17 April 2012

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Mail Stop Patent Board
Director of the United States Patent and Trademark Office
P.O. Box. 1450
Alexandria, VA 22313-1450

Attn: Lead Judge Michael Tierney, Patent Trial Proposed Rules, Derivation Proposed Rules, *Inter partes* Review Proposed Rules, Post-Grant Review Proposed Rules, Covered Business Methods Patent Review Proposed Rules

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, Information Collection, and Information Quality issues raised in sections III.B, III.C, III.D, and III.E starting at page 20, and Information Quality in section IV starting at page 31)

Office of the Solicitor
United States Patent and Trademark Office
P.O. Box. 1450
Alexandria, VA 22313-1450

Attn: Raymond T. Chen, Solicitor, issues of administrative law and enforceability of judgments issued by the USPTO, raised in section III, starting at page 17

Re: Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions, RIN 0651-AC70, 77 Fed. Reg. 6879 (Feb. 9, 2012) ("Umbrella rules"), patent_trial_rules@uspto.gov

Re: Changes to Implement Inter Partes Review Proceedings, RIN 0651-AC71, 77 Fed. Reg. 7041 (Feb. 10, 2012), inter_partes_review@uspto.gov

Re: Changes to Implement Post-Grant Review Proceedings, RIN 0651-AC72, 77 Fed. Reg. 7060 (Feb. 10, 2012), post_grant_review@uspto.gov

Re: Changes To Implement Transitional Program for Covered Business Method Patents, RIN 0651-AC73, 77 Fed. Reg. 7080 (Feb. 10, 2012), TPCBMP_Rules@uspto.gov

Re: Changes to Implement Derivation Proceedings, RIN 0651–AC74, 77 Fed. Reg. 7028 (Feb. 10, 2012), derivation@uspto.gov

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Dear Judge Tierney and Mr. Fraser:

IEEE-USA submits these consolidated comments on all of the above-captioned notices of proposed rulemaking ("NPRM"). 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, mechanical, and biomedical engineers, working in 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.

The America Invents Act enacted on September 16, 2011 ("AIA") established new proceedings at the U.S. Patent and Trademark Office ("USPTO" or the "Office") for contested patent cases that would be decided by the Patent Trial and Appeal Board ("Board") in *trial*-type proceedings. These new proceedings will be fundamentally different in nature from existing post-grant *inter partes* reexaminations, *ex parte* reexaminations, and reissue conducted by examiners. The IEEE-USA's Intellectual Property Committee, which prepared these comments, commends the USPTO for its monumental efforts under statutory deadline constraints to craft workable rules for conducting Board reviews in *inter partes*, post grant, covered business method patents, and derivation proceedings. We also commend the USPTO for preparing and holding numerous "road-show" meetings in which the Office explained its proposed rules. These meetings were helpful for understanding the rules and in framing some of our comments below.

This comment letter, directed to the trial practice elements of these five Notices of Proposed Rulemaking ("NPRM"), is offered in addition to the comment letter that we sent on April 10, 2012 addressing the transitional post grant review of covered business method patents.

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I. COMMENTS ON SPECIFIC PROVISIONS OF THE UMBRELLA RULES, IPR RULES, PGR RULES, AND DERIVATION RULES

A. Opening observation: the USPTO is about to enter an unfamiliar realm, where the classes of issues and kinds of evidence to be submitted will be qualitatively different than in the past

Essentially, the only trial-type proceeding at the USPTO—a category which the USPTO calls Contested Cases—are interferences, which are governed by Subparts D and E of 37 C.F.R. § 41. These detailed existing regulations governing contested cases highlight the Board's role in such cases as an impartial arbiter of an adversarial dispute between two parties. The proposed rules in the NPRM will expand the Contested Cases category to new realms, dealing with new issues and new types of evidence, including adduced evidence and testimony of "public use" and "on sale" *from all over the world*.

The new post-grant review of 35 U.S.C. §§ 321-326 ("PGR") and the transitional covered business methods patent review of § 18 of the AIA are qualitatively different than any of the current intra-USPTO post-issue examination proceedings (*ex parte* reexamination, *inter partes* reexamination, and reissue). If the rules are adopted as proposed, for the first time in history, an intra-USPTO procedure would provide for review of invalidity under a "broadest reasonable interpretation" standard (as opposed to a *Markman* "in light of the specification and prosecution history" standard) in view of "public use" and "on sale" evidence. In contrast, current reexamination proceedings are confined to "patents and printed publications"[1]; no "public use" or "on sale" issues can be raised in pre-AIA post-grant reexamination. However, the new AIA post-grant review and new transitional covered business methods patent review permit challenges of *issued patents* over "public use" and "on sale" evidence for the first time at the USPTO. Further, if these rules are adopted, the new proceedings would be essentially the first *ever* in American law that permit "public use" and "on sale" challenges under a "broadest reasonable interpretation" claim interpretation and "preponderance of evidence" standard. "Public use" and "on sale" prior art, almost by definition, require affidavit or oral testimony, and that in turn requires live cross-examination in a forum that permits the fact-finder to evaluate credibility. Both "public use" and "on sale" evidence should be supported by "corroboration."[2]

In addition, *all* prior art (patents, printed publication, public use, and on sale) in *inter partes* reviews ("IPR"), PGR, and transitional covered business methods patent reviews will be subject to an enablement inquiry under the "otherwise available to the public" language of new

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[1] The only current intra-USPTO forum for "public use" and "on sale" issues is a "public use proceeding" under existing rules in 37 C.F.R. § 1.292—however, because § 1.292 public use proceedings are only permitted during initial pendency, they are seldom used. USPTO fee reports obtained under FOIA request reflect fee income under Fee Code 1451 ("Petition to Institute a Public Use Proceeding") from about 3 petitions per year averaged over the last 10 fiscal years. It is likely that on average, fewer than 3 such petitions per year are actually granted.

[2] *Washburn & Moen Mfg. Co. v. Beat 'Em All Barbed-Wire Co.* (the "*Barbed Wire*" cases), 143 U.S. 275, 284-5 (1892) ("The very fact … that almost every important patent … has been attacked by the testimony of witnesses who imagined they had made similar discoveries long before the patentee had claimed to have invented his device, has tended to throw a certain amount of discredit upon all that class of evidence, and to demand that it be subjected to the closest scrutiny."); *see also* 37 C.F.R. § 41.204(a)(2) (Interference rules require that petitioner's statement of facts be supported by *corroborating* evidence).

§ 102(a)(1).[3] This will turn many anticipation cases that are simple inquiries of fact under current law into complex "battles of experts."

Further, in the past, the USPTO has used proceedings before examiners to develop the evidentiary record, so that a case arrives at the Board in an appellate posture on relatively small number of issues that have been winnowed down and developed for final resolution. In contrast, in these new proceedings, the opening petition will be filed before the parties have a clear understanding of what issues will ultimately matter, little evidence, and the like. The Board should not underestimate the work that will be required to develop a case to a point analogous to the point at which *inter partes* appeals have traditionally arrived at the Board.

A good part of the reason that interferences have been complicated is that they often turn on facts outside of paper documents, and require oral and affidavit testimony to establish facts. These new AIA proceedings move all of those complications into the post-grant review world, and add an additional layer of complexity: where no-document evidence was typically only necessary in interferences to establish *facts* (what a party did, and when), these new AIA proceedings will often turn on *inferences* from facts (for example, whether the external facts support inherency of internal operation of a software system, or whether a sale made an invention "available to the public," and how that relates to claims). These new proceedings will be high stakes litigation, and will often turn on very small differences in experts' interpretations and inferences—if the USPTO aims to be a fair forum alternative to litigation, the procedural regulations must provide for a full opportunity to vet out no-document evidence, adduce expert testimony, and the like, and full opportunity for opposition to evidence and expert testimony. And the Board should be prepared to take the necessary time and pains to make that forum fair.

The Board should not underestimate either the complexity that "public use," "on sale," and "otherwise available to the public" will add, and should not underestimate the change to the character of post-grant proceedings. Furthermore, contrary to the statements made by proponents of the AIA, the elimination of interferences under the AIA does not remove the need for evidentiary determinations that mirror those of interferences. The Board should not discard its long-standing rules and practices used to decide such disputes, as many of the existing interference rules will be required for derivation proceedings and the new trial-type proceedings. At least 60 years of learning, insight, tuning, and familiarity, for both the Board and the bar, are embedded in the existing interference rules, and should not lightly be discarded. The trial-type evidentiary and procedural problems that will arise under these new proceedings will, in many cases, be more similar to existing interferences than to existing reexaminations. The regulations for these new proceedings should carry forward much more of the existing interference regulations, so at least some default regulations are in place for situations when they arise under the new statute.

These general observations affect a number of specific provisions.

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[3] Remarks of Sen. Kyl, Cong. Rec. A 1042 (Mar. 1, 2011); Remarks of Sen. Kyl, Cong. Rec. S1370 (Mar. 8, 2011) ("And second, it limits all non-patent prior art to that which is available to the public. This latter change is clearly identified in Senate Report 110–259, the report for S. 1145, the predecessor to this bill in the 110th Congress. The words 'otherwise available to the public' were added to section 102(a)(1) during that Congress's Judiciary Committee mark up of the bill. The word 'otherwise' makes clear that the preceding clauses describe things that are of the same quality or nature as the final clause—that is, although different categories of prior art are listed, all of them are limited to that which makes the invention 'available to the public.'")

B. The rules for Petitions for Review should explicitly specify a burden of proof

The rules for initiating an *inter partes* review, post-grant review, or transitional covered business methods patent review are silent as to allocation of burden of persuasion. Although proposed §§ 42.104, 42.204 and 42.304 in the NPRMs allocate the *burden of going forward* to the petitioner, it does not explicitly state that the petitioner must also bear the burden of *persuasion*. Because 35 U.S.C. §§ 316(e) and 326(e) place the burden of persuasion on the patent challenger in *inter partes* review and post grant review respectively, IEEE-USA requests that the implementing regulations clarify that the burden of persuasion does not shift to the patentee.

C. Petitions invoking "on sale" and "public use" prior art should require proof in the opening Petition, including evidence of corroboration

The statute for post grant review, 35 U.S.C. § 326(e), requires that the patent challenger prove its case to a preponderance of evidence. The implementing regulation, 37 C.F.R. § 42.204, in cases involving "on sale" and "public use," should expressly remind petitioners of the requirement for "corroboration" of no-document evidence. For over 100 years, since *The Barbed Wire Cases*,[4] a party asserting invalidity or priority based on no-document "on sale" or "public use" has been required to corroborate any oral or affidavit testimony. The "corroboration" requirement applies even under "preponderance of evidence" standards at the USPTO, such as interferences.[5] In cases involving no-document prior art, "the purpose of corroboration ... is to prevent fraud, by providing independent confirmation of the inventor's testimony. As such, the corroboration requirement provides an additional safeguard against courts being deceived by inventors who may be tempted to mischaracterize the events of the past through their testimony."[6] The need for corroboration of oral or affidavit testimony is independent of the evidentiary standard of proof the patent challenger must meet to persuade the fact-finder.

Documents used to corroborate testimony must be sufficiently complete, clear and detailed to show that each and every element of a claim is present.[7]

Therefore, IEEE-USA proposes an amendment to § 42.204(b)(4)-(5) as shown below, with the underlined text being added:

> (4) How the construed claim is unpatentable under the statutory grounds identified in paragraph (b)(2) of this section. Where the grounds for unpatentability are based on prior art, the petition must specify where each element of the claim is found in the prior art. <u>Oral testimony or affidavits regarding public use or on sale evidence must be corroborated.</u> For all other grounds of unpatentability, the petition must identify the specific part of the claim that fails to comply with

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[4] See footnote 2

[5] *Hahn v. Wong*, 892 F.2d 1028, 1032-33 (Fed. Cir. 1989); *Medichem, S.A. v. Rolabo, S.L.* 437 F.3d 1157, 1169-70 (Fed. Cir. 2006) (requiring preponderance of the *corroborated* evidence to determine priority of invention).

[6] *Medichem* 437 F.3d at 1169 (internal quotations and citations omitted).

[7] *Lacks Indus., Inc. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335, 1350 (Fed. Cir. 2003) ("[t]he relevant documents do not serve to persuasively corroborate the testimony of defendants' own witness, because the documents themselves are also too incomplete or contradictory to meet that standard"); *Woodland Trust v. Flowertree Nursery, Inc*, 148 F.3d 1368, 1373 (Fed. Cir. 1998) (disregarding two undated photographs offered as corroboration, because "their lack of detail and clarity can not have provided documentary support").

the statutory grounds raised and state how the identified subject matter fails to comply with the statute; and

(5) The exhibit number of the supporting and corroborating evidence relied upon to support the challenge and state the relevance of the evidence to the challenge raised, including identifying specific portions of the evidence that support the challenge. The Board may exclude or give no weight to the evidence where a party has failed to state its relevance or to identify specific portions of the evidence that support the challenge.

D. IPR and PGR trials are not examinations, and the claim construction rules should reflect that

Proposed Rules §§ 42.100(b) and 42.200(b) adopt the "broadest reasonable interpretation in light of the specification standard" ("BRI") for claim construction in IPR and PGR Board proceedings. Citing two Federal Circuit decisions adopting the BRI standard in reexaminations, the NPRM explains that such rules would be "consistent with long-standing established principles of claim construction before the Office." 77 Fed. Reg. at 7044. It is well established that the BRI standard is *not* a standard for construing claims of issued patents in a judicial tribunal but is rather an *examination tool* used only by the Office when the applicant can amend the claims successively "in order to achieve a complete *exploration* of the applicant's invention and its relation to the prior art" (emphasis added).[8] The examination process is iterative, requiring more than two Office actions on average. Congress also recognized that additional iterations for examination and amending the claims may be required and provided for continued examination of applications in 35 U.S.C. § 132(b). Similarly, *inter partes* reexamination is a *bona fide* examination process permitting multiple opportunities to amend the claims,[9] including additional opportunities in certain circumstances by filing a Request for Continued Reexamination ("RCR").[10] Even at the last potential stage after examination or reexamination, if the Board issues a new rejection on appeal, prosecution is reopened with full rights to amend the claims again. 37 C.F.R. §§ 41.50(a)(2)(i), 41.50(b)(1) and 41.77(b). Indeed, as in regular examinations, a "complete exploration of the applicant's invention and its relation to the prior art" can take place during *inter partes* reexamination. Therefore, as the Federal Circuit authorities cited by the NPRM explain, the BRI standard is appropriately applied in reexaminations.

However, IPR and PGR trials are *not* patent examination proceedings. Rather, these proceedings are adjudicative in nature with a primary purpose of determining whether an issued

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[8] *In re Zletz*, 893 F.2d 319, 321-322 (Fed. Cir. 1989) ("During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow. When the applicant states the meaning that the claim terms are intended to have, the claims are examined with that meaning, *in order to achieve a complete exploration* of the applicant's invention and its relation to the prior art. … An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way [using BRI] can uncertainties of claim scope be removed, as much as possible, during the administrative process," internal citation and quotations omitted, emphasis added); *see In re Prater*, 415 F.2d 1393, 1404-05 (CCPA 1969) ("before the application is granted, there is no reason to read into the claim the limitations of the specification. The reason is simply that during patent prosecution when claims *can be amended*, ambiguities should be recognized, *scope and breadth of language explored*, and clarification imposed," internal citation and quotations omitted, emphasis added).

[9] Even after final rejection or action closing prosecution, amendments necessitated by the new rejection can be made. 37 C.F.R. § 1.116.

[10] MPEP § 2440(II), Second or Subsequent Request Filed During Reexamination.

patent is invalid. Unlike reexaminations which permit multiple iterations of claim amendments moving the prosecution forward, the patentee is limited to only "one motion to amend the patent," 35 U.S.C. § 316(d)(1) – a motion which may or may not be granted. Thereafter, the patentee would have no opportunity to further amend the claims in response to new arguments or new evidence *later* advanced by the petitioner or by the Board, as these rules permit. Under the AIA, IPR and PGR proceedings will surely provide no opportunity for "a complete *exploration* of the applicant's invention and its relation to the prior art."

Because a substantial number of IPR and PGR trials are likely to operate in concurrence with federal district court litigation—as the statute requires for virtually all transitional covered business method patent reviews—they will effectively constitute adjudications dealing with the validity part of a concurrent infringement suit. Under these proposed BRI standards for IPR and PGR, the patentee's claims will be construed broadly in the validity part and narrowly in the infringement part, prejudicing the rights of the patentee and creating a substantive conflict that Congress did not intend.

Congress expressly provided in 35 U.S.C. §§ 316(e) and 326(e) the USPTO-specific standards to be applied in IPR and PGR. While the preponderance of evidence standard was specified, the BRI standard was not. Furthermore, in contrast with regular examinations and reexaminations, Congress provided no "continued examination" statutes for IPR and PGR. Congress intended no "scope and breadth of language exploration" by claim amendments in IPR and PGR proceedings. The USPTO proposed adoption of the BRI standard for patentability decisions in IPR and PGR trials which provide no adequate opportunity to amend claims, is an inappropriate application of an examination tool where no examination exists. IEEE-USA believes this would be a radical departure from equitable precedents and a substantive change in the rights of patentees. As such, these rules would appear to exceed the authority of the USPTO, which lacks substantive rule making power.[11]

IEEE-USA believes that the rules in §§ 42.100(b) and 42.200(b) should be amended to provide for claim construction used in a federal district court proceeding—claim construction "in light of the specification and prosecution history."[12]

E. The PTO should publish some "ascertainable standard" to interpret the phrase "charged with infringement" in proposed § 42.302(b)

AIA § 18(a)(1)(B) reads as follows:

> (B) A person may not file a petition for a transitional proceeding with respect to a covered business method patent unless the person or the person's real party in interest or privy has been sued for infringement of the patent or has been charged with infringement under that patent.

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[11] *Tafas v. Doll*, 559 F.3d 1345, 1352 (Fed. Cir. 2009). See Section III.A.

[12] In our letter of April 10, 2012 on transitional covered business method patent review, we urged that "broadest reasonable interpretation" be part of the jurisdictional test for transitional business method patents. We also noted at page 6 of our April 10 letter that the *jurisdictional* test need not track the *substantive patentability* test. That observation applies here as well: there is no inconsistency in using "broadest reasonable interpretation" as the *jurisdictional* test for transitional covered business methods review, while using *Markman* "in light of the specification and prosecution history" claim construction to decide substantive patentability.

Proposed 37 C.F.R. § 42.302(b) (of the Transitional Covered Business Methods Patent Review rule) reads as follows:

> (b) A petitioner may not file a petition to institute a covered business method patent review of the patent where the petitioner, the petitioner's real party in interest, or a privy of the petitioner is estopped from challenging the claims on the grounds identified in the petition.

The USPTO should provide some ascertainable standard[13] for the term "charged with infringement." Two possible standards are readily available, the narrower standard for declaratory judgment as it stood before *MedImmune, Inc. v. Genentech, Inc.*,[14] and the broader standard for declaratory judgment as it stands after *MedImmune*.

The USPTO should pick a standard and state it in the text of the regulation.

F. Expert testimony

"Evidentiary conflicts with respect to technology and science arise in a variety of cases; and the conflicting testimony of expert witnesses is ubiquitous." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 1025 (Fed. Cir. 1995) (Newman, J., dissenting).

As we noted in our opening observation in section I.A at page 4 of this letter, expert testimony (both as evidence in chief and as cross-examination of an opposing expert) will be central features of *inter partes* review, post-grant review, and the transitional covered business method patent review. Yet these Notices of Proposed Rule Making are strikingly silent on expert testimony. The sole significant mention of expert testimony is the verbatim repetition of existing rule § 41.158, which gives no guidance as to the procedure for introducing expert testimony:

> **§ 42.65 Expert testimony; tests and data.**
>
> (a) Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight. Testimony on United States patent law or patent examination practice will not be admitted.
>
> (b) If a party relies on a technical test or data from such a test, the party must provide an affidavit explaining:
>
> (1) Why the test or data is being used;
>
> (2) How the test was performed and the data was generated;
>
> (3) How the data is used to determine a value;
>
> (4) How the test is regarded in the relevant art; and
>
> (5) Any other information necessary for the Board to evaluate the test and data.

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[13] *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.'"); *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.")

[14] *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).

The uses of experts in the new *inter partes* review, post-grant review, and the transitional Covered Business method review will be significantly different than existing use of experts in interferences under current § 41.158. For example, expert testimony will often be essential to *initiating* the review at petition phase (in contrast, an interference is initiated on a simple showing by the party who "makes" the count as a matter of claim amendments). Expert testimony will be far more common in the future, on a broader range of issues, and in more varied procedural settings, than it has been in the past, as we discussed in section I.A at page 4. Rule 42.65 leaves a long list of unanswered questions:

- Will experts be subject to *voir dire*, *Daubert* challenges, and the like? "[T]he spirit of *Daubert* is applicable to [proceedings before administrative agencies]… 'Junk science' has no more place in administrative proceedings than in judicial ones."[15] What will the USPTO do to ensure the integrity of its proceedings, and to ensure that they can survive review at the Federal Circuit? If an opening petition relies on expert testimony, it seems both unfair and arbitrary and capricious for the USPTO to rely on that testimony, with no opportunity for the patent owner to challenge that expert testimony.
- Will the USPTO take expert testimony at a live trial-type hearing? This will often be crucial, in order for the Board to evaluate demeanor and credibility, and to have the opportunity to ask its own questions of the parties' experts. With the addition of "on sale," "public use," and "available to the public" issues to its jurisdiction, the Board is about to be confronted with conflicting expert testimony—how does the Board intend to resolve these conflicts?
- What procedures will be used for disclosure of expert evidence? Will the USPTO use expert witness reports, analogous to Fed.R.Civ.P. 26(a)(2)? Or will the USPTO require that a challenger present *all* evidence supporting the challenge in the opening petition for review? If the latter, how will the USPTO provide for fair opportunity to challenge that expert testimony at petition phase? The limitations of Rules 42.107(c) and 42.207(c), both providing that "no new testimony evidence" may be used in a response to a petition, seems extraordinarily unfair, especially in cases where the challenger relied on expert testimony in its opening petition.
- Will the Board appoint neutral experts, analogous to Fed.R.Ev. 706?

The NPRMs do not address these important issues. The choice of one's own expert, and fully vetting out the other side's, are among the most important tasks in conducting a patent dispute.[16] The paucity of discussion in these NPRMs is troubling, because it suggests that the USPTO has not fully considered the dynamics of patent disputes, and sought insufficient input from the public to gain an appreciation of the problem before promulgating these NPRMs.

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[15] *Pasha v. Gonzalez*, 433 F.3d 530, 535 (7th Cir. 2005) (Posner, J.) (vacating agency decision because the agency relied on an unqualified expert).

[16] "The expert is in some ways the most important person on your litigation team. The right expert can testify with regard to something that is not visible or easily accessible…" David Makman, *Adapting Your IP Strategies to Today's Litigation Environment*, in Litigation Strategies for Intellectual Property Cases, 2011 Edition, Thomson Reuters/Aspatore Books (June 2011), 2011 WL 2532973 at *6.

G. Timing of patent owner's reply to opening petition

The USPTO should include (either by formal regulation or as guidance in the Final Rule Federal Register Notice) some recognition of an inherent unfairness: in cases where no suit is yet pending, the challenger will have had ample time to build his/her invalidity case, but the patent owner will be under a sharply-constrained time schedule to defend.

One of the key tasks that takes time is finding an appropriate technical expert. Locating an appropriate expert is often one of the most important and challenging tasks in preparing a case[17]—the existence of *expertise* and *availability* in a single person are inherently in tension, and it can take *months* to find a suitable expert. This should be one of the tasks that the USPTO recognizes as good cause or the interest of justice for extension of time to respond.

Likewise, where a petitioner raises a "public use" or "on sale" challenge, it can take a year for a patent owner to fully investigate the facts, to develop an appropriate rebuttal. The AIA makes this task even more daunting by opening "public use" and "on sale" evidence from foreign countries as eligible for these proceedings—obtaining a deposition of a foreign party under the Hague convention is an extraordinarily complicated task. The worldwide availability of prior art under these categories is likely to create an abuse: a cottage industry of false "public use" and "on sale" evidence that is only capable of verification through use of foreign legal systems. At least in some countries, these legal systems may be inadequate or may not provide a level playing field to foreign parties. Prudence dictates time and venue flexibility to counter these potential abuses.

Under 35 U.S.C. §§ 316(b) and 326(b), the USPTO is empowered to promulgate regulations authorizing the Board to deny petitions if the issues raised would harm "the integrity of the patent system" or if the USPTO lacks "ability … to timely complete proceedings." IEEE-USA believes that this statute authorizes the Office to promulgate regulations to the effect that petitions relying solely on contested foreign "on sale" or "public use" evidence will be denied, or at least granted only under the strictest scrutiny.

One appropriate procedural avenue is to permit the patent owner to extend time for reply to an opening petition on a very low showing of good cause. Since the statutory time deadlines run from the date of *grant* of the petition for review, there seems to be little institutional barrier to granting this time.

H. Discovery—proposed § 42.51

The proposed discovery rule is stated as follows:

"§ 42.51 Discovery.

(a) *Limited discovery.* A party is not entitled to discovery except as authorized in this subpart. The parties may agree to discovery between themselves at any time.

(b) Routine discovery. Except as the Board may otherwise order:

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[17] "[I]f a patent owner is taking a patent case to trial at the present time or is getting ready to sue for infringement, it would be especially important to pick an expert to develop the litigation theory, and make sure the patent owner has dotted their i's and crossed their t's, knowing that the Federal Circuit is going to take a strict look at everything in the case…" Frederick S. Frei & Sean S. Wooden, *Revising Patent Strategies in Light of New Trends In Case Law,* in The Impact Of Recent Patent Law Cases and Developments, 2011 Edition, Thomson Reuters/Aspatore Books (Nov. 2010).

(1) Unless previously served, any exhibit cited in a paper or in testimony must be served with the citing paper or testimony.

(2) Cross examination of affidavit testimony is authorized within such time period as the Board may set.

(c) Additional discovery. (1) A party may move for additional discovery. Except in post-grant reviews, the moving party must show that such additional discovery is in the interests of justice. The Board may specify conditions for such additional discovery."

The Board should be especially sensitive to permitting discovery on issues where the party proffering a position has had the luxury of time to fully develop that position, and the other party needs a similar amount of time (often more) to vet that position. For example, attorneys working on this letter have experienced patent litigations where vetting of *American* "on sale" and "public use" prior art took a great deal of discovery—and the "cracks" in the invalidity position that eventually prevailed were not apparent at the outset of the case. The Board's historic practice of only permitting discovery where some pre-existing evidence suggests the need for further discovery[18] will likely not be a good fit in the Board's new world of "public use" and "on sale" prior art.

The regulation should make clear that the discovery threshold in "the interest of justice" is easily carried by a patent owner opposing a no-document prior art challenge.

I. The Umbrella Rule imposes an estoppel beyond that authorized by statute

37 C.F.R. § 42.73(d)(3)(ii) is set forth in the Umbrella Rule NPRM at 77 Fed. Reg. 6913, as follows:

"§ 42.73 Judgment.

(3) *Patent applicant or owner*. A patent applicant or owner whose claim is canceled is precluded from taking action inconsistent with the adverse judgment, including obtaining in any patent:

(i) A claim to substantially the same invention as the finally refused or cancelled claim;

(ii) A claim that could have been filed in response to any properly raised ground of unpatentability for a finally refused or cancelled claim; or

(iii) An amendment of a specification or of a drawing that was denied during the trial proceeding."

This regulation would be problematic in the following two respects.

First, by statute, 35 U.S.C. § 120, an applicant that is entitled to file a continuation application is entitled to all rights arising in that application. The USPTO cannot by regulation attenuate this statutory right.

Second, § 42.73(3)(ii) requires a patent owner to contemplate all possible resolutions of all possible issues that might be raised or resolved in the proceeding, and preemptively file claims to

[18] "The basic problem is that the burden is on the movant to show that its opponent has something in its file that the board should consider in reaching its judgment. However, since the movant usually doesn't know what its opponent has in its file, it usually can't satisfy 'the interest of justice' requirement as interpreted by the board." Charles Gholz, Patent Interferences -- Big Ticket Litigation With No Effective Discovery, Intellectual Property Today Vol. 4 No. 9 (1997)

meet every conceivable contingency. This imposes burdens well above the "the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives," 5 C.F.R. § 1320.5(d)(1)(1) implementing the Paperwork Reduction Act, 44 U.S.C. § 3506(c)(2)(A)(iv). The AIA does not authorize the USPTO to override the Paperwork Reduction Act.

J. The proposed rules to require submission of claim construction in derivation proceedings are unnecessary and therefore inappropriate

The proposed rules require a petitioner to provide a claim construction for every disputed claim in a derivation proceeding. § 42.405(b)(3)(ii). IEEE-USA submits that these requirements are unnecessary and inappropriate for derivation.

The proposed rules already require the petitioner to show under § 42.405(a)(2) that the petitioner's claim is "(i) the same or substantially the same as the respondent's claimed invention; and (ii) not patentably distinct from the invention disclosed to the respondent." If these requirements are not sufficiently descriptive as to form, perhaps the USPTO may consider using a rule similar to existing Rule § 41.202(a)(3) to clarify the required form.

IEEE-USA therefore recommends that proposed Rule § 42.405(b)(3)(ii) be stricken.

II. COMMENTS ON THE DERIVATION NPRM

A. The proposed derivation rules ignore critical elements in the law of derivation and are therefore incomplete

Proposed Rule § 42.405 for derivation addresses only aspects of communication of the derived invention and lack of authorization to file. However, a proof of communication of subject matter from the person alleging derivation to the accused deriver is insufficient to prove derivation. For example, in joint development efforts, the person alleging derivation could be the only person to have documented an invention made in fact by the accused deriver, wherein the communication conveys that documentation for the benefit of the parties to the joint development effort. The mere showing of a communication from the person alleging derivation does not prove conclusively that person to be the inventor from whom the invention is derived. It is incontrovertible that there can be no derivation of an invention or its description without possession of a conception of the critical features of that invention by the party alleging derivation prior to the time of the asserted derivation.[19]

The AIA did not change the meaning of the term "derivation" or the law of derivation. Because the legal standard for proving derivation requires a showing of earlier conception by the party alleging derivation, *all derivation determinations require determinations of invention prior to the alleged communication*. Moreover, allegation of derivation must fail upon a showing of conception by the accused deriver on a date earlier than the alleged communication. These determinations are not dissimilar to those made in interferences. There is a wide body of pertinent law which the NPRM appears to ignore: *Price v. Symsek*, 988 F.2d 1187, 1190 (Fed. Cir. 1993) (derivation is a question of fact; to prove derivation, the movant must establish *prior conception* of the claimed subject matter *and* communication of the conception to the adverse claimant);

[19] *Egnot v. Looker*, 387 F.2d 680, 687 (CCPA 1967) ("There can be no derivation without prior conception on the part of the party alleging derivation").

Brand v. Miller, 487 F.3d 862, 869 (Fed.Cir.2007) (to meet the burden of proof on derivation, a claimant "must make two showings. First, he must establish prior conception of the claimed subject matter. Second, he must prove communication of that conception to the patentee that is sufficient to enable [him] to construct and successfully operate the invention.") (Internal citations and quotations omitted).

The derivation rules should therefore include requirements for showing conception (applied to both parties) *and* communication (applied to the party alleging derivation). It is therefore troubling that the USPTO appears to have discarded useful constructs in Part 41 of its rules which address these very matters. For example, the derivation rules in Part 42 should be augmented by rules requiring both parties to submit corroborated conception evidence as in Rules § 41.204(a)(2) subparagraphs (i) and (iv).

Similarly, IEEE-USA proposes the following amendment to rule § 42.405(c), with new text underlined:

> (c) Sufficiency of showing. A derivation showing is not sufficient unless it is supported by substantial evidence, including at least one affidavit addressing <u>conception and</u> communication of the derived invention and lack of authorization that, if unrebutted, would support a determination of derivation. The showing of <u>conception and</u> communication must be corroborated.

B. The derivation rules should clarify that the Board would normally not defer action on petitions for derivation

The AIA provides under 35 U.S.C. § 135(c) as follows:

> DEFERRAL OF DECISION.—The Patent Trial and Appeal Board *may* defer action on a petition for a derivation proceeding until the expiration of the 3-month period beginning on the date on which the Director issues a patent that includes the claimed invention that is the subject of the petition. The Patent Trial and Appeal Board also *may* defer action on a petition for a derivation proceeding, or stay the proceeding after it has been instituted, until the termination of a proceeding under chapter 30, 31, or 32 involving the patent of the earlier applicant. (Emphasis added).

Although the statute authorizes the Board to defer action on a petition for derivation until after a patent is issued to the alleged deriver, the Board has full authority to proceed with action on such petitions without delay. In fact, the legislative intent is clearly to have derivation disputes resolved *before* a patent is issued to the alleged deriver: The House Report accompanying the AIA legislation clearly states that the Derivation proceeding "will ensure that a person *will not be able to obtain a patent* for the invention that he did not actually invent. If a dispute arises as to which of two applicants is a true inventor (as opposed to who invented it first), it *will* be resolved through an administrative proceeding by the Patent Board." H. Rep.112-98, (June 1, 2011), p. 42 (emphasis added). It therefore appears that Congress intended that deferral of action on derivation until after a patent issues to the alleged deriver would be the exception rather than the rule.

Principles of equity demand this result as well. Given the long pendencies at the USPTO, deferring action on a derivation petition can be highly prejudicial to inventors who would be irreversibly denied a patent or not be able to continue prosecuting their patent applications for several years and would be at great business risks until their adversary receives a patent. Many can be forced out of business by that time. Furthermore, if an actual deriver is permitted to obtain

an undeserved patent, he can sue the inventor alleging derivation for infringement, unjustly inflicting substantial economic harm on the inventor or his company.

Therefore, IEEE-USA requests that a rule be adopted expressly setting forth the rare circumstances (if any) under which deferral will take place.

C. The derivation rules should clarify the process for determining the scope of derived subject matter

The NPRM proposes that unlike patent interferences, derivations would be conducted in a single phase without the use of a "count." 77 Fed. Reg. 7029, Col.2. However, the proposed rule in § 42.405(a)(2) requires a showing that "the petitioner has at least one claim that is: (i) the same or substantially the same as the respondent's *claimed invention*; and (ii) not patentably distinct from the *invention disclosed* to the respondent." The proposed rule in § 42.405(b)(3)(i) requires that the petitioner "for each of the respondent's claims to the *derived invention*, (i) show why the claimed invention is not patentably distinct from the *invention disclosed* to the respondent" (emphasis added). Thus, without using the term "count," but using terms other than *claims* ("claimed invention," "invention disclosed"), the proposed rules imply, as they should, that a determination of the *scope of the derived subject matter* would be made.

In fact, the "invention disclosed to the respondent" may contain no claim language to be compared to respondent's "claimed invention." Yet, a *single textual description* of the derived subject matter is necessary for determining derivation. Such a single description is otherwise known as a "count." The need for such single textual description of scope in derivation proceedings is no different from such need for the determination of the scope of interfering subject matter in resolving priority of invention disputes. Indeed, the Federal Circuit has considered whether the "count" phase can be eliminated and concluded that it cannot.[20] The USPTO has also come to the same conclusion in prior considerations of the Board's rules.[21] The apparent reversal on this issue now is remarkable, particularly as the instant NPRM gives no reasons or rationales for discarding the only known effective tool for making subject matter scope determinations in derivation proceedings.

IEEE-USA is skeptical that real incidences of derivation can be adequately addressed by mere comparison of claims from the two contested applications. By not clarifying whether a "two-way" test for common subject matter will be applied in derivations, the proposed rules ignore situations where the derived subject matter disclosed and the subject matter claimed by the first applicant differ, as with genus and species claims. In these situations, despite clear evidence of derivation, the petitioner's claim may not be "the same or substantially the same as the respondent's claimed invention," as § 42.405(a)(2)(i) requires. Similarly, proposed Rule § 42.405(a)(2)(ii) requires that a petition must present a claim that is "not patentably distinct" from the invention disclosed to the respondent. A claim is not "patentably distinct" if it is either anticipated by, or obvious over another claim. A claim to a genus cannot be "patentably distinct"

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[20] *Slip-Track Sys. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1264 (Fed. Cir. 2002) ("[I]t is necessary for us to hold that given interfering patents, *a single description* of the interfering subject matter *is necessary* for a determination of priority," emphasis added).

[21] USPTO, *Rules of Practice Before the Board of Patent Appeals and Interferences*, 68 Fed. Reg. 66648, 66664-5 (Nov. 26, 2003) ("The costs associated with the count are outweighed by the advantages flowing from having a single description of the interfering subject matter both for the purpose of determining priority and, perhaps more importantly, for the purpose of claim correspondence.").

from a claim to a species that anticipates the genus, but a claim to a species or subcombination may be patentably distinct from a broader claim. Thus, for an equitable determination of true inventorship in derivation proceedings, the textual definition of the derived subject matter must be broad enough to encompass the common subject matter of the claims in *both* applications, as used in defining interfering subject matter.[22]

It is therefore unclear how the parties can address the requirements in § 42.405(b)(3) and how the Board would make these determinations without a two-phase process: a first phase to examine issues related to the scope of the derived subject matter (i.e. "count") and a second phase to determine whether it was derived from the petitioner.

D. The rules should implement procedures for correcting the name of the inventor in derivation proceedings

The AIA statute creating derivation procedure, 35 U.S.C. § 135(b) provides: "In appropriate circumstances, the Patent Trial and Appeal Board may correct the naming of the inventor in any application or patent at issue." Presumably, this correction would be based on the Board's determination of derivation. However, the proposed derivation regulations fail to implement the statute or provide any guidance, as they must, on the "appropriate circumstances" or the process by which the Board will "correct the naming of the inventor in any application or patent at issue."

The NPRM is silent on how non-patentably distinct claims to joint inventions or the remaining patentably distinct claims in the *same* applications will be treated in derivations. It will often be necessary to determine the status of other claims that are not patentably distinct from the derived claims, reciting additional subject matter that was not conceived or communicated to the deriving party by the original inventor. Because the proposed rules indicate that derivations will be conducted in a single phase without a "count," there appears to be no mechanism for the Board to properly exercise its authority to "correct the naming of the inventor." To the extent that derivations involve a number of claims of differing scope, some definition of the claims that define the same or substantially the same invention will be essential to define the scope of the petitioner's proofs of conception and communication. IEEE-USA notes that these rules should be sufficiently unambiguous in order that the Board's decisions thereunder in naming the correct inventors be free from constitutional 'taking' challenges.

E. Implementing regulations for showing derivation over a non-patent disclosure that appears to be, but is not actually, prior art

In framing discovery and rebuttal procedure, IEEE-USA suggests that the USPTO consider the following hypothetical situation to make sure that the procedural regulations are adequate to implement the intent of the substantive statute:

[22] *Slip Track Sys.*, 304 F.3d at 1265 ("[T]he description of interfering subject matter must be broad enough to encompass the common subject matter of the claims in both patents").

1. True inventor **A** invents, and then discloses to **B**.
2. **B** publishes a description of **A**'s invention, but does not file a patent application. For example, **B** may be a magazine reporter. **B**'s publication may be either as complete as **A**'s disclosure to **B**, or may be a somewhat abridged description of what **A** disclosed to **B**.
3. **C** reads **B**'s disclosure, and files a patent application. **C**'s application may be a fleshed-out version of **B**'s abridged disclosure—**C**'s application may disclose the same subject matter as **A** disclosed to **B**, or may disclose a slightly different way to achieve **A**'s invention as disclosed to the public by **B**.
4. **A** then files a patent application, after **C**'s filing date, but less than one year after **A**'s disclosure to **B**.

A should have sufficient procedural avenues to compel discovery from nonparty **B** *and* party **C** to establish the flow of information from **A** to **B** to **C**, thereby to show derivation.[23]

III. ISSUES UNDER THE ADMINISTRATIVE PROCEDURE ACT AND OTHER RULE MAKING PROCEDURAL LAW

When the USPTO 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.

These regulations are specifically directed at high value patent disputes that are already—or are soon to be—in litigation. Litigants are motivated to pursue every avenue. If the USPTO does not dot its i's and cross its t's in its final regulations, many of the USPTO's judgments—which are already in court—are likely to be attacked based on impropriety of the USPTO's rule making processes.

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[23] During the debate leading up to passage of the AIA, IEEE-USA repeatedly raised the following fact pattern, and asked for assurances that the law would provide a procedural implementation for the substantive right set forth in the statute in cases of *non-patent* disclosures by a deriver. For example, consider the sequence:

1. **A** is the first true inventor. Inventor A discloses to deriver **B**.
2. **B** then discloses but without attribution back to true inventor **A**. Perhaps **B**'s disclosure is exactly the same material that **A** disclosed to **B**; perhaps deriver **B**'s disclosure is slightly modified from inventor **A**'s disclosure to him. However, deriver **B** *does not file an application*.
3. True inventor **A** files a patent application after deriver **B**'s disclosure of step 2
4. Deriver **B**'s disclosure of step 2 is cited as prior art against inventor **A**'s application from step 3

Under the AIA, § 102(b)(1), true inventor **A** has a substantive right to show that **B**'s apparent prior art of step 2 is an excluded derivation. True inventor **A** will require the procedural ability to take discovery of deriver **B** to prove that derivation.

This situation is not covered in any of the February 9-10 NPRMs. IEEE-USA recognizes that this issue is near the boundary of the issues that one would expect to see addressed in these NPRMs, and that the omission is not yet critical. Nonetheless, IEEE-USA received assurances that the USPTO would provide implementing regulations for this fact pattern, and we look forward to seeing them before the AIA takes effect.

A. Almost all of the provisions of these regulations are "legislative" (as opposed to "interpretative") and "procedural" (as opposed to "substantive")

The Umbrella rule NPRM at page 6892 reads as follows:

> Rulemaking Considerations
>
> A. *Administrative Procedure Act (APA)*: This notice proposes rules of practice concerning the procedure for requesting an inter partes review, post-grant review, covered business method patent review, or a derivation, and the trial process after initiation of such a review. The notice also proposes changes to the rule of practice to consolidate the procedure for appeal of a decision by the Board and to require that a copy of the notice of appeal, notice of election, and complaint be provided to the Board. 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. …
>
> Accordingly, prior notice and opportunity for public comment are not required pursuant to 5 U.S.C. 553(b) or (c) (or any other law), and thirty-day advance publication is not required pursuant to 5 U.S.C. 553(d) (or any other law). *See Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336-37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), does not require notice and comment rule making for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice") (*quoting* 5 U.S.C. 553(b)(A)). …

The USPTO continues to have difficulty classifying its regulations properly. That, in turn, leads the USPTO to omit required steps in the rule making process.

A good part of this difficulty likely arises because the statute itself is less than clear. First, "interpretative" rules are mentioned in the Administrative Procedure Act, but never defined. Second, the opposite of an "interpretative" rule is not given a name in the statute. Various cases and treatises call noninterpretative rules either "legislative" or "substantive." We will use "legislative" as the opposite of "interpretative," because interpretative rules in most agencies can be either procedural or substantive in character.

Many concepts of administrative rule making turn on appropriate classification, "substantive" vs. "procedural" and "legislative" vs. "interpretative." That is, there are four categories, "substantive legislative," "substantive interpretative," "procedural legislative," and "procedural interpretative."

1. Very little (if any) of the regulatory text in the NPRM is "interpretative," essentially all is "legislative"

The characterization as "interpretative" is clearly in error: interpretative rules are not enforceable against the public, and are not binding on courts. The USPTO erred in characterizing the rules as "interpretive" in another respect: many courts (including the Supreme Court) have noted that when an agency characterizes its rules as "interpretative," the resultant rule is only "hortatory" and "lacking force of law."[24] The President has likewise instructed agencies that they

[24] *Chrysler Corp. v. Brown*, 441 U.S. 281, 315 (1979) (after agency characterizes a rule as "interpretative," Court holds "[A] court is not required to give effect to an interpretative regulation."); *National Latino Media Coalition v. F.C.C.*, 816 F.2d 785, 788–89 (D.C. Cir. 1987) ("A valid legislative rule is binding upon all persons, and on the courts, to the same extent as a congressional statute. … [A]n interpretative rule does not have the force of law and is not binding on anyone, including the courts…."); *Drake v. Honeywell, Inc.*, 797 F.2d 603,607 (8th Cir. 1986) ("Being in nature hortatory, rather than mandatory, interpretive rules can never be violated."); *Cubanski v. Heckler*, 781 F.2d 1421, 1426 (9th Cir.

cannot give determinative effect to their interpretative rules so as to "foreclose agency consideration of positions advanced by affected private parties."[25]

There are a few notes in the various NPRM *preambles* that could fairly be characterized as interpretative, but we do not observe any "interpretative" provision in the regulatory text itself. Further, a regulation promulgated pursuant to a delegation of regulatory authority from Congress, using notice and comment procedure, will generally be classified as "legislative" rather than "interpretative,"[26] and that general rule covers all of the regulatory text here.[27]

IEEE-USA believes that the characterization as "interpretive" is error. (We also note that § 553 of the Administrative Procedure Act uses the term "interpretative," not "interpretive.") The "interpretative" exclusion does not apply to these regulations, at least not in any significant degree.

2. The USPTO's statement of its obligations for promulgation of procedural rules is incorrect

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

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 USPTO must engage in notice and comment rule making when promulgating rules it is otherwise empowered to make—namely, procedural rules."[28] The USPTO appealed this specific issue to the Federal Circuit. Several months after *Cooper*, the USPTO moved to dismiss the *Tafas* appeal on grounds of mootness. By asserting *mootness*, the USPTO 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."[29] When a federal agency asserts mootness, it is

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1986) ("an interpretive rule is one issued without delegated legislative power. … Such rules are essentially hortatory and instructional in that they go more 'to what the administrative officer thinks the statute or regulation means.'").

[25] Executive Office of the President, Office of Management and Budget, *Final Bulletin for Agency Good Guidance Practices*, OMB Memorandum M-07-07, http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf § II(2)(h) (Jan. 18, 2007), 72 Fed. Reg. 3432 (Jan. 25, 2007).

[26] *Nigro v. Sullivan*, 40 F.3d 990, 996 (9th Cir 1994) ("These statutes delegate authority to the executive to establish substantive rules governing prisons. [These] regulations are therefore not interpretive. Rather, they are legislative."); *see also Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 843–44 (1984) (where the Congress "has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation … Such legislative regulations …").

[27] Exceptions include regulations in these NPRMs that are *ultra vires* the delegation from Congress, for example, the provision we discuss at section I.I of this letter.

[28] *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).

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

"only because" the agency ceases all "offending conduct" by accepting the position of the opposing party.[30] In *Tafas*, the Federal Circuit accepted the USPTO's acquiescence to mootness.[31] Further, the Federal Circuit denied the USPTO's request to vacate the District Court's decision.[31] Thus, by the USPTO's own actions, the USPTO bound itself to use notice and comment for procedural rule making.

These rulemaking issues have been brought to the attention of the USPTO (and specifically the Board) in the past.[32] This is at least the third position that the USPTO has taken in its NPRMs since *Tafas* to try to avoid the obligations to which it stipulated.[33] Each time; the USPTO simply ignores the issue without replying in its final Rule Notices—thereby violating the Administrative Procedure Act[34]—and then goes a bit farther out on a limb in the next NPRM.[35]

IEEE-USA incorporates by reference the comments noted at footnote 32, and requests the USPTO to address them fairly in its response to comments. If the PTO believes that *Tafas* does not apply, then it should clearly say so and provide a reasoned legal defense for the position. If the USPTO cannot state a legal theory to distinguish *Tafas*, IEEE-USA requests that the USPTO follow it rather than continue to ignore it.

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

The USPTO's task, and the public's task of commenting on the USPTO's proposal, has been made more difficult because the USPTO 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

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

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

[32] http://www.uspto.gov/ip/boards/bpai/procedures/rules/rule_comment_nov2010_boundy2.pdf at pages 42-43.

[33] 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.

[34] *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).

[35] 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.

comment and challenge the agency's basis.[36] 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:[37]

> 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.[38] Release of

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[36] USPTO's Information Quality Guidelines, http://www.uspto.gov/web/offices/ac/ido/infoqualityguide.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.").

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

[38] *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,

summary information is insufficient to meet an agency's duty to disclose its models, data, and assumptions.[39]

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 estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used."[40]

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.[41]

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*

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").

[39] *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).

[40] 5 C.F.R. § 1320.8(d)(1).

[41] 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)]").

Products v. Shalala,[42] 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."[43] The Third Circuit also held that a challenger need not show prejudice from an omission.[44] 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.[45]

The Third Circuit explained the need for a well-maintained, integral record, timely made available to the public.[46] 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.

2. The NPRMs neglect to disclose significant material information

There are a number of points where the USPTO reports figures of one sort or another, but no underlying data or a transparent showing of how these figures were derived. In some cases, the USPTO's estimates appear to be too low, because of analytical oversights:

- At page 6897, the USPTO estimates that "for a petition for *inter partes* review with 20 or fewer challenged claims, it is anticipated that 98.7 hours of judge time would be required." The USPTO's estimate appears to have been calculated to a precision of one part in 1000—yet none of the underlying data or estimation methodology are disclosed.
- The NPRM does not disclose whether or how the Office accounted for sample bias that will sharply skew the USPTO's conclusions. Since *inter partes* rexamination was created in 1999, only ¼ of the total *inter partes* proceedings instituted have been completed.[47] Indeed, it took the USPTO *eight years* to complete the *very first* full proceeding. By using only *completed* reexaminations, the USPTO selects only the simplest and least complex disputes and systematically excludes complex disputes from its sample. This introduces a large sample bias. The Information Quality Act requires estimates to be corrected for this bias.

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

[43] *Hanover Potato*, 989 F.2d at 129–30.

[44] *Hanover Potato*, 989 F.2d at 128–29.

[45] *Hanover Potato*, 989 F.2d at 130–31.

[46] *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).

[47] Between inception in 1999 and the end of FY 2011, there have been only 1187 *inter partes* reexamination requests granted. Of those, only 305 have been concluded since 1999. See http://www.uspto.gov/patents/IP_quarterly_report_September_2011.pdf

- At page 6898, the USPTO estimates that a request to treat a settlement as business confidential can be prepared in two hours. This estimate ignores the burdens on the parties for *generating* the *inter partes* or post grant review settlement agreements or arbitration decisions, which would not have been borne, but for the proceedings under these rules. Thus, in cases where no concurrent court litigation is involved, the full amount of attorney time, client time, and so forth for settlement discussions or for arbitration are fully cognizable under the Paperwork Reduction Act as "burden."[48] The actual burden is therefore 30-100 times greater than the 2 hours the USPTO estimated.
- How will the Board manage the transition period, during which a ten-year tail of appeals from old *inter partes* reexamination proceedings will be pending and flowing in to the Board, at the same time as an influx of new post-grant reviews and *inter partes* reviews arrives simultaneously?

There are two errors noted in the list above: substantive errors in reporting numbers that are clearly too low, and procedural errors in failing to observe the laws we note in section III.B.1. Those laws required inquiry, reliance on objective sources, and other Information Quality procedures designed to prevent such factor-of-ten errors.

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:

- Much of the data underlying the table on page 6906 is undisclosed. For example, how was the estimated number of petitions derived?
- At page 6897, the USPTO estimates "For a petition for *inter partes* review with 20 or fewer challenged claims, it is anticipated that 98.7 hours of judge time would be required." The NPRM contains *absolutely no* disclosure of any basis for this "anticipation." The accuracy of this estimate is *crucial* to the success of the program—if the estimate is low by only 10%, the USPTO will be unable to meet its obligations of timely decision.[49] This is prototypical of issues that should be analyzed in a Regulatory Impact Analysis (see section III.C at page 25).
- Any spreadsheets or other models that the USPTO 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 USPTO's Information Quality Guidelines (see section IV at page 31 of this letter) and the laws noted in section III.B.1 at page 20 require disclosure of the USPTO's estimation models.
- The distribution of the number of claims in patents to be submitted for post grant and *inter partes* review is undisclosed. 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

[48] 5 C.F.R. § 1320.3(b)(1), implementing 44 U.S.C. § 3502(2). ("*Burden* means the total time, effort, or financial resources expended by persons to *generate*, maintain, retain, or disclose or provide information to or for a Federal agency…").

[49] The USPTO's mounting examination backlog in the late 1990s' and early 2000's arose out of a mismatch of only about 5% between the USPTO's examination capacity and actual filing rates.

patents in turn tend to have more claims. Since no claim information is disclosed, the analysis cannot be independently reproducible.

Proposed § 42.65(b) notes good ground rules for disclosure—IEEE-USA suggests that the USPTO consider them as useful standards for its own disclosure.

C. The USPTO is statutorily obligated to base its rulemaking on analysis that the USPTO appears not have performed

A number of laws in addition to 35 U.S.C. §§ 316(b) and 326(b) require the USPTO to consider broader effects on the economy, to consider issues like:

- Time of inventors and company management, not only attorney time (cognizable as "burden" under the Paperwork Reduction Act, "economic impact" under the Regulatory Flexibility Act, and as "economic effect" under E.O. 12,866)
- Disruption of businesses (direct disruption to collect information is cognizable as Paperwork "burden," and all disruption is cognizable as "economic impact" and "economic effect")
- Any settlement or arbitration discussion and contract costs, when there is no concurrent district court litigation (cognizable as "burden," "economic impact," and "economic effect")
- Effect on investment (particularly angel and venture capital) when patent rights are less secure than they have been (cognizable as "economic impact" and "economic effect")
- Effect on new business formation (cognizable as "economic impact" and "economic effect")
- Effect on employment (cognizable as "economic impact" and "economic effect")

We will refer to this list of economic effects in our discussions of Executive Order 12,866 (section III.D) and the Paperwork Reduction Act (section III.E), administrative law requirements that obligated the USPTO to provide disclosure of a level of economic analysis that is absent from the NPRMs. Further, the America Invents Act itself requires the USPTO to consider "the effect of any such regulation on the economy" and "the integrity of the patent system." 35 U.S.C. §§ 316(b) and 326(b). The USPTO does not show its work in the NPRM, making any final rule vulnerable to challenge.

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

The USPTO represents that each of these rulemakings is "significant" under Executive Order 12,866. This is the lower threshold for review by the Office of Management and Budget (OMB). All "significant" proposed regulations are required to include an "assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions." None of the proposed rules contain this information.

In fact, each of these rules satisfies the criteria for an "economically significant" regulation set forth in § 3(f)(1) of the Executive Order:

> [h]ave 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, or State, local, or tribal governments or communities…

The "Umbrella Rules" easily exceed this threshold. The USPTO acknowledges $209 million in paperwork burdens ***alone*** for FY 2013.[50] It offers no estimates at all for these rules' costs, benefits, and other effects on the economy. Nor does the USPTO provide estimates of the costs, benefits, and other effects the regulations in the other four NPRMs may be expected to have.

A rule is economically significant, and requires an RIA, if it "may" have effects this large. For the February 9-10 rules, effects of this magnitude are *certain*.

This omission is all the more peculiar given that non-paperwork annual economic effects in excess of $100 million are commonplace in USPTO regulatory actions that change patent rights. Just a week ago, 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 USPTO jointly concluded that "Patent-intensive … industries accounted for 5.3 … percent of GDP, with $763 billion … in value added" in 2010."[51]

For the February 9-10 proposed rules to be economically significant, they need only perturb the patent-intensive portion of the economy by 0.013%.

Likewise, a regulation is "economically significant" under § 3(f)(4) if it "raise[s] novel legal or policy issues arising out of legal mandates." These regulations raise a host of "novel legal issues," as we discussed in sections I.A, I.C, I.D, I.H, and I.I above.

Because of these economically significant characteristics, Executive Order 12,866 § 6(a)(C)(ii)-(iii) obligated the USPTO 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.

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[50] The USPTO attempts to circumvent the $100 million threshold by deducting from the $209 million in direct burden paperwork burdens that the USPTO believes would vanish because of other provisions of the AIA. Even if the USPTO's figures were reliable, nothing in Executive Order 12866 permits the USPTO to claim a "credit" for reduced paperwork burdens resulting from congressional action.

[51] 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, 43.

In the proposed Umbrella Rule NPRM, the numbers were apparently forced below $100 million by (a) counting only attorney fee burdens, and ignoring all other paperwork burden and all other economic effects,[52] and then (b) deducting from an estimated $209 million in first-year paperwork burden $129 million in purported reduced paperwork burden that were not part of the proposed rule. Neither of these *sui generis* deductions from the true numbers are permitted by the Executive Order or any other law.

Whether intended or not, the introduction of exclusions (a) and (b) above, and forcing the numbers below $100 million enabled the USPTO to avoid the obligation of careful analysis and planning, and to avoid disclosing that analysis for public comment. The USPTO should not engage in numerical gymnastics to avoid these obligations. An accurate analysis is essential to the USPTO's implementation plans, if the USPTO is to keep to its commitments for timely disposition of these cases. An analysis and disclosure is also essential to ensure that the UPTO is exercising its public policy power responsibly.

These are unquestionably "economically significant" regulations. The USPTO 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, permit the public to comment, to ensure adequate planning and staffing, and to avoid unintended consequences.

E. Paperwork Reduction Act issues

1. The estimates of burden in these NPRMs are not "objectively supported" and appear to be biased too low

The Paperwork Reduction Act does not only require agencies to reduce paperwork burdens but it also requires them to provide "specific, objectively supported estimate of burden."[53] The PTO's history of estimating costs and burdens is not a strong one:

- In the USPTO's "white paper" of April 2010 advocating for passage of the patent reform legislation, "Patent Reform: Unleashing Innovation, Promoting Economic Growth & Producing High-Paying Jobs,[54] Dr. Graham, the USPTO's Chief Economist, estimated that costs (apparently direct paperwork burden alone) of a post-grant review (PGR) process would "not exceed $100,000." Now that the USPTO is no longer advocating for passage of the bill, the USPTO now puts the *agency fee alone* at $50,000, and concedes that no less than 60,000 attorney hours costing tens of millions of dollars in paperwork burden alone will be required for 50 PGR reviews.[55]
- In its 2006-08 attempted rulemakings, informed members of the patent bar provided well-informed, fully-supported, and peer-reviewed estimates that showed that the USPTO's estimates were too low by several orders of magnitude.[56]

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[52] We list many of those economic effects in section III.C at page 23.

[53] 44 U.S.C. § 3506(c)(1)(A)(iv).

[54] See http://www.commerce.gov/sites/default/files/documents/migrated/Patent_Reform-paper.pdf, p. 7, note 18, ("$100,000 is a conservative (meaning high) estimate of the maximum cost for an enhanced post-grant review proceeding").

[55] 77 Fed. Reg. at 7078.

[56] *E.g.*, http://www.reginfo.gov/public/do/DownloadDocument?documentID=57744&version=1 (based on peer-reviewed estimates, estimating the aggregate costs of five rule packages at $20-$30 billion

The USPTO's burden estimates for these rules are not objectively supported. Indeed, they are nontransparent and beyond the capacity of qualified third parties to reproduce:

- The estimates for number of proceedings are unsupported, and obviously too low:
  - *Inter partes* reexaminations are only available for cases that arise under 35 U.S.C. §§ 102 and 103 and only on the basis of patents or printed publications, and AIA post grant reviews permit *any* challenge arising under §§ 102 and 103 (adding "public use" and "on sale"), § 101, and § 112. Therefore, *inter partes* reviews are a very poor—and downward biased—proxy for the number of new post grant reviews. While the NPRM acknowledged these differences,[57] it fails to disclose its numerical assumptions, and fails to analyze the effects of the fundamental difference between old *inter partes* reexamination proceedings and new AIA post grant review. The empirical ratio between these categories can be derived from a recent analysis by the University of Houston of patent court cases decided in the years 2005-2009.[58] It shows that for every 15 decisions involving §§ 102 and 103 printed prior art grounds, there were 13 decisions on grounds involving "public use," "on sale" or § 112. Moreover, many petitions for the transitional covered business method review are likely to raise a § 101 ground. Thus, a doubling of the estimate for post grant reviews would be an objective estimate.
  - At page 6893, the USPTO predicts the number of petitions for review having grown by *40% per year* over the last five years. The USPTO gives no estimate of future growth—by silence, the USPTO apparently estimates that this 40% growth will suddenly become a flat line at 2011 levels.
  - The USPTO provides no estimate for the number of post-grant reviews that will be filed during the second and third year of the Paperwork coverage window. The USPTO states that "the estimated number of post-grant review petitions … is based on the number of *inter partes* reexamination requests filed in fiscal year 2011 for patents having an original classification in class 705," with no year-on-year growth. In past rule makings, commenters have noted the USPTO's failure to estimate year-on-year growth over the three-year period of a typical Paperwork clearance.
  - The USPTO's estimation methods are internally inconsistent. At page 6894, col. 3, the USPTO states that "20 small entity-owned applications or patents would be affected by derivation proceedings." At page 6895, col. 2, the USPTO states "The Office predicts that it will institute 10 derivation proceedings … in fiscal year 2013," that is, 20 patents *total* in two-way derivation proceedings for small and large entities. How can the USPTO's estimates of 20 small entity patents and 20 total patents be consistent with each other?
- The attorney hourly rate is too low:

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per year—the USPTO's estimates had totaled under $150 million); http://www.reginfo.gov/public/do/DownloadDocument?documentID=57760&version=1 (estimating private sector effect at $7 billion per year, when USPTO had estimated the burden at "not significant"—that is, near zero)

[57] 77 Fed. Reg. 6893, col 1.

[58] The University of Houston Law Center, http://www.patstats.org/2005-2009_composite.htm

- The USPTO states that it uses the *median* attorney rate of $340 as its rate for estimating burden of these proceedings. Multiple parties in past rule makings have noted that use of the *median* is analytically wrong; the correct unbiased number is the *mean*, which is higher.[59] This error has been pointed out in multiple USPTO's rule makings, yet remains uncorrected.
- Furthermore, the $340 *median* rate is too low for the attorneys that will be involved in these reviews—these proceedings will be conducted by more-senior attorneys with higher billing rates, possibly around $ 500/hr on average. The error of using any rate averaged over all attorneys when estimating burden for more-advanced proceedings has likewise been brought to the USPTO's attention on multiple occasions,[60] and yet it goes uncorrected.

- The USPTO's estimates systematically understate burden because of methodological flaws and omissions:
  - The USPTO states that it bases its estimates only on *attorney* billable fees. However, the USPTO's estimates ignore the burdens and costs within the attorney's *client* company. The costs to businesses of producing documents, the costs of building a document production infrastructure, and the economic effects we listed in section III.C at page 25 are likewise ignored. This is an error in both the USPTO's E.O. 12,866 and Paperwork analyses.
  - In assessing the effects of these rules on small entities, the Office estimates only the number of entities whose *patents* are challenged in the various proceedings. But small entities may also be on the other side of the dispute, having to challenge patents of others and having to contend with the enormous petition fees and other proceeding costs. Similarly, the USPTO inappropriately ignored effects on small entities that may

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[59] The *mean* cost must be used because the Paperwork Reduction Act requires "estimate of the *total* annual reporting and recordkeeping burden" 5 C.F.R. § 1320.5(a)(1)(iv)(B)(5) (emphasis added). Only the *mean* cost, not the median, multiplied by the total number of responses produces the *total* burden. An Information Quality Act request for correction ("RFC") of this recurring USPTO error was filed with detailed explanations and examples. Unfortunately, in its reply, the USPTO refused to correct the error, failed to acknowledge its obligations under 5 C.F.R. § 1320.5(a)(1)(iv)(B)(5), and did not provide a reasoned, statistically valid defense for using medians. Filing by Ron D. Katznelson, RFC (Nov. 23, 2010), USPTO rejection of the RFC (Jan. 21, 2011), appeal of USPTO rejection (Mar. 22, 2011), and USPTO's reply (May 19, 2011). The USPTO summarily denied the RFC appeal without any explanations. See the top 4 USPTO items at http://ocio.os.doc.gov/ITPolicyandPrograms/Information_Quality/PROD01_009472.

[60] David Boundy, comment in response to Notice of Proposed Rulemaking, Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals (RIN 0651-AC37), 75 Fed. Reg. 69828 (Nov. 15, 2010), http://www.uspto.gov/ip/boards/bpai/procedures/rules/rule_comment_nov2010_boundy.pdf (Jan. 14, 2011) at page 41 ("The PTO also ignores what it surely knows: appeals are typically prepared by more senior attorneys, who bill at rates higher than the average for all patent attorneys."); Stephen J. Moore, comments on Ex parte Appeal ICR 0651-0063 (Aug. 10, 2008), http://www.uspto.gov/web/offices/dcom/bpai/bpai_comments/moore_lelley_drye_and_warren.pdf (when PTO used $310 as median rate, experienced senior attorney comments "A more senior associate would be the one who would most likely be assigned the task of preparing an appeal brief. Given current rate structures, this would be an associate with an hourly rate of about $360/hr. Further more, all associate attorney work is reviewed … by the partner in charge whose billable hour rate may be 1.5 times that of the associate who prepared the original brief. Therefore, I believe a rate of at least $380/hr is more in order.").

not be direct parties to these proceedings but would be directly impacted by them. For example, small entity licensees of the patents under review may lose much of their competitive protection in the market as these patents would be rendered practically unenforceable during the pendency of the proceeding. This is "economic impact" that must be considered under E.O. 12,866.

- The USPTO's estimates neglect to consider how prosecution of initial applications will change because of the existence of these regulations. Hal Wegner's "The 2011 Patent Law, Law and Practice," circulated in updated versions from time to time by email, recommends several prophylactic steps that should be taken during initial prosecution to reduce the likelihood that a patent will be challenged under the AIA post-grant review proceedings, and to reduce the damage of such a proceeding. Prof. Wegner's recommendations add burden, burden that is not accounted for in the NPRM.

- The USPTO's estimates violate requirements of the Information Quality Act, and are therefore not "objectively supported" or reliable:
  - To obtain its burden estimates the USPTO relies on the AIPLA Economic Survey. Previous commenters have shown the Economic Survey to be statistically substandard and unreliable for estimating paperwork burden.[61]

2. Excessive burdens

The Paperwork Reduction Act requires that regulations must be written to "minimize the burden of the collection of information on those who are to respond."[62] Executive Order12,866 § 1(b)(11) echoes this directive: "Each agency shall tailor its regulations to impose the least burden on society … consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations."

Likewise, the Paperwork Reduction Act[63] requires the USPTO to only require parties to submit papers with "practical utility," a term defined in 44 U.S.C. § 3501 to "mean[ ] the ability of an agency to use information, particularly the capability to process such information in a timely and useful fashion."

The following provisions can be retailored to reduce burden or may be omitted because the requested information has no "practical utility:"

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[61] *See, e.g.*, the public comment by Richard B. Belzer on the USPTO's estimates of paperwork burden on the 2011 proposed Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals. Richard B. Belzer, "Public Comment on Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals; Notice of Proposed Rulemaking (RIN 0651–AC37; Docket ID PTO–P–2009–002, ICR Reference Number 201010-0651-001, 75 Fed. Reg. 69,828); and Error Correction Request submitted pursuant to USPTO's Information Quality Guidelines" (Jan. 14, 2011), http://www.uspto.gov/ip/boards/bpai/procedures/rules/rule_comment_nov2010_belzer.pdf. Dr. Belzer specifically addressed the unreliability of the AIPLA data for governmental use and formally submitted an error correction request under the USPTO's Information Quality Guidelines. Fifteen months later, the USPTO has not responded.

[62] 44 U.S.C. § 3506(c)(2)(A)(iv), § 3506(c)(3)(C); *Dole v. United Steelworkers of America*, 494 U.S. 26, 33 (1990) ("Agencies are also required to minimize the burden on the public to the extent practicable.")

[63] § 3506(c)(2)(A)(i).

- As explained in Section I.J at page 13, the requirement for submission of claim constructions in *derivation* petitions (proposed § 42.405(b)(3)(ii)) is unnecessary and inappropriate. These burdens are substantial as submission of claim construction by one party would often require a rebuttal by the other party setting forth an alternative construction, when the identity of language of a count establishes all that is required to provoke a derivation proceeding.

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

In several recent rule making proceedings—including the Board's own rulemakings—members of the public have noted the USPTO's troubling habit of mischaracterizing public comments, and then responding only to the mischaracterized comment, leaving the actual comment unaddressed.

IEEE-USA observes that this will be self-defeating in the long run. When the USPTO shortcuts its obligations under the procedural law, the resultant regulations may be unenforceable.[64]

IEEE-USA urges the USPTO to be accurate and fair in its characterization of public comments, and provide thoughtful, reasoned responses.

IV. REQUEST FOR CORRECTION UNDER USPTO INFORMATION QUALITY GUIDELINES

In its Information Quality Guidelines,[65] the USPTO promises as follows:

> "A proper request received concerning information disseminated as part of and during the pendency of the comment period on a proposed rule …, including a request concerning the information forming the record of decision for such proposed rule, plan or action will be treated as a comment filed on that proposed rulemaking, plan, or action, and *be addressed in the issuance of any final rule* …." (emphasis added).

A number of our comments above implicate USPTO noncompliance with its own Information Quality Guidelines. IEEE-USA requests correction in the USPTO's submissions to OMB under the Paperwork Reduction Act, and in the final rule publication.

Please email an Information Quality ticket number to e.wissolik@ieee.org.

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[64] See cases cited in footnote 34.

[65] United States Patent and Trademark Office, Information Quality Guidelines, http://www.uspto.gov/products/catalog/infoqualityguide.jsp

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

Respectfully submitted,

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