

From: Erica Wissolik
Sent: Monday, November 05, 2012 3:26 PM
To: fitf_rules; fitf_guidance; Till, Mary; Fonda, Kathleen; Tamayo, Raul; Knight Jr., Bernard J.;
Nicholas_A._Fraser@omb.eop.gov; USPTO Info; Jamie.Belcore@sba.gov
Subject: IEEE-USA Comments on First-to-File NPRM and Examination Guidelines

Re: Changes to Implement the First Inventor to File Provisions of the Leahy-Smith America Invents Act,
RIN 0651-AC77, 77 Fed. Reg. 43742 (Jul 26, 2012) and Examination Guidelines, 77 Fed. Reg. 43759 (Jul.
26, 2012)

IEEE-USA respectfully submits the attached consolidated comments on the Notice of Proposed
Rulemaking for the first-to-file regulations (the NPRM) and related examination guidelines.

Sincerely,

--

Erica R. Wissolik
Program Manager, Government Relations
IEEE-USA
2001 L Street, NW, Suite 700
Washington, DC 20036
202 530 8347 direct | 202 785 0835 fax
e.wissolik@ieee.org | www.ieeeusa.org

++++
IEEE - Advancing Technology for Humanity
++++

5 November 2012

By email: fitf_rules@uspto.gov, fitf_guidance@uspto.gov, Mary.Till@uspto.gov;
Kathleen.Fonda@uspto.gov; Raul.Tamayo@uspto.gov; Bernard.Knight@uspto.gov;
Nicholas_A._Fraser@omb.eop.gov; usptoinfo@uspto.gov; Jamie.Belcore@sba.gov

Mail Stop Comments—Patents
Commissioner for Patents
P.O. Box. 1450
Alexandria, VA 22313-1450

Attn: Pinchus Laufer, Senior Legal Advisor, Susy Tsang-Foster and Mary Till, Legal Advisors,
Office of Patent Legal Administration

Attn: Raul Tamayo, Legal Advisor, Office of Patent Legal Administration, Paperwork reduction
Act issues at § III.D starting at page 20

Attn: GC Bernard Knight re legal compliance, discussed in § III starting at page 16

Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building, Room 10202
725 17th St. NW
Washington D.C. 20503

Attn: Nicholas A. Fraser, Desk Officer for the United States Patent and Trademark Office (E.O.
12,866, Paperwork Reduction Act, and Information Collection issues raised in §§ III.C,
III.D, and III.F)

Attn: Jamie Belcore Saloom, SBA Office of Advocacy, issues under the Regulatory Flexibility
Act, § III.E at page 23

Re: Changes to Implement the First Inventor to File Provisions of the Leahy-Smith America
Invents Act, RIN 0651-AC77, [77 Fed. Reg. 43742](#) (Jul 26, 2012) and Examination
Guidelines, [77 Fed. Reg. 43759](#) (Jul. 26, 2012)

Dear Ms. Tsang-Foster, Dr. Laufer, Ms. Till, Ms. Fonda, Mr. Frasier, and Ms. Belcore Saloom:

IEEE-USA respectfully submits these consolidated comments on the Notice of Proposed Rulemaking for the first-to-file regulations (the “NPRM”) and related examination guidelines. IEEE-USA is the United States unit of the IEEE, the world’s largest professional association for technological professionals. IEEE-USA has 210,000 members, largely electrical, electronic, software, mechanical, and biomedical engineers, working in universities and thousands of companies from the largest and most-established to the smallest and newest. IEEE-USA’s interest in this rulemaking reflects the immense effect that it will have on our members, their careers, and their ability to create the next generation of America’s companies and jobs.

IEEE-USA is grateful to and impressed by the monumental efforts and personal dedication of professionals at the U.S. Patent & Trademark Office (“PTO”) who have shepherded a series of rulemaking proceedings prescribed by the America Invents Act (“AIA”) under an impossible schedule. IEEE-USA recognizes the immense task that Congress gave the PTO in coming up with rules and guidance to implement the largest changes to American patent law since at least 1870. Because of the magnitude of these changes, careful and transparent analysis is crucial. We urge the PTO to take care that the laws be faithfully executed, particularly the laws that require that careful analysis, and that ensure due process in rule-making, as we discuss below.

TABLE OF CONTENTS

I.	Comments on Specific Provisions of the First-to-File NPRM	3
A.	Regulations relating to 1952 Act applications should be retained.....	3
B.	The structure of Proposed § 1.55 and § 1.78 should be clarified.....	3
C.	New regulation numbers should certainly not reuse numbers of existing regulations that will continue to be in effect, and advisedly should avoid conflict with old regulations that are retired	4
D.	Does the PTO propose to initiate and resolve derivation issues when the derived prior art is neither a patent nor an application? How is the applicant to obtain evidence to support an affidavit?	5
II.	Comments on Specific Provisions of the First-to-File Examination Guidelines.....	5
A.	The Examination Guidelines should correctly state the legal effect of the Guidelines	5
1.	The Guidelines should expressly warn the public that the Guidelines cannot be relied on outside the PTO, and are not entitled to <i>Chevron</i> deference	7
2.	The Guidelines should state that the procedures set forth are binding on and enforceable against examiners	9
B.	The Office lacks authority to resolve substantive ambiguities, and should follow its historical practice of forcing issues to the Federal Circuit for resolution.....	12
C.	The Examination Guidelines should clarify that an amendment of claims that lacks § 112(a) support does not convert that application into a First-to-File application.....	15
D.	How does the PTO propose to avoid granting a false patent on a later-filed application issued early?.....	15
E.	The PTO must prepare a “robust response to comments” for both the NPRM and for the Examination Guidelines	16
III.	Comments Arising Under Rule Making Law	16
A.	Several provisions of the NPRM are “substantive,” and thus the requirement for notice-and-comment and for Regulatory Flexibility Analysis is triggered	16
B.	The NPRM misstates the law—the PTO is required to use notice-and-comment procedure for its procedural rulemaking.....	17
C.	These regulations are “economically significant” under Executive Order 12,866, and thus they require a Regulatory Impact Analysis	18

D. The NPRM fails to comply with numerous provisions of the Paperwork Reduction Act...	20
E. The Regulatory Flexibility analysis is insufficient	23
F. Disclosure issues under the Information Quality Act, Paperwork Reduction Act, e- Government Act, and Executive Order 12,866.....	25
1. Laws that require disclosure	25
2. The NPRMs neglect to disclose significant material information	28
G. IEEE-USA requests that the PTO take care to characterize all comments accurately and to answer them fairly.....	28
IV. Conclusion.....	29

I. COMMENTS ON SPECIFIC PROVISIONS OF THE FIRST-TO-FILE NPRM

A. Regulations relating to 1952 Act applications should be retained

We have not carefully combed through all of the proposed regulations to ensure that all provisions that relate solely to 1952 Act applications are retained. For example, old 37 C.F.R. § 1.130 and § 1.131 will remain in effect for at least the next 20 years, as 1952 Act applications work through prosecution. Asking the public to retain the 2011 edition of 37 C.F.R. for the next 20 years creates undue paperwork retention burden.

Before promulgating final rules, the PTO should ensure that the regulations relating to 1952 Act applications are retained, and appropriately labeled and distinguished for clarity.

B. The structure of Proposed § 1.55 and § 1.78 should be clarified

Several of the proposed regulations use stacked “if” clauses in a way that is unclear. We note that Proposed § 1.130(a), (b), and (c) are structured to separate out a single common “if” test in (a) that applies broadly, and subtests in (b) and (c). This makes it much easier to find the relevant provision. On the other hand, § 1.55(a)(4) and § 1.78(a)(3), each stated in one *very* long paragraph with multiple “if” clauses buried within, are very difficult to navigate. Also, without internal subsection designators, terms such as “in addition” are unclear.

IEEE-USA suggests that § 1.78(a)(3) might be structured as follows, with the added text underlined:

(3)(i) Priority claims to provisional applications. Any nonprovisional application or international application designating the United States of America that claims the benefit of one or more prior-filed provisional applications must contain, or be amended to contain, a reference to each such prior-filed provisional application, identifying it by the provisional application number (consisting of series code and serial number). If the later-filed application is a nonprovisional application, the reference required by this paragraph must be included in an application data sheet (§ 1.76(b)(5)).

(ii) 2011 Act application claims priority to both a 1952 Act provisional application and a 2011 Act application. If a nonprovisional application filed on or after March 16, 2013, claims the benefit of the filing date of a provisional application filed prior to March 16, 2013, and also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013, the applicant must provide a statement to that effect within the later of four months from the actual filing date of the later-filed

application, four months from the date of entry into the national stage as set forth in § 1.491 in an international application, sixteen months from the filing date of the prior filed provisional application, or the date that a first claim to a claimed invention that has an effective filing date on or after March 16, 2013, is presented in the application.

(iii) 2011 Act application claims priority to 1952 Act provisional application and discloses additional subject matter in a 2011 Act application. In addition to the provisions of (a)(i), if a nonprovisional application filed on or after March 16, 2013, claims the benefit of the filing date of a provisional application filed prior to March 16, 2013, does not contain a claim to a claimed invention that has an effective filing date on or after March 16, 2013, but discloses subject matter not also disclosed in the provisional application, the applicant must provide a statement to that effect within the later of four months from the actual filing date of the later-filed application, four months from the date of entry into the national stage as set forth in § 1.491 in an international application, or sixteen months from the filing date of the prior-filed provisional application.

C. New regulation numbers should certainly not reuse numbers of existing regulations that will continue to be in effect, and advisedly should avoid conflict with old regulations that are retired

For many years, 37 C.F.R. Rules 130 and 131 have stood as follows:

- 37 CFR 1.130 Affidavit or declaration to disqualify commonly owned patent or published application as prior art.
- §1.131 Affidavit or declaration of prior invention.

The NPRM proposes to switch the closest match between the old rules and new rules. This will create unnecessary confusion. Applicants will have to file Rule 130 and Rule 131 affidavits as these rules exist today for many years after March 2013 as they file new applications that claim priority to existing applications having effective filing date earlier than March 16, 2013.

IEEE-USA suggests that § 1.130 and 131 be rewritten essentially as follows:

§1.130 Affidavit or declaration to disqualify commonly owned patent or published application as prior art.

(a) *1952 Act applications.* [retain 2005 language]

(b) *2011 Act applications.* [add § 1.131 as proposed (or as modified through notice-and-comment) here]

§1.131 Affidavit or declaration of prior invention, antedating or removing derived prior art.

(a) *1952 Act applications.*

(1) [retain 2004 language of current § 1.131(a)]

(2) [retain 2004 language of current § 1.131(b)]

(b) *2011 Act applications.* [add § 1.130 as proposed (or as modified through notice-and-comment) here]

That is, proposed § 1.130, directed to antedating or removing derived prior art, should be preferably numbered with a new unused number, or if the Office cannot find another number among the field of integers, add new paragraphs to § 1.131. Proposed § 1.131, directed to commonly-owned subject matter, should be preferably renumbered with a new unused number or added as new paragraphs to § 1.130.

Similarly, to the degree possible, when paragraphs are removed, they should be reserved, and the following subsections should retain their former numbers. Electronic research becomes difficult when the same provision is assigned a new number gratuitously.

D. Does the PTO propose to initiate and resolve derivation issues when the derived prior art is neither a patent nor an application? How is the applicant to obtain evidence to support an affidavit?

In our letter on derivation proceedings,¹ we asked how the PTO proposed to deal with the situation where the examiner asserts prior art, the applicant suspects that the prior art is derived from his own work, the deriver has not submitted an application, and the applicant lacks access to the information necessary to prove derivation. The applicant could submit an affidavit or declaration that “provides a satisfactory showing that the inventor ... is the inventor of the subject matter of the disclosure and ... indirectly communicated the subject matter of the disclosure to the party,” but such a submission will not prove derivation. After all, the information necessary to show derivation *is the state of mind of the deriver*—often the applicant will have *no information whatsoever* to support a showing of flow of information from the applicant to the deriver. In most cases, the only relevant information will reside with the deriver.

At page 43767, col.1, the Guidelines state, “Any documentation which provides evidence of the communication of the subject matter by the inventor or a joint inventor to the entity that earlier disclosed the subject matter should accompany the affidavit or declaration.” However, that evidence and documentation will almost always be in the hands of the deriver, not of the applicant. The NPRM does not provide any regulatory mechanism to obtain this evidence.

This was a key concern raised repeatedly by the public during the PTO’s “road shows” in 2009-2011. Director Kappos insisted that the problem would be addressed in the PTO’s regulations. If the PTO considered this issue at all, it is not meaningfully reflected in either the NPRM or Proposed Guidelines.

What does an applicant do in this situation?

II. COMMENTS ON SPECIFIC PROVISIONS OF THE FIRST-TO-FILE EXAMINATION GUIDELINES

A. The Examination Guidelines should correctly state the legal effect of the Guidelines

New legislation often brings ambiguity and uncertainty into the area that the legislation addresses. The AIA is no exception. Indeed, commentators (academics, practitioners, and retired jurists) are already discussing the considerable ambiguity in the AIA’s § 102.² On the other hand, pursuant to 35 U.S.C. § 3(b)(2)(A), the PTO is obligated to instruct examiners in *some* standard for examination, pursuant to the Commissioner’s duty to “be responsible for the management and direction of all aspects of the activities of the Office that affect the administration of patent ... operations.” The Guidelines should clearly and correctly state their precise legal effect.

¹ http://www.uspto.gov/aia_implementation/comment-ieee2.pdf at § II(E), pages 16-17

² *E.g.*, *Retired Judges Slam AIA*, Managing Intellectual Property (Oct 26, 2012), <http://www.managingip.com/Article/3109482/Managing-Patents-Archive/Retired-US-judges-slam-AIA.html>

The opening statement of the Examination Guidelines (page 43760 at col. 2-3) reads as follows.

These proposed guidelines do not constitute substantive rulemaking and do not have the force and effect of law. The proposed guidelines set out the Office's interpretation of 35 U.S.C. 102 and 103 as amended by the AIA, and advise the public and the Patent Examining Corps on how the changes to 35 U.S.C. 102 and 103 in the AIA impact the provisions of the Manual of Patent Examining Procedure (MPEP) pertaining to 35 U.S.C. 102 and 103. The guidelines have been developed as a matter of internal Office management and are not intended to create any right or benefit, substantive or procedural, enforceable by any party against the Office. Rejections will continue to be based upon the substantive law, and it is these rejections that are appealable. Failure of Office personnel to follow the guidelines is not, in itself, a proper basis for either an appeal or a petition.

This paragraph conveys a number of misunderstandings of basic principles of administrative law:

- The PTO lacks substantive rule making authority, and thus has no authority to offer *any* “interpretation of 35 U.S.C. 102 and 103.”
- The Guidelines correctly note that they are “a matter of internal Office management” and directed to “the Patent Examining Corps.” That is, the Guidelines are guidance promulgated under the Housekeeping Act.³ The term “rulemaking” applies under the Administrative Procedure Act to rules that affect the public. Therefore, the reference to “substantive rulemaking” in the context of guidance is a *non sequitur*.
- This paragraph overlooks the PTO's *obligation* to provide examiners with mandatory “management and direction” for examination of patent applications.

Because of these points of confusion, this paragraph incorrectly states the rights, obligations, and duties of both the public and PTO personnel. Part of the confusion arises because examination guidelines (and all of Chapter 2100 of the MPEP) occupy a rather obscure, seldom-litigated niche in the world of administrative law. The basic principle is simple: guidance outside an agency's statutory delegation of rulemaking authority has no binding effect on the public or on courts, but it *is* binding (asymmetrically) against the agency's employees.

IEEE-USA suggests the following replacement (and replacement of the analogous disclaimers stated at various points throughout Chapter 2100 of the MPEP):

These examination guidelines are issued to the Patent Examining Corps pursuant to the Office's authority and obligation to manage and direct the conduct of its own employees, under 5 U.S.C. § 301, 35 U.S.C. § 2(b)(2), § 3(a)(2)(A).

The PTO has no statutory authority to interpret substantive patent law, such as 35 U.S.C. § 102 or § 103. These guidelines are therefore limited to instructing the Patent Examining Corps as a matter of internal Office management. These Guidelines also advise the public of the ascertainable and consistent standards that the Office expects examiners to use in examination. However, the Office takes no position on the interpretation of these statutes to be applied in any court. The public is advised that they are not official agency interpretation, nor are they entitled to deference in any court.

The Guidelines set forth reasoning that examiners are required and authorized to use, and minimum procedural standards for setting forth a full statement of a rejection.

³ 5 U.S.C. § 301 (“The head of an Executive department ... may prescribe regulations for the government of his department, the conduct of its employees, [etc.]”).

Examiners are bound by these Guidelines, and the public is entitled to rely on them, to the following extent. Because the Guidelines state procedural obligations of examiners to set forth specific findings, these guidelines are enforceable against examiners during examination under 35 U.S.C. § 131 and § 132. An action may not be made final if it omits explanation of a required finding. The public may seek enforcement of the Guidelines via the examiner's supervisory chain, via the ombudsman, via pre-appeal brief review, via petition to withdraw premature finality of rejection, and via petition to invoke the supervisory duty of the Commissioner under 37 C.F.R. § 1.181(a)(1) or (a)(3). These Guidelines are enforceable by petition only as to procedural issues, where an examiner departs from these Guidelines in the following respects:

- examiner silence where the Guidelines require that a finding or explanation be set forth;
- application of a legal test by the examiner that is unauthorized by any written law; and
- failure to answer material traversed.

Petitionable subject matter jurisdiction is limited to disagreements between an examiner and the Office's instructions, and to breaches of procedural law such as 37 C.F.R. § 1.104 and the Administrative Procedure Act. However, once a written rejection is procedurally complete (even if wrong), the petitions process has no further jurisdiction. Resolution of any disagreement between an applicant and an examiner's written findings is exclusively appealable to the Patent Trial and Appeals Board under 35 U.S.C. § 134 and 37 C.F.R. Part 41.

Our rationale for this replacement follows.

1. The Guidelines should expressly warn the public that the Guidelines cannot be relied on outside the PTO, and are not entitled to *Chevron* deference

The PTO has no general substantive rule making authority.⁴ Both the Supreme Court and Federal Circuit have noted that agencies without substantive rule making authority likewise lack any claim to *Chevron* deference for their interpretations.⁵ The PTO should take care not to imply

⁴ *Koninklijke Philips Electronics N.V. v. Cardiac Science Operating Co.*, 590 F.3d 1326, 1337, 93 USPQ2d 1227, 1235 (Fed. Cir. 2010) (“We remind ... the Board that they must follow judicial precedent instead of [PTO-formulated substantive rules] because the PTO lacks the substantive rulemaking authority to administratively set aside judicial precedent.”); *Cooper Technologies Co. v. Dudas*, 536 F.3d 1330, 1336, 87 USPQ2d 1705, 1709 (Fed. Cir. 2008) (“To comply with § 2(b)(2)(A), a Patent Office rule must be ‘procedural’—*i.e.*, it must ‘govern the conduct of proceedings in the Office.’ ... We have also previously held that 35 U.S.C. § 2(b)(2) does not authorize the Patent Office to issue ‘substantive’ rules.”); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549–50, 38 USPQ2d 1347, 1351 (Fed. Cir. 1996) (statute “does NOT grant the Commissioner the authority to issue substantive rules.”); MPEP § 713.02 (“The Patent and Trademark Office cannot act as an expounder of the patent law.”).

⁵ *Gonzalez v. Oregon*, 546 U.S. 243, 255–56 (2006) (“Deference in accordance with *Chevron*, however, is warranted only “when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.”); *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649 (1990) (“even if [the statute’s] language ... is ambiguous, we need not defer to the Secretary of Labor’s view of the scope of § 1854 because Congress has expressly established the Judiciary and not the Department of Labor as the adjudicator of private rights of action arising under the statute. A precondition to deference under *Chevron* is a congressional delegation of administrative authority.”); *Brand v. Miller*, 487 F.3d 862,

that the Guidelines are in any way an “interpretation” of a statute that the PTO has no authority to interpret.

Rather, the Guidelines are guidance. The law applicable to guidance is rather different than the law applicable to rulemaking.

Much of the law of guidance was restated in a 2007 memorandum to all agencies from the Executive Office of the President, Office of Management and Budget, issued the *Final Bulletin for Agency Good Guidance Practices*.⁶ The President reminded agencies that guidance manuals cannot be treated as binding law against the public: Guidance, such as the MPEP and the Guidelines, may not be cited as primary authority to impose any requirement on applicants, and *may not* be applied as “law” against applicants:⁷

§ II(2)(h): Each significant guidance document shall: ... not include mandatory language such as “shall,” “must,” “required” or “requirement,” unless the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose consideration by the agency of positions advanced by private parties.²³

²³ As the courts have held, agencies need to follow statutory rulemaking requirements, such as those of the APA, to issue documents with legally binding effect, *i.e.*, legislative rules. ...

§ III(2)(b). Each agency shall designate an office (or offices) to receive and address complaints by the public that the agency ... is improperly treating a significant guidance document as a binding requirement. The agency shall provide, on its website, the name and contact information for the office(s).⁸

However, just as surely as the PTO cannot enforce the Guidelines against applicants as if they had force and effect of law, § 3(a) and (b) obligate the PTO to issue mandatory guidance to examiners, *and to enforce it*, as we describe next.

869 n.3, 82 USPQ2d 1705, 1709 n.3 (Fed. Cir. 2007) (“the Board does not earn *Chevron* deference on questions of substantive patent law”); *Federal National Mortgage Ass’n v. United States*, 379 F.3d 1303, 1307 (Fed. Cir. 2004) (agency pronouncement promulgated outside delegated authority “is not entitled to deference”); *see also Pesquera Mares Australes Ltda. v. United States*, 266 F.3d 1372, 1382 n.6 (Fed. Cir. 2001) (contrasting the antidumping authority of the Department of Commerce, which does include substantive rule making authority, to the PTO, which does not).

⁶ Executive Office of the President, *Final Bulletin for Agency Good Guidance Practices*, OMB Memorandum M-07-07, <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf> (Jan. 18, 2007), 72 Fed. Reg. 3432 (Jan. 25, 2007).

⁷ *Good Guidance Practices* (footnote 6) § II(2)(h), 72 Fed. Reg. 3440 col. 1; 72 Fed. Reg. at 3436 col. 3; <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf> at 12–13, 20. Note that the President has imposed an additional requirement on agencies, above the requirements of statute, because 5 U.S.C. § 552(a)(2) permits agencies to apply a “staff manual” against a member of the public if “if has been indexed and either made available or published as provided by this paragraph.” The President has authority over agencies to limit authority granted by Congress, and agencies are bound by whichever requirement is more rigorous. In any event, the PTO cannot rely on § 552(a)(2), because (as far as we know) it has never published the required notice in the Federal Register.

⁸ *Good Guidance Practices* (footnote 6) § III(2)(b), 72 Fed. Reg. 3440 col. 2; <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf> at 21.

2. The Guidelines should state that the procedures set forth are binding on and enforceable against examiners

The PTO's introductory paragraph suggests that examiners have no mandatory obligations for examination, and that the public has no right to any procedural regularity. This is simply wrong.

The PTO would be in violation of the law if it did *not* issue mandatory, binding, enforceable instructions to examiners. The Director and Commissioner are obligated to “manage and direct *all* activities” relating to examination, 5 U.S.C. § 3(b)(2)(A), § 3(a)(2)(A), to cause examination to be made “under the law,” § 131, and to ensure that examination is carried out in a “fair, impartial, and equitable manner,” § 3(a)(2)(A). The obligation to “manage and direct *all* activities” is an *extraordinary* charge, nearly unique among agency heads or supervisory staff. The Administrative Procedure Act requires agencies to have written procedures that specify ascertainable standards for agency adjudication.⁹

These duties *obligate* the PTO to issue written, uniformly-applied, standards, *and to enforce them during examination*. Applicants have both the substantive rights arising under § 102 *et seq.* of the Patent Act, *and also* rights to proper *procedure* during examination, rights arising under the Administrative Procedure Act, and §§ 2, 3, and 131 of the Patent Act, in the form of predictable, complete examination. If an examiner skips a step in the Guidelines, or makes up an alternative analysis that has no basis in the Guidelines or any other law, the PTO is required to “manage and direct” during §§ 131/132 examination to get proceedings back on track.

The Guidelines themselves concede the point at page 43763, col. 1, emphasis added:

⁹ “[D]ue process requires that [government programs] be administered to ensure fairness and freedom from arbitrary decision-making ... [An agency head] has the responsibility to administer the program to ensure the fair and consistent application of eligibility requirements. ... At the hearing [the agency head] admitted that he and his staff determine eligibility based upon their own unwritten personal standards. Such a procedure, vesting virtually unfettered discretion in [the agency head] and his staff, is clearly violative of due process.” *White v. Roughton*, 530 F.2d 750, 753–54 (7th Cir. 1976); *see also Holmes v. New York City Housing Auth.*, 398 F.2d 262, 265 (2d Cir. 1968) (“It hardly need be said that the existence of an absolute and uncontrolled discretion in an agency of government vested with the administration of a vast program ... would be an intolerable invitation to abuse. For this reason alone due process requires that selections among applicants be made in accordance with ‘ascertainable standards.’”). *Holmes* goes on to explain that the existence of a reasonable regulation is insufficient, if it isn’t followed, if some applicants are rejected for secret reasons, and never informed. *See also Moon v. U.S. Dep’t of Labor*, 727 F.2d 1315, 1318 (D.C. Cir. 1984) (“an agency must provide a reasoned explanation for its actions and articulate with some clarity the standards that governed its decision.”); *Duchek v. National Transportation Safety Bd.* 364 F.3d 311, 314, 318 (D.C. Cir. 2004) (Roberts, J.) (agency may not act beyond the authority it grants itself in its written regulations, and enforcement beyond them is arbitrary and capricious); *Batterton v. Marshall*, 648 F.2d 694, 707 n.68 (D.C. Cir.1980) (“The drafters [of the APA] specifically wanted publication of [agencies’ practices and procedures] to permit full public awareness of them.”); *In re Henriksen*, 399 F.2d 253, 261–62, 158 USPQ 224, 231 (CCPA 1968) (when the Board acted without written rules, “The action of the board is akin to a *retroactive* rule change which may have the effect of *divesting* applicants of valuable rights to which, but for the change in Patent Office position brought about by the board’s decision, they were entitled. Nothing appears in the Patent Office Rules of Practice or the Manual of Patent Examining Procedure which sanctions such a result.”).

Office personnel should note that the introductory phrase “[a] person shall be entitled to a patent unless” remains unchanged from the pre-AIA version of 35 U.S.C. 102. Thus, 35 U.S.C. 102 continues to provide that *the Office bears the initial burden of explaining* why the applicable statutory or regulatory requirements have not been met if a claim in an application is to be rejected. The AIA also does not change the requirement that in rejecting any claim of an application, *the Office must establish a prima facie case of unpatentability*.

IEEE-USA agrees—the law *requires* the examiner to “explain,” to frame that explanation within the applicable law, and to touch on every material issue in that explanation.¹⁰ An explanation that omits consideration of an essential claim element or legal element is inadequate to meet the examiner’s procedural obligation.

The Guidelines err in attempting to disclaim any obligation to enforce its guidance during examination. The PTO is required by both the Administrative Procedure Act¹¹ and the Patent Act¹² to give its examiners binding guidance on *prima facie* elements of various rejections and objections. Once guidance is issued and made public, the PTO is required by Presidential directive and the Administrative Procedure Act to enforce that guidance.¹³ All too many SPEs, T.C. Directors, and petitions decision-makers read the disclaimer, that the Guidelines “are not intended to create any right or benefit, substantive or procedural, enforceable by any party against the Office,” to imply that examiners are totally off-leash, free to do *anything*, and an applicant’s only remedy is appeal. It is difficult to see how such a disclaimer can possibly be either legal, consistent with the President’s Good Guidance instructions, or consistent with Director Kappos’ focus on efficiency and backlog reduction.

¹⁰ 5 U.S.C. § 555(e); *Iowa State Commerce Comm’n v. Office of Federal Inspector of Alaska Natural Gas Transp. System*, 730 F.2d 1566, 1578 (D.C. Cir. 1984) (explaining the importance of agency explanation of reasons); *Gechter v. Davidson*, 116 F.3d 1454, 1460, 43 USPQ2d 1030, 1035 (Fed. Cir. 1997) (PTO explanations of anticipation or obviousness rejections must state limitation-by-limitation findings); *In re Oetiker*, 977 F.2d 1443, 1445–46, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

¹¹ *Service v. Dulles*, 354 U.S. 363, 373–76 (1957) (agency’s procedures must be “scrupulously observed”); *Vitarelli v. Seaton*, 359 U.S. 535, 545 (1959) (an agency action in violation of the agency’s internal procedural handbook is “illegal and of no effect”); *Lopez v. Federal Aviation Administration*, 318 F.3d 242, 246–47 (D.C. Cir. 2003) (explaining the relevant Supreme Court cases and the obligation of agencies to follow and enforce their own rules); *Powell v. Heckler*, 789 F.2d 176, 178 (3d Cir. 1986) (courts have no tolerance “in matters pertaining strictly to an agency’s observance and implementation of its self-prescribed procedures”).

¹² 35 U.S.C. § 3(b)(2)(A) (Commissioner for Patents shall be “responsible for the management and direction of all aspects of the activities of the Office that affect the administration of patent . . . operations”).

¹³ Agencies may not relieve themselves of rules “intended primarily to confer important procedural benefits upon individuals in the face of otherwise unfettered discretion.” *American Farm Lines*, 397 U.S. at 538; *City of Fredericksburg Virginia v. Federal Energy Comm’n*, 876 F.2d 1109, 1112 (4th Cir. 1989) (“*American Farm Lines* held that an administrative agency has discretion to relax or modify internal housekeeping regulations . . . However, the exception announced in *American Farm Lines* does not apply if the agency regulations were intended ‘to confer important procedural benefits upon individuals’ or other third parties outside the agency. . . . The applicability vel non of *American Farm Lines* thus turns on whether the regulation . . . was designed to aid [the agency] or, instead, to benefit outside parties”).

The analytical error in the Guidelines is a failure to recognize that “rejection” and “failure of Office personnel to follow the guidelines” are two different agency actions.¹⁴ “Rejection” is one agency action; IEEE-USA agrees with the PTO that this agency action is substantive and appealable. “Perceived failure by Office personnel to follow the guidelines” is a *separate agency action*, one that is *not* appealable.¹⁵ 37 C.F.R. § 1.181(a)(1) ensures that there is no such thing as an agency action by an examiner during *ex parte* prosecution that is “neither appealable nor petitionable”—the PTO may not use a guidance document to carve out exceptions to the procedural remedies granted the public by § 1.181(a). The PTO’s delegation of “independent judgment” to examiners in doing their work, in no way diminishes examiners’ duty to follow the guidelines. Therefore, an examiner’s failure to follow mandatory instructions is petitionable and subject to management oversight, just as any other employee’s misconduct and failure to follow a supervisor’s instructions that may injure a third party are the responsibility of the supervisor to correct.¹⁶

The analytical error is not an academic, hypertechnical legal angel dancing on the head of a pin; it has immense practical consequences for applicants and for the Office. The erroneous statement of the effect of the Guidelines creates immense burdens that are inconsistent with the Administrative Procedure Act, Paperwork Reduction Act, Regulatory Flexibility Act,¹⁷ Executive Order 12,866, and the *Good Guidance Bulletin*. When examiners are not held accountable for failure to follow instructions, abuses and unpredictable examination are likely to occur. When applicants have no means to enforce procedurally-correct and complete examination, prosecution

¹⁴ It is commonplace that a single body of facts or single agency decision may give rise to separate “agency actions,” 5 U.S.C. § 551(13), with corresponding separate claims for relief under different bodies of law, and those claims for relief may require parallel proceedings in different fora. *E.g.*, *Federal Communications Comm’n v. Nextwave Personal Communications*, 537 U.S. 293, 303–04 (2003) (bankruptcy proceeding on the merits originated in New York bankruptcy court, APA review of same facts originated in D.C. Circuit. The earlier case denied relief under bankruptcy, but the APA case resulted effectively in discharge of the debt, which the Supreme Court affirmed). Any notion that all issues relating to rejections of claims must necessarily all go to the same tribunal would have few if any analogies elsewhere in the law, and has no support in any known case from any appellate court.

¹⁵ The Board lacks jurisdiction to hear issues that “dispute the administrative processing of [a rejection alleged to be procedurally improperly raised during] the prosecution.” The Board insists that “the proper procedure is to seek review by way of petition...” *Ex parte Edwards*, Appeal No. 98-1396, <http://des.uspto.gov/Foia/RetrievePdf?system=BPAI&flNm=fd981396> at 4, 1998 WL 1736081 at *2 (BPAI Apr. 27, 1999) (non-precedential). In its decisions, the Board has often reiterated that “The board does not exercise supervisory authority over examiners.” Board of Patent Appeals, Frequently Asked Questions page, <http://www.uspto.gov/web/offices/dcom/bpai/bpaifaq.htm>; *Ex parte Gambogi*, 62 USPQ2d 1209, 1212 (BPAI 2001) (“We decline to tell an examiner precisely how to set out a rejection”).

¹⁶ Restatement 2d (Agency) § 214 (“A ... principal who is under a duty to ... to have care used to protect others or their property and who confides the performance of such duty to a servant or other person is subject to liability to such others for harm caused to them by the failure of such agent to perform the duty.”); *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 376–77 (1998) (“Because reasoned decisionmaking demands it, and because the systemic consequences of any other approach are unacceptable, the [agency] must be required to apply in fact the clearly understood legal standards that it enunciates in principle... Reviewing courts are entitled to take those standards to mean what they say...”).

¹⁷ We discuss the particular application of the Regulatory Flexibility Act in § III.E starting at page 23.

will drag on—IEEE-USA believes this is a major contributor to the PTO’s backlog. IEEE-USA urges the PTO to follow the *procedural* and *administrative* law, and to carry out its obligation to ensure examiner compliance with guidance, so that applicants and examiners can proceed from a common set of assumptions, and under predictable procedures, for the efficiency of all concerned.

IEEE-USA notes that the ambiguity in the scope of petitionable vs. appealable subject matter, and the disagreement between the Board and the Office of Petitions as to how to treat breaches of procedure relating to examination of claims, is an “ambiguity” that must be clarified pursuant to the Paperwork Reduction Act.¹⁸ IEEE-USA commends to the PTO’s attention a number of notice-and-comment letters that have raised this issue in the past. Some have suggested a replacement for MPEP § 1201 that more correctly states the scope of petitionable and appealable subject matter jurisdiction.¹⁹

The *Good Guidance Bulletin* requires the PTO to create a process for examiners to request waivers from MPEP requirements.²⁰ This would have three important advantages: (a) creating a culture of procedural regularity and compliance with written PTO instructions, (b) increasing uniformity of examination policy, and (c) bringing errors in the MPEP promptly to the attention of the Office of Patent Examination Policy and the editors of the MPEP, so that errors can be corrected.

B. The Office lacks authority to resolve substantive ambiguities, and should follow its historical practice of forcing issues to the Federal Circuit for resolution

As we noted in § II.A.1 at page 7 of this letter, the PTO has no authority to interpret substantive law. Because of this lack of substantive interpretative authority, the PTO’s traditional approach has been to instruct examiners in the view of the law that forces issues to the courts as promptly as possible, and avoids the issuance of invalid patents in the interim.

The PTO should do so here, particularly in view of the asymmetric right of appeal, wherein the Appeal Board does not review examiner allowances. IEEE-USA recommends a two-level approach.

1. Where the AIA carries forward the 1952 statutory language, the PTO should instruct that examiners are to continue to apply the courts’ interpretations of the carried-forward language.
2. However, where the AIA introduces new language or expressly repeals the 1952 statute, the PTO should instruct examiners to apply the meaning that will force the issue to the courts as rapidly as possible.

¹⁸ 44 U.S.C. § 3506(c)(3)(D) (the PTO must certify that its regulations are “written using plain, coherent, and unambiguous terminology and [are] understandable to those who are to respond”)

¹⁹ *E.g.*, http://www.uspto.gov/ip/boards/bpai/procedures/rules/rule_comment_nov2010_boun dy.pdf Attachment B, at PDF pages 92-98.

²⁰ *Good Guidance Practices* (footnote 6) § II(1)(b), 72 Fed. Reg. 3440 col. 1; <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf> at 20 (“Agency employees should not depart from significant guidance documents without appropriate justification and supervisory concurrence.”).

To do otherwise would be particularly detrimental to individual inventors and small businesses, who, with their limited financial resources, are unable to re-address well-established points of law, but need to resolve areas of uncertainty and ambiguity as soon as possible.

Our two-level approach applies to § 102 as amended by the AIA as follows:

- There has been considerable debate as to whether the term “or otherwise available to the public” used in AIA § 3 is purely a disjunctive “or” to add a catch-all category, or whether “or” means a conjunctive “and” to engraft an “available to the public” or “enablement” requirement onto the “on sale” and “public use” bars. At page 43765, col. 1-2, the PTO requests public comment for the PTO to develop an “interpretation.”
 - The PTO lacks statutory authority to “issue an interpretation” of this statute, as we explain in § II.A.1 at page 7 of this letter. Final Examination Guidelines should make clear that they are *only* examination guidelines, not “interpretation.”
 - IEEE-USA urges that the PTO maintain the *status quo*, under which the terms “on sale” and “public use” maintain their meanings as established in over 140 years of case law.²¹ This result follows under both prongs of our suggested approach. If the word “or” means “and,” the issue must be forced up to the courts as soon as possible, and that result will be obtained if the examination guidelines state the *status quo ante*.
 - The statement of the prior law at page 43764, col. 2, is not quite correct—the “enablement” requirement for prior art has always been narrower than stated there. The “Second” provision, requiring “enablement” for *any* prior art disclosure, is only applicable to written prior art (patented, described in a patent, or described in a printed publication). The 1952 Act did not require enablement of an “on sale” or “public use” to be prior art.²² IEEE-USA urges that the PTO maintain the *status quo*: “enablement” should be required for “printed publication,” “described in a patent,” or “patented” prior art, but not for public use or on sale prior art.
 - IEEE-USA urges that the Guidelines instruct that sales kept “secret from the trade” are still subject to the “on sale” bar, as long as the sale is a commercial sale (rather than a sale among corporate affiliates, or a sale for research purposes). This follows both prongs of our approach, maintaining the *status quo* and forcing court resolution sooner rather than later.²³

²¹ See Kurtis A. Kemper, When is Public Use of Invention, More Than One Year Before Patent Application, 171 A.L.R. Fed. 39 (updated 2010); William G. Phelps, When does on-sale bar of 35 U.S.C.A. § 102(b), which denies patentability to invention that has been on sale for more than one year prior to date of patent application, prevent issuance of valid patent, 155 A.L.R. Fed. 1 (updated 2010).

²² Footnote 63 of the Guidelines correctly notes that the “enablement” requirement only applies to “patent or publication” prior art.

²³ *Brasseler v. Stryker Sales Corp.*, 182 F.3d 888, 891, 51 USPQ2d 1470, 1473 (Fed. Cir. 1999); *In re Caveney*, 761 F.2d 671, 675–76, 226 USPQ 1, 3–4 (Fed. Cir. 1985).

- Sales between joint venture partners can be anticipations: there is no blanket “joint development” exception to the “on sale” bar,²⁴ unless there is a joint research agreement.
- A use that’s underground and inherently invisible—or deliberately concealed—from the public is still “public use,” if the user is under no obligation of confidentiality. This follows both prongs of our approach, maintaining the *status quo* and setting up earlier court resolution.²⁵
- The Examination Guidelines should maintain the *status quo*, that “appreciation of the invention is not a requirement to trigger the statutory [on sale] bar.”²⁶
- The Examination Guidelines should instruct examiners to apply the narrowest credible definition of “disclosure” for triggering the § 102(b) grace period.
 - With great sadness and reluctance, IEEE-USA agrees with the analysis at page 43767, col. 2, starting at the middle of the page, that the § 102(b) grace period applies only to the *exact* subject matter disclosed, and that a third party that creates prior art with “insubstantial changes” bars broad claims that cover that prior art. This result is disastrous for startups and small inventors, and was a major impetus for IEEE-USA’s opposition to AIA passage. But IEEE-USA sees no alternative within the statutory language.
 - IEEE-USA is unaware of any basis to resolve whether an “on sale” or “public use” event by the applicant must communicate sufficient information about the invention to enable one of ordinary skill, for that event to be a “disclosure” under § 102(b). IEEE-USA does not believe that the courts will be bound by a colloquy among two Senators on the meaning of “disclosure” inserted in the Congressional Record a day after passage. IEEE-USA recognizes that requiring “enablement” for “on sale” or “public use” events to qualify as “disclosures” effects a near-complete evisceration of the § 102(b) grace period for many inventions, but sees no meaningful alternative.
 - This proposed guidance would prevent issuance of patents that would otherwise issue under a broader definition of “disclosure” and would therefore set up an earlier court resolution.
- There has likewise been considerable debate as to whether the AIA repeals the *Metallizing Engineering*²⁷ bar for secret commercial use. Earlier versions of the patent reform act plausibly effected such repeal; the plain language as finally enacted does not. IEEE-USA urges that the only prudent course of action is for the PTO to instruct

²⁴ *Brasseler v. Stryker Sales Corp.*, 182 F.3d 888, 890, 51 USPQ2d 1470, 1472 (Fed. Cir. 1999); *Buildex Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1465, 7 USPQ2d 1325, 1328 (Fed. Cir. 1988); *but see* 35 U.S.C. § 103(c) (carving out joint R&D from obviousness).

²⁵ *New Railhead Mfg. Co. Vermeer Mfg. Co.*, 298 F.3d 1290, 1298–99, 63 USPQ2d 1843, 1849 (Fed. Cir. 2002); *Egbert v. Lippmann*, 14 Otto (104 U.S.) 333, 336 (1881) (a single use of a women’s corset stay was a “public use”).

²⁶ *Scaltech, Inc. v. Retec/Tetra, L.L.C.*, 269 F.3d 1321, 1330–31, 60 USPQ2d 1687, 1693–94 (Fed. Cir. 2001) (*Scaltech III*).

²⁷ *Metallizing Eng. Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (2nd Cir. 1946).

examiners that they are to maintain the *status quo*, and continue to reject claims based on *Metallizing Engineering*. This proposed guidance would prevent issuance of patents that would otherwise issue under the PTO's proposed interpretation and would therefore set up an earlier court resolution.

C. The Examination Guidelines should clarify that an amendment of claims that lacks § 112(a) support does not convert that application into a First-to-File application

Some commentators have suggested that an accidental amendment to an application filed after March 2013, where the post-March-2013 application claims priority to a pre-March-2013 application, and where the amendment lacks support in the pre-March-2013 application, would necessarily force the application into the AIA statute, even if the amendment also lacks support in the post-March-2013 specification.

IEEE-USA believes that this is not the case, and urges that the Examination Guidelines provide clarification. The statutory definition for “effective filing date” only applies if the amended claim actually relies on a post-March-2013 specification for support—a claim that is *unsupported at all* has no “effective filing date” and thus does not trigger the transition.

D. How does the PTO propose to avoid granting a false patent on a later-filed application issued early?

When an earlier applicant files an application for regular track examination and requests non-publication under §122(b), and a later applicant files an application, perhaps for accelerated examination, claiming subject matter disclosed in the earlier application, the later-filed application may be allowed and ready to issue first. Because the earlier-filed application would not be available as prior art under the AIA and because § 102(g) is repealed, the Office may issue a false patent on the later-filed application a couple of years before a patent may issue on the first-filed application. Temporarily holding a presumed “valid” patent, the later applicant can even sue the first applicant for patent infringement.

When the PTO was asked about this scenario during a recent roundtable on the first-to-file rules, the answer that was given was wholly unsatisfactory: it suggested that the earlier applicant can ask for publication of his otherwise secret application when the later-filed application issues and subsequently challenge the false patent in a Post Grant Review (“PGR”) proceeding. This “solution” forces the earlier applicant to publically disclose trade secrets prior to being assured of a patent, and in any event years earlier than is required under law. It also requires the earlier applicant to gratuitously spend over \$100,000 on the PGR proceeding. Neither result is acceptable.

The examination guidelines must make clear that a search for pending applications with interfering subject matter must be conducted before any application—especially an accelerated examination application—is allowed to issue, and that no such application would be allowed if any of its claims appear unpatentable over a first-filed application.

E. The PTO must prepare a “robust response to comments” for both the NPRM and for the Examination Guidelines

The *Good Guidance Bulletin* from the Executive Office of the President requires as follows (emphasis added):²⁸

IV. Notice and Public Comment for Economically Significant Guidance Documents.

1. In General: Except as provided in Section IV(2), when an agency prepares a draft of an economically significant guidance document, the agency shall:

- a. Publish a notice in the Federal Register announcing that the draft document is available;
- b. Post the draft document on the Internet and make it publicly available in hard copy (or notify the public how they can review the guidance document if it is not in a format that permits such electronic posting with reasonable efforts);
- c. Invite public comment on the draft document; and
- d. ***Prepare and post on the agency’s website a response-to-comments document.***

IEEE-USA looks forward to reviewing the PTO’s response to comments for *both* the regulations and the Examination Guidelines.²⁹

III. COMMENTS ARISING UNDER RULE MAKING LAW

When the PTO shortcuts statutory rule making procedure, it runs the risk of having its regulations rendered invalid or unenforceable under provisions of the Administrative Procedure Act, Regulatory Flexibility Act, Paperwork Reduction Act, and other laws.

A. Several provisions of the NPRM are “substantive,” and thus the requirement for notice-and-comment and for Regulatory Flexibility Analysis is triggered

The NPRM states that “The changes being proposed in this notice do not change the substantive criteria of patentability. These proposed changes involve rules of agency practice and procedure and/or interpretive rules.” This is not correct. At least two provisions in the NPRM are substantive rather than procedural:

- Proposed 37 C.F.R. § 1.130 allocates the burden of proof to show derivation to the applicant. This is a departure from the standard allocation of burden of proof to the PTO. “[T]he assignment of the burden of proof is a rule of substantive law.” *Director, Office of Workers’ Compensation Programs, Dep’t of Labor v. Greenwich Collieries*, 512 U.S. 267, 271, 275–81 (1994).
- Proposed 37 C.F.R. § 1.78(e) proposes to give the Office the authority to require cancellation of claims. Canceling claims is “substantive.” “[T]he assignment of the

²⁸ *Good Guidance Bulletins* (footnote 6) § I(5) at 17, 72 Fed. Reg. at 3438, col. 2.

²⁹ We note that this requirement has been brought to the attention of the PTO in the past. *E.g.*, David Boundy, comments on “Improving Regulation and Regulatory Review,” at page 13 (May 23, 2011) <http://www.uspto.gov/patents/law/comments/boundy23may2011.pdf>; David Boundy, comments on KSR Guidelines Update, [http://www.uspto.gov/patents/law/comments/ updatedksr_boundy2nd_15feb2011.pdf](http://www.uspto.gov/patents/law/comments/updatedksr_boundy2nd_15feb2011.pdf) at page 6 (Feb. 15, 2011); Boston Patent Law Ass’n, comments on Interim Examination Instructions for Evaluating Subject Matter Eligibility, [http://www.uspto.gov/patents/ law/comments/bpla.pdf](http://www.uspto.gov/patents/law/comments/bpla.pdf) at page 10 (Oct. 6, 2009); To the knowledge of IEEE-USA, the PTO has *never* complied with this directive from the President.

burden of proof is a rule of substantive law.” *Director, Office of Workers’ Compensation Programs, Dep’t of Labor v. Greenwich Collieries*, 512 U.S. 267, 271, 275–81 (1994).

Because the NPRM includes at least some “substantive” content, the notice-and-comment obligations under the Administrative Procedure Act and Regulatory Flexibility Act unquestionably attach.

B. The NPRM misstates the law—the PTO is required to use notice-and-comment procedure for its procedural rulemaking

The NPRM cites *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336-37 (Fed. Cir. 2008) for the proposition that the PTO need not use notice and comment rule making for procedural rules. First, *Cooper* decided an issue under the interpretative” provision of § 553—the “procedural” issue for which the NPRM cites it is at best *dictum*. Second, because of a subsequent stipulation by the PTO, *Cooper* is no longer good law for the “procedural” proposition.

In the lower court decision of *Tafas*, the United States District Court for the Eastern District of Virginia held that “the structure of [35 U.S.C. § 2(b)(2)] makes it clear that the PTO must engage in notice and comment rule making when promulgating rules it is otherwise empowered to make—namely, procedural rules.”³⁰ The PTO appealed this specific issue to the Federal Circuit. Several months after *Cooper*, the PTO moved to dismiss the *Tafas* appeal on grounds of mootness. By asserting *mootness*, the PTO irrevocably committed itself to the district court’s holding—the assertion of mootness carried with it a statement “with assurance that there is no reasonable expectation that the alleged violation will recur.”³¹ When a federal agency asserts mootness, it is “only because” the agency ceases all “offending conduct” by accepting the position of the opposing party.³² In *Tafas*, the Federal Circuit accepted the PTO’s acquiescence to mootness.³³ Further, the Federal Circuit denied the PTO’s request to vacate the District Court’s decision. By the PTO’s own actions in asserting mootness, the PTO bound itself to use notice and comment for procedural rule making. By reinstating the district court *Tafas* decision, the Federal Circuit left the district court *Tafas* decision as the law.

These rulemaking issues have been brought to the attention of the PTO in the past.³⁴ This is at least the third position that the PTO has taken in its NPRMs since *Tafas* to try to avoid the obligations to which it stipulated.³⁵ Each time; the PTO simply ignores the issue without replying

³⁰ *Tafas v. Dudas*, 541 F.Supp.2d 805, 812 (E.D. Va. 2008), *reinstated sub nom. Tafas v. Kappos*, 586 F.3d 1369, 1371 (Fed. Cir. 2009) (granting PTO’s motion to dismiss the appeal on grounds of mootness, and holding that district court decision is reinstated).

³¹ *County of Los Angeles v. Davis*, 440 U.S. 625, 631 (1979).

³² *Adarand Constructors Inc. v. Slater*, 528 U.S. 216, 221–22 (2000).

³³ *Tafas v. Kappos*, 586 F.3d 1369, 1371 (Fed. Cir. 2009).

³⁴ IEEE-USA, Comments on AIA Post-Grant rules, at pages 19-20 (Apr. 17, 2012). http://www.uspto.gov/aia_implementation/comment-ieee2.pdf

³⁵ For example, in the November 2010 *ex parte* appeal NPRM, the Board cited *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996) for a proposition relating to procedural rules and notice and comment, when *Merck* only concerns “interpretative” rules, and is entirely silent on notice and comment.

in its final Rule Notices—thereby violating the Administrative Procedure Act³⁶—and then goes a bit farther out on a limb in the next NPRM.³⁷

For example, IEEE-USA raised this issue in comments on the Inter Partes, Post-Grant, and Business Methods rules. The PTO’s response to Comment No. 109, 77 Fed. Reg. 48710, replied as follows:

In both the notice of proposed rulemaking and this final rule, the Office cites *Cooper Technologies. Co v. Dudas*, 536 F.3d 1330, 1336–37 (Fed. Cir. 2008), for the proposition that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), does not require notice and comment rulemaking for “interpretive rules, general statement of policy, or rules of agency organization, procedure or practice.” The Office’s reliance on *Cooper Technologies* is appropriate and remains an accurate statement of administrative law.

This is extremely puzzling. First, the PTO does not dispute that *Cooper* is at best *dictum* for the PTO’s proposition. Second, the PTO does not dispute that it took the “mootness” position in *Tafas*, described above. Third, the PTO offers no contrary view of the legal consequences of the PTO’s own actions in *Tafas*, as we describe above. Fourth, the PTO does not dispute that Supreme Court authority on mootness applies as we describe above. Fifth, the PTO does not explain how Federal Circuit *dictum* would be superior to Supreme Court holding. Sixth, the basis of the *Tafas* decision was a statute *sui generis* to the PTO, a statute that was not at issue in *Cooper*. IEEE-USA is left to ponder why the PTO’s understanding of *Tafas* is so contrary to the rule of law as it applies throughout the rest of the U.S. legal system. If the PTO has a valid basis to distinguish its mootness position in *Tafas*, it’s appropriate for the PTO to explain the distinction in its response to comments. Otherwise, ignoring the key fact—the PTO’s assertion of mootness in *Tafas*—may reasonably be interpreted as a concession by the PTO of error.

IEEE-USA notes that the superseding of *Cooper* by *Tafas* has been discussed in the comments noted at footnote 34, and requests the PTO to address them in its response to these Comments. If the PTO believes that *Tafas* does not apply, and that the Supreme Court’s law of mootness does not apply as we understand it, then the PTO should clearly say so and provide a reasoned legal defense for the position. If the PTO cannot state a legal theory to distinguish *Tafas*, IEEE-USA requests that the PTO follow it rather than continue to ignore it.

C. These regulations are “economically significant” under Executive Order 12,866, and thus they require a Regulatory Impact Analysis

At page 43743, col. 2, the NPRM states, “This rulemaking is not economically significant as that term is defined in Executive Order 12866 (Sept. 30, 1993).” The NPRM gives no rationale or analysis for its position.

³⁶ *Kennecott v. Environmental Protection Agency*, 780 F.2d 445, 449 (4th Cir. 1985) (“The court best acts as a check on agency decisionmaking by scrutinizing process... Whether the agency has provided notice and an opportunity to comment, and has fairly considered all significant data and comments, is the heart of the judicial inquiry.”), *Home Box Office Inc. v. Fed Communications Comm’n*, 567 F.2d 9, 35–36 (D.C. Cir. 1977) (“the opportunity to comment is meaningless unless the agency *responds* to significant points raised by the public,” emphasis added).

³⁷ For example, in the current “Definition of Technological Invention” NPRM, 77 Fed. Reg. 7095, RIN 0651-AC75, the PTO characterizes the definition as “interpretative,” thereby waiving any power to enforce it. See IEEE-USA’s more complete discussion in our letter of April 10, 2012.

The Examination Guidelines simply ignore the issue, and fail to state any classification.

The NPRM satisfies the criteria for an “economically significant” regulation as set forth in § 3(f)(1) of the Executive Order:

(f) "Significant regulatory action" means any regulatory action that is likely to result in a rule that *may*:

(1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety,

The Examination Guidelines satisfy the criteria for an “economically significant guidance document” of the *Good Guidance Bulletin*.³⁸

5. The term “economically significant guidance document” means a significant guidance document that may reasonably be anticipated to lead to an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy or a sector of the economy

The First-to-File rule easily exceeds the \$100 million threshold. This NPRM admits that the paperwork burdens *alone* for complying with the First-to-File rule is \$289 million per year (77 Fed. Reg. at 43754, col.1), without considering the collateral economic effect of reallocation of patent rights. \$289 million is more than the \$100 million threshold for an “economically significant” rule. This NPRM offers no estimates at all for these rules’ costs, benefits, and other effects on the economy.

The PTO and many of the bill’s sponsors described the “first inventor to file” provision as the most significant change to patent law in over a century. One economic study showed that the provision would have a large adverse effect on small entities.³⁹ Another estimated the added costs to startups and small entities at about \$1 billion per year.⁴⁰ A third finds that “the March 2013 implementation of a first-to-file rule in the U.S. is likely to result in reduced patenting behavior by individual inventors.”⁴¹ In a separate joint letter with the National Small Business Association filed on this date, IEEE-USA provides additional evidence and analysis, clearly showing that economic effects of \$100 million or more are *certain*. The First-to-File NPRM and examiner guidelines are unquestionably “economically significant” and require a Regulatory Impact Analyses.

In March 2012, Director Kappos and Rebecca Blank, Acting Deputy Secretary of Commerce and Under Secretary for Economic Affairs, Economics and Statistics Administration, published a report suggesting that “patent-intensive” industries were responsible for 3.9 million direct and 7.1 million direct or indirect jobs in the U.S. economy, and that these figures “may tend to under-represent the broad impact of IP in the American economy.” Further, the ESA and PTO

³⁸ *Good Guidance Practices* (footnote 6) § I(5).

³⁹ Lo & Sutthiphisal, Does it Matter Who Has the Right to Patent: First-to-Invent or First-to-File? Lessons from Canada, *NBER Working Paper No. w14926*, http://ssrn.com/abstract_id=1394833

⁴⁰ Boundy & Marquardt, Patent Reform’s Weakened Grace Period: Its Effects On Startups, Small Companies, University Spin-Offs And Medical Innovators, “Medical Innovation & Business Journal, vol. 2 no. 2 at 35 (Summer 2010) http://journals.lww.com/medinnovbusiness/Citation/2010/0610/Patent_Reform_s_Weakened_Grace_Period__Its_Effects.6.aspx

⁴¹ Wagner & Abrams, Poisoning the Next Apple: How the America Invents Act Harms Inventors, 65 *Stanford L.Rev.* (2012) http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1883821

jointly concluded that “Patent-intensive ... industries accounted for 5.3 ... percent of GDP, with \$763 billion ... in value added” in 2010.”⁴² For the First-to-file rule to be economically significant, it needs only perturb the patent-intensive portion of the economy by 0.013%.

Likewise, a regulation is “economically significant” under § 3(f)(4) if it “may ... raise novel legal or policy issues arising out of legal mandates.” These regulations raise a host of “novel legal issues,” as we discussed in §§ I.D and II.B above.

Because of these economically significant characteristics, Executive Order 12,866 § 6(a)(C)(ii)-(iii) and the *Good Guidance Bulletin* obligated the PTO to submit to OMB, along with the draft proposed rule:

(ii) An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs; and

(iii) An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives.

Nonetheless, the PTO asserts without substantiation that the first-to-file regulation is “not significant as that term is defined in Executive Order 12866 (Sept. 30, 1993).” NRPM p. 43743, col. 2. Whether intended or not, the assertion that total economic effect is either near zero (“not significant”) or below the “economically significant” threshold of \$100 million enabled the PTO to avoid careful analysis and planning, or to avoid disclosing whatever analysis it did for public comment. The PTO should not avoid its obligations through bald assertion of plainly counterfactual representations. An accurate analysis is essential to the PTO’s implementation plans, if the PTO is to keep to its commitments implementation for the benefit of the U.S. economy. An analysis and disclosure is also essential to ensure that the UPTO is exercising its public policy power responsibly.

The NPRM and Examination Guidelines are unquestionably “economically significant” regulations and guidance. The PTO should provide a Regulatory Impact Analysis pursuant to OMB Circular A-4, to enable fair evaluation of the costs and benefits of various alternative regulatory approaches, to permit the public to comment, to ensure adequate planning and staffing, and to avoid unintended consequences.

D. The NPRM fails to comply with numerous provisions of the Paperwork Reduction Act

At page 43754, the NPRM presents its Paperwork Reduction Analysis as follows:

⁴² Economics and Statistics Administration and U.S. Patent and Trademark Office, “Intellectual Property and the U.S. Economy: Industries in Focus,” Washington, D.C.: Economic and Statistics Administration, U.S. Department of Commerce (2012), http://www.uspto.gov/news/publications/IP_Report_March_2012.pdf at pp. vi-vii, 45.

O. *Paperwork Reduction Act*: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public. ... The collection of information involved in this notice has been submitted to OMB under OMB control number 0651-00xx. The collection of information submitted to OMB under OMB control number 0651-00xx also includes information collections (e.g., affidavits and declarations under 37 CFR 1.130, 1.131, and 1.132) previously approved and currently being reviewed under OMB control number 0651-0031. The proposed collection will be available at OMB's Information Collection Review Web site (www.reginfo.gov/public/do/PRAMain). ...

Estimated Number of Respondents: 189,150 responses per year.

Estimated Time per Response: The Office estimates that the responses in this collection will take the public from 1 to 10 hours. Specifically, the Office estimates that: (1) Preparing an affidavit or declaration under 37 CFR 1.130, 1.131, or 1.132 will require, on average, 10 hours; (2) identifying under 37 CFR 1.55(a)(4), 1.78(a)(3), or 1.78(c)(2) whether there is any claim or subject matter not disclosed in the prior foreign, provisional, or nonprovisional application will require, on average, 2 hours; and (3) identifying under 37 CFR 1.110 inventorship and ownership of the subject matter of claims will require, on average, 2 hours.

Estimated Total Annual Respondent Burden Hours: 778,300 hours per year.

Estimated Total Annual Respondent Cost Burden: \$288,749,300 per year.

The Office is soliciting comments to: (1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the Office, including whether the information will have practical utility; (2) evaluate the accuracy of the Office's estimate of the burden; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of collecting the information on those who are to respond, including by using appropriate

There are multiple statements here that are not true:

- This collection has *not* been submitted to OMB, let alone as 0651-00xx, or if they were submitted, they have not been posted on the OMB Information Collection Review (ICR) website. We have monitored the OMB ICR web site; as of October 31, 2012, no relevant submission exists.
- The PTO is correct, that the PTO does have a legal obligation to make a submission to OMB before a NPRM, when a regulation imposes or modifies any "information collection" burden on the public.⁴³ Strikingly, after conceding that such a submission was required by law, IEEE-USA is unable to locate any evidence that the PTO actually did so.
- At the NPRM stage, the PTO was required to develop, disclose to the public, and include in its filing to OMB, "specific" and "objectively supported" estimates, no later than the time of a Notice of Proposed Rulemaking.⁴⁴ Neither the estimates nor the objective support exist in the NPRM or on OMB's web site.

Likewise, there are a host of omissions:

⁴³ Reading 44 U.S.C. § 3507(d)(1) and § 3506(c)(2)(A) together.

⁴⁴ Reading 44 U.S.C. § 3507(d)(1) and § 3506(c)(2)(A) together. Strikingly, several of the PTO's Notices of Proposed or Final Rule Making in 2006-2008 stated that the PTO refused to make a Paperwork filing with OMB, for reasons that have no grounding in any statute or regulation.

- This regulation has *immense* ripple effects in the information to be collected under OMB control numbers 0651-0031 (patent processing, updating), and 0651-0032 (initial applications). For example, the number of newly-filed patent applications is almost certain to increase due to the earlier “use it or lose it” deadlines of the AIA.⁴⁵ The NPRM is simply silent about the ripple effects of the AIA.
- Rather than updating its existing OMB information collections under control numbers OMB 0651-0031 and – 0032, the PTO has expressed its intention to organize its new OMB information collections into a new ICR 0651-00xx. IEEE-USA urges that the PTO should *not* split these information collections into a new ICR, but rather should update the existing line items in 0651-0031 and -0032.
- The Paperwork Reduction Act requires agencies to supply “*specific* ... estimate of burden” so that the public can comment.⁴⁶ The NPRM does not do so. It does not break out the number of responses or burden for the individual information collection elements, but rather reports only aggregate numbers, 189,150 responses, 778,300 hours, for a total of \$288,749,300 per year. “Specific” estimates of burden means individual elements set out line-item by line-item, with estimates and rationale, so that the public can usefully comment. Aggregating into a single final number is not helpful to the public.
- What hourly rate was used to convert hours to dollars? The NPRM is silent.
- The Paperwork Reduction Act also requires disclosure of “*objectively supported* estimate of burden.”⁴⁷ No such support is disclosed. Indeed, they are nontransparent and beyond the capacity of qualified third parties to reproduce.
- “Burden” is defined to include “adjusting the existing ways to comply with any previously applicable instructions and requirements”⁴⁸ The NPRM is also silent on this component of burden, which will be extensive under the AIA.

The PTO is clearly not in compliance with the Paperwork Reduction Act.

In preparing this letter, we reviewed the OMB web page for Paperwork ICR 0651-0032. We observe that in July 2012 and September 2012, the PTO made its Paperwork Reduction Act filings for the AIA changes to the oath. Both were filed as “Nonmaterial/Nonsubstantive Change,” rather than as “Revision of a currently approved collection.” The oath regulation effects changes ownership of patent applications—surely a “substantive” change! By classifying the changes as less material and less substantive than the changes actually were, the PTO may have saved itself some work, but it denied the public the 30-day comment period that should have been provided by statute. Because of the misclassification, the PTO incorrectly invoked the “nonmaterial/nonsubstantive” “short cut,” and OMB approved these two filings in five and four days respectively, instead of the minimum of 60 days required by statute.

⁴⁵ See, for example, Boundy & Marquardt, Patent Reform’s Weakened Grace Period: Its Effects On Startups, Small Companies, University Spin-Offs And Medical Innovators, “Medical Innovation & Business Journal, vol. 2 no. 2 at 34-35, 34 n. 21 (Summer 2010) http://journals.lww.com/medinnovbusiness/Citation/2010/06010/Patent_Reform_s_Weakened_Grace_Period_Its_Effects.6.aspx

⁴⁶ 44 U.S.C. § 3506(c)(1)(A)(iv).

⁴⁷ 44 U.S.C. § 3506(c)(1)(A)(iv).

⁴⁸ 44 U.S.C. § 3502(2)(C); 5 C.F.R. § 1320.3(b)(i)(v).

IEEE-USA is concerned that the PTO's repeated noncompliance with the law as established in the Paperwork Reduction Act will render the PTO's adjudications subject to collateral attack in subsequent infringement litigation,⁴⁹ and could lead to allegations of a pattern of false representations to *ex parte* tribunals under ABA's Model Rule for Professional Conduct 3.3, as we discuss in § III.G starting at page 29 of this letter.

E. The Regulatory Flexibility analysis is insufficient

Three significant studies have analyzed the likely effect of the first-to-file provisions on small entities.

- The Lo & Sutthiphisal paper, published by the National Bureau of Economic Research (the same body that issues the official designation of recessions and recoveries), concluded that a switch from first-to-invent to first-to-file “appeared unfavorable to independent inventors and small businesses, and it channeled inventive activity towards large corporations. ... a switch to a first to file system contradicts the very essence of the longstanding U.S. patent laws: making patent protection equally accessible to anybody.”⁵⁰
- Boundy & Marquardt⁵¹ explained how the loss of the § 102(a) and (e) grace period of the 1952 statute would selectively disadvantage startups and small firms, and is likely to impose costs on small entities in the range of \$1 billion per year.
- Abrams & Wagner⁵² “find that the Canadian change to FTF generally harmed individual inventors. One simple measure of its impact is a drop in the share of patents granted to individuals after the law change.”

In addition, in letters to Congress, IEEE-USA, the National Small Business Association, the U.S. Business and Industry Council, and several organizations of small companies and inventors explained the likely effects of the weak grace period on small entities.⁵³

Remarkably, the NPRM stands alone among the *entire body of scholarship* in the field, and *certifies* that the first-to-file regulation “will not have a significant economic effect on a substantial number of small entities.”

How is it that the PTO's analysis departs so remarkably from every other analysis? Simple: the PTO considered *only* effects on *paperwork*. The courts have invalidated prior regulations when an agency omits economic effects from its Regulatory Flexibility considerations.⁵⁴ The PTO totally ignores any other economic effect:

⁴⁹ 44 U.S.C. § 3512; 5 C.F.R. § 1320.6.

⁵⁰ Lo & Sutthiphisal, footnote 39 at 28-29.

⁵¹ Boundy & Marquardt, footnote 40, at 35.

⁵² Abrams & Wagner, footnote 41, at 5

⁵³ *e.g.*, letter of Feb. 23, 2011, <http://www.ieeeusa.org/policy/policy/2011/022311.pdf>

⁵⁴ *American Federation of Labor v. Chertoff*, 552 F.Supp.2d 999, 1012 (N.D. Cal. 2007) (rule vacated because challenger “raised serious doubts about the veracity” of several steps in the agency’s “no impact” certification analysis—agency asserted that compliance is “voluntary” but noncompliance subjects parties to threat of civil and criminal liability); *Aeronautical Repair Station Ass’n v. Federal Aviation Admin.*, 494 F.3d 161, 176–77 (D.C. Cir. 2007) (rule vacated because FAA only considered economic impacts on some parties, but not others that were affected even though not directly regulated); *United*

- loss of access to investment capital,
- diversion of inventor time into patent applications,
- weaker patent protection due to hasty filing,
- higher patent prosecution costs due to a hastily-prepared initial application,
- higher abandonment rates,
- adaptive responses, changes in ways of doing business, that are directly driven by the regulation.

The Small Business Administration and the Inspector General in the Department of Commerce have both issued guidance that applies to how the PTO should analyze effect on small entities.⁵⁵ Both instruct that the agency's analysis must consider the economic effect beyond paperwork costs. Likewise, the courts have vacated agency regulations when an agency falsely certified "no substantial economic effect" by the device of simply ignoring inconvenient economic effects.⁵⁶

The erroneous statement of the effect of guidance that we discuss in § II.A.2 at page 11 creates special burdens on small entities. While examiner non-compliance with guidance creates additional expense and delay for all applicants, small entities are particularly exposed. Small entities often lack resources to pursue appeals to the PTAB and Federal Circuit. When faced with unenforced and incomplete examination procedure at the examiner stage, and the costs of PTAB and court appeal, many individual inventors and small businesses will be forced to make the decision to forego patent protection because of the additional time and expense of appealing beyond the supervisor's review.

States Telecom Ass'n v. Federal Communications Comm'n, 400 F.3d 29, 42 (D.C. Cir. 2005) (rule vacated when agency stipulated that it "utterly failed to follow the RFA"); *HLI Lordship Indus. Inc. v. Committee for Purchase from the Blind*, 791 F.2d 1136, 1141 (4th Cir. 1986) (agency's "cryptic and perfunctory" certification under a predecessor statute that "[t]he actions will [not] have a serious economic impact," with no analysis, is "far less than 'a concise general statement' of the basis of its decision. It is literally no response."); *Home Builders' Ass'n of Northern Cal. v. U.S. Fish & Wildlife Service*, 268 F.Supp.2d 1197, 1234 (E.D. Cal. 2003) (remanding rule because agency omitted economic impact on certain parties); *Harlan Land Co. v. U.S. Dep't of Agriculture*, 186 F.Supp.2d 1076, 1097 (E.D. Cal. 2001) (rule vacated because agency's investigation of the possible effects of introduction of agricultural pests on small farmers on was flawed); *Southern Offshore Fishing Ass'n v. Daley*, 55 F.Supp.2d 1336, 1338 (M.D. Fla. 1999) (rule vacated because agency's "apparent lapses and inconsistencies" and "studied underestimation" "transgress the knowledge and common sense that are insinuated into reality; it is a contrivance that imports arrogance."), vacated by settlement, *Southern Offshore Fishing Ass'n v. Mineta*, 2000 WL 33171005, 2000 U.S. Dist. Lexis 20496 (M.D. Fla. Dec. 7, 2000); *North Carolina Fisheries Ass'n Inc. v. Daley*, 27 F.Supp.2d 650, 661 (E.D. Va. 1998) (agency's "conscious refusal to recognize the economic impacts of his regulatory actions calls into question the agency's willingness to consider less severe alternatives").

⁵⁵ Small Business Administration, Office of Advocacy, *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act*, <http://www.sba.gov/advo/laws/rfaguide.pdf> (May 2003) and (June 2010); Office of General Counsel, Dep't of Commerce, *Guidelines For Proper Consideration Of Small Entities In Agency Rulemaking*, <http://www.ogc.doc.gov/ogc/legreg/zregs/guidelines.htm> (Feb. 2003).

⁵⁶ See footnote 54.

A sound Regulatory Flexibility certification or analysis must consider the full range of economic effects that flow from the regulation, including the factors we listed above.

Also, the PTO's attempted disclaimer of the Guidelines' enforceability that we discuss in § II.A.2 at page 9 creates particularly large adverse economic effects on small entities. That disclaimer cannot be maintained consistent with the Regulatory Flexibility Act.

No one benefits when an agency exposes essentially all of its adjudications to collateral attack because the agency short-cut its compliance with rule-making law.

F. Disclosure issues under the Information Quality Act, Paperwork Reduction Act, e-Government Act, and Executive Order 12,866

The PTO's task, and the public's task of commenting on the PTO's proposal, has been made more difficult because the PTO neglected its duties of disclosure under the Paperwork Reduction Act, Information Quality Act, e-Government Act, and Executive Order 12,866.

1. Laws that require disclosure

An agency must disclose all material facts in the Notice of Proposed Rulemaking. The agency must make its evidence available in a publicly-available rule making file at the time of the Notice of Proposed Rulemaking, so that the public has fair notice and meaningful opportunity to comment and challenge the agency's basis.⁵⁷ The information must be made available during the notice and comment period in the rule making file, so that the information can be vetted by the public. This was explained by the *Connecticut Light* court as follows:⁵⁸

⁵⁷ USPTO's Information Quality Guidelines, <http://www.uspto.gov/web/offices/ac/ido/ifoqualityguide.html>, § VII(B) ("when asked the USPTO does provide disclosure of the data sources that have been used and the specific quantitative methods and assumptions (if any) that have been employed."); *Chamber of Commerce v. Securities & Exchange Comm'n*, 443 F.3d 890, 901–02 (D.C. Cir. 2006) (agency rule vacated where agency relied on undisclosed extra-record materials in arriving at its cost estimates); *Engine Mfrs' Ass'n v. EPA*, 20 F.3d 1177, 1181–82 (D.C. Cir. 1994) (R.B. Ginsberg, J.) (APA requires agency to make available "data and studies in intelligible form so that public sees 'accurate picture of reasoning' used by agency to develop proposed rule"); *Solite Corp. v. EPA*, 952 F.2d 473, 484 (D.C. Cir. 1991) ("Integral to the notice requirement is the agency's duty 'to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules... An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary."); *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 534–35 (D.C. Cir. 1983) (agency has "a duty to examine key assumptions as part of its affirmative 'burden of promulgating and explaining a non-arbitrary, non-capricious rule.' ... [The agency] must justify that assumption even if no one objects to it during the comment period. ... The agency must 'explain the assumptions and methodology used in preparing the model' and, if the methodology is challenged, must provide a 'complete analytic defense.'"); *Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375, 392, 393 (D.C. Cir. 1973) ("It is not consonant with the purpose of a rule-making proceeding to promulgate rules on the basis of inadequate data, or on data that, critical degree, is known only to the agency.").

⁵⁸ *Connecticut Light & Power Co. v. Nuclear Regulatory Comm'n*, 673 F.2d 525, 531–32 (D.C. Cir. 1982); see also *Kern County Farm Bureau v. Allen*, 450 F.3d 1072, 1076 (9th Cir. 2006) ("Integral to an agency's notice requirement is its duty to 'identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules. An agency commits serious

The purpose of the comment period is to allow interested members of the public to communicate information, concerns, and criticisms to the agency during the rule-making process. If the notice of proposed rule-making fails to provide an accurate picture of the reasoning that has led the agency to the proposed rule, interested parties will not be able to comment meaningfully upon the agency's proposals. As a result, the agency may operate with a one-sided or mistaken picture of the issues at stake in a rule-making. In order to allow for useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules. To allow an agency to play hunt the peanut with technical information, hiding or disguising the information that it employs, is to condone a practice in which the agency treats what should be a genuine interchange as mere bureaucratic sport. An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary.

The information that must be disclosed includes statistics, mathematical or computer models, and assumptions. The agency must "explain the assumptions and methodology used in preparing the model" and "provide a complete analytic defense" if the model is challenged.⁵⁹ Release of summary information is insufficient to meet an agency's duty to disclose its models, data, and assumptions.⁶⁰

Additionally, the Paperwork Reduction Act and its implementing regulations require the agency to consult with the public to solicit comment to "evaluate the accuracy of the agency's

procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary.").

⁵⁹ *Owner-Operator Independent Drivers Ass'n v. Fed Motor Co.*, 494 F.3d 188, 199 (D.C. Cir. 2007) (rule invalid when agency failed to provide opportunity for comment on model's methodology, or to disclose data and assumptions); *U.S. Air Tour Ass'n v. Federal Aviation Administration*, 298 F.3d 997, 1008–09 (D.C. Cir. 2002) (rule adequately supported when FAA modeled the problem using "the most widely used civilian software program," and gave a reasonable explanation that it had used the software reasonably); *Appalachian Power Co. v. EPA*, 251 F.3d 1026, 1035 (D.C. Cir. 2001) ("there is no question that agency determinations based upon highly complex and technical matters are 'entitled to great deference.' ... However, this Court cannot excuse the EPA's reliance upon a methodology that generates apparently arbitrary results particularly where, as here, the agency has failed to justify its choice. ... we have no choice but to remand the [agency decision] so that the agency may fulfill its obligation to engage in *reasoned* decisionmaking," emphasis the court's, citations and quotations omitted); *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 535 (D.C. Cir. 1983) (agency has "affirmative 'burden of promulgating and explaining a non-arbitrary, non-capricious rule.' ... The agency must 'explain the assumptions and methodology used in preparing the model' and, if the methodology is challenged, must provide a 'complete analytic defense.'"); *Sierra Club v. Costle*, 657 F.2d 298, 334, 334 n.132 (D.C. Cir. 1981) (agency may use a mathematical econometric model if it explains its assumptions and methodology, and responds to objections—indeed, modeling is often essential if the agency is to consider costs, alternatives, and interconnecting effects); *American Public Gas Ass'n v. Federal Power Comm'n*, 567 F.2d 1016, 1039 (D.C. Cir. 1977) ("in the absence of empirical confirmation of accuracy, we believe that the Commission is obligated to provide a complete analytical defense of its [econometric] model to respond to each objection with a reasoned presentation").

⁶⁰ *Washington Trollers Ass'n v. Kreps*, 645 F.2d 684 (9th Cir. 1981) (high-level summary, without underlying model or data to "enable an interested or affected party to comment intelligently," is arbitrary and capricious).

estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.”⁶¹

Executive Order 12,866, § 1(b) reiterates the same requirement:

(6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

(7) Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

Since 2002, agencies have been required to make this information available on the agency’s web site contemporaneously with a Notice of Proposed Rulemaking.⁶²

If an agency fails to make its underlying data available in time for meaningful notice and comment, the rule is invalid, and the agency is likely liable for attorney fees. In *Hanover Potato Products v. Shalala*,⁶³ the FDA failed to maintain a proper rule making record during notice and comment. Instead, the FDA waited until it was sued, and then assembled the record. Because there was no integral record during notice and comment, the public had no opportunity to inspect it. The Third Circuit held that the public has no duty to ferret out the documents missing from a less-than-complete record, because “one obviously cannot know the facts one does not know.”⁶⁴ The Third Circuit also held that a challenger need not show prejudice from an omission.⁶⁵ The court not only held the rule in question arbitrary and capricious, the court awarded fees under the Equal Access to Justice Act, because the agency’s position—without a timely record to support it—was unjustified.⁶⁶

The Third Circuit explained the need for a well-maintained, integral record, timely made available to the public.⁶⁷ The court quoted the excerpt from *Connecticut Light & Power Co. v. Nuclear Regulatory Commission*, from just above, and then elaborated (citations and quotations omitted):

[E]ven the possibility that there is here one administrative record for the public and this court and another for the [agency] and those ‘in the know’ is intolerable. We believe a regulated party automatically suffers prejudice when members of the public who may submit comments are denied access to the complete public record.

⁶¹ 5 C.F.R. § 1320.8(d)(1).

⁶² E-Government Act of 2002, Pub.L. 107-347 (Dec. 17, 2002), § 206(d), codified in notes to 44 U.S.C. § 3501 (“To the extent practicable, as determined by the agency in consultation with the Director, agencies shall ensure that a publicly accessible Federal Government website contains electronic dockets for rulemakings under [5 U.S.C. § 553]. ... Agency electronic dockets shall make publicly available online ...other materials that by agency rule or practice are included in the rulemaking docket under [5 U.S.C. § 553(c)]”).

⁶³ *Hanover Potato Prods. v. Shalala*, 989 F.2d 123 (3d Cir. 1993).

⁶⁴ *Hanover Potato*, 989 F.2d at 129–30.

⁶⁵ *Hanover Potato*, 989 F.2d at 128–29.

⁶⁶ *Hanover Potato*, 989 F.2d at 130–31.

⁶⁷ *Hanover Potato*, 989 F.2d at 130 n.9 (emphasis added); see also *National Crushed Stone Ass’n v. EPA*, 601 F.2d 111, 117 (4th Cir. 1979), *reaff’d in relevant part* 643 F.2d 163 (4th Cir. 1981).

2. The NPRMs neglect to disclose significant material information

The data on which the PTO relies for its analyses under the Paperwork Reduction Act (§ III.D starting at page 20) and Regulatory Flexibility Act (§ III.E at page 23) should be disclosed on the PTO's web site concurrently with a new Notice of Proposed Rulemaking.

IEEE-USA observes that the following items that *should* have been disclosed appear to be missing from the NPRM preamble and from the electronic docket required under the e-Government Act:

- There is no disclosure whatsoever of “number of responses” or “hours per response” data, let alone underlying “objective support,” in the Paperwork Reduction Act burden estimates.
- There is no disclosure of how the PTO expects filing rates to change.
- Any spreadsheets or other models that the PTO uses to project growth and future filing rates should be disclosed. Because the Paperwork Reduction Act clearance is for 3 years, burden projections are required up to and including FY 2015, and the objectivity and reproducibility required by the PTO's Information Quality Guidelines⁶⁸ and the laws noted in § III.F.1 at page 25 require disclosure of the PTO's estimation models.
- The NPRM contains no discussion whatsoever of the additional time that will be required to change procedures. For example the table on page 6906 shows that all 460 petitions for *inter partes* post grant review would be subject to the lowest fee category. However, the practical reality is that the patents that become subject to these reviews will overwhelmingly be drawn from the most economically-significant patents, and those patents in turn tend to have more claims. Since no claim information is disclosed, the analysis cannot be independently reproducible.

G. IEEE-USA requests that the PTO take care to characterize all comments accurately and to answer them fairly

In several recent rule making proceedings, members of the public have noted that the PTO has mischaracterized public comments, and then responding only to the mischaracterized comment, leaving the actual comment unaddressed.⁶⁹

IEEE-USA observes that this practice is self-defeating in the long run. When the PTO shortcuts its obligations under the procedural law, the resultant regulations may be unenforceable. Also, the submissions to OMB and SBA are submissions to *ex parte* tribunals, and

⁶⁸ United States Patent and Trademark Office, Information Quality Guidelines, <http://www.uspto.gov/products/catalog/infoqualityguide.jsp>

⁶⁹ *E.g.*, IEEE-USA, comments on Patent Processing (Updating) paperwork collection 051-0031, http://www.uspto.gov/news/fedreg/comments/0651-0031_IEEE_Comment.pdf at page 39 (May 26, 2012); David Boundy, comments on Improving Regulation and Regulatory Review, at page 5 (May 23, 2011) <http://www.uspto.gov/patents/law/comments/boundy23may2011.pdf> (discussing one specific example where PTO mischaracterized similar comments by multiple parties repeatedly, and the mischaracterization persisted at least three successive submissions, after correction was requested at each stage); Regulatory Checkbook, comments on Ex parte Appeal Rules, (Feb. 25, 2010). at page 22 n.58 http://www.uspto.gov/ip/boards/bpai/procedures/rules/rule_comments2010_regulatory_checkbook_belzer.pdf

characterizations of public comments are “statements of fact,” some of which may be “adverse,” within ABA’s Model Rule for Professional Conduct 3.3.⁷⁰

IV. CONCLUSION

IEEE-USA thanks the PTO for considering these comments in crafting its rules. We would welcome any further discussions with the PTO on these matters.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Keith Grzelak". The signature is fluid and cursive, with a long horizontal stroke extending to the left.

Keith Grzelak
Vice President for Government Relations
IEEE-USA

⁷⁰ See also Virginia Rules of Professional Conduct, <http://www.vsb.org/docs/2009-10-pg-rpc.pdf> , Rules 3.3 and 3.4, especially Rule 3.3(c) and comments 3.3[4], [5], and [14] (pages 61-65); New York State Rules of Professional Conduct, <http://www.nysba.org/Content/NavigationMenu/ForAttorneys/ProfessionalStandardsforAttorneys/NYRulesofProfessionalConduct4109.pdf> , Rules 3.3 and 3.4, especially Rule 3.3(d); and California Rules of Professional Conduct, Rule 5-200, http://calbar.ca.gov/calbar/pdfs/rules/Rules_Professional-Conduct.pdf