burden added when an agency amends its rules or guidance documents,

⁶ Office of Management and Budget, Notice of Action to PTO, 200809-0651-003, available at http://www.reginfo.gov/public/do/DownloadNOA?requestID=216727.

⁷ 73 Fed. Reg. 32559 (June 9, 2008), *available at* http://edocket.access.gpo.gov/2008/pdf/E8-12820.pdf.

revises a regulation by internal agency tribunal decision, or by any other mechanism that increases paperwork burdens on the public.

The Board stated "the PTO's policy is for the examiner to compare the rejected claims feature-by-feature or limitation-by limitation with each of the references relied upon in the rejection." MPEP § 1207.02(A); *Ex parte Forest*, Appeal No. 2000-1901, 2002 WL 33951036 at *2 (B.P.A.I. May 30, 2002). Appellants argue that the Board's new interpretation of Section 41.37 created a new burden of proof on the Appellants (Appellants' Tan Br. at 12-13). Any increase in the burden of proof would increase information collection burden, requiring a new OMB approval. 44 U.S.C. § 3507; 5 C.F.R. § 1320.11, 1320.12. OMB's records show that the PTO did not request such an approval. 8

III. The PTO's PRA Violations Began Before 1993 and Continued Even After Public Commenters Pointed Them Out

Appellants' failure to raise the Section 3512 defense earlier is explained by the PTO's misconduct. The PTO systematically evaded its PRA responsibilities, misinformed the public about how the PRA applies to the Board's rules of practice, and after having gained unambiguous knowledge that it was in violation, refused to inform the public. This misconduct is not an "honest mistake" because it continues unabated.

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⁸ The absence of any filing can be seen at the OMB's web page tracking the PTO's filings relating to appeals, http://www.reginfo.gov/public/do/ PRAOMBHistory? ombControlNumber=0651-0063

A. The PTO Neither Sought Nor Obtained an OMB Control Number for the 2004 Appeal Rules

The PTO's noncompliance with the PRA extends at least a decade. In the 2003 NPRM to revise the Board's rules of practice, the PTO acknowledged that the information collections contained therein were covered by the PRA, but inaccurately stated that the information collections contained in existing rules had been approved by OMB and that the NPRM contained no new informational requirements. 68 Fed. Reg. 66648, 66668 col. 1 (Nov. 26, 2003). The PTO neither sought public comment nor submitted any approval request to OMB as required by 5 C.F.R. § 1320.11(a)-(b). The PTO repeated these statements in its 2004 Final Rule Notice, 69 Fed. Reg. 49960, 49996 col. 3 (Aug. 12, 2004), but no record shows that the PTO ever requested approval from OMB before December 2009.

B. The PTO Failed to Comply with the PRA When It Promulgated the Board's 2008 Rules of Practice

In its July 2007 NPRM to revise the Board's rules of practice, the PTO again acknowledged that the information collections contained therein were covered by the PRA, and again inaccurately stated that the information collections contained in existing rules had been approved by OMB and that the NPRM contained no new informational requirements. 72 Fed. Reg. 41472, 41484 col. 1 (Jul. 30, 2003). Again, the PTO neither sought public comment nor requested OMB approval as required by 5 C.F.R. § 1320.11(a)-(b).

In fall 2007, several public commenters pointed out the PRA violations.⁹

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⁹ See public comments are posted at http://www.uspto.gov/ip/rules/comments/bpai1.jsp.

The PTO and Board thus knew no later than October 2007 that its July 2007 NPRM had fatal procedural defects. The Board attempted to cure these defects nine months later, acknowledging that existing rules *did* include unapproved paperwork burdens and the NPRM did contain new information requirements. The Board published a description of these information collections, estimated their annual respondent burden at exactly \$239,907,450 per year, and sought 60 days' public comment. 73 Fed. Reg. 32559, 32560 col. 2 (Jun. 9, 2008). Inexplicably, the Board then short-circuited the statutory process by promulgating the Final Rule the very next day. 73 Fed. Reg. 32938 (Jun. 10, 2008). The PTO ignored the PRA's intentional statutory alignment with the Administrative Procedure Act rulemaking process it was designed to complement and requested approval from OMB three months late. 73 Fed. Reg. 58943 (Oct. 8, 2008). After the public alerted OMB to these fatal procedural defects, OMB declined to issue a control number. 10 Lacking approval, the PTO stayed the effective date, but obfuscated the reason. 73 Fed. Reg. 74972 col. 1 ("[R]eview by OMB has not been completed."). The PTO never informed the public that it was legally entitled to ignore all of 37 C.F.R. Part 41.

The PTO and the Board continue to behave disingenuously. In an Advance Notice of Proposed Rulemaking (ANPRM) regarding starting over from scratch, the Board's rules of practice rulemaking process curiously implied that its

¹⁰ The public comments are posted at http://www.reginfo.gov/public/do/PRAViewDocument?ref nbr=200809-0651-003.

December 2008 stay of the Final Rule was motivated by a memorandum issued by the President's Chief of Staff on January 21, 2009. 74 Fed. Reg. 67987, 67988 col. 3 (Dec. 22, 2009). The PTO again failed to notify the public that it lacked a valid OMB control number for all previously submitted responses to 37 C.F.R. Part 41 collections of information save the two administrative forms, and that Appellants were not obligated to comply. The PTO subsequently published an NPRM that omitted transparent and reproducible objective support for its burden estimates, as required by 44 U.S.C. § 3506(c)(2)(B) and (c)(3) and 5 C.F.R. § 1320.8(d)(1) and § 1320.9. 75 Fed. Reg. 69828, 69844-69846 (Nov. 15, 2010). Several public comments noted the PTO's continued noncompliance and lack of transparency.¹¹

IV. Conclusion

Because the PTO did not comply with its obligations under the PRA, the PTO cannot enforce the portions of 37 C.F.R. § 41.37 at issue. Thus, this Court should grant Appellants' request for rehearing *en banc* to address this issue.

Respectfully submitted,

September 20, 2011

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¹¹ The public comment letters are at http://www.uspto.gov/ip/boards/bpai/procedures/rules/comments_to_nprm_of_nov_15_2010.jsp

ADDENDUM (FRAP 28(f))

THE PAPERWORK REDUCTION ACT (Excerpts)¹²

44 U.S.C. § 3501. Purpose

The purposes of this subchapter are to--

(1) minimize the paperwork burden for individuals, small businesses, educational and nonprofit institutions, Federal contractors, State, local and tribal governments, and other persons resulting from the collection of information by or for the Federal Government;

...

(11) improve the responsibility and accountability of the Office of Management and Budget and all other Federal agencies to Congress and to the public for implementing the information collection review process, information resources management, and related policies and guidelines established under this subchapter.

44 U.S.C. § 3502. Definitions

As used in this chapter -

- (2) the term "burden" means time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal agency, including the resources expended for—
 - (A) reviewing instructions;
 - (B) acquiring, installing, and utilizing technology and systems;
 - (C) adjusting the existing ways to comply with any previously applicable instructions and requirements;
 - (D) searching data sources;
 - (E) completing and reviewing the collection of information; and
 - (F) transmitting, or otherwise disclosing the information;
 - (3) the term "collection of information"—

¹² The text of the PRA is available at http://www.archives.gov/federal-register/laws/paperwork-reduction.

- (A) means the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for either—
 - (i) answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons, other than agencies, instrumentalities, or employees of the United States; or
 - (ii) answers to questions posed to agencies, instrumentalities, or employees of the United States which are to be used for general statistical purposes.

. . .

(11) the term "practical utility" means the ability of an agency to use information, particularly the capability to process such information in a timely and useful fashion;

. . .

(14) the term "penalty" includes the imposition by an agency or court of a fine or other punishment; a judgment for monetary damages or equitable relief; or the revocation, suspension, reduction, or denial of a license, privilege, right, grant, or benefit.

44 U.S.C. § 3506. Federal agency responsibilities

- (c) With respect to the collection of information and the control of paperwork, each agency shall—
 - (1) establish a process within the office headed by the Chief Information Officer designated under subsection (a), that is sufficiently independent of program responsibility to evaluate fairly whether proposed collections of information should be approved under this subchapter, to—
 - (A) review each collection of information before submission to the Director for review under this subchapter, including—
 - (i) an evaluation of the need for the collection of information;
 - (ii) a functional description of the information to be collected;

- (iii) a plan for the collection of the information;
- (iv) a specific, objectively supported estimate of burden;
- (v) a test of the collection of information through a pilot program, if appropriate; and
- (vi) a plan for the efficient and effective management and use of the information to be collected, including necessary resources;
- (B) ensure that each information collection—

- (iii) informs the person receiving the collection of information of—
 - (I) the reasons the information is being collected;
 - (II) the way such information is to be used;
 - (III) an estimate, to the extent practicable, of the burden of the collection;
 - (IV) whether responses to the collection of information are voluntary, required to obtain a benefit, or mandatory; and
 - (V) the fact that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number; and
- (C) assess the information collection burden of proposed legislation affecting the agency;
- (2)(A) except as provided under [§ 3506(c)(2)(B)] or [§ 3507(j)], provide 60-day notice in the Federal Register, and otherwise consult with members of the public and affected agencies concerning each proposed collection of information, to solicit comment to—
 - (i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;
 - (ii) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;

- (iii) enhance the quality, utility, and clarity of the information to be collected; and
- (iv) minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology; and
- (B) for any proposed collection of information contained in a proposed rule (to be reviewed by the Director under § 3507(d)), provide notice and comment through the notice of proposed rulemaking for the proposed rule and such notice shall have the same purposes specified under [§ 3506(c)(2)(A)(i)] through [§ 3506(c)(2)(A)(iv)]; and
- (3) certify (and provide a record supporting such certification, including public comments received by the agency) that each collection of information submitted to the Director for review under § 3507—
 - (A) is necessary for the proper performance of the functions of the agency, including that the information has practical utility;
 - (B) is not unnecessarily duplicative of information otherwise reasonably accessible to the agency;
 - (C) reduces to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency, including with respect to small entities...
 - (D) is written using plain, coherent, and unambiguous terminology and is understandable to those who are to respond;
 - (E) is to be implemented in ways consistent and compatible, to the maximum extent practicable, with the existing reporting and recordkeeping practices of those who are to respond;

. .

(G) contains the statement required under [§ 3506(c)(1)(B)(iii)];

44 U.S.C. § 3507. Public information collection activities — submission to Director; approval and delegation

- (a) An agency shall not conduct or sponsor the collection of information unless in advance of the adoption or revision of the collection of information—
 - (1) the agency has—
 - (A) conducted the review established under [§ 3506(c)(1)];
 - (B) evaluated the public comments received under [§ 3506(c)(2)];
 - (C) submitted to the Director the certification required under [§ 3506(c)(3)], the proposed collection of information, copies of pertinent statutory authority, regulations, and other related materials as the Director may specify; and
 - (D) published a notice in the Federal Register—
 - (i) stating that the agency has made such submission; and
 - (ii) setting forth—
 - (I) a title for the collection of information;
 - (II) a summary of the collection of information;
 - (III) a brief description of the need for the information and the proposed use of the information;
 - (IV) a description of the likely respondents and proposed frequency of response to the collection of information;
 - (V) an estimate of the burden that shall result from the collection of information; and
 - (VI) notice that comments may be submitted to the agency and Director;
 - (2) the Director has approved the proposed collection of information or approval has been inferred, under the provisions of this section; and
 - (3) the agency has obtained from the Director a control number to be displayed upon the collection of information.

- (c)(1) For any proposed collection of information not contained in a proposed rule, the Director shall notify the agency involved of the decision to approve or disapprove the proposed collection of information.
 - (2) The Director shall provide the notification under paragraph (1), within 60 days after receipt or publication of the notice under subsection (a)(1)(D), whichever is later.

. . .

- (d)(1) For any proposed collection of information contained in a proposed rule—
 - (A) as soon as practicable, but no later than the date of publication of a notice of proposed rulemaking in the Federal Register, each agency shall forward to the Director a copy of any proposed rule which contains a collection of information and any information requested by the Director necessary to make the determination required under this subsection...

. . .

- (d)(2) When a final rule is published in the Federal Register, the agency shall explain—
 - (A) how any collection of information contained in the final rule responds to the comments, if any, filed by the Director or the public; or
 - (B) the reasons such comments were rejected.

. . .

44 U.S.C. § 3512. Public protection

- (a) Notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information that is subject to this subchapter if—
 - (1) the collection of information does not display a valid control number assigned by the Director in accordance with this subchapter; or
 - (2) the agency fails to inform the person who is to respond to the collection of information that such person is not required to respond to the collection of information unless it displays a valid control number.
- (b) The protection provided by this section may be raised in the form of a complete defense, bar, or otherwise at any time during the agency administrative process or judicial action applicable thereto.

5 C.F.R. PART 1320 — CONTROLLING PAPERWORK BURDENS ON THE PUBLIC (Excerpts)

5 C.F.R. § 1320.3 Definitions.

. .

- (b)(1) *Burden* means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency, including:
 - (i) Reviewing instructions;
 - (ii) Developing, acquiring, installing, and utilizing technology and systems for the purpose of collecting, validating, and verifying information;
 - (iii) Developing, acquiring, installing, and utilizing technology and systems for the purpose of processing and maintaining information;
 - (iv) Developing, acquiring, installing, and utilizing technology and systems for the purpose of disclosing and providing information;
 - (v) Adjusting the existing ways to comply with any previously applicable instructions and requirements;
 - (vi) Training personnel to be able to respond to a collection of information;
 - (vii) Searching data sources;
 - (viii) Completing and reviewing the collection of information; and
 - (ix) Transmitting, or otherwise disclosing the information.

. . .

(c) *Collection of information* means, ..., the obtaining, causing to be obtained, soliciting, or requiring the disclosure to an agency, third parties or the public of information by or for an agency by means of identical questions posed to, or identical reporting, recordkeeping, or disclosure requirements imposed on, ten or more persons, whether such collection of information is mandatory, voluntary, or required to obtain or retain a benefit. "Collection of information" includes any

requirement or request for persons to obtain, maintain, retain, report, or publicly disclose information. As used in this Part, "collection of information" refers to the act of collecting or disclosing information, to the information to be collected or disclosed, to a plan and/or an instrument calling for the collection or disclosure of information, or any of these, as appropriate.

(1) A "collection of information" may be in any form or format, including the use of report forms; application forms; schedules; questionnaires; surveys; reporting or recordkeeping requirements; contracts; agreements; policy statements; plans; rules or regulations; planning requirements; circulars; directives; instructions; bulletins; requests for proposal or other procurement requirements; interview guides; oral communications; posting, notification, labeling, or similar disclosure requirements; telegraphic or telephonic requests; automated, electronic, mechanical, or other technological collection techniques; standard questionnaires used to monitor compliance with agency requirements; or any other techniques or technological methods used to monitor compliance with agency requirements. A "collection of information" may implicitly or explicitly include related collection of information requirements.

. . .

(f) Display means:

- (1) In the case of forms, questionnaires, instructions, and other written collections of information sent or made available to potential respondents (other than in an electronic format), to place the currently valid OMB control number on the front page of the collection of information;
- (2) In the case of forms, questionnaires, instructions, and other written collections of information sent or made available to potential respondents in an electronic format, to place the currently valid OMB control number in the instructions, near the title of the electronic collection instrument, or, for online applications, on the first screen viewed by the respondent;
- (3) In the case of collections of information published in regulations, guidelines, and other issuances in the Federal Register, to publish the currently valid OMB control number in the Federal Register (for example, in the case of a collection of information in a regulation, by publishing the OMB control number in the preamble or the regulatory text for the final rule, in a technical amendment to the final rule, or in a separate notice announcing OMB approval of the collection of information). In the case of a collection of information published in an issuance that is also included in the Code of Federal Regulations, publication of the currently valid control number in the

Code of Federal Regulations constitutes an alternative means of "display." In the case of a collection of information published in an issuance that is also included in the Code of Federal Regulations, OMB recommends for ease of future reference that, even where an agency has already "displayed" the OMB control number by publishing it in the Federal Register as a separate notice or in the preamble for the final rule (rather than in the regulatory text for the final rule or in a technical amendment to the final rule), the agency also place the currently valid control number in a table or codified section to be included in the Code of Federal Regulations. For placement of OMB control numbers in the Code of Federal Regulations, see 1 CFR 21.35.

- (4) In other cases, and where OMB determines in advance in writing that special circumstances exist, to use other means to inform potential respondents of the OMB control number.
- (h) *Information* means any statement or estimate of fact or opinion, regardless of form or format, whether in numerical, graphic, or narrative form, and whether oral or maintained on paper, electronic or other media. "Information" does not generally include items in the following categories; however, OMB may determine that any specific item constitutes "information":
 - (1) Affidavits, oaths, affirmations, certifications, receipts, changes of address, consents, or acknowledgments; provided that they entail no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument (by contrast, a certification would likely involve the collection of "information" if an agency conducted or sponsored it as a substitute for a collection of information to collect evidence of, or to monitor, compliance with regulatory standards, because such a certification would generally entail burden in addition to that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument);
 - (2) Samples of products or of any other physical objects;
 - (3) Facts or opinions obtained through direct observation by an employee or agent of the sponsoring agency or through nonstandardized oral communication in connection with such direct observations;

...

(j) *Penalty* includes the imposition by an agency or court of a fine or other punishment; a judgment for monetary damages or equitable relief; or the revocation, suspension, reduction, or denial of a license, privilege, right, grant, or benefit.

- (k) *Person* means an individual, partnership, association, corporation (including operations of government-owned contractor-operated facilities), business trust, or legal representative, an organized group of individuals, a State, territorial, tribal, or local government or branch thereof, or a political subdivision of a State, territory, tribal, or local government or a branch of a political subdivision;
- (l) *Practical utility* means the actual, not merely the theoretical or potential, usefulness of information to or for an agency, taking into account its accuracy, validity, adequacy, and reliability, and the agency's ability to process the information it collects ...

5 C.F.R. § 1320.5 General requirements.

- (a) An agency shall not conduct or sponsor a collection of information unless, in advance of the adoption or revision of the collection of information—
 - (1) The agency has—
 - (i) Conducted the review required in §1320.8;
 - (ii) Evaluated the public comments received under §1320.8(d) and §1320.11;
 - (iii) Submitted to the Director, in accordance with such procedures and in such form as OMB may specify,
 - (A) The certification required under §1320.9,
 - (B) The proposed collection of information in accordance with §1320.10, §1320.11, or §1320.12, as appropriate,
 - (C) An explanation for the decision that it would not be appropriate, under §1320.8(b)(1), for a proposed collection of information to display an expiration date;
 - (D) An explanation for a decision to provide for any payment or gift to respondents, other than remuneration of contractors or grantees;
 - (E) A statement indicating whether (and if so, to what extent) the proposed collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and an explanation for the decision;

- (F) A summary of the public comments received under §1320.8(d), including actions taken by the agency in response to the comments, and the date and page of the publication in the Federal Register of the notice therefor; and
- (G) Copies of pertinent statutory authority, regulations, and such related supporting materials as OMB may request; and
- (iv) Published, except as provided in §1320.13(d), a notice in the Federal Register
 - (A) Stating that the agency has made such submission; and
 - (B) Setting forth—
 - (1) A title for the collection of information;
 - (2) A summary of the collection of information;
 - (3) A brief description of the need for the information and proposed use of the information;
 - (4) A description of the likely respondents, including the estimated number of likely respondents, and proposed frequency of response to the collection of information;
 - (5) An estimate of the total annual reporting and recordkeeping burden that will result from the collection of information;
 - (6) Notice that comments may be submitted to OMB; and
 - (7) The time period within which the agency is requesting OMB to approve or disapprove the collection of information if, at the time of submittal of a collection of information for OMB review under §1320.10, §1320.11 or §1320.12, the agency plans to request or has requested OMB to conduct its review on an emergency basis under §1320.13; and
- (2) OMB has approved the proposed collection of information, OMB's approval has been inferred under §1320.10(c), §1320.11(i), or §1320.12(e), or OMB's disapproval has been voided by an independent regulatory agency under §1320.15; and

- (3) The agency has obtained from the Director a control number to be displayed upon the collection of information.
- (b) In addition to the requirements in paragraph (a) of this section, an agency shall not conduct or sponsor a collection of information unless:
 - (1) The collection of information displays a currently valid OMB control number; and
 - (2)(i) The agency informs the potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.
 - (ii) An agency shall provide the information described in paragraph (b)(2)(i) of this section in a manner that is reasonably calculated to inform the public.
 - (A) In the case of forms, questionnaires, instructions, and other written collections of information sent or made available to potential respondents (other than in an electronic format), the information described in paragraph (b)(2)(i) of this section is provided "in a manner that is reasonably calculated to inform the public" if the agency includes it either on the form, questionnaire or other collection of information, or in the instructions for such collection.
 - (B) In the case of forms, questionnaires, instructions, and other written collections of information sent or made available to potential respondents in an electronic format, the information described in paragraph (b)(2)(i) of this section is provided "in a manner that is reasonably calculated to inform the public" if the agency places the currently valid OMB control number in the instructions, near the title of the electronic collection instrument, or, for on-line applications, on the first screen viewed by the respondent.
 - (C) In the case of collections of information published in regulations, guidelines, and other issuances in the Federal Register, the information described in paragraph (b)(2)(i) of this section is provided "in a manner that is reasonably calculated to inform the public" if the agency publishes such information in the Federal Register (for example, in the case of a collection of information in a regulation, by publishing such information in

the preamble or the regulatory text, or in a technical amendment to the regulation, or in a separate notice announcing OMB approval of the collection of information). In the case of a collection of information published in an issuance that is also included in the Code of Federal Regulations, publication of such information in the Code of Federal Regulations constitutes an alternative means of providing it "in a manner that is reasonably calculated to inform the public." In the case of a collection of information published in an issuance that is also included in the Code of Federal Regulations, OMB recommends for ease of future reference that, even where an agency has already provided such information "in a manner that is reasonably calculated to inform the public" by publishing it in the Federal Register as a separate notice or in the preamble for the final rule (rather than in the regulatory text for the final rule or in a technical amendment to the final rule), the agency also publish such information along with a table or codified section of OMB control numbers to be included in the Code of Federal Regulations (see §1320.3(f)(3)).

- (D) In other cases, and where OMB determines in advance in writing that special circumstances exist, to use other means that are reasonably calculated to inform the public of the information described in paragraph (b)(2)(i) of this section.
- (c)(1) Agencies shall submit all collections of information, other than those contained in proposed rules published for public comment in the Federal Register or in current regulations that were published as final rules in the Federal Register, in accordance with the requirements in §1320.10. Agencies shall submit collections of information contained in interim final rules or direct final rules in accordance with the requirements of §1320.10.
 - (2) Agencies shall submit collections of information contained in proposed rules published for public comment in the Federal Register in accordance with the requirements in §1320.11.
 - (3) Agencies shall submit collections of information contained in current regulations that were published as final rules in the Federal Register in accordance with the requirements in §1320.12.
 - (4) Special rules for emergency processing of collections of information are set forth in §1320.13.

- (5) For purposes of time limits for OMB review of collections of information, any submission properly submitted and received by OMB after 12:00 noon will be deemed to have been received on the following business day.
- (d)(1) To obtain OMB approval of a collection of information, an agency shall demonstrate that it has taken every reasonable step to ensure that the proposed collection of information:
 - (i) Is the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives;
 - (ii) Is not duplicative of information otherwise accessible to the agency; and
 - (iii) Has practical utility. The agency shall also seek to minimize the cost to itself of collecting, processing, and using the information, but shall not do so by means of shifting disproportionate costs or burdens onto the public.
 - (2) Unless the agency is able to demonstrate, in its submission for OMB clearance, that such characteristic of the collection of information is necessary to satisfy statutory requirements or other substantial need, OMB will not approve a collection of information—
 - (i) Requiring respondents to report information to the agency more often than quarterly;
 - (ii) Requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
 - (iii) Requiring respondents to submit more than an original and two copies of any document;
 - (iv) Requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;
 - (v) In connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;
 - (vi) Requiring the use of a statistical data classification that has not been reviewed and approved by OMB;

- (vii) That includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- (viii) Requiring respondents to submit proprietary, trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.
- (e) OMB shall determine whether the collection of information, as submitted by the agency, is necessary for the proper performance of the agency's functions. In making this determination, OMB will take into account the criteria set forth in paragraph (d) of this section, and will consider whether the burden of the collection of information is justified by its practical utility. In addition:
 - (1) OMB will consider necessary any collection of information specifically mandated by statute or court order, but will independently assess any collection of information to the extent that the agency exercises discretion in its implementation; and
 - (2) OMB will consider necessary any collection of information specifically required by an agency rule approved or not acted upon by OMB under §1320.11 or §1320.12, but will independently assess any such collection of information to the extent that it deviates from the specifications of the rule.
- (f) Except as provided in §1320.15, to the extent that OMB determines that all or any portion of a collection of information is unnecessary, for any reason, the agency shall not engage in such collection or portion thereof. OMB will reconsider its disapproval of a collection of information upon the request of the agency head or Senior Official only if the sponsoring agency is able to provide significant new or additional information relevant to the original decision.
- (g) An agency may not make a substantive or material modification to a collection of information after such collection of information has been approved by OMB, unless the modification has been submitted to OMB for review and approval under this Part.
- (h) An agency should consult with OMB before using currently approved forms or other collections of information after the expiration date printed thereon (in those cases where the actual form being used contains an expiration date that would expire before the end of the use of the form).

5 C.F.R. § 1320.6 Public protection.

- (a) Notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information that is subject to the requirements of this part if:
 - (1) The collection of information does not display, in accordance with § 1320.3(f) and § 1320.5(b)(1), a currently valid OMB control number assigned by the Director in accordance with the Act; or
 - (2) The agency fails to inform the potential person who is to respond to the collection of information, in accordance with § 1320.5(b)(2), that such person is not required to respond to the collection of information unless it displays a currently valid OMB control number.
- (b) The protection provided by paragraph (a) of this section may be raised in the form of a complete defense, bar, or otherwise to the imposition of such penalty at any time during the agency administrative process in which such penalty may be imposed or in any judicial action applicable thereto.
- (c) Whenever an agency has imposed a collection of information as a means for proving or satisfying a condition for the receipt of a benefit or the avoidance of a penalty, and the collection of information does not display a currently valid OMB control number or inform the potential persons who are to respond to the collection of information, as prescribed in § 1320.5(b), the agency shall not treat a person's failure to comply, in and of itself, as grounds for withholding the benefit or imposing the penalty. The agency shall instead permit respondents to prove or satisfy the legal conditions in any other reasonable manner.
 - (1) If OMB disapproves the whole of such a collection of information (and the disapproval is not overridden under § 1320.15), the agency shall grant the benefit to (or not impose the penalty on) otherwise qualified persons without requesting further proof concerning the condition.
 - (2) If OMB instructs an agency to make a substantive or material change to such a collection of information, the agency shall permit respondents to prove or satisfy the condition by complying with the collection of information as so changed.
- (d) Whenever a member of the public is protected from imposition of a penalty under this section for failure to comply with a collection of information, such penalty may not be imposed by an agency directly, by an agency through judicial process, or by any other person through administrative or judicial process.

(e) The protection provided by paragraph (a) of this section does not preclude the imposition of a penalty on a person for failing to comply with a collection of information that is imposed on the person by statute—e.g., 26 U.S.C. § 6011(a) (statutory requirement for person to file a tax return), 42 U.S.C. § 6938(c) (statutory requirement for person to provide notification before exporting hazardous waste).

5 C.F.R. § 1320.8 Agency collection of information responsibilities.

The [agency] shall review each collection of information before submission to OMB for review under this part.

(a) This review shall include:

- (4) A specific, objectively supported estimate of burden, which shall include, in the case of an existing collection of information, an evaluation of the burden that has been imposed by such collection;
- (5) An evaluation of whether (and if so, to what extent) the burden on respondents can be reduced by use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses;
- (6) A test of the collection of information through a pilot program, if appropriate; and
- (7) A plan for the efficient and effective management and use of the information to be collected, including necessary resources.
- (b) Such office shall ensure that each collection of information:
- (1) Is inventoried, displays a currently valid OMB control number, and, if appropriate, an expiration date;
- (2) Is reviewed by OMB in accordance with the clearance requirements of 44 U.S.C. § 3507; and
- (3) Informs and provides reasonable notice to the potential persons to whom the collection of information is addressed of—
 - (i) The reasons the information is planned to be and/or has been collected;
 - (ii) The way such information is planned to be and/or has been used to further the proper performance of the functions of the agency;

- (iii) An estimate, to the extent practicable, of the average burden of the collection (together with a request that the public direct to the agency any comments concerning the accuracy of this burden estimate and any suggestions for reducing this burden);
- (iv) Whether responses to the collection of information are voluntary, required to obtain or retain a benefit (citing authority), or mandatory (citing authority);
- (v) The nature and extent of confidentiality to be provided, if any (citing authority); and
- (vi) The fact that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

. .

- (d)(1) Before an agency submits a collection of information to OMB for approval, and except as provided in paragraphs (d)(3) and (d)(4) of this section, the agency shall provide 60-day notice in the Federal Register, and otherwise consult with members of the public and affected agencies concerning each proposed collection of information, to solicit comment to:
 - (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
 - (ii) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
 - (iii) Enhance the quality, utility, and clarity of the information to be collected; and
 - (iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.
 - (2) If the agency does not publish a copy of the proposed collection of information, together with the related instructions, as part of the Federal Register notice, the agency should—

- (i) Provide more than 60-day notice to permit timely receipt, by interested members of the public, of a copy of the proposed collection of information and related instructions; or
- (ii) Explain how and from whom an interested member of the public can request and obtain a copy without charge, including, if applicable, how the public can gain access to the collection of information and related instructions electronically on demand.

5 C.F.R. § 1320.9 Agency certifications for proposed collections of information.

As part of the agency submission to OMB of a proposed collection of information, the agency (through the head of the agency, the Senior Official, or their designee) shall certify (and provide a record supporting such certification) that the proposed collection of information—

- (a) Is necessary for the proper performance of the functions of the agency, including that the information to be collected will have practical utility;
- (b) Is not unnecessarily duplicative of information otherwise reasonably accessible to the agency;
- (c) Reduces to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency, including with respect to small entities, as defined in the Regulatory Flexibility Act (5 U.S.C. § 601(6)), the use of such techniques as:
 - (1) Establishing differing compliance or reporting requirements or timetables that take into account the resources available to those who are to respond;
 - (2) The clarification, consolidation, or simplification of compliance and reporting requirements; or
 - (3) An exemption from coverage of the collection of information, or any part thereof; ...

5 C.F.R. § 1320.11 Clearance of collections of information in proposed rules.

Agencies shall submit collections of information contained in proposed rules published for public comment in the Federal Register in accordance with the following requirements:

(a) The agency shall include, in accordance with the requirements in §1320.5(a)(1)(iv) and §1320.8(d)(1) and (3), in the preamble to the Notice of Proposed Rulemaking a statement that the collections of information contained in

the proposed rule, and identified as such, have been submitted to OMB for review under section 3507(d) of the Act. The notice shall direct comments to the Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for [name of agency].

- (b) All such submissions shall be made to OMB not later than the day on which the Notice of Proposed Rulemaking is published in the Federal Register, in such form and in accordance with such procedures as OMB may direct. Such submissions shall include a copy of the proposed regulation and preamble.
- (c) Within 60 days of publication of the proposed rule, but subject to paragraph (e) of this section, OMB may file public comments on collection of information provisions. The OMB comments shall be in the form of an OMB Notice of Action, which shall be sent to the Senior Official or agency head, or their designee, and which shall be made a part of the agency's rulemaking record.
- (d) If an agency submission is not in compliance with paragraph (b) of this section, OMB may, subject to paragraph (e) of this section, disapprove the collection of information in the proposed rule within 60 days of receipt of the submission. If an agency fails to submit a collection of information subject to this section, OMB may, subject to paragraph (e) of this section, disapprove it at any time.
- (e) OMB shall provide at least 30 days after receipt of the proposed collection of information before submitting its comments or making its decision, except as provided under §1320.13.
- (f) When the final rule is published in the Federal Register, the agency shall explain how any collection of information contained in the final rule responds to any comments received from OMB or the public. The agency shall include an identification and explanation of any modifications made in the rule, or explain why it rejected the comments. If requested by OMB, the agency shall include OMB's comments in the preamble to the final rule.

. . . .

(h) On or before the date of publication of the final rule, the agency shall submit the final rule to OMB, unless it has been approved under paragraph (g) of this section (and not substantively or materially modified by the agency after approval). Not later than 60 days after publication, but subject to paragraph (e) of this section, OMB shall approve, instruct the agency to make a substantive or material change to, or disapprove, the collection of information contained in the final rule. Any such instruction to change or disapprove may be based on one or more of the following reasons, as determined by OMB:

- (1) The agency has failed to comply with paragraph (b) of this section;
- (2) The agency had substantially modified the collection of information contained in the final rule from that contained in the proposed rule without providing OMB with notice of the change and sufficient information to make a determination concerning the modified collection of information at least 60 days before publication of the final rule; or
- (3) In cases in which OMB had filed public comments under paragraph (c) of this section, the agency's response to such comments was unreasonable, and the collection of information is unnecessary for the proper performance of the agency's functions.
 - (i) After making such decision to approve, to instruct the agency to make a substantive or material change to, or disapprove, the collection of information, OMB shall so notify the agency. If OMB approves the collection of information or if it has not acted upon the submission within the time limits of this section, the agency may request, and OMB shall assign an OMB control number. If OMB disapproves or instructs the agency to make substantive or material change to the collection of information, it shall make the reasons for its decision publicly available.
 - (j) OMB shall not approve any collection of information under this section for a period longer than three years. Approval of such collection of information will be for the full three-year period, unless OMB determines that there are special circumstances requiring approval for a shorter period.
- (k) After receipt of notification of OMB's approval, instruction to make a substantive or material change to, disapproval of a collection of information, or failure to act, the agency shall publish a notice in the Federal Register to inform the public of OMB's decision.
- (l) As provided in §1320.5(b) and §1320.6(a), an agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

§ 1320.12 Clearance of collections of information in current rules.

Agencies shall submit collections of information contained in current rules that were published as final rules in the Federal Register in accordance with the following procedures:

- (a) In the case of a collection of information contained in a published current rule which has been approved by OMB and has a currently valid OMB control number, the agency shall:
- (1) Conduct the review established under § 1320.8, including the seeking of public comment under § 1320.8(d); and
- (2) After having made a reasonable effort to seek public comment, but no later than 60 days before the expiration date of the OMB control number for the currently approved collection of information, submit the collection of information for review and approval under this part, which shall include an explanation of how the agency has used the information that it has collected.
 - (b) ...

United States Court of Appeals
for the Federal Circuit No. 2010-1499 (Serial No. 10/924,633)
IN RE JEFF LOVIN, ROBERT ADAMS, and DAN KURUZAR

CERTIFICATE OF SERVICE

I, John C. Kruesi, Jr., being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by PILLSBURY WINTHROP SHAW PITTMAN LLP, Attorneys for Amicus Curiae, to print this document. I am an employee of Counsel Press.

On the **20th Day of September, 2011**, I served the within **BRIEF OF AMICUS CURIAE** upon:

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via Express Mail, by causing 2 true copies of each, enclosed in a properly addressed wrapper, to be deposited in an official depository of the U.S. Postal Service.

Unless otherwise noted, 19 copies have been hand-delivered to the Court on the same date as above.

September 20, 2011