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July 2, 2010

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Re: 0651-0032 Comment: Initial Patent Applications, 75 Fed. Reg. 23227 (May 3, 2010)

I am hereby submitting comments on USPTO's May 3, 2010 60-day notice concerning ICR 0651-0032 ("Initial Patent Applications"). My comments begin with an overarching concern about the Patent Office's demonstrated mismanagement of its responsibilities under the Paperwork Reduction Act (PRA). Perhaps more than anything else, radical management reform of USPTO's information resources management office is clearly needed. Subsequent sections deal with specific aspects of the 60-day notice.

I. USPTO MISMANAGEMENT OF ITS PRA RESPONSIBILITIES

The 60-day public comment period mandated by 5 C.F.R. § 1320.12 began on May 3, 2010 and expires today, July 2, 2010. However, the normal three-year approval for ICR 0651-0032 expired on June 30, 2010. Agency resource management offices normally schedule their PRA reviews so that lapses in OMB approval do not occur. USPTO's office, however, has displayed a persistent inability to meet regular deadlines.

To avoid a lapse in approval, USPTO petitioned OMB for an "emergency extension" on May 6, 2010, which OMB issued on May 27, 2010, extending the current approval until September 30, 2010.[1] Of course, agency mismanagement is

[1] OMB Notice of Action on ICR 200702-0651-008, online at http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200702-0651-008.

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not a bona fide emergency of the kind anticipated by the law.[2] Rather, it reflects incompetent information resources management by USPTO. There is no reason why the Patent Office could not have initiated the review process with sufficient time for the statutorily mandated 60-day public comment period, adequate time for USPTO to review comments received and make changes justified by these comments, submit the ICR to OMB with the required Supporting Statement for 30 additional days of public comment, and provide OMB sufficient time to review the package well before USPTO's previous clearance expired on June 30, 2010. The reliance on statutory procedures for emergency processing to cover up agency mismanagement is an abuse of the law.

Occasional failures to initiate the ICR review process in a timely manner may be understandable, especially at an agency with a complex set of information collections. That is not the case here, however. Rather, USPTO's information resources management failures are routine. This ICR was last submitted to OMB on February 28, 2007 and approved by OMB on June 5, 2007 (200702-0651-008). However, the previous approval would have lapsed without an "emergency extension", which OMB gave on July 12, 2006. OMB insisted on a short approval period—until January 31, 2007—in order to motivate the Patent Office to fix its glaring information resources management defects. OMB's approval includes the following terms of clearance:

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[2] 5 C.F.R. § 1320.13(a)(2) provides for emergency processing under narrowly defined conditions, none of which apply in this case:

> The agency cannot reasonably comply with the normal clearance procedures under this part because:
>
> (i) Public harm is reasonably likely to result if normal clearance procedures are followed:
>
> (ii) An unanticipated event has occurred; or
>
> (iii) The use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information or is reasonably likely to cause a statutory or court ordered deadline to be missed.

> The agency is reminded that it should have in place an internal planning process so that completion of the public notification and comment period required by 5 CFR 1320 occurs prior to an information collection's expiration date. Agencies should submit non-emergency extension requests sufficiently prior to expiration dates to allow for a 60-day period of OMB review.

USPTO met this deadline, but now has reverted to its longstanding practice of incompetent information resources management. Since 2002, USPTO has sought and obtained five "emergency" extensions for ICR 0651-0032 alone— half of the total number of actions taken by OMB.

It is understandable why OMB would grant an emergency extension request solely to ensure that a lapse in approval does not occur. The record shows, however, that these concessions have not led to improved conduct at USPTO. Behavioral economic theory predicts that by granting "emergency" extensions in non-emergency circumstances, OMB would reward agencies that fail to comply with the law and incentivize agencies to fail more often. USPTO's performance is fully consistent with these predictions.[3]

II. ANALYTICAL AND METHODOLOGICAL FAILURES

A. *"USPTO believes that…"*

A longstanding complaint that I and other public commenters have made with respect to previous 60-day notices and Supporting Statements is USPTO's predilection for relying on conjecture concerning paperwork burden estimates. These claims are characteristically preceded by the phrase, "USPTO believes that…"

Neither the Paperwork Reduction Act nor OMB's Information Collection Rule permit agencies to estimate burden based on mere "belief" or conjecture. Indeed, both statute and OMB's Rule are clear. They state that agency burden estimates "shall include … [a] specific, objectively supported estimate of burden" (44 U.S.C. § 3506(c)(1)(a)(iv); 5 C.F.R. § 1320.8(a)(4)). OMB's Rule goes further, stating that "in the case of an existing collection of information, an evaluation of the

[3] Since 2002, USPTO has sought and obtained "emergency" extensions four times for ICR 0651-0031 ("Patent Processing").

burden that has been imposed by such collection" (emphasis added) is required in order for OMB to legally approve a renewal.

Four times in the 60-day notice, USPTO relies on its own "belief" instead of providing an objectively supported basis for a burden estimate or a relevant component thereof:

- "The USPTO believes that, on balance, it takes the same amount of time to gather the necessary information, prepare the new utility, design, or provisional application, and submit it to the USPTO, whether the applicant submits it in paper form or electronically" (p. 23228, col. 3)
- "The USPTO believes that all of the information in this collection will be prepared by an attorney (p. 23228, col. 3)
- "The USPTO believes that these back-up copies [of CD-based submissions] will be prepared by paraprofessionals with an estimated hourly rate of $100,…" (p. 23230, col. 1)
- "As a basis for calculating the drawing costs, the USPTO believes that all applicants will have their drawings prepared by the patent illustration firms" (p. 23230, col. 2)

USPTO is required by law to provide an objectively supported basis for each of these claims.

The first claim, that electronic filing entails the same number of burden-hours, is facially suspect. If the Patent Office has representative data showing that there is no statistically significant difference in burden between paper and electronic application formats, this 60-day notice was the proper place to disclose them. The absence of such data in the 60-day notice, however, implies that the claim is either demonstrably false or that USPTO has no clue about the relative burdens of paper versus electronic filing. Patent attorneys I have consulted—an admittedly nonrandom sample, to be sure—say that the electronic ADS is fussy because its contents must be capable of perfect optical character recognition, and thus it is maddeningly difficult to complete.

USPTO's second "belief", that all information is prepared by attorneys, is incompatible with the legal obligations of inventors. USPTO ignores the time and effort required by inventors to assemble information in a manner amenable to use by

their patent attorneys, and the time it takes inventors to respond to inquiries their attorneys inevitably make to clarify and elaborate this information. Although it surely is convenient for USPTO to assume that all burdens are borne by the attorneys, the assumption is counterfactual.

The 60-day notice includes no analysis whatsoever of "the burden that has been imposed" (emphasis added) on the public by previous editions of ICR 0651-0032. Contrary to law, which requires USPTO to objectively estimate the actual burden that it has imposed on the public based on historical data, the Patent Office merely recycles previous burden "estimates" as if they were objectively based and valid.

B. *"USPTO estimates that…"*

Thirty-seven times in the 60-day notice, USPTO "estimates" the quantitative value of a burden or burden component. In none of these cases does USPTO disclose the objective basis for its "estimate" or show its work.

There are four unnumbered tables in the 60-day notice containing "estimates" of the number of responses, the average (?) time per response, or both. None of these tables is transparent or reproducible.

C. *USPTO's burden estimates are not transparent, not reproducible, and in every respect utterly in violation of the Paperwork Reduction Act and the Information Quality Act*

The largest IC is the submission of an application, and USPTO "estimates" this burden at 33 hours and 12 minutes. Where is the supporting analysis showing how USPTO estimated this crucial figure? We don't know, because the Patent Office has declined to disclose it.

USPTO's burden-hour estimate is the same for utility, plant, and design applications. It is the same whether the application is submitted electronically or on paper. It is the same across technology centers. It is the same regardless of the number of claims. Where is the supporting analysis showing that burden is extraordinarily constant across the many margins—margins on which the Patent Office has in recent years tried to promulgate substantive regulations expressly for

the purpose of changing applicant behavior in ways that would make it easier for the Patent Office? We don't know, because the Patent Office has declined to disclose it.

USPTO reports "estimates" of the expected number of responses with as many as five significant figures. In no case has USPTO provided an objective basis for its "estimate" or provided useful information about known sources of variability and uncertainty.

Despite known volatility in the number of applications, and the existence of a substantial model that USPTO uses to predict application filing rates several years in advance, USPTO assumes a constant number of submissions for each of the three years of the proposed PRA approval. This is not a credible burden estimation practice.

In short, nothing about the USPTO's burden estimates in this 60-day notice satisfies the statutory requirements of the Paperwork Reduction Act. Even though the Patent Office is the source of tens of billions of dollars in annual paperwork burden, it treats the PRA as a nuisance to be endured, it continues to ignore its paperwork reduction responsibilities, and as noted above, it chooses to manage information resources incompetently.

D. *Burden estimation methodology issues*

On February 25, 2010, USPTO sought public comment on a "Methodology for Conducting an Independent Study of the Burden of Patents-Related Paperwork."[4] I submitted comments on this report in my capacity as President of Regulatory Checkbook, a nonpartisan nonprofit organization whose mission is to improve the quality of information and analysis used in support of regulatory decision□making. USPTO has not posted the comments it received, and because there is no justification for keeping them out of public view I am including them as an attachment to this public comment to ensure that they are available to the public.

[4] The announcement of the request for comment is located at report is located at http://www.uspto.gov/patents/announce/pra_study.jsp. The Report itself is located at http://www.uspto.gov/patents/announce/pra_methodology_study.pdf. Public comments on the Report are not on the USPTO website.

Some of my comments on the methodology study apply to this 60-day notice. For example:

1. USPTO has no systematic inventory of all the burdens imposed on the public via regulation and guidance (such as the MPEP). The Patent Office is obligated by law to estimate the burdens of all regulation and guidance, and to maintain a systematic inventory. See 44 U.S.C. § 3506(b)(4). It has become clear that USPTO is not complying with this statutory obligation, and that there is a vast array of burdens that the Patent Office has not yet even acknowledged, let alone obtained a valid OMB Control Number necessary for the information collection to be legal. No paperwork burden methodology is complete unless and until it is assured of including all the information collection requirements actually imposed.
2. For several important burden components, USPTO incorrectly relies exclusively on helpful but methodologically inadequate surveys produced on behalf of the American Intellectual Law Property Association. The AIPLA surveys are incompatible with Federal Statistical Policy Standards because the sample frame is not representative and the response rate (in the most recent edition) is no more than 21%. Thus, even if there were no errors in reporting, the AIPLA survey could not be used for estimating burden.
3. USPTO routinely makes false certifications concerning its compliance with the procedural and substantive requirements of the Paperwork Reduction Act. These false certifications run the gamut from falsely certifying that duplicative burdens have been avoided, falsely certifying that impacts on small entities have been minimized, and falsely certifying that the Patent Office has planned and allocated resources for the efficient and effective management and use of the information to be collected.
4. With the advent of government-wide information quality standards in 2002, USPTO has added to its list of false certifications the claim that it has complied with applicable information quality guidelines. To the contrary, USPTO 60-day notices and Supporting Statements are not transparent, "estimates" provided are not capable of being substantially reproduced by competent third parties, and they are systematically

biased to severely understate the true burdens of Office rules and guidance.

5. The February 2010 burden estimation methodology report notes correctly that burdens are distributed unevenly, but no aspect of this variation is captured in the 60-day notice. As noted above, USPTO "estimates" that the average burden of preparing and submitting a patent application is 33 hours and 12 minutes regardless of the nature of the application and irrespective of whether it is submitted electronically or on paper.
6. A priori principles must be established for managing the input provided by public commenters. I have been involved in several ICR reviews over the past few years, and I have supplied independent quantitative estimates for various burdens and burden components. However, I am unaware of any evidence suggesting that USPTO has actually used these data. The public comment process triggered by 60-day notices such as this one cannot succeed if the public becomes convinced that USPTO will not take comments seriously.
7. USPTO's 60- and 30-day notices are inscrutable. The Patent Office routinely declines to provide any objective support for its estimates, and this 60-day notice is no exception.

E. *An obsession with minutiae*

USPTO has devoted an extraordinary proportion of its total effort to getting penny-level precision for the burden associated with preparing and submitting CDs. The discussion stretches across approximately one full Federal Register page (see pp. 23229 col. 1 through 23230 col. 1) for a burden whose magnitude is about $100 per response for 232 responses per year.[5] Meanwhile, there is no credible explanation at all for the burdens associated with preparing hundreds of thousands of patent applications, which USPTO "estimates" at $3.7 billion per year. This is a material error in focus. Non-burden hour costs must be accounted for, but it is

[5] Leaving aside the question whether USPTO's calculations are accurate, the Office does not show enough of its work for these calculations to be reproducible by a competent third party. This violates the Information Quality Act and USPTO's Information Quality Guidelines.

foolish to waste time and effort trying to obtain penny-level precision for a $100 line item when estimates of burden for larger information collection components may be understated by factors of 10 or more.

III. INFORMATION COLLECTIONS MISSING FROM THE ICR

This ICR should include every paperwork burden element related to the preparation and submission of a patent application.[6] Several information collections appear to be missing from the list in the first unnumbered table in the 60-day notice. For example:

1. Inventor time. As I noted above, the time that inventors spend generating, disclosing, or providing information to attorneys, answering follow-up questions to complete patent applications, and reviewing patent applications before filing, is totally omitted. It is simply untrue to assume, as USPTO does, that patent applicants bear no burdens at all and that all burdens fall on their attorneys. USPTO's assumption is inconsistent with actual practice, and with legal obligations for review and correctness. Inventor time is neither trivial in magnitude nor in value, and it should not be surprising to discover that it amounts to billions of dollars per year.
2. Time of in-house counsel. Likewise, the 60-day notice neglects to consider the time spent by in-house counsel in generating, disclosing, or providing information to outside counsel for preparation of patent applications, and for overseeing their work. Under the USPTO's theory, in-house patent counsel who do not actually prepare applications are free resources.
3. Declarations. A patent application must be accompanied by an oath or declaration of the inventor. The 60-day notice for ICR 0651-0032 does not include any rows capturing these burdens. These declarations are not trivial and they entail significant burdens that heretofore USTPTO appears to have ignored. For example, applicants declare: "I hereby state

[6] Burdens related to the prosecution of a patent application should be included in ICR 0651-0031 ("Patent Processing"). It is essential that each burden associated with application or prosecution be contained in one of these ICRs.

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that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above." To date, USPTO appears to have assumed that it requires patent applicants zero time to conduct this review, which is clearly nonsensical.

4. Assignments. ICR 0651-0027 includes an information collection item for cover sheets related to assignments, and the most recent Supporting Statement includes an "estimate" of 0.5 hour for this burden. However, it appears that nowhere in USPTO's array of ICRs is there an information collection related to the actual assignment.

5. Preliminary amendments. Preliminary amendments often are necessary elements of filing an application with USPTO, for example, for filing of a U.S. application based on a previous foreign filing. The burdens of preparing and filing preliminary amendments are not accounted for in ICR 0651-0032 (where they most logically fit) and do not appear to be accounted for anywhere else. Transmittal letters related to preliminary amendments are included in ICR 0651-0050 (with an "estimated" burden of fractions of an hour), but the burdens of preparing and submitting preliminary amendments do not appear to be accounted for anywhere.

6. Error correction. USPTO has never accounted for the burdens imposed on the public having to seek the correction of USPTO data entry errors. The introduction of the electronic Application Data Sheet (ADS) has dramatically reduced the incidence of data entry errors by USPTO, which appear to have been exceedingly common. Nonetheless, data entry error rates remain well above zero, and USPTO must account for burden in obtaining correction.

IV. ICR 0651-0032 INCLUDES INFORMATION COLLECTIONS THAT ARE NOT PERMITTED UNDER THE PAPERWORK REDUCTION ACT

USPTO often imposes paperwork requirements that have burdens vastly greater than the practical utility of the information obtained. These information collections violate the Paperwork Reduction Act.

One example is the requirement for drawings in 37 C.F.R. § 1.83(a):

> **§ 1.83 Content of drawing.**
>
> (a)The drawing in a nonprovisional application must show every feature of the invention specified in the claims. However, conventional features disclosed in the description and claims, where their detailed illustration is not essential for a proper understanding of the invention, should be illustrated in the drawing in the form of a graphical drawing symbol or a labeled representation (*e.g.*, a labeled rectangular box).

However, all that is required by statute is:

> **35 U.S.C. 113 Drawings.**
>
> The applicant shall furnish a drawing where necessary for the understanding of the subject matter sought to be patented.

Whereas the law is clearly reasonable (drawings must be furnished where necessary for understanding), Rule 83(a) is not (drawings must be furnished for every feature regardless of whether it is necessary for understanding).

The PRA requires agencies to carefully examine their information collection requirements to ensure that they are not superfluous, redundant, or lacking in practical utility. It appears that USPTO's resources management office has never conducted a reasoned inquiry to ensure that these statutory provisions are being met, but nevertheless it always certifies that it has done so.

V. CONCLUSIONS

My review of this 60-day notice leads me to four conclusions:

1. Radical reform of USPTO's information resources management office is essential and long overdue. The Office's inability to perform its work in a timely manner has become an established fact, and its inability or unwillingness to competently perform its PRA responsibilities is by now legendary. Previous efforts at reform, if any have been undertaken, have demonstrably failed.
2. USPTO needs to revise and complete the independent burden estimation methodology project on a much more timely basis than the Office currently envisions. The completion dates proposed in the February 2010 Report were too generous, and even these dates seem certain to have slipped given the number and severity of defects in the Report.

Unless and until this project is completed, and completed in a way that is faithful to the Paperwork Reduction Act, USPTO will face an endless series of highly (and increasingly) critical public comments on 60-day notices and Supporting Statements. USPTO will be obligated to respond to these comments.

3. USPTO needs to expand its burden estimation methodology project to develop a full and accurate inventory of all the ICs contained in its rules and guidance. As first became apparent during the public comment periods associated with ICR 0651-0031, USPTO has no legal authority to compel the submission of a wide array of information that is integral to the patent system. USPTO lacks this authority because it has never obtained valid OMB Control Numbers for the omitted information collections. This 60-day notice confirms that the problem is not limited to patent processing; rather, it begins with patent application.

4. USPTO needs to replace "beliefs" and "estimates" with objective evidentiary bases for its estimated number of respondents and average burden level for each information collection element in the ICR. Moreover, the evidentiary bases must be transparent and capable of being reproduced by competent third parties. This 60-day notice is virtually worthless insofar as it fails to provide the public the information it needs to supply informed review. I strongly urge USPTO to revise the 60-day notice accordingly and republish it for public comment.

If you have any questions regarding these comments, do not hesitate to contact me.

Sincerely,

Attachment: Public Comment on Methodology for Conducting an Independent Study of the Burden of Patent-Related Paperwork (75 Fed. Reg. 8649)

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REGULATORY CHECKBOOK

12 April 2010

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RE: Request for Comments on Methodology for Conducting an Independent Study of the Burden of Patent-Related Paperwork (75 Fed. Reg. 8649)

Dear Mr. Tamayo,

On behalf of Regulatory Checkbook, I am pleased to submit these comments on the PRA burden estimation methodology consulting report submitted to the Patent Office by ICF International.[1] For the record, Regulatory Checkbook is a nonprofit organization whose mission is to improve the quality of information and analysis used in support of regulatory decision-making. It does not take positions on substantive policy matters, such as what the patent laws should look like. I personally have over 20 years' experience in federal regulatory analysis related to the issues presented in the ICF Report, including 10 years as a staff economist in OMB's Office of Information and Regulatory Affairs (OIRA), which is statutorily responsible for administering the Paperwork Reduction Act (PRA).

I am pleased to see the USPTO is interested in developing credible estimates of the paperwork and recordkeeping burdens it imposes on the public. Armed with this information, the Patent Office will be much better able to tailor its regulatory requirements in ways that minimize paperwork burdens and stop its illegal practice of using the imposition of paperwork burden as a management tool for adjusting its workload and reducing patent pendency. The Paperwork Reduction Act and its implementing regulations expressly forbid agencies from imposing duplicative information collection requirements (5 C.F.R. § 1320.5(d)(1)(ii)) and shifting burdens to the public (5 C.F.R. § 1320.5(d)(1)(iii)). For several recent regulatory actions, however, the USPTO clearly stated in the Regulatory Agenda that its

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[1] **ICF International.** "Methodology for Conducting an Independent Study of the Burden of Patents-Related Paperwork; Submitted to United States Patent and Trademark Office, Contract No. GS23F8182H/DOC44PAPT0809009," 2010.

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purpose was to "share" the burden of patent examination with its customers.[2] Meanwhile, the USPTO has never credibly estimated these burdens, which created an obvious need for the ICF project.

In these comments I review the ICF Report as written, then suggest changes and modifications that are essential for the project to be successful.

Introduction

Study Objectives (§ 1.1)

The stated objectives of ICF's proposed methodology are generally sound. They emphasize both correct procedure (e.g., independence from USPTO officials and senior staff; public vetting) and substance (e.g., substantive objectivity). Also, they do not rely exclusively on *ex ante* estimation but include explicit provisions for *ex post* review and calibration of *ex ante* estimates.

I infer that ICF proposes that each of the specific analyses listed in § 1.2 would be subject to public vetting at a stage that is late enough for the public to know what is being proposed but early enough that changes can be made based on public comments. Moreover, each analysis must be fully disclosed and transparent so that competent third parties can substantially reproduce their work. Neither public vetting without transparency nor transparency too late for meaningful public review have any value.

Specific Analyses to be Addressed in the Study (§ 1.2)

Each of the four listed analyses has potential value, though I have several concerns. First, ambiguity in the task descriptions that may prevent ICF from actually achieving the enumerated study objectives. With respect to Analysis 1, for example, it is true that the stated reasons for significant changes in USPTO burden estimates need to be *validated*, but it is not clear that this can be accomplished

[2] See, e.g., **U.S. Patent and Trademark Office.** "Regulatory Agenda #741. Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, And Applications Containing Patentably Indistinct Claims [RIN 0651-AB93]." *Federal Register*, 2005c, *70*(209), pp. 64479, ___**.** "Regulatory Agenda #742. Changes to Practice for the Examination of Claims in Patent Applications [RIN 0651-AB94]." *Federal Register*, 2005b, *70*(209), pp. 64479, ___**.** "Regulatory Agenda #743. Changes to Information Disclosure Statement Requirements and Other Related Matters [RIN 0651-AB95]." *Federal Register*, 2005a, *70*(209), pp. 64479-80.

merely by *evaluating* the stated reasons. An *evaluation* could reveal that the stated reasons are insufficient or impermissible under the Information Collection Rule.[3] The methodology does not make clear what ICF's next steps would be.

Second, the text excludes from review the equally important task of validating the *absence* of significant changes in burden estimates subsequent to any material change in regulation or guidance, whether published or unpublished.[4] The decision to even consider making a regulatory or nonregulatory change must automatically trigger a paperwork review, with specific attention given to the magnitude of paperwork burden implied and the extent to which existing paperwork burdens have caused or contributed to the problem the regulatory or nonregulatory change is intended to remedy. Currently, the USPTO's burden estimation efforts appear to be completely disconnected from the regulatory development process. They are at best an afterthought, do not contribute to the decision-making process, and begin long after decisions are made. By law, agencies must incorporate information collection analyses at the *beginning* of their regulatory planning and development.[5] To be successful, the ICF methodology must be modified to ensure that the USPTO's processes are radically reformed. Even a perfect methodology accomplishes nothing if the Patent Office does not implement it.

Third, two of the four proposed analyses are premature. It is premature to attempt to estimate *aggregate* paperwork burden (Analysis 3) when a credible methodology has not yet been demonstrated for estimating *any* paperwork burden (Analysis 2), and when the proposed approach to estimating burdens for individual paperwork requirements has serious defects because it relies on existing surveys. It is never too early to solicit input from affected parties concerning how paperwork

[3] The USPTO often relies on the "beliefs" or "expectations" of unnamed Office personnel, which by definition are subjective and thus do not comply with 5 C.F.R. § 1320.8(a)(4) ("specific, objectively supported estimate of burden").

[4] Unpublished guidance has become a serious problem within the USPTO, both with respect to their paperwork burdens and the fact they always violate applicable government-wide good guidance practices. For the applicable federal policy on guidance, see **Office of Management and Budget.** "Bulletin on Good Guidance Practices," 2007.

[5] Agencies cannot comply with the planning requirements in 5 C.F.R. § 1320.8 or the certification requirements in 5 C.F.R. § 1320.9 if they wait until the end of the regulatory process to perform their Paperwork Reduction Act responsibilities.

burdens could be reduced — indeed, the Paperwork Reduction Act requires such consultations. However, proposed Analysis 4 has no content, which strongly suggests that it is merely a placeholder ICF has used to justify future contract work it perhaps hopes to secure on a noncompetitive basis.

Fourth, the methodology all but assumes that ICF's review of the American Intellectual Property Law Association (AIPLA) economic survey[6] will succeed in validating it for use by the USPTO. This is a huge assumption that is certain to be prove false, at least if ICF performs the validation in accordance with applicable federal statistical policy standards and information quality guidelines.[7]

As noted above, the ICF methodology clearly includes a public vetting process, which I infer to be a conventional public comment. The number and location of the points in the process where public vetting is proposed to occur is not clear, however. There is a serious risk that public vetting will occur too late to be able to ensure that mid-course corrections are made.

While public comment is necessary, it is certain not to be sufficient because the patent community is gravely uninformed about the Paperwork Reduction Act. I strongly urge the USPTO to add a formal, independent peer review process to ensure IQG compliance.[8] Peer review panels can be created with a mix of patent attorneys and paperwork burden experts, and they need not be chartered under the Federal Advisory Committee Act as long as they are organized and operated by independent third parties. Such panels are uniquely capable of providing the most focused and useful input, and would enable ICF to produce higher quality analyses.

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[6] **American Intellectual Property Law Association**, "Report of the Economic Survey: 2009," 2009. Rockville, Md.: Association Research, Inc.

[7] The proposed methodology obliquely anticipates this outcome, stating that other information (and possibly new surveys) may be needed. ICF should revise the methodology to make clear to the USPTO now that a major new survey research program will be needed.

[8] For government-wide guidelines on peer review, see **Office of Management and Budget.** "Final Information Quality Bulletin for Peer Review." *Federal Register*, 2005, *70*(10), pp. 2664-67. The proposed version of this guidance is superior in many respects and provides a better starting point for an agency such as the USPTO, which has no experience in peer review. See **____.** "Proposed Bulletin on Peer Review and Information Quality; Notice and Request for Comments." *Federal Register*, 2003, *68*(178), pp. 54023-29.

Overall Approach for Developing the Methodologies

Working Principles and Standards (§ 2.1)

I applaud the ICF report's five working principles, most importantly the commitment to full adherence to standards and principles in the USPTO's Information Quality Guidelines (IQG).[9] These standards and principles are an integral part of the Paperwork Reduction Act, and any credible methodology for burden estimation must adhere to them.

Compliance with the IQG is a very good start, but it should be understood that it is *only* a start. What the USTPO needs is a process by which an IQG-compliant burden estimation methodology, once completed, is verifiably incorporated into the USPTO's planning and management of all of its PRA responsibilities. In my experience reviewing recent USPTO recent ICR submissions, I have noticed that the Patent Office's has routinely but falsely certified compliance with the IQG.[10] This practice, which betrays an utter absence of agency interest in actual compliance, must be terminated immediately. The Patent Office must not certify compliance with the IQG unless and until it can convincingly demonstrate that its burden estimates actually do comply.

For this reason, I suggest appending to the fifth working principle the following subtask:

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[9] **U.S. Patent and Trademark Office.** "Information Quality Guidelines," Alexandria, VA, 2002.

[10] **Belzer, Richard B.** "Cost of Complying with the Proposed IDS Rule," 2007a, **____.** "Letter to Susan E. Dudley, Administrator, Office of Information and Regulatory Affairs [October 26, 2007]," 2007b, **____.** "Letter to Susan E. Dudley, Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget RE ICR 0651-0031," Mt. Vernon, VA, 2008c, 1-120, **____.** "Letter to Nicholas A. Fraser, Desk Officer for the U.S. Patent and Trademark Office, Office of Information and Regulatory Affairs, Office of Management and Budget RE: ICR 0651-00xx ["October 14th ICR Comment"]," Mount Vernon, Va., 2008a, **____.** "Letter to Nicholas A. Fraser, Desk Officer for the U.S. Patent and Trademark Office, Office of Information and Regulatory Affairs, Office of Management and Budget RE: ICR 0651-00xx: ICs and Burden Estimates ["November 17th ICR Comment"]," Mount Vernon, Va., 2008b.

- *An independently verifiable means of ensuring actual USPTO adherence to IQG-compliant burden estimation methodologies.*

A series of burden-estimation methodologies that prescribe how to perform these tasks is clearly necessary, but cannot be sufficient without a means of independently verifying that the methodologies have actually been followed.

The Importance of Adequate Data, Transparency and Appropriate Granularity (§ 2.2)

ICF is correct that paperwork burdens often are highly variable and that this variability ought to be accounted for. Furthermore, ICF also is correct that the proper way to account for variability is by estimating distributions, not just point estimates. My experience is similar to that of ICF: cost distributions often (and perhaps usually) are positively skewed such that a substantial portion of the affected population faces disproportionately great effects. Further, I agree with ICF that good-faith subjective judgments about the central tendency of asymmetrical distributions tend to be biased toward the mode. I also agree with ICF's claim that public commenters tend to be those whose costs are above average, a fact that I believe reinforces the case for supplementing public comment with expert assistance and independent peer review.

ICF says burdens are distributed unevenly, and I wholeheartedly agree. There are numerous margins for which it would be surprising to discover that they are *not* strong explanatory factors. These margins include such things as the 4-digit art unit code; the applicant's characteristics, experience, and history with the USPTO; and the skill of the applicant's attorney or agent (perhaps estimated by proxy by number of years' experience).

Review of Existing Burden Estimates (§ 2.3)

The sample of ICRs and NPRMs reviewed

The sample of ICRs that ICF proposes to review appears to be reasonable, but the selection of proposed rules is not. The former list includes ICRs 0651-0031 0651-0063, both of which are known to have been highly controversial and on which multiple public comments were submitted. However, the latter list is limited to the 2007 BPAI Rules of Practice NPRM, which lacked the 60-day notice required by law. Obvious by their exclusion are the proposed rules limiting claims and continuations and imposing information disclosure statement requirements.[11]

[11] **U.S. Patent and Trademark Office.** "Changes To Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications

These NPRMs contain the 60-day notices that made ICR 0651-0031 controversial. It makes no sense to include the ICRs but not the rules. Their omission must be rectified.

ICF's discussion of its review of these two samples is obtuse, and thus fundamentally deficient. A knowledgeable reader can infer that ICF failed to find anything useful in these documents. ICF casually acknowledgement that the burden estimates contained in these documents — to the extent they contained *any* information at all — fail to satisfy the IQG even though the USPTO certified full compliance speaks volumes about how extraordinarily substandard has been the Patent Office's recent performance.

Estimates for requirements that already are being met

The USPTO's past (selective) reliance on the AIPLA economic is emblematic. AIPLA conducts these biennial surveys for its own purposes and thus can choose what data to collect and make of them whatever it wants. However, when the USPTO disseminates AIPLA survey data in a way that conveys agreement or support, or utilizes AIPLA data for burden estimation or any other purpose, the IQG requires the USPTO to demonstrate that these data satisfy applicable information quality standards. As noted below, the AIPLA survey data do not meet federal statistical policy standards, and thus they cannot adhere to the IQG.[12]

Estimates for new requirements

I applaud ICF for specifically proposing to utilize the data submitted by public commenters (including me) on ICRs 0651-0031 and 0651-0063. None of the commenters (including me) have claimed that their estimates are the "last word" on the subject. Rather, commenters correctly noted that the burden "estimates" put forth by the USPTO lacked any credibility whatsoever.

Containing Patentably Indistinct Claims; Proposed Rule [0651-AB93]." *Federal Register*, 2006c, *71*(1), pp. 48-61, ____. "Changes To Information Disclosure Statement Requirements and Other Related Matters; Proposed Rule [0651-AB95]." *Federal Register*, 2006a, *71*(131), pp. 38808-23, ____. "Changes to Practice for the Examination of Claims in Patent Applications; Proposed Rule [0651-AB94]." *Federal Register*, 2006b, *71*(1), pp. 61-69.

[12] **Office of Management and Budget.** "Standards and Guidelines for Statistical Surveys," Washington, D.C.: Office of Management and Budget, 2006.

ICF proposes to "use these estimates in conjunction with ICF's own estimates." Unfortunately, the text is sparse with respect to how ICF proposes to use them. It is essential that this not be reduced to a contest in competing opinions or judgments. Commenters' insights should be considered to the extent that they have objective merit, particularly with respect to the technical expertise related to actually performing the tasks for which burdens are to be estimated. ICF has experience estimating burden based on valid external data, but has no experience actually performing the functional tasks involved.

For this reason, it is essential that the methodology be revised to establish *a priori* principles for the interpretation and disposition of public commenters' burden estimates. It is unacceptable for ICF to make these decisions subjectively, after the fact, inconsistently, in coordination with (or at the direction of) USPTO staff, or without full and complete documentation. Any methodology that lacks *a priori* principles for evaluating public comments would be *per se* defective and have no credibility.

Other Comments

The ICF Report does not include specific elements related to the clear, accurate and unbiased reporting of paperwork burden estimates, such as in agency Supporting Statements and (most notably) *Federal Register* notices. USPTO *Federal Register* notices are consistently inscrutable. The public is not at all informed when, for example, a 60-day notice says that the estimated time per response ranges from 1.8 minutes to 12 hours.[13]

Public comments will be helpful to calibrate burden estimates, but it will not be sufficient. Public comment has all sorts of limitations, including self-selection and a confounding interest in the substance of regulation that may make strategic behavior in burden estimation difficult to detect.[14] For this reason, I strongly believe that expert peer review should be part of the methodology for each of the four analyses.

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[13] **U.S. Patent and Trademark Office.** "Changes To Information Disclosure Statement Requirements and Other Related Matters; Proposed Rule [0651-AB95]." *Federal Register*, 2006a, *71*(131), pp. 38808-23. 38819.

[14] USPTO staff also has a confounding interest in the substance of regulation, which is an important reason why Patent Office estimates have been consistently criticized by public commenters as egregiously underestimated.

Methodologies for the Four Analyses

Analysis 1: Validate Reasons for Changes in Burden (§ 3.2)

ICF's methodology presumes that the information recorded in ROCIS is valid and reliable. This assumption is highly suspect. My review of information uploaded to ROCIS by the USPTO, which admittedly is not nearly as complete a record as ICF proposes to create, indicates that much of the information in ROCIS is suspect, incomplete, or otherwise unhelpful. The "stated reasons" usually given for changes are too vague to be used for the purposes of this analysis[15] or orthogonal to the purpose of burden estimation.[16] The purpose of Analysis 1 should be to develop a valid, reliable, objective, transparent, and reproducible methodology for assigning burden changes to their respective causes, and that all changes are counted exactly once. I am concerned the proposed methodology may stray into an apologia for existing procedures.

This concern is enhanced by the planned interaction between ICF and USPTO staff in this analysis, which could easily compromise ICF's objectivity and independence.[17] As a regular supplier of consulting services to the USPTO, ICF cannot help but be tempted to accommodate suggestions and changes proposed by Patent Office staff irrespective of their technical merit. It makes sense for ICF to consult with USPTO staff for information and to clarify its past procedures and practices, but these consultations must be informational only. Moreover, every consultation must be fully documented, and its results transparently disclosed, publicly vetted, and (in my view) subject to peer review.

Finally, ICF's proposed completion date (12 to 18 months after authorization) is unreasonably distant. A more appropriate schedule is 1 to 3 months. While it is true that the number of existing ICRs that must be reviewed is large, it is highly likely that ICF will very quickly what can be known about the stated reasons for changes. If, however, ICF proceeds down this path and performs

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[15] To be concrete, agencies have a strategic interest in avoiding clarity in their descriptions of the reasons for a change.

[16] To be concrete, whether a change in burden is the result of statutory change, regulatory change, the issuance or revision of guidance, or some other factor has no effect on the objective magnitude of the burden or the validity of the estimated change. It is worth keeping track of the category because agencies have a strategic interest in attributing the most burdensome changes to Congress.

[17] These interactions are alluded to vaguely on pp. 14-15.

an extended (and unduly expensive) search through the Patent Office's archives and email to uncover the sources of these opinions, ICF (and the USPTO) must be prepared to fully disclose all of the information obtained.[18]

Analysis 2: Compare Accuracy of New versus Revised ICR Estimates (§ 3.3)

ICF's proposed approach to this analysis is fundamentally and fatally flawed. It is built from the ground up based on the assumption that the AIPLA economic survey is an acceptable data source for burden estimation. The AIPLA survey is a serious effort, to be sure, but it does not satisfy federal statistical policy standards and thus cannot be used as the basis for USPTO burden estimates.

Sample frame

The 2009 AIPLA survey is not a survey at all; it is a census of 15,395 members and known nonmembers. This sample frame may be representative, but representativeness cannot be simply assumed. Thus, ICF's first task is to determine who in the patent community has relevant information but is not included in this sample frame, and determine if these omissions are randomly distributed across the important margins of patent prosecution.

Response rate

Federal Statistical Policy Standard 1.3 states:

> Agencies must design the survey to achieve the highest practical rates of response, commensurate with the importance of survey uses, respondent burden, and data collection costs, to ensure that survey results are representative of the target population so that they can be used with confidence to inform decisions. Nonresponse bias analyses must be conducted when unit or item response rates or other factors suggest the potential for bias to occur.

Standard 3.2 states:

> Agencies must appropriately measure, adjust for, report, and analyze unit and item nonresponse to assess their effects on data quality and to inform users. Response rates must be computed using standard

[18] Disclosure is required by presidential directive. See **Obama, Barack.** "Memorandum of January 21, 2009: Freedom of Information Act." *Federal Register*, 2009, *74*(15), pp. 4683-84.

> formulas to measure the proportion of the eligible sample that is represented by the responding units in each study, as an indicator of potential nonresponse bias.

Both of these standards are mandatory. The USPTO cannot use the AIPLA survey unless it meets these (and other) statistical policy standards. Operationally, the need for a nonresponse bias analysis kicks in the overall unit response rate is less than 80 % or an item response rate is less than 70%. The 2009 AIPLA includes responses from 3,221 members, a maximum response rate of only 21%.[19]

The 2009 AIPLA report states:

> All data submitted by respondents were reviewed and evaluated for reasonableness and consistency; data anomalies and outliers were analyzed and corrected or deleted.

How these procedures were performed was not disclosed, a facial violation of the transparency standard in the IQG as well as a presumptive violation of the objectivity standard.

In short, there is no way ICF can credible validate the results of the AIPLA survey. Despite these fatal defects, ICF proposes that Analysis 2 use AIPLA survey data as benchmarks for evaluating the accuracy of USPTO burden estimates. This procedure has no merit. Of course, it would be valuable for ICF to interview AIPLA staff and its consultants to learn more about its procedures (including professed data quality validation efforts), but these interviews should be used only for guiding the development of a new, IQG-compliant survey.

ICF proposes to conduct this analysis in conjunction with Analysis 3, which is the aggregation of burdens across the myriad ICRs facing multiple classes and types of applicants. Because ICF's proposed Analysis 2 cannot succeed, this plan condemns Analysis 3 to failure. There is no value in aggregating quantities that have no objective merit.

Analysis 3: Estimate total PRA Burdens on Applicants (§ 3.3)

The ICF proposal proceeds from the imaginary state in which Analysis 2 has already produced credible burden estimates for some but not all information collections contained in the sample of ICRs previously listed. The remaining task, it is assumed, is top fill in the gaps. Yet the proposal also says that Analysis 3 is where

[19] The report states that "only" 230 firm representatives completed the survey. The response rate for firms cannot be determined.

ICF would begin "validating data sources" and "addressing issues raised in previous ICR estimates." If ICF waits until this late stage to *begin* validating data, the entire project is defeated even before it begins.

Validating and estimating burden for existing requirements

ICF's proposal assumes that the AIPLA survey will provide a valid benchmark for evaluating and calibrating USPTO burden estimates. As noted above, this assumption is false because the AIPLA survey cannot be used for this purpose without violating the IQG and federal statistical policy standards. ICF and USPTO may be correct that AIPLA survey results "often are likely to provide the most credible and up-to-date readily available data." Even so, the AIPLA data cannot be used simply because they are "readily available" and superior to anything the USPTO has because the USPTO has nothing. The Paperwork Reduction Act does not permit an agency to decline to prepare objectively supported burden estimates because it is hard to do, nor does it permit an agency to rely on readily available data that do not adhere to applicable information quality requirements or violate statistical policy standards.

ICF is correct, though it understates the case, when it says:

> It also is plausible that for the purposes of estimating burdens in ICRs and regulatory analyses, the Agency would need additional statistics or a broader representation of the data than are provided in the AIPLA survey reports to more completely characterize the full distribution of cost or to more finely subcategorize the results for USPTO's purposes, as discussed in Section 2.2 (the importance of data, transparency and appropriate granularity). In addition, previous AIPLA surveys have not collected all of the data that the Agency has needed to estimate burdens in ICRs, such as paraprofessional rates or applicant time (p. 18).

Diplomacy aside, there is no question that the proper thing to do is start over. With the few exceptions noted above, ICF has presented a sound approach to the problem in Section 2. The problem is that Section 3 does not actually propose to implement Section 2.

Section 3 of the ICF methodology must be discarded and replaced with a plan to develop and implement a survey using a representative sample of appropriate size to achieve the necessary statistical power. This survey must comply with the IQG and federal statistical policy standards and guidelines. It is possible that AIPLA,

and perhaps additional professional associations, would be willing to collaborate on the project.[20]

The ICF Report hints at new surveys, but primarily as "limited follow-on" efforts, yet tactfully recognizes that the need is fundamental and not merely ancillary:

> Alternatively, ICF may determine that the best approach for validating the Agency's use of the AIPLA survey data, as well as to augment it as needed, is to perform an independent survey that specifically targets all of the data required by the study. This would serve not only to provide the data needed for estimating the total PRA burden on patent applicants as described in Section 3.3.3 below, but also would serve as a basis for validating the use of the AIPLA survey data for Agency's purposes as well as serve as the basis for Analysis 2 (p. 20).

The USPTO should recognize the wisdom of this advice, however indirectly it has been offered. Continuing to treat this project as a conventional but limited burden-estimation exercise will ensure that it fails. Numerous survey research firms, possibly including ICF, are capable of developing and implementing a survey instrument that meets these criteria. The USPTO should publish a new RFP specifically designed for that purpose.

Analysis 3 should be redesigned to utilize information obtained from a new survey for the purpose of estimating burden. Unless and until such a survey is built and administered, the objectives set out for Analyses 2 and 3 cannot be achieved.

Potential opportunity for additional input

ICF proposes, albeit obliquely, to solicit input from genuine experts. The plan should be amended to establish and implement formal procedures for performing the consultations already required by law but which the USPTO does not do. Given the Patent Office's history of estranged relations with it customers, a much better approach would be to establish formalized procedures for soliciting input through a FACA-chartered advisory group and separately contracting for the conduct of rigorous external and independent peer review.

[20] A comprehensive review of the AIPLA survey is likely to reveal defects so large that AIPLA no longer has confidence in it.

Analysis 4: Identify Options for Reducing Applicant Burden

Analysis 4 is, quite simply, premature. This is self-evident in the abbreviated discussion in the ICF Report. When the major problems inherent in the ICF methodology are taken into account, it becomes clear that the resources ICF proposes to devote to Analysis 4 should be redirected elsewhere.

Suggested Modifications to the ICF Proposed Methodology

The previous sections have taken the ICF Report at face value and commented on their technical merits. In this section, specific modifications are suggested to improve it on a more fundamental level.

Postpone premature analyses

Until a credible methodology is developed for estimating paperwork generally, no effort should be devoted to estimating aggregate burden (Analysis 3). Similarly, Analyses 1 and 4 are worth doing but ought not be included *in this project*. Analysis 1 has nothing to do with burden estimation, and Analysis 4 concerns overcoming the USPTO's historic disregard for minimizing burden as required by law. All of the effort here should be expended on the development of a credible and implementable procedure for estimating burden generally. At this time, everything else is a distraction.

Learn lessons from, but do not even consider using, the AIPLA survey

Analysis 2 is the core of the Report, but ICF goes about the task incorrectly by presuming that the AIPLA economic survey can be used as is, or with a few minor tweaks, as the basis for USPTO burden estimation. Although much can be learned from the AIPLA survey, this plan is mistaken and should be abandoned because it will fail.

Inventory paperwork burdens

A much more promising approach is to build a *de novo* inventory of information collections (ICs) based on a systematic review of USPTO regulations and guidance. Many can be matched to existing ICs in one or another existing ICR. However, we now know from our experience with ICRs 0651-0031 and 0651-0063 that many significant USTPO paperwork burdens do not have valid OMB Control Numbers. These information collections are illegal. Only a comprehensive review of the paperwork burdens of existing rules and guidance can reveal the magnitude of this problem, and no burden estimation methodology will succeed if it ignores the problem of illegal information collection.

Devise a new survey

The USPTO should candidly recognize that it cannot credible use the AIPLA survey. A new survey should be designed from the ground up that meets applicable federal statistical policy standards and the IQG. It can be built from the ground up with modules derived from the *de novo* inventory of information collections recommended above. This could be done within the existing ICF project, but I recommend that it be removed from the methodology study and conducted as a separate, freestanding effort subject to a new RFP to ensure that it is performed by the best available survey research team, as determined by a fully competitive bidding process.

Concluding Comments

The ICF Report provides a welcome first start toward a credible methodology for estimating paperwork burdens related to USPTO activities. The Report is especially strong in its theoretical elements. But the methodology ultimately fails because it relies on the use of available data, and the available data are insufficient to implement it.

Sincerely,

President
Regulatory Checkbook