

From:

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To: Restriction_Comments

Cc:

Subject: Comments in reply to Request for Comments of June 14, 2010

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August 16, 2010

By Email Restriction_Comments@uspto.gov

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Re: Comments on Proposed Changes to Restriction Practice in Patent Applications, 75 Fed. Reg. 33584 (June 14, 2010)

Dear Ms. Therkorn:

When David Kappos was inaugurated, the patent bar gave a huge sigh of relief, with the hopes that the PTO's era of regulating in its own self-interest had ended, along with the practice of ignoring burden on applicants, fabricating statements of fact and burden with no objective support, selectively misquoting current law, and ignoring inconvenient provisions of administrative law. This Notice comes very close to the overt cheating and defiance of rulemaking law and procedure that permeated 2006-2009. If this proposal goes any further, the PTO risks litigation, and the individual attorneys involved expose themselves to risks under the rules of ethics.

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I. Restriction must be administered within the limits of the PTO’s statutory authorization, and for the benefit of the public, not solely for the PTO’s internal benefit

At least two laws require the PTO to set its restriction rules to minimize total cost to applicants and for the PTO, not to simply benefit the PTO. The changes “proposed” in Question 1 seem to violate these two laws, and the Patent Act.

A. Economics of restriction practice

Related claims are much more easily, efficiently, and consistently examined and prosecuted in a single application. When related claims are split among multiple applications, costs, complexity, inefficiency, and risk of inconsistent determinations rise remarkably. Once an applicant has one set of claims fully in mind, it is far easier and more efficient to handle all related claims concurrently, while those claims and the associated specification are all in mind. There is less likelihood of omitting consideration of prior art that was cited in another application, there is less relearning time, less work to comply with the obligations under inequitable conduct law, and the like. To take one specific example, recent inequitable conduct decisions of the Federal Circuit counsel that applicants cross-cite all Office Actions and replies to

Office Actions in all applications that are related.¹ The work to comply with this law goes up as n^2 with the number of daughter applications—that is, a 5-way divisional takes 25 times creates 25 times as much work under this law, as prosecuting exactly the same claims in an undivided application. Double patenting issues are entirely eliminated if the applications are not divided. The paperwork management issues are much smaller for a single application than for multiple divisionals.

The processes of prosecution and examination are remarkably similar, and I can't imagine that it's any more efficient for examiners to consider the same claims fragmented among multiple divisional cases than it is for applicants—it has to be more efficient to consider them in consolidated form. Divisionals of a single application often go to different examiners—which is terribly inefficient for all concerned. Even if the divided claims are handled by a single examiner, the examiner has to relearn the case multiple times, carefully remember what actions were taken where, etc.

Thus, divisionals are not a mere redistribution of the same amount of work among more applications. Divisionals are a huge **cost-creator** for applicants, and—unless there is something I'm totally missing—almost certainly for the Office as well.

Any regulatory action that would increase the rate of divisionals will require high-quality, objective, evidentiary support, that fully complies with the Office's

¹ Under *McKesson Information Solutions Inc v Bridge Medical Inc.*, 487 F.3d 897, ___, 82 USPQ2d 1865, ___ (Fed. Cir. 2009), *Larson Mfg. Co. of South Dakota Inc v. Aluminart Products Ltd.*, 559 F.3d 1317, 1339, 90 USPQ2d 1257, ___ (Fed. Cir. 2009), and *Therasense, Inc v Becton Dickinson & Co.*, 593 F.3d 1289, 1301-02, 93 USPQ2d 1489, ___ (Fed. Cir. 2010), applicants can reduce risk of findings of inequitable conduct by citing all Office Actions and replies to Office Action for all related applications.

Information Quality Guidelines² and the requirement for "objective support" to show that the PTO minimized burdens under the Paperwork Reduction Act.³

B. The changes "proposed" in Question 1 exceed the PTO's authority to require restriction

"Serious burden" is not the criterion on which restriction authority was delegated to the PTO. The Notice does not explain why the PTO has substituted its own choice of criteria, "examination burden," for the statute's grant of authority to divide only "independent and distinct" inventions.

35 U.S.C. § 121 sets the limits on the PTO's authority to divide applications:

35 U.S.C. 121 Divisional applications.

If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. ...

The MPEP has long deviated from the statute by permitting restriction based on "independent or distinct." However, the MPEP further confined examiner discretion by requiring one of three additional showings:

- separate status in the art based on separate classification
- separate status in the art based on divergent subject matter
- different field of search based on different classes/subclasses

Note that these three essentially restore focus back to where it belongs, whether the inventions are directed to substantively different technologies. More often than not, the combination of "independent or distinct" **and** "serious search burden" (under the traditional three categories) comes out, at least in the computer, mechanical, and business methods technologies, reasonably close to the statute's "independent and

² The PTO is reminded of the Information Quality Guidelines to which it bound itself in 2002. <http://www.uspto.gov/products/cis/infoqualityguide.jsp>.

³ 44 U.S.C. § 3506(c)(1)(A)(iv), § 3506(c)(2)(A)(iv).

distinct.” The PTO’s departure from statute has been practically tolerable (though legally problematic) only because the PTO placed this additional limitation on itself.

C. The Notice misstates the current legal status of several “proposed” changes

The Notice states that the Office is “considering” divisions based on:

- prior art applicable to one invention would not likely be applicable to another invention
- the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 or 35 U.S.C. 112, first paragraph.

First, this is a misrepresentation. These two criteria were provided to examiners in a 2007 memo to examiners by John Love⁴ and a January 2010 memo to examiners by Robert Bahr.⁵ What does the PTO mean in this notice when these changes are characterized as “proposed” or “under consideration” when they’ve been in effect for over three years? The PTO should explain any theory it has under which this characterization could be considered truthful. If the PTO cannot do so, the pattern of lying in rule making notices must stop. Is the PTO attempting an *ex post* whitewashing of two previous actions that are now acknowledged to be illegal, without acknowledging the existence of these two previous actions?

Second, note that the § 101 / § 112 ¶ 1 criterion has nothing whatsoever to do with “independent and distinct” *inventions*, it relates only to other technical legal requirements that have nothing to do with “independence” or “distinctness” of the inventions.

⁴ John Love, Changes to Restriction form paragraphs (Apr. 25, 2007), http://www.uspto.gov/web/offices/pac/dapp/opla/documents/20070425_restriction.pdf

⁵ Robert W. Bahr, Acting Associate Commissioner for Patent Examination Policy, Changes to Restriction Form Paragraphs (Jan. 25, 2010), http://www.uspto.gov/patents/law/exam/20100121_rstrctn_fp_chngs.pdf

Third, “different applicable prior art” has proven problematic in practice since it was released to examiners in 2007, because examiners often observe that dependent claims require searches different from the independent claims, and insist on election of species among inventions that cannot be divided today.

Fourth, the Notice also includes this criterion for restriction:

- employing different electronic resources, or employing different search queries

Before August 2005, MPEP § 808.02(C) (8th Ed. Rev. 2 (May 2004)) defined

“different field of search” as follows, in pertinent part:

(C) **A different field of search:** Where it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims.

The revision of August 2005 broadened “different field” considerably:

(C) **A different field of search:** Where it is necessary to search for one of the inventions in a manner that is not likely to result in finding art pertinent to the other invention(s) (e.g., searching different classes/subclasses or electronic resources, or employing different search queries, a different field of search is shown, even though the two are classified together.

Note that the 2005 changes focus almost entirely on the PTO’s internal examination plumbing, and have little to nothing to do with statutory “independence and distinctness” of the technological inventions as presented by an applicant. The 2005 amendment to MPEP § 808.02(C) was outside the PTO’s statutory restriction authority, and should be withdrawn.

Fifth, I requested, obtained and reviewed all of the PTO’s Paperwork Reduction filings within Control Number 0651-0031 for the period 2003-2008. The most relevant are included in the Appendices to the Attachment to this letter. The record is clear that the PTO never even sought required OMB clearance under the Paperwork Reduction Act for this change, let alone obtained a valid OMB control number. Likewise, the PTO never published a Federal Register Notice as was required by 5 U.S.C. § 552(a)(1) and (2). The August 2005 redefinition of “different

field of search” was not validly promulgated, and both § 552(a) and 44 U.S.C. § 3512 forbid the PTO from enforcing it.

The PTO’s Office of Patent Legal Administration administered the legal patent law issues illegally. The PTO cheated. This change should be backed out, and the PTO should start at the beginning, and follow proper rule making procedure (see § III.B at page 21 of this letter).

D. The Notice’s representations of “burden” are not accurate statements of the PTO’s history

The Notice’s statement of current MPEP policy reflects an apparent attempt to rewrite history. The Notice states “Typically, the burden prong has been viewed as referring to the burden imposed by searching for patentably distinct inventions.” The Notice errs by referring to this as “typical,” it has been the plain wording of the MPEP for decades.⁶ The Notice attempts to expand the definition of “burden” to “examination burden” rather than “search burden.” If the PTO has authority to do so at all, that authority is confined by rule making procedure required by the Administrative Procedure Act, the Paperwork Reduction Act, the Regulatory Flexibility Act, Executive Order 12,866, and the like. Rule making by lying about the past is not an alternative within the PTO’s legal authority.

⁶ “a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP Section 808.02.” MPEP § 803; “unduly extensive and burdensome search is necessary.” MPEP § 806.01; “serious search burden if restriction were not required,”: MPEP § 806.05(c); “serious search burden > if restriction were not required” MPEP § 806.05(c)(II); *etc.*

E. The statements of effect on the agency violate Information Quality Act principles

At 73 Fed.Reg. 33585 col. 3, the Notice states “The burden imposed by examination of patentably distinct inventions is, in many cases, as serious as the burden imposed by searching for such inventions.”

The PTO broke the law by making this statement, without providing the support required by the PTO’s Information Quality Guidelines. What is the basis for this statement? Without a disclosed basis that is reproducible, the public has no way to know whether this statement is truthful, or merely another in the long line of questionable-at-best unsupported statements made up by the Office of Patent Legal Administration. What is “many cases?” Why would an apparatus claim to a computer programmed to perform a process, and a process claim to the process—which are “patentably distinct” and raise different § 101 and § 112 ¶ 1 issues—be more “burdensome” on the PTO to examine than any other pair of apparatus and method claims? I have been told that the PTO keeps no record of the time spent examining particular applications—if this information is not gathered, what basis does the PTO have for this statement? What has the PTO done to confine the reach of any rule and its associated Paperwork burden to the precise scope of situations that create the agency burden that the PTO hopes to address? The Notice answers none of these questions.

F. Paperwork Reduction Act and Executive Order 12,866 limits on regulations

All agencies are under several legal obligations to regulate for the benefit of the public, not in the agency’s self interest. At least Question 1 is clearly directed solely to the PTO’s self interest, and those changes are not merely imprudent, they’re illegal.

The Paperwork Reduction Act, 44 U.S.C. § 3501 *et seq.* has several provisions that limit the PTO’s authority to impose restriction costs on the public:

- The PTO must “minimize the burden of the collection of information on those who are to respond”⁷
- The PTO must certify that all information to be sought “is not unnecessarily duplicative of information otherwise reasonably accessible to the agency”⁸
- The PTO must “reduce[] to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency”⁹

It will be exceedingly difficult to show that any of the changes proposed in Question 1 (or to obtain retroactive clearance for the 2005 amendment adding “different search queries” to the MPEP) meet these statutory obligations, since each of the changes is directed to increasing divisional applications, the sole effect of which is to increase burden, and require duplicative submission of information.

Likewise, Executive Order 12,866 as available on whitehouse.gov¹⁰ states the following Regulatory Philosophy and Regulatory Principles:

The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth... and regulations that are effective, consistent, sensible, and understandable....

Accordingly, by the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Statement of Regulatory Philosophy and Principles. (a) *The Regulatory Philosophy.* Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. ...

⁷ § 3506(c)(2)(A)(iv)

⁸ § 3506(c)(3)(B).

⁹ § 3506(c)(3)(C).

¹⁰ http://www.whitehouse.gov/omb/inforeg_eo12866_index_eo12866 and http://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/eo12866/eo12866_ amended_01-2007.pdf

Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

(b) *The Principles of Regulation.* To ensure that the agencies' regulatory programs are consistent with the philosophy set forth above, agencies should adhere to the following principles, to the extent permitted by law and where applicable:

(1) Each agency shall identify in writing the specific market failure (such as externalities, market power, lack of information) or other specific problem that it intends to address (including, where applicable, the failures of public institutions) that warrant new agency action, as well as assess the significance of that problem, to enable assessment of whether any new regulation is warranted.

(2) Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.

(3) Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

...

(5) When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

(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.

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

(10) Each agency shall avoid regulations and guidance documents that are inconsistent, incompatible, or duplicative with its other regulations and guidance documents or those of other Federal agencies.

(11) Each agency shall tailor its regulations and guidance documents to impose the least burden on society, including individuals, businesses of differing sizes ..., consistent with obtaining the regulatory objectives...

(12) Each agency shall draft its regulations and guidance documents to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

The Notice identifies no benefit to regulated entities, let alone the public—it does not even suggest that the “proposed” changes might be cost neutral. Surely the PTO knows that every restriction is a pure cost to the applicant, yet the PTO makes no mention of how these costs are to be “minimized” as required by the Paperwork Reduction Act, and makes no mention of the economic efficiency and cost-benefit criteria required by the paperwork Reduction Act and Executive Order 12,866. The only benefits identified in Question 1 accrue to the PTO itself. By that display of selfishness, the PTO concedes that the “proposals” under Question 1 are illegal.

G. Restriction requirements, like any other agency decision, require statements of reasons

When an applicant makes any filing of claims in an application or amendment, those claims are a “written application.” Thus, to deny any part of the application, including by restriction, the PTO must comply with 5 U.S.C. § 555(e):

(e) Prompt notice shall be given of the denial in whole or in part of a written application, petition, or other request of an interested person made in connection with any agency proceeding. Except in affirming a prior denial or when the denial is self-explanatory, the notice shall be accompanied by a brief statement of the grounds for denial.

Any agency denial of an application must articulate a “statement of grounds” that communicates “reasoned decisionmaking.” Since *State Farm* in 1983,¹¹ courts have increasingly recognized that agency proceedings are at high risk of being arbitrary and capricious if there is no accountability, the kind of accountability that can only be enforced through requiring individual agency employees to set forth written findings that can be judicially reviewed. The Administrative Procedure Act obliges an agency,

¹¹ *Motor Vehicle Manufacturers’ Ass’n of the U.S. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 48, 50, 52 (1983).

in any adverse decision, to give a “statement of grounds” that identifies the specific legal standard relied on, the facts that are relevant to the decision, the evidence that supports any fact or inference, and a sufficient statement of the application of the law to the facts to apprise a party of the agency’s basis for decision.¹² § 555(e) requires that the “statement of grounds” must be sufficiently detailed to ensure that the agency gives careful consideration of the issues, to give parties the opportunity to apprise the agency of any errors, and to facilitate judicial review.¹³ The requirement of § 555(e) for rationally-supported written decisions applies both to final agency action and to

¹² *Burandt v. Dudas*, 528 F.3d 1329, 1332, 87 USPQ2d 1134, 1137 (Fed. Cir. 2008) (in a review of PTO informal adjudication by petition, citing *State Farm* for definition of “arbitrary and capricious”); *In re Lee*, 277 F.3d 1338, 1344, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002) (citing *State Farm* for definition of “arbitrary and capricious” in review of decision of Board of Appeals); *Cook v. Heckler*, 783 F.2d 1168, 1172–73 (4th Cir. 1986) (vacating Social Security decision when the ALJ merely provided a list of possibly-relevant facts, and referred to a list of possible legal grounds, without identifying which particular grounds or facts were considered, and failed to provide any discussion applying the law to the facts).

¹³ *Clark County Nevada v. Federal Aviation Admin.*, 522 F.3d 437, 443 (D.C. Cir. 2008) (adjudication fails *State Farm* tests for explanation of reasons); *Niam v. Ashcroft*, 354 F.3d 652, 654, 660 (7th Cir. 2004) (Posner, J.) (after finding the ALJ relied on impermissible analyses and ignored relevant evidence, “The immigration judge’s analysis was so inadequate as to raise questions of adjudicative competence...”); *Dr. Pepper/Seven-Up Companies Inc. v. Federal Trade Comm’n*, 991 F.2d 859, 864–65 (D.C. Cir. 1993) (agency’s “conclusory dismissal” that failed to consider key evidence and a key claim was “wholly inadequate” and “leaves too many questions unanswered to qualify as reasoned decisionmaking”); *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.”). *Cf. Dunlop v. Bachowski*, 421 U.S. 560, 571 (1975) (for Labor Management Reporting and Disclosure Act cases, “When action is taken by [the Secretary] it must be such as to enable a reviewing Court to determine with some measure of confidence whether or not the discretion, which still remains in the Secretary, has been exercised in a manner that is neither arbitrary nor capricious... [I]t is necessary for [him] to delineate and make explicit the basis upon which discretionary action is taken. ... Moreover, a statement of reasons serves purposes other than judicial review. ... [A] ‘reasons’ requirement promotes thought by the Secretary and compels him to cover the relevant points and eschew irrelevancies, and ... the need to assure careful administrative consideration ‘would be relevant even if the Secretary’s decision were unreviewable.’”).

underlying preliminary or initial adjudications, such as examiners' Office Actions. The statement of reasons must satisfy these criteria:¹⁴

A court must set aside agency action it finds to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A). At a minimum, that standard requires the agency to "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of United States, Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)).

A "fundamental" requirement of administrative law is that an agency "set forth its reasons" for decision; an agency's failure to do so constitutes arbitrary and capricious agency action. *Roelofs v. Secretary of the Air Force*, 628 F.2d 594, 599 (D.C. Cir. 1980); see *State Farm*, 463 U.S. at 43. That fundamental requirement is codified in section 6(d) of the APA, 5 U.S.C. § 555(e). Section 6(d) mandates that whenever an agency denies "a written application, petition, or other request of an interested person made in connection with any agency proceeding," the agency must provide "a brief statement of the grounds for denial," unless the denial is "self-explanatory." This requirement not only ensures the agency's careful consideration of such requests, but also gives parties the opportunity to apprise the agency of any errors it may have made and, if the agency persists in its decision, facilitates judicial review. Although nothing more than a "brief statement" is necessary, the core requirement is

¹⁴ *Tourus Records Inc. v. Drug Enforcement Admin.*, 259 F.3d 731, 736–37 (D.C. Cir. 2001) (citations, quotations, and footnotes omitted); see also *American Bioscience Inc. v. Thompson*, 269 F.3d 1077, 1084–85 (D.C. Cir. 2001) (agency vacated because agency's statement of reasons in an informal adjudication was "sadly inadequate"); *Dr. Pepper/Seven-Up Companies Inc. v. Federal Trade Comm'n*, 991 F.2d 859, 864–65 (D.C. Cir. 1993) (agency's "conclusory dismissal" that failed to consider key evidence and a key claim was "wholly inadequate" and "leaves too many questions unanswered to qualify as reasoned decisionmaking," citing *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 419 (1971)); *Moon v. U.S. Dep't of Labor*, 727 F.2d 1315, 1318 (D.C. Cir. 1984) ("To fulfill its function under any appropriate standard of review, however, a court must be able to ascertain the reasons for an agency's decision. We cannot determine whether an agency has acted correctly unless we are told what factors are important and why they are relevant. Therefore, an agency must provide a reasoned explanation for its actions and articulate with some clarity the standards that governed its decision."); *Arnold v. Sec'y of Health Educ. & Welfare*, 567 F.2d 258, 259 (4th Cir. 1977) ("Unless the [ALJ] has analyzed all evidence and has sufficiently explained the weight he has given to obviously probative exhibits, to say that his decision is supported by substantial evidence approaches an abdication of the court's duty to scrutinize the record as a whole to determine whether the conclusions reached are rational"), quoted in *Dante Coal Co. v. Director, Office of Workers' Compensation Programs*, 164 Fed. Appx. 338, 345 (4th Cir. 2006) (unpublished).

that the agency explain “why it chose to do what it did.” Henry J. Friendly, *Chenery Revisited: Reflections on Reversal and Remand of Administrative Orders*, 1969 DUKE L.J. 199, 222.

The DEA’s letter denying [the] petition ... does not meet the APA standard. The letter says nothing other than that the “Affidavit of Indigency you submitted in lieu of a cost bond is not adequately supported.” ... That is not a statement of reasoning, but of conclusion. It does not “articulate a satisfactory explanation” for the agency’s action, because it does not explain “why” the DEA regarded [the] affidavit as unsupported. Nor are the grounds for denying [the] application ... “self-explanatory,” 5 U.S.C. § 555(e), since the [agency stated no rebuttal to the petition’s showings of fact]. The letter thus provides no basis upon which we could conclude that it was the product of reasoned decisionmaking.

In *Dickinson v. Zurko*,¹⁵ the PTO fought for and won the right to be fully within the embrace of the Administrative Procedure Act, and subsequent case law makes clear that this includes the obligation to set out written findings that at least identify the specific legal principle at issue, the facts that are relevant to the decision, and a sufficient statement of the application of the law to the facts to apprise a party of the PTO’s basis for decision.¹⁶

The absence of required findings is fatal to the procedural validity of any adverse PTO decision.¹⁷ For decades, MPEP Chapter 800 has required examiners

¹⁵ *Dickinson v. Zurko*, 527 U.S. 150, 163–64, 50 USPQ2d 1930, 1936 (1999) (PTO is an “agency” that must observe Administrative Procedure Act requirements).

¹⁶ *In re Gartside*, 203 F.3d 1305, 1313–14, 53 USPQ2d 1769, 1774 (Fed. Cir. 2000) (“the Board’s decision must be justified within the four corners of that record. ... We cannot look elsewhere to find justification for the Board’s decision. ... [T]he Board’s opinion must explicate its factual conclusions, enabling us to verify readily whether those conclusions are indeed supported by “substantial evidence” contained within the record.”); *Gechter v. Davidson*, 116 F.3d 1454, 1460, 43 USPQ2d 1030, 1035 (Fed.Cir.1997) (“[W]e hold that the Board is required to set forth in its opinions specific findings of fact and conclusions of law adequate to form a basis for our review.”); *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992) (“[T]he *examiner* bears the initial burden, on review of the prior art or on **any other ground**, of presenting a *prima facie* case of unpatentability,” emphasis added).

¹⁷ *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 811, 229 USPQ 478, 479 (1986) (Supreme Court holds that obviousness has separate procedural and substantive components, notes that the Federal Circuit’s silence on issues that were procedurally

to “provide reasons and/or examples to support conclusions” in support of any restriction requirement.¹⁸

In contrast, the Love memo¹⁹ gave examiners form paragraphs that allow examiners to simply list five possible criteria, with no identification of any of the five that might apply or the facts that support any of the five.

The Bahr memo does no better, inviting examiners to simply plug in a fixed laundry list, with no identification of the particular legal ground, and no identification of the applicable facts:

¶ 8.02 *Requiring an Election of Species; No Species Claim Present*

There is a search and/or examination burden for the patentably distinct species set forth above because at least the following reason(s) apply: **[4]**

Note 5. In bracket 4 insert the applicable reason(s) why there is a search and/or examination burden:

--the species or groupings of patentably indistinct species have acquired a separate status in the art in view of their different classification

required makes substantive review impossible, and remanding for clarification due to the “lack [of] an adequate explanation of the basis for the Court of Appeals’ judgment”); *Jang v. Boston Scientific Corp.*, 532 F.3d 1330, 1335, 87 USPQ2d 1459, 1462–64 (Fed. Cir. 2008) (noting the general principle that “[t]he Supreme Court has recognized the authority to remand for clarification judgments that suffer from ambiguity,” and vacating an agreed consent judgment because the underlying claim construction was procedurally too inadequately articulated to permit the parties to govern their future conduct); *Nazomi Communications Inc. v. ARM Holdings PLC*, 403 F.3d 1364, 1371–72, 74 USPQ2d 1458, 1463 (Fed. Cir. 2005) (remanding for clarification of ruling due to “the absence of findings of fact” on technological and claim construction issues and inadequate analysis that did not “supply [a] basis ... sufficient for a meaningful review”); *Koito Mfg. Co. v. Turn-Key-Tech LLC*, 381 F.3d 1142, 1151, 72 USPQ2d 1190, 1197 (Fed. Cir. 2004) (merely placing a reference in evidence but providing no “demonstrate[ion] ... how that reference met the limitations of the claims” fell below minimal procedural requirements for raising an anticipation issue); *Anglo-Canadian Shipping Co. v. Federal Maritime Comm’n*, 310 F.2d 606, 617 (9th Cir. 1962).

¹⁸ MPEP § 803(II).

¹⁹ Love memo, http://www.uspto.gov/web/offices/pac/dapp/opla/documents/20070425_restriction.pdf providing a new form paragraph 8.21 that merely sets out a laundry list of possible grounds, and does not require the examiner to identify any grounds.

--the species or groupings of patentably indistinct species have acquired a separate status in the art due to their recognized divergent subject matter

--the species or groupings of patentably indistinct species require a different field of search (e.g., searching different classes /subclasses or electronic resources, or employing different search strategies or search queries).

Asking an examiner to fill in a form, then giving the examiner fixed text with which to fill in that form, fixed language that gives no indication of the specific applicable reason and no identification of the relevant facts, is a breach of § 555(e).

The previous Deputy Commissioner for Examination Policy and the current Acting Associate Commissioner for Examination Policy instructed examiners to break the law.

H. The letters filed in response to the restriction Request for Comment of <write me>

On May 30, 2003, the PTO published a Request for Comments on the Study of the Changes Needed to Implement a Unity of Invention Standard in the United States, 68 Fed. Reg. 27536 (May 30, 2003). 26 letters were posted on the PTO's web site for a time. I read them. I recall that a number of them gave the Office valuable insights into how restriction affects applicants, and how it is sometimes abused, and how that abuse could be curbed.

Those insightful letters were replaced by a "Summary"²⁰ by Charles Pearson and Robert Clarke. Mr. Pearson's and Mr. Clarke's "summary" omits a number of the most relevant points, and mischaracterizes several of the comments. The Office would do well to retrieve the originals of these letters and post them again, and reread them in the context of this Request for Comment.

The Office would also do well to reform its practice of mischaracterizing and whitewashing public comments in its filings to OMB, the Small Business

²⁰ <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/unitycommentssummary.pdf>

Administration, and the public record,²¹ and to inform the attorneys that work on responses to comments of their individual liabilities, under Virginia ethics rules, which I discuss at § III.D at page 31 of this letter.

II. The PTO should correctly advise the public of the status of the Love and Bahr memoranda

Question 1 is rather curious. It asks about “proposed” changes that the PTO is “considering.” The PTO implemented these changes in a memorandum to the examining corps of January 2010.²² Shortly before the June 2010 publication date of the Notice, the PTO was actively applying them.

Thankfully, this Request for Comments notes that the changes to restriction posed in the Bahr memorandum are (from June 2010 forward) only “proposed” changes, which suggests that the PTO thought better of its earlier action, and recanted the Bahr memo at some time between the anomalous restriction requirements I received in March and April, and the June publication date. Because the MPEP was republished in July 2010 without incorporation of the Bahr memo, by operation of law, that memorandum “may be considered obsolete.”²³

The Bahr memo appears to have been issued in response to three petitions I filed in October and November 2009. Excerpts from one of these petitions are attached to this letter as an appendix. Strikingly, in promulgating the Bahr memo, the PTO repeated many of the legal errors I pointed out in my petition. Perhaps Mr. Bahr

²¹ See the discussion of Rule for Professional Conduct 3.3 at § III.D at page 31 of this letter.

²² See footnote 5

²³ MPEP 8th Ed. Rev. 8, Foreword “Orders and Notices, or portions thereof, relating to the examiners’ duties and functions which have been omitted or not incorporated in the text may be considered obsolete.”

acted in haste, and this Request for Comment is the PTO's belated realization that Mr. Bahr's memo could not have been issued within the bounds of the law.

Please publish another memorandum on the "Memoranda to Examiners" web page indicating that the Love and Bahr memoranda are withdrawn, and that all restriction requirements raised pursuant thereto are likewise withdrawn, with no act required by the applicant. Also please follow the President's directive to you,²⁴ and note on the "Memoranda" page that the Love memo and the Bahr memo are withdrawn.

In any event, because the PTO never sought clearance under the Paperwork Reduction Act for either memo, the Love and Bahr memo is unenforceable.

If the PTO disagrees and has any basis to believe that the Bahr memo is still in force, the PTO must explain its disagreement with each point set forth above, and must address each point raised in the attached petition.

III. A primer in rule making

A. The Love memo, the Bahr memo, and any change that matures out of this RFC are "rules" covered by a number of rule making laws

Any PTO regulation or guidance that matures out of the Request for Comment—and indeed, the PTO's two most recent excursions into this area, the Love memo and the Bahr memo, are unquestionably "rules" within the Administrative Procedure Act and Regulatory Flexibility Act, "regulatory actions" within Executive

²⁴ 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> (Jan. 18, 2007), 72 Fed. Reg. 3432 (Jan. 25, 2007), § III(1)(a) and (b) ("Each agency shall maintain on its website... a current list of its significant guidance documents in effect. The list shall include the name of each significant guidance document, any document identification number, and issuance and revision dates. ... The list shall identify significant guidance documents that have been added, revised or withdrawn in the past year.")

Order 12,866, information collections under the Paperwork Reduction Act, and the like. One of the key administrative law cases from the D.C. Circuit notes as follows:²⁵

The Administrative Procedure Act (APA), 5 U.S.C. §§ 551 et seq., broadly defines an agency rule to include nearly every statement an agency may make:

(4) “rule” means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing (.)

5 U.S.C. § 551(4) (1976). The breadth of this definition cannot be gainsaid. ... In keeping with the general commitment to public notice and participation, the APA provides only limited exceptions to these requirements.

The definition of “regulatory action” under Executive Order 12,866 is substantially identical.

The Love memo, the Bahr memo, and any action arising out of this Request for Comments are also likely “substantive” rules, though within a delegation of rule-making authority impliedly granted by 35 U.S.C. § 121.

35 U.S.C. § 2(b)(ii)(B) requires that all PTO rulemaking is subject to the notice-and-comment procedures of 5 U.S.C. § 553.²⁶ Because all PTO rulemakings are subject to notice-and-comment requirements, the PTO is required to fully comply with the Regulatory Flexibility Act for all rulemakings.

²⁵ *Batterton v. Marshall*, 648 F.2d 694, 700–01 (D.C. Cir. 1980).

²⁶ *Tafas v. Dudas*, 541 F.Supp.2d 805, 812, 86 USPQ2d 1623, 1628 (E.D. Va. 2008) (“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”), *reinstated sub nom. Tafas v. Kappos*, 586 F.3d 1369, 1371, 92 USPQ2d 1693, 1694 (Fed. Cir. 2009). By requesting dismissal of the appeal for mootness, the PTO promised “*with assurance* that there is *no* reasonable expectation that the alleged violation will recur,” *County of Los Angeles v. Davis*, 440 U.S. 625, 631 (1979), and that the practice of issuing even procedural rules without notice and comment will end permanently. *Byrd v. U.S. Environmental Protection Agency*, 174 F.3d 239, 244–45 (D.C. Cir. 1999).

B. A rule-making time line

The PTO's compliance with basic rule making law has been shockingly poor in the last four years. To give the PTO the benefit of doubt, I will assume that the pattern of noncompliance arises because the PTO has never developed a checklist of its rule making responsibilities. To help ensure that no further accidental breach occurs, and to assist the public and reviewing tribunals in inferring intent in the event of future breaches, here is a synopsis of all the steps the PTO must take to promulgate a rule. Not every step is required for every rule, of course, but it will be easier for the PTO to comply if it has all the steps consolidated in a single list.

1. When the PTO begins to develop a rule, the PTO must file with OMB to put the rule on the “Regulatory Agenda.”²⁷
2. In the process of developing a rule, before publication in a Notice of Proposed Rulemaking, the PTO must “consult with members of the public”²⁸ to evaluate the following:²⁹
 - (i) whether the proposed collection of information is necessary for the proper performance of the functions of the agency;
 - (ii) the accuracy of the agency’s estimate of the burden;
 - (iii) how to enhance the quality, utility, and clarity of the information to be collected; and
 - (iv) minimize the burden of the collection of information on those who are to respond.
3. The PTO may publish an “advance notice of proposed rulemaking,” either to request information to develop the rule, or to float a preproposal trial balloon. ANPRM’s are not provided by statute, and do not advance any of the PTO’s statutory rule making obligations, but an ANPRM can be a useful opportunity

²⁷ 5 U.S.C. § 602(a); Executive Order 12,866 (as amended), § 4(b). For an example, see Department of Commerce, Spring 2009 Semiannual Agenda of Regulations, 74 Fed. Reg. 21887–914 (May 11, 2009).

²⁸ The requirement to “consult with members of the public” before a Notice of Proposed Rule Making (NPRM) is not literally in the text of the statute, but arises out of the interdependencies between required steps, and the practical reality that the PTO has no internal sources of objective compliance cost information, and can only obtain objective cost information by conferring with the public. For information collection requests contained in a proposed rule, 44 U.S.C. § 3507(d)(1)(A), 5 C.F.R. § 1320.5(a)(3) and § 1320.11(b) require that an agency submit an ICR to OMB “as soon as practicable, but no later than the date of publication of a notice of proposed rulemaking in the Federal Register.” An agency also is required, by 44 U.S.C. § 3507(a)(1)(D)(ii)(V) and 5 C.F.R. § 1320.5(a)(iv), to publish a notice in the Federal Register “setting forth ... an estimate of the burden that shall result from the collection of information.” § 3506(c)(1)(A)(iv) and § 1320.8(a)(4) require that any burden estimate submitted to the OMB Director, including those under § 3507(d)(1)(A), be “objectively supported.” For the types of burden in most PTO rule makings—*i.e.*, new requirements for content or form of papers—the only practical source of “objective support” for burden estimates is “conferring” with attorneys who do similar work. This set of critical path events requires consultation with the public sufficiently before the Notice of Proposed Rule Making to permit “objectively supported estimates” to be included with and supported in the NPRM and in submissions to OMB under the Paperwork Reduction Act.

²⁹ 44 U.S.C. § 3506(c)(2) and 5 C.F.R. § 1320.8(d)(1).

for the PTO to collect some of the information and feedback it needs for later steps.

4. If the rule is “economically significant” under Executive Order 12,866,³⁰ then the PTO must prepare a Regulatory Impact Analysis under OMB Circular A-4 before the PTO publishes a Notice of Proposed Rulemaking.³¹
5. Any rule³² that imposes or modifies any “information collection” burden on the public must be submitted to the Director of OMB, with “objectively supported” estimates, no later than the time of a Notice of Proposed Rulemaking.³³ As part of this submission, the PTO must certify or demonstrate (depending on the setting), and provide a record in support of the certification,³⁴ that:
 - (a) the information to be collected “is necessary for the proper performance of the functions of the agency”;³⁵

³⁰ Executive Order 12,866 § 3(f) defines “significant regulatory action” as any rule making that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive order.

³¹ Executive Order 12,866 is available at http://www.whitehouse.gov/omb/foreg/EO12866/index_eo12866.html. Circular A-4 is at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>.

³² Whether that rule is published in the Code of Federal Regulations, a guidance document, or some other document.

³³ Reading 44 U.S.C. § 3507(d)(1) and § 3506(c)(2)(A) together. Strikingly, several of the PTO’s Notices of Proposed or Final Rule Making in 2006–2008 stated that the PTO refused to make a Paperwork filing with OMB, for reasons that have no grounding in any statute or regulation.

³⁴ 44 U.S.C. § 3506(c)(3) and 5 C.F.R. § 1320.9.

³⁵ 44 U.S.C. § 3506(c)(3)(A) and 5 C.F.R. § 1320.5(d)(1)(i) (“ To obtain OMB approval of a collection of information, an agency shall demonstrate that it has taken every reasonable step to ensure that the proposed collection of information: (i) Is the least burdensome necessary for the proper performance of the agency’s functions...”).

- (b) the agency is not seeking “unnecessarily duplicative” collection of “information otherwise reasonably accessible to the agency”;³⁶
 - (c) the agency “has taken every reasonable step to ensure that the proposed collection of information ... is the least burdensome necessary”;³⁷ and
 - (d) the regulations are “written using plain, coherent, and unambiguous terminology.”³⁸
6. If a rule making may mature into a rule that may result in expenditure (direct costs minus direct savings) by state, local, or tribal governments or the private sector of \$100 million per year,³⁹ then the PTO must prepare an unfunded mandates analysis, before publishing a Notice of Proposed Rulemaking.⁴⁰
- (a) the PTO must “identify and consider a reasonable number of regulatory alternatives and from those alternatives select the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule”;⁴¹
 - (b) The PTO must “develop an effective process to permit elected officers of State, local, and tribal governments (or their designated employees with authority to act on their behalf) to provide meaningful and timely input in the development of regulatory proposals.”⁴² This would appear to require the PTO to consult with at least the major state research universities (the Universities of California, Michigan, Wisconsin, and Washington) before promulgating any economically significant rule.
 - (c) No later than a Notice of Proposed Rulemaking, the PTO must prepare a written statement containing “a qualitative and quantitative assessment of the anticipated costs and benefits,” estimates of compliance costs, estimates of the effect on the national economy, and summaries of comments received from state, local, and tribal governments.⁴³

³⁶ 44 U.S.C. § 3506(c)(3)(B) and 5 C.F.R. § 1320.5(d)(1)(ii).

³⁷ 44 U.S.C. § 3506(c)(2)(A)(iv) and 5 C.F.R. § 1320.5(d)(1)(i).

³⁸ 44 U.S.C. § 3506(c)(3)(D) and 5 C.F.R. § 1320.9(d).

³⁹ Adjusted for inflation, relative to 1995.

⁴⁰ The core of the Unfunded Mandates Reform Act as applicable to agency rule making is at 2 U.S.C. §§ 1511 and 1531–1538. Judicial review is provided by 2 U.S.C. § 1571.

⁴¹ 2 U.S.C. § 1535(a).

⁴² 2 U.S.C. § 1534(a).

⁴³ 2 U.S.C. § 1532.

7. The PTO should “seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation.”⁴⁴ This is separate from notice and comment, and must occur before a Notice of Proposed Rulemaking is published.
8. A Notice of Proposed Rulemaking or Request for Comment is required when:
 - (a) the rule does not meet any of the exemptions set forth in § 553(b)(3)(A) or (B) (“interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice”); or
 - (b) the rule arises under a grant of statutory rule making authority that has a separate requirement for notice and comment, for example 35 U.S.C. § 2(b)(2);⁴⁵ or
 - (c) the rule adds any burden cognizable under the Paperwork Reduction Act, or modifies any “collection of information” *whether or not* the “collection of information” is embodied in a regulation;⁴⁶ or
 - (d) an amendment reverses or repeals any previous rule;⁴⁷ or
 - (e) if the rule is promulgated by publication in a guidance document such as the MPEP, and meets tests for “economically significant” guidance under the President’s *Final Bulletin for Agency Good Guidance Practices*,⁴⁸ then the rule requires notice and comment.

⁴⁴ Executive Order 12,866 § 6(a).

⁴⁵ *Tafas v. Dudas*, 541 F.Supp.2d 805, 812, 86 USPQ2d 1623, 1628 (E.D. Va. 2008) (“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”), *district court decision reinstated sub nom. Tafas v. Kappos*, 586 F.3d 1369, 1371, 92 USPQ2d 1693, 1694 (Fed. Cir. 2009).

⁴⁶ 5 C.F.R. § 1320.11 covers rules in notices of proposed rulemaking, § 1320.12 covers final rules, and § 1320.10 covers collections of information other than those in proposed or final rules.

⁴⁷ This is the law in the D.C. and Fifth Circuits. *Alaska Professional Hunters Assn. v. Federal Aviation Admin.*, 177 F.3d 1030, 1033–34 (D.C. Cir. 1999) (“Once an agency gives its regulation an interpretation, it can only change that interpretation as it would formally modify the regulation itself: through the process of notice and comment rulemaking.”); *Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 629 (5th Cir. 2001).

⁴⁸ Executive Office of the President, Office of Management and Budget, *Final Bulletin for Agency Good Guidance Practices*, § IV, OMB Memorandum M-07-07, <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf> (Jan. 18, 2007), 72 Fed. Reg. 3432 (Jan. 25, 2007).

If a Notice of Proposed Rulemaking is required, then the following requirements apply:

- (w) the Notice must be accompanied by disclosure of the PTO's assumptions, factual data and bases, and analyses;⁴⁹
- (x) the Notice must present (or be accompanied by) the PTO's burden estimates, and permit a 30- or 60-day comment period for the burden estimates under the Paperwork Reduction Act;⁵⁰
- (y) the Notice of Proposed Rulemaking must be accompanied by either a certification of "no substantial economic impact" on small entities or an Initial Regulatory Flexibility Analysis;⁵¹
- (z) because information disseminated in a Paperwork Reduction Act submission to OMB (step 5) or a Notice of Proposed Rulemaking (step 8)

⁴⁹ 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 [of OMB], agencies shall ensure that a publicly accessible Federal Government website contains electronic docket 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)]"); *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"); *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.'").

⁵⁰ 44 U.S.C. § 3506(c)(2)(B) and 5 C.F.R. § 1320.8(d)(1). Notice of the rule and the agency's estimates must be provided to OMB and published in the Federal Register no later than the Notice of Proposed Rulemaking or other notice of the rule, then the agency must allow 30 days for comments, and then OMB has up to 60 days to approve or disapprove. 5 C.F.R. § 1320.11(b), (c) and (h) (collections of information in proposed rules and final notices); 5 C.F.R. § 1320.12 (current rules); 5 C.F.R. § 1320.10(a) and (b) (collections of information not in proposed or final rules).

⁵¹ 5 U.S.C. §§ 603 and 605.

is “influential” information, the PTO must observe OMB Information Quality Guidelines and the PTO’s own Information Quality Guidelines.⁵²

9. The PTO must receive comments from the public and from OMB for the required amount of time (usually 30 days under the APA,⁵³ 60 days for any rule covered by the Paperwork Reduction Act,⁵⁴ 60 days under Executive Order 12,866, etc.)
10. If the PTO amends the rule sufficiently so that the amended rule is no longer a “logical outgrowth” of the rule as published for notice and comment, then the PTO must go back to step 8 for another round of notice and comment.
11. If the information collections of a rule are “substantially modified” at any time between the Notice of Proposed Rulemaking and publication as a final rule, the PTO must resubmit the rule to OMB for another pass at step 5, at least 60 days before publication of the final rule.⁵⁵
12. After the PTO has a rule largely in condition to be published as a final rule, if the rule is “significant” or “economically significant,” the PTO must submit the rule to OMB for a 90-day regulatory review under Executive Order 12,866.⁵⁶
13. The PTO must transmit the rule and all supporting documentation to Congress and the General Accounting Office for review under 5 U.S.C. § 801. If the rule is a “major rule,” the submission must occur at least 60 days before the PTO’s proposed effective date.⁵⁷

⁵² The Information Quality Act is embodied in Public Law 106-554 § 515, codified in notes to 44 U.S.C.A. §§ 3504 and 3516. The PTO bound itself to this statute in its Information Quality Guidelines, <http://www.uspto.gov/web/offices/ac/ido/ifoqualityguide.html>.

⁵³ 5 U.S.C. § 553(b) (“General notice of proposed rule making shall be published in the Federal Register,” except “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice” and other exceptions immaterial to the Patent Office);

⁵⁴ 44 U.S.C. § 3506(c), 5 U.S.C. § 553(c) (“agency shall give interested persons an opportunity to participate in the rule making”).

⁵⁵ 44 U.S.C. § 3507(d)(4)(D) and 5 C.F.R. § 1320.11(h)(2).

⁵⁶ Executive Order 12,866 § 6(b).

⁵⁷ 5 U.S.C. § 801–808.

14. On or before the date of publication of the Federal Register notice of a final rule:
- (a) the PTO must submit the rule to OMB for another round of review under the Paperwork Reduction Act, with a 30-day public comment period.⁵⁸ OMB must approve or disapprove the information collections embodied in the rule within 60 days of the submission.⁵⁹ A wise agency completes this step before publishing a final rule notice for a controversial rule.
 - (b) The PTO must certify “no substantial economic effect” on small entities or provide a Final Regulatory Flexibility Analysis.⁶⁰
15. All rules must be published in some form before the PTO may enforce.⁶¹
- (a) All rules of general applicability and legal effect must be published in the Code of Federal Regulations.⁶²
 - (b) Rules of procedure, substantive rules of general applicability, statements of the general course and method by which the agency’s functions are channeled and determined, statements of general policy or interpretations of general applicability, and each amendment, revision, or repeal of the foregoing must be published in the Federal Register.⁶³
 - (c) Interpretative rules (for which the agency is willing to forego any claim to “force of law” against the public) may be promulgated by publication elsewhere (e.g., in a guidance document), with a Federal Register notice informing the public of the publication.
 - (d) For non-interpretative rules, the PTO must give 30 days’ notice.⁶⁴
 - (e) An interpretative rule, or a legislative rule that “recognizes an exemption or relieves a restriction,” may take effect immediately on publication.⁶⁵

⁵⁸ 5 C.F.R. § 1320.11(h).

⁵⁹ 5 U.S.C. § 3507(b) and § 3507(d)(4).

⁶⁰ 5 U.S.C. §§ 604 and 605.

⁶¹ 5 U.S.C. § 552(a)(1)(D) (requires publication in the Federal Register of all “interpretations of general applicability”), 5 U.S.C. § 553(d)(1) (rules must be published, but interpretative rules are exempt from 30-day provision).

⁶² 44 U.S.C. § 1510, 1 C.F.R. § 8.1.

⁶³ 5 U.S.C. § 552(a)(1).

⁶⁴ 5 U.S.C. § 553(d).

⁶⁵ 5 U.S.C. § 553(d)(1) and (2).

16. In the Federal Register notice of a final rule:
 - (a) The PTO must explain its response to all comments from OMB or the public, and the reasons any comments were rejected;⁶⁶
 - (b) The final rule notice must include supporting explanation and factual data sufficient to satisfy *State Farm* criteria for “arbitrary and capricious.”⁶⁷
17. If the rule is promulgated through publication in guidance, such as the MPEP, then the PTO must follow the procedures set forth in the *Final Bulletin for Agency Good Guidance Practices*.⁶⁸ Because the MPEP is an “economically significant” guidance document, any amendment thereto must follow the higher level procedures in the *Good Guidance Bulletin*, including notice and comment, and inclusion on the PTO’s list of significant guidance documents.
18. The PTO must “periodically review its existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency’s regulatory program more effective.”⁶⁹

C. Costs that must be considered by the PTO in all filings under Executive Order 12,866, the Regulatory Flexibility Act, and the Paperwork Reduction Act

The PTO must include at least the following costs in consideration of any rule or regulatory action relating to restriction:

- Attorney fees. In the *Markush* IRFA, the PTO conceded that attorney fees for a divisional are typically over \$10,000. 73 Fed.Reg. at 12681 col. 3.
- Burdens on inventors or clients. Often, choosing among species requires deep analysis by the client.

⁶⁶ The requirements for fair or robust responses to comments arise under the Paperwork Reduction Act, 44 U.S.C. § 3507(a)(1)(B) and § 3507(d)(2)(A) and (B); 5 C.F.R. § 1320.5(a)(1)(ii) and § 1320.11(f); the Administrative Procedure Act (5 U.S.C. § 553); the Regulatory Flexibility Act, and the President’s *Final Bulletin for Agency Good Guidance Practices*.

⁶⁷ *Motor Vehicle Manufacturers’ Ass’n of the U.S. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 52 (1983).

⁶⁸ See footnote 48.

⁶⁹ Executive Order 12,866 § 5.

- Costs of analysis of information. The Paperwork Reduction Act requires that the PTO include the cost of **analyzing** any restriction requirement and *choosing* from among the groups.
- Additional bookkeeping costs. Dividing a patent into pieces creates many costs--accounting, transfer costs, etc.
- The loss of patent asset value, for example the value of patent protection lost when a claim must be divided and refiled at a filing date after the parent, therefore issuing long after the claims in the original application. This time to permit market entry will, in many cases, deprive an applicant of any meaningful patent protection.
- The economic value of lost patent term adjustment and extension for the claims of that must be moved to later-filed divisional applications.
- The value of patent protection abandoned because of divisionals not filed
- The cost of litigating divided patents. Often, it is not clear precisely what an accused competitors' product is, and which particular prong of which patent claim might be infringed, only that there is infringement of the generic claim. The PTO must consider the additional litigation cost that would be imposed by litigating *precisely* which divisional is infringed.

The CCPA expressly noted costs and economic effects that arise in any restriction, especially an intra-claim restriction:

As a general proposition, an applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification

In re Weber, 580 F.2d 455, 458, 198 USPQ 328, 331 (CCPA 1978) (emphasis in original). These costs must be accounted for in any Paperwork Reduction Act, Regulatory Flexibility Act, Executive Order 12,866, or Good Guidance filing.

D. The PTO's pattern of misrepresenting facts to tribunals by mischaracterizing public comments exposes individual PTO attorneys to ethical sanctions, up to and including disbarment

The ABA's Model Rule for Professional Conduct 3.3 reads as follows:

Rule 3.3 Candor Toward The Tribunal

(a) A lawyer shall not knowingly:

(1) make a false statement of fact or law to a tribunal or fail to correct a false statement of material fact or law previously made to the tribunal by the lawyer;

(2) fail to disclose to the tribunal legal authority in the controlling jurisdiction known to the lawyer to be directly adverse to the position of the client and not disclosed by opposing counsel; or

(3) offer evidence that the lawyer knows to be false. If a lawyer, the lawyer's client, or a witness called by the lawyer, has offered material evidence and the lawyer comes to know of its falsity, the lawyer shall take reasonable remedial measures, including, if necessary, disclosure to the tribunal. A lawyer may refuse to offer evidence, other than the testimony of a defendant in a criminal matter, that the lawyer reasonably believes is false.

(b) A lawyer who represents a client in an adjudicative proceeding and who knows that a person intends to engage, is engaging or has engaged in criminal or fraudulent conduct related to the proceeding shall take reasonable remedial measures, including, if necessary, disclosure to the tribunal.

(c) The duties stated in paragraphs (a) and (b) continue to the conclusion of the proceeding, and apply even if compliance requires disclosure of information otherwise protected by Rule 1.6.

(d) In an *ex parte* proceeding, a lawyer shall inform the tribunal of all material facts known to the lawyer that will enable the tribunal to make an informed decision, whether or not the facts are adverse.

A response-to-comments document is submitted to at least three *ex parte* tribunals, the Office of Management and Budget during review under Executive Order 12,866 (no part of the agency's submission is made available to the public until publication of the final rule), the Office of Management and Budget during review under the Paperwork Reduction Act (for example, the December 2009 review of the 2004 Appeal Rule was not visible to the public at the OMB web site until the day after the conclusion of the review and issue of a final Notice of Action letter), and the Small Business Administration under the Regulatory Flexibility Act. The PTO's response to

comments is also evidence submitted to an Article III court in the event of any Administrative Procedure Act review.

Thus, PTO attorneys who respond to comments have two duties. First, the attorneys are individually accountable for ensuring that the PTO's response to comments documents fairly represent facts, including public comments, in the record that it provides to these tribunals. Second, pursuant to Rule 3.3(d), facts may not be omitted or hidden through the device of creative characterization.

I have received communications from multiple past and current PTO employees involved in the response to comments process. I have been told that internal PTO reviewers have reported remarkable differences between the public's submitted comments and the characterization of the comment in an under-review draft response to comment document. The issue was squarely brought to the attention of higher-ups. The mischaracterization persisted and was reflected in a final submission to a tribunal.

It is difficult to avoid an inference that the PTO has a historical pattern of making intentional false statements of fact (the content of public comment letters) to tribunals, apparently with the knowledge and sign-off of senior legal staff. Every individual lawyer involved in PTO rule making should be made aware of Rule 3.3, and informed that omission and misrepresentation must stop. If this Request for Comment matures into a rule, that rule must be cleared through OMB and SBA Advocacy, and that clearance will require a fair and accurate statement of the facts—the public comments—to the regulatory review tribunals.

IV. Question 2: More effective review

The Notice asks for comments on how review could be made more effective.

A. Current Petitions practice is terribly broken

The current Petitions process does not work (at least not in 2100 and 3600, and in the Office of Petitions and decisions signed personally by Mr. Bahr), and needs substantial reforms. This might be a good opportunity to implement those reforms.

Because T.C. Directors have a direct financial stake in maintaining production, they have a direct stake in denying petitions that seek enforcement of the PTO's procedural rules. That delegation of authority is constitutionally suspect.⁷⁰ Also, very few T.C. Directors and very few SPRE's have sufficient legal training to decide the legal issues that arise in petitions, let alone to be able to do so fairly.

In particular, any petition relating to allocation of burden between the PTO and an applicant (restriction, duties of an examiner under compact prosecution, etc.) are somewhere between difficult and impossible, because petitions decision-makers so rarely honor precedent, the precise framing of issues in a petition, and the facts. T.C. Directors and the Office of Petitions (including decisions signed by Acting Associate Commissioner Robert Bahr) **adamantly** refuse to enforce the PTO's rules relating to compact prosecution.⁷¹ The practical effect is that examiners are permitted to do **anything**, and will be rewarded with full examination counts, as long as the action is denominated a "rejection,"⁷² and limits on restriction are enforced only at the personal

⁷⁰ *Concrete Pipe and Products of California Inc. v. Construction Laborers Pension Trust for Southern California*, 508 U.S. 602, 617–18 (1993), citing *Marshall v. Jerrico, Inc.*, 446 U.S. 238, 242, and n. 2 (1980), *Ward v. Village of Monroeville*, 409 U.S. 57, 61-62 (1972), *Tumey v. Ohio*, 273 U.S. 510, 522 (1927).

⁷¹ 09/385,394, Decision of Jun 21, 2010.

⁷² The Board has persistently noted that it cannot adjudicate when the examiner's analysis is incompletely set forth in the written record. *E.g.*, *Ex parte Daleiden*, Appeal 2007-1003, <http://des.uspto.gov/Foia/RetrievePdf?system=BPAl&filNm=fd2007100303-14-2007> at 2, 2007 WL 774805 at 1 (BPAl Mar. 14, 2007) (nonprecedential) (remanding because examiner failed to respond to arguments in the Appeal Brief); *Ex parte Domei*, Appeal No. 2001-2358, App. 09/454,723, <http://www.uspto.gov/go/dcom/bpai/decisions/rm012358.pdf> at 5-6 (BPAl Feb. 7, 2002) (nonprecedential) ("Without a fact-based explanation from the

whim of petitions decision makers. Inconvenient precedent matters nothing in the Office of Petitions;⁷³ it is brushed aside without comment.

If petitions relating to enforcement of PTO guidance and 37 C.F.R. rules were moved from T.C. Directors to the Good Guidance Officer (see § V.E at page 40 of this letter), and the Good Guidance Officer were given independence from line management and were charged with enforcing the full spectrum of the PTO's administrative law and procedural obligations to applicants, many of the PTO's backlog, customer satisfaction, and other problems could be resolved.

examiner as to why appellants' arguments and evidence are insufficient ... this merits panel is not in a position to evaluate the ultimate propriety of the examiner's rejection. The Board serves as a board of review, and does not perform examination in the first instance. See 35 U.S.C. § 1.6(b);" remanding with an order to the examiner to examine, but without MPEP-class instructions to identify what that job is); *Ex parte Siefert*, Appeal No. 2001-1995, <http://des.uspto.gov/.../filNm=fd011995> at 5, 2003 WL 25277985 at *2 (BPAI Jun. 24, 2003) (nonprecedential) (examiner's inadequate action is "not ripe" for review: "we have no choice but to VACATE ... due to the noted substantive and procedural improprieties to put the prosecution of this application back in a proper procedural posture"; examiner argument isn't substantial evidence); *Ex parte Borody*, Appeal No. 2002-1371, <http://des.uspto.gov/...&filNm=fd021371> at 3, 5, 2004 WL 77301 at *1, *3 (BPAI Feb. 27, 2003) (nonprecedential) (because "rejection ... is not based upon the correct legal standards ... we vacate.... In addition, there are a number of issues that need to be clarified by the examiner," with reminder to examiner to make findings supported by substantial evidence); *Ex parte Rozzi*, 63 USPQ2d 1196, 1200-03 (BPAI Jan. 16, 2002) (McKelvey, Senior APJ, nonprecedential) (when "the examiner makes no cogent attempt" to explain basis, Board remands without decision); *Ex parte Gambogi*, 62 USPQ2d 1209, 1212 (BPAI Dec. 10, 2001) (McKelvey, Senior APJ, nonprecedential) ("We decline to tell an examiner precisely how to set out a rejection."); *Ex parte Schricker*, 56 USPQ2d 1723, 1725 (BPAI Jun. 7, 2000) (nonprecedential) ("The examiner has left applicant and the board to guess as to the basis of the rejection ... We are not good at guessing; hence, we decline to guess."); *Ex parte Braeken*, 54 USPQ2d 1110, 1112-13 (BPAI Dec. 21, 1999) (McKelvey, Senior APJ) (nonprecedential) (noting that the appeal is "not ripe" because of omissions and defects in the examiner's analysis).

⁷³ *In re Oku*, 25 USPQ2d 1155, 1157 (Comm'r Pats. & TM 1992) (stating the issue is both appealable and also petitionable, because it "involves the important question of whether [a PTO employee] followed PTO regulations established by the Commissioner" and when the relief requested is solely within the jurisdiction of the Commissioner).

B. Examiners and Petitions decision makers should be required to consult with the Good Guidance Office on legal issues

The PTO should provide a cadre of lawyers with substantial administrative law experience to serve as consultants to PTO staff, and **require** that they be consulted.

Under today's practice, a lawyer that reads the regulations and MPEP and Supreme Court administrative law precedent, and asks the PTO to follow them, courts disaster and retaliation. Asking a PTO employee to observe procedural requirements creates a large risk of adding retaliatory delays, not advancement of prosecution. When an examiner or petitions decision-maker:

- rewrites the form paragraphs, leaving out the "hard parts" that require a showing⁷⁴
- invents new grounds of analysis for the statutory requirements, instead of using the step-by-step analysis of MPEP Chapter 2100⁷⁵
- fails to issue a corrected office action as provided by MPEP § 710.06⁷⁶
- fails to consider whether a rejection is premature or not, before jumping to the conclusion that an amendment must be denied entry because it raises new issues⁷⁷

then the SPE and T.C. Director should be the first line defenders of PTO procedure. All too often, SPE's, T.C. Directors and the Acting Associate Commission for

⁷⁴ In 3690, nearly 100% of requirements for election of species, and a solid majority of requirements for restriction, omit one or more of the showings required by MPEP Chapter 800. *E.g.*, 10/913,727 (Office paper of Jan. 2008 carves out "inconvenient" parts of the form paragraphs; omissions diagnosed in applicant's paper of May 2008; examiner's paper of September 2008 still omits use of one of form paragraph 8.21.01-8.21.03)

⁷⁵ See, e.g., 09/611,548, Office Actions of Nov. 1, 2006 – a § 101 rejection with *no resemblance whatsoever* to MPEP § 2106, the statutory text, or the case law.

⁷⁶ See 09/672,841, July 2007 through September 2009 – when the applicant attempted to avail himself of the provisions of MPEP § 710.06, T.C. Director Jack Harvey forced the application into abandonment, affirmatively stating his refusal to follow the PTO's instructions in MPEP § 710.06.

⁷⁷ 10/113,841, April-October 2009 (examiner insists on entitlement to a "disposal" count even though the examiner concedes (by silence) that examination of the application was incomplete, the examiner refuses to consider issues of premature final rejection, and the examiner refuses to answer all material traversed); 11/608,303 (same).

Examination Policy refuse to do so. When I ask an examiner/SPE/T.C. Director/attorney in Office of Patent Legal Administration to refer to a provision of statute, 37 C.F.R., or the MPEP that purports to govern PTO conduct, far too often the answer is one of the following:

- There's an exception that applies to this specific situation—the exception exists in no written document, but the examiner/SPE/T.C. Director/OPLA insists that the PTO is excused from the written requirement in this one case.⁷⁸
- The issue is simply ignored—the next PTO paper is written as if the issue was never raised, and often the same error is repeated.
- “I’ve been here in the Office 15 years, no one has ever brought that to my attention before, I’ve never done it before, I’m not going to do it now”
- Federal Circuit and PTO precedent for definitions of terms like “new ground of rejection,” “appealable subject matter,” “moot” and the like need not even be consulted, let alone followed—if the T.C. Director disagrees with the Federal Circuit, the T.C. Director refuses to follow the Federal Circuit’s interpretation of the law.⁷⁹
- SPE’s and T.C. Directors affirmatively state that they will not enforce procedural law (whether PTO procedures, the Administrative Procedure Act and similar statutes originating outside the PTO)⁸⁰

⁷⁸ *E.g.*, 10/938,413, Petition of Nov. 17, 2009 at 11 (Robert Clarke, then head of Office of Patent Legal Administration, made up an excuse out of thin air, with no support or justification in any written document, for the PTO’s non-compliance with a statutory obligation); 09/385,394, Decision of Robert Bahr of June 21, 2010 (the MPEP has force of law against applicants); *id.* at 13 (Mr. Bahr states that an application that has 133 claims and in which 239 references were cited is exempt from PTO rules against premature final rejection); *id.* at 13 (Mr. Bahr exempts such applications from requirements for compact prosecution and 37 C.F.R. § 1.104(c)(2) (“the non-final Office action and the final Office action were **not** required to particularly point out where every claim limitation is met by the references.”)).

⁷⁹ See footnote 82.

⁸⁰ *E.g.*, 09/239,194, Summary of Interview with SPE (filed July 25, 2005) (“This attorney asked for supervisory intervention regarding the procedural issue of premature final rejection. [The SPE] stated that she did not consider [procedural] issues, that she only considered the merits”). The SPE did not explain how the PTO could make accurate or fair determinations on the merits if it refuses to enforce its procedures.

- Robert Bahr states that he will not decide the issue as presented, because he considers the issue as framed “creative.” Rather, he recharacterizes the issue as he sees fit, then he decides *his* issue. Mr. Bahr takes no note of Supreme Court precedent or directives from the Executive Office of the President that draw a bright line that Mr. Bahr wishes to blur, or that the PTO’s issued decisions go an applicant’s direction, Mr. Bahr relies on his personal opinion to trump them all.⁸¹

Many of the SPE’s and T.C. Directors that I interact with do not have the habit of mind to find out what the law is, to read the relevant rule, case, etc. or to apply the law they find there. In one telephone call, T.C. Director Jack Harvey stated in so many words that he refused to even read the PTO’s and courts’ precedent on an issue of procedure. Even after being told that the conversation was being taped, T.C. Director Harvey insisted that he would not look up the law or attempt to follow it; he would act on his own whim and leave it to the applicant to petition on up the chain.⁸² In a written decision, he stated that he would ignore precedent on the definition of the term “new ground of rejection” simply because “it cannot be seen” why the court held as it did.⁸³ When T.C. Directors and the Petitions Office adjudicate according to their personal whims, based on rules that exist nowhere in writing, and refuse to follow the written law, and recharacterize petitioned issues instead of deciding the precise issues presented, then interactions between the PTO and applicants can only be unpredictable, inefficient, and illegal.⁸⁴

⁸¹ 09/385,394, Robert Bahr, Decision of Jun. 21, 2010, at pages 13-14.

⁸² 09/385,394, Summary of Interview of 10/30/2005 (filed Dec. 1, 2005), at page 3, (T.C. Director Harvey states that he believes it would not be “helpful” for him to look at “the Board cases and CCPA cases on defining ‘new ground of rejection’”).

⁸³ 09/385,394, Decision of Nov. 8, 2005, at page 5, lines 15-17 (T.C. Director Harvey quotes back the CCPA’s own language from *In re Wiechert* and *In re Kronig*, and states that it will not be applied, simply because “it cannot be seen” why the court ruled as it did).

⁸⁴ T.C. Director Harvey has established an extensive record of retaliation against applicants that petition for enforcement of PTO procedure. I invite Director Kappos to telephone so that we can develop a case study in how the Petitions process fails, so that reforms can be designed and implemented.

V. Question 6: other issues

A. Examiners should be given counts commensurate with the complexity of the applications they examine

Restriction is not a solution to complexity or efficiency—indeed, as I noted in the opening paragraphs of this letter, restriction *creates* complexity and inefficiency. Rather, the problem is the count system, that gives examiners the same number of counts for each application, without regard for complexity. If examiners and work units were given an appropriate number of counts, then complex applications would not be considered a burden. The “problem” that Question 1 purports to address is not a problem; the problem is with the PTO’s internal accounting system.

POPA has acknowledged that the “flat rate” count system creates perverse incentives to misexamine the most complex (and therefore most likely to be most economically important) applications:⁸⁵

Applicants pay substantial fees for excess claims, large specifications and information disclosure statements. Examiners must be given time proportional to these fees to ensure that applicants will get what they have paid for.

Everyone knows this is the problem—why does the PTO keep trying to tamper with everything except fixing the root problem?

I analyzed this issue carefully in a submission to the White House Office of Management and Budget in June 2007. That analysis is available at the [whitehouse.gov](http://www.whitehouse.gov) web link in this footnote,⁸⁶ and I personally handed copies to John Love and Jennifer McDowell, so they should be aware of the ideas there. and the PTO would do well to read it and consider the proposals set forth there.

⁸⁵ Testimony of Ron Stern, Hearing Before the Subcommittee on Courts, the Internet, and Intellectual Property of the Committee on the Judiciary, House of Representatives, 109th Cong. 1st Sess. Sept. 8, 2005, Serial No. 109-48, at page 149.

⁸⁶ http://www.whitehouse.gov/omb/oir/0651_meetings_619, especially <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/oir/0651/meetings/619-3.pdf> at Attachment F

B. Rule 145 should be amended to clarify that restrictions beyond the statute are not authorized

35 U.S.C. § 121 only permits “divisional applications” (that is, a division into two or more daughters) when “two or more ... inventions are claimed” (present tense) in one application. Section 121 does not permit restriction between pending and cancelled claims. 37 C.F.R. § 1.145 should be amended to eliminate the ambiguity and clearly state the intent of the rule, without ambiguity that can be interpreted overbroadly:

§ 1.145 Subsequent addition of claims for a different invention in an application filed under 35 U.S.C. 111(a).

If, after an Office action on the merits, the applicant adds by amendment one or more claims directed to an invention distinct from and independent of the invention previously examined, and the previously-examined claims remain pending, the applicant may be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in §§ 1.143, 1.144 and 1.181. Any requirement for restriction requires showings that the invention added by amendment is independent of and distinct from the examined invention, and creates serious burden of search.

The current unauthorized practice leads to significant satellite petition practice, and loss of patent term.

C. MPEP Chapter 800, particularly § 802.01, Misstates the Law, and Should be Corrected

35 U.S.C. § 121 permits the PTO to restrict claims if the claims are “independent and distinct.” However, MPEP Chapter 800 permits restriction if two inventions are independent or distinct. Chapter 800 should be redrafted to conform PTO policy to statute.

D. The PTO has no Paperwork Reduction Act clearance for any aspect of restriction practice

The PTO has never included replies to restriction requirements in any Paperwork inventory or Information Collection Request submission. As of today, no

restriction requirement issued by the PTO is enforceable—applicants can reply to every restriction requirement as provided by 44 U.S.C. § 3512 and 5 C.F.R. § 1320.6.

I'm sure that several of my petitions have reached OPLA and the Office of the Associate Commissioner for Examination Policy, yet these offices have taken no action. Apparently these two Offices have no regard for following the law for its own sake. The Office's failure to seek Paperwork clearance is fine, so long as the Acting Associate Commissioner informs all PTO personnel of the Public Protection provisions of the Paperwork Reduction Act, and lets them know that any applicant that invokes it is entitled to the complete withdrawal of all restriction requirements.

E. The Executive Office of the President directed the PTO to take certain steps 2½ years ago; the PTO has not done so, and should follow the President's instructions now

The Executive Office of the President directed the PTO to appoint a "Good Guidance" officer in the *Final Bulletin for Agency Good Guidance Practices*, a directive issued by the Executive Office of the President in January 2007.⁸⁷

Inexplicably, the PTO has never implemented the President's instructions. The required information is not on the PTO's web site. In telephone interviews with examiners, SPE's, and T.C. Directors, it is clear that the PTO has not conducted the training in basic administrative law concepts that the President directed the PTO to give its employees.

In particular, three provisions of the *Good Guidance Bulletin* would provide a great deal more predictability in restriction practice:

- When the MPEP uses mandatory language with respect to the PTO or a PTO employee, that language is binding against the PTO or employee, and the employee needs supervisory pre-clearance (probably from a Technology

⁸⁷ 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> (Jan. 18, 2007), 72 Fed. Reg. 3432 (Jan. 25, 2007). The *Good Guidance Bulletin* has force vis-à-vis the PTO equivalent to a numbered Executive Order.

Center Director or above), to depart.⁸⁸ When a 37 C.F.R. Rule uses mandatory language, the PTO has *no discretion whatsoever* to depart *ever*—if the PTO wishes to change a 37 C.F.R. rule or create an exception, it can only do so after full rule making procedure.⁸⁹

- Documents (or examiner opinions) that have not been promulgated with full statutory authority or rule making procedure are not binding against applicants, and must not be enforced as if they had force of law.⁹⁰
- The PTO is required to appoint a Good Guidance officer, and to make contact information available on the PTO’s web site.⁹¹ Among other duties, the Good Guidance Officer is required to enforce the two previous bullet points.

Appointment of a Good Guidance Officer is not optional—the PTO must comply with the President’s instructions in any event, and one hopes that 3 years of delay is enough. Once the PTO has complied with the President’s instructions, that Good Guidance officer would be responsible for resolving many of the issues that arise in prosecution. Perhaps Good Guidance officer responsibilities should be added to the scope of responsibilities of the ombudsmen created earlier this year, but that would require adding substantial executive authority to the role of ombudsman, rather than the current power to cajole.

⁸⁸ *Good Guidance Practices* § II(1)(b), [.../m07-07.pdf](#) at page 20; 72 Fed. Reg. 3440 col. 1 (“Agency employees should not depart from significant guidance documents without appropriate justification and supervisory concurrence”); *Service v. Dulles*, 354 U.S. 363, 374–76 (1957) (agency departure from procedural protections in an unpublished Manual of Regulations and Procedures was illegal).

⁸⁹ *Berkovitz v. United States*, 486 U.S. 531, 544 (1988) (“The agency has no discretion to deviate” from the procedure mandated by its regulatory scheme.); *Reuters v. Federal Communications Comm’n*, 781 F.2d 946, 950 (D.C. Cir. 1986) (“It is elementary that an agency must adhere to its own rules and regulations. *Ad hoc* departures from those rules, even to achieve laudable aims, cannot be sanctioned”).

⁹⁰ 5 U.S.C. § 553; *Tafas v. Dudas*, 541 F.Supp.2d 805, 812, 86 USPQ2d 1623, 1628 (E.D. Va. 2008) (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”), *district court reinstated sub nom. Tafas v. Kappos*, App. No. 2008-1352, ___ F.3d ___, __ USPQ2d ___ (Fed. Cir. Nov. 13, 2009).

⁹¹ *Good Guidance Practices* § III(2)(b), [.../m07-07.pdf](#) at page 21; 72 Fed. Reg. 3440 col. 2.

VI. Conclusion

Thank you for the opportunity to comment.

Sincerely,

/s/ David E. Boundy

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.: 10/147,218 Confirmation No.: 8753
Petitioner: Asif Khalfan
Title: AUTO-SECURITY MONITOR THAT MAKES MARKETS
Filed: May 14, 2002
Art Unit: 3694
Examiner: Mary Cheung

Atty. Docket: 01-1048
Customer No. 63710

**PETITION TO IMPLEMENT INSTRUCTIONS FROM THE PRESIDENT, AND
TO VACATE AN ILLEGALLY-ISSUED MEMORANDUM OF JOHN LOVE OF APRIL
2007, TO VACATE EXAMINER'S PAPERS OF APRIL 2008, AUGUST 2008, AND
APRIL 2009 BASED THEREON, AND TO VACATE ABANDONMENT,
OR IN THE ALTERNATIVE, TO REVIVE UNINTENTIONALLY ABANDONED
APPLICATION¹**

Mail Stop T.C. Director 3600
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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

Pursuant to 37 C.F.R. § 1.181(a)(1) and (3), Petitioner petitions that the Director exercise his supervisory authority as follows:

- An April 25, 2007 memorandum from John Love to the examining corps regarding restriction practice should be vacated, because the PTO violated at least two dozen laws, listed in summary form in § I at page 5 and in Exhibit B of this Petition. This portion of the Petition arises under 5 U.S.C. § 553(c)(3)(a) ("Any person subject to a rule, interpretive rule, ... or guidance may petition an agency for the amendment or repeal of any rule,

¹ Because the subject matter of this petition is partially directed to subject matter normally delegated to T.C. Directors and partially to subject matter normally decided in the Office of Petitions, this paper is being filed in duplicate, one to each office.

interpretive rule,... or guidance.”), and the authority of the PTO to “establish regulations” but only those regulations “not inconsistent with law,” 35 U.S.C. § 2(b)(2), and 37 C.F.R. § 1.181(a)(3).

- The examiner's Notice of Abandonment of April 27, 2009 and underlying papers of August 13, 2008 and April 14, 2008 should be vacated because they rely on the Love memo, and therefore were void when issued.
- Even if the Love memo is valid, the examiner's Notice of Abandonment of April 27, 2009 and underlying papers of August 13, 2008 and April 14, 2008 should be vacated because the examiner impermissibly deviated from the MPEP and other PTO directives.
- In the alternative, Petitioner requests revival of an unintentionally abandoned application.
- The PTO should implement instructions issued by the President of the United States to agencies. This is now two years overdue.

There are two striking things about this petition. First, it shows that *senior PTO officials brazenly ignored the law*, even after the requirements of law were brought to their attention. Surprisingly, the officials involved are three of the PTO's senior-most officials responsible for compliance with the law: the former Deputy Commissioner for Examination Policy, the former head of the Office of Patent Legal Administration, the person formerly directly responsible for the PTO's compliance with the Paperwork Reduction Act, and (apparently) the member of the Office of General Counsel directly involved in PTO rule making. Second, it shows that *the PTO broke over two dozen laws*, suggesting that the PTO's legal apparatus needs systemic reform. For these reasons, Petitioner suggests that some level of personal involvement by Director Kappos is appropriate. Director Kappos should be made aware that the performance of the PTO's senior legal staff is at best suspect.

Petitioner suggests that delegation to a T.C. Director pursuant to MPEP § 1002.02(c) ¶ (3)(b) is not likely to be within the PTO's statutory obligation to “within a reasonable time... proceed to conclude a matter presented to it” under § 555(b). Petitioner also suggests that individuals whose conduct is implicated should not be involved in the adjudication of this Petition. See Exhibit C and Exhibit D.

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I. Introduction: issues presented, summary of argument, and relief requested

In April 2007, John Love (the former Deputy Commissioner for Patent Examination Policy) issued a memorandum to the examining corps, titled "Changes to restriction form paragraphs," attached as Exhibit A. This memo fundamentally restructures restriction under 35 U.S.C. § 121: under current law, an examiner must make several specific fact-based showings to show "serious burden of search," but the Love memo encourages an examiner to give an undifferentiated laundry list of possible grounds (some of which have nothing to do with search burden), without specifically identifying which one applies, and without identifying facts that might support any requirement.

The PTO withheld the Love memo from any public view for almost two years and never ran the Love memo through rule making procedures, yet examiners applied it as if it were "law."

Any rule promulgated by the PTO "must conform with any procedural requirements imposed by Congress. For agency discretion is limited ... by the procedural requirements which assure fairness and mature consideration of rules of general application."² The Love memo, and the procedures by which it was implemented, violate a number of procedural requirements imposed by Congress and the President:

- The PTO was required to obtain clearance from the White House Office of Management and Budget (OMB) under the Paperwork Reduction Act. After diligent research of OMB's files, and email queries to the two people at the PTO most likely to know, it now seems clear that the PTO never even *sought*, let alone obtained, Paperwork clearance for the Love memo. Further, in spring 2008, OMB retroactively withdrew all Paperwork clearances back to late 2005, thus withdrawing any clearance conceivably covering the Love memo. Without the required clearance, the Love memo is unenforceable. This is discussed in detail at § III.B of this Petition, starting at page 13.
- The Administrative Procedure Act (5 U.S.C. § 552(a)(1) and (2)) and several other laws require that rules such as the Love memo be published and indexed, and that a notice be published in the Federal Register. There was no timely publication, indexing or notice, and no one involved with this application had timely notice. Pursuant to § 552 and other laws, the Love memo must be retracted until the PTO observes required procedures, and the PTO may not "adversely affect" Petitioner until the PTO does so. See § III.D.1 and III.D.2 starting at page 19.
- The Administrative Procedure Act, § 552(a)(1), requires that agencies "may not in any manner [require a person] to resort to, or [] adversely affect[] [the person] by" an agency

² *Chrysler Corp. v. Brown*, 441 U.S. 281, 303 (1979) (quotations omitted).

staff manual, unless certain preconditions are met. The PTO has not observed those preconditions with respect to the Love memo. See § III.D.4 starting at page 25.

- The President issued instructions to all agencies in Executive Order 13,422 and in the *Final Bulletin for Agency Good Guidance Practices*, a bulletin that has force against agencies equivalent to a numbered Executive Order. These two Presidential directives require:
 - Agencies may not bind the public through guidance. If the PTO wishes to bind the public, it must do so using statutory rule making, not informal guidance. The Love memo violates this principle. See § III.C.1 starting at page 16.
 - Agencies must submit documents in the nature of the Love memo to OMB for approval. There is no indication on PTO's or OMB's web site that the PTO ever did so. See § III.C.4 at page 18
 - Guidance documents of the nature of the Love memo must be put up for notice and comment, if published after July 2007. Since the memo was not published or made "publicly available on the {PTO's} website" until after this effective date, the *Good Guidance Bulletin* applies, and notice and comment was required. Because there was no notice and comment, the Love memo is not validly promulgated. See § III.C.2 at page 17.
 - Guidance documents in the nature of the Love memo must be made available on the PTO's web site, with certain annotation information, and guidance documents obsoleted by the Love memo were also required to be noted on the PTO's web site. The PTO did not make the Love memo available to the public in *any* form any earlier than the last week of March 2009, and *still* has not provided the required annotation information. See § III.C.3 at page 17.
- The Love memo is an invalid attempt at retroactive rule making in excess of authority delegated to the PTO. See § III.E at page 27.
- The PTO informs the public of the scope of authority delegated to the examiner by the MPEP. Therefore under the same law of principal and agent vis-à-vis third parties that would apply in any other context, when a principal communicates the scope of authority delegated to an agent to a third party, and the agent acts outside the manifested scope of delegation, then a third party that realizes this is entitled to reject the agent's action as not an action of the principal. Because the PTO never published the Love memo during the time that the events of this Petition were occurring, attorneys for petitioner would have been in error in *not* assuming that the Examiner was acting outside the scope of delegation, and in *not* refusing to comply. As a principal that neglected to properly advise third parties of a delegation to an agent, the PTO must hold Petitioner harmless from the PTO's neglect. See § IV.C.1(a) at page 30.

The Love memo was never legally issued, and violates about two dozen laws, as summarized in Exhibit B. The memo itself, and all restriction requirements raised pursuant thereto, should be withdrawn. The PTO may, of course, re-promulgate the Love memo, but must start over at square one, fully complying with all laws applicable to rule making. Several of the laws noted above forbid the PTO from enforcing the Love memo until the requisite procedures are

completed. In the mean time, restriction practice as of this application's filing date—July 2004—applies.

In § IV starting at page 28, Petitioner requests that this application should be revived as if the Examiner's papers had never been mailed, for several reasons:

- The Love memo was illegal and invalid for over two dozen reasons summarized in Exhibit B, and any agency action thereunder is likewise illegal and invalid—thus all of the examiner's papers are void.
- Even if the PTO belatedly rehabilitates the Love memo by starting the rule making process over, the examiner's papers are void. The PTO has leave to reapply the Love memo after the rule making process is complete, but that will take a minimum of six months, and in the mean time, the PTO may not “adversely affect” applicant by declining to examine.
- Even if the Love memo was validly promulgated, the Examiner breached other legal requirements because he did not follow the provisions of the MPEP and the Love memo that bind examiners. Though neither the MPEP nor the Love memo create any obligations on applicants, both are unilaterally binding on the PTO—because the Examiner failed to observe the requirements set out in the Love memo and in pre-memo MPEP, his papers are simply void.
- The PTO would violate instructions from the President of the United States if the PTO excused the examiner's papers, or adhered to the examiner's positions.

For each of these reasons, the Examiners' restriction papers and the Notice of Abandonment were void when mailed. This application is not abandoned. Further, no valid requirement for election or restriction has been issued by the PTO, only unauthorized papers issued by an examiner who was acting on illegal instructions from the Deputy Commissioner. No requirement to elect was raised. This Petition merely requests that PAIR be updated to reflect those legal facts.

The Examiner should be instructed to commence examination,³ and to do so in conformance with the PTO's published guidance, imposing only those requirements for which the PTO has complied with all laws applicable to rule making.

In the alternative, and only if all grounds for vacating the examiner's papers are specifically ruled on and denied, Petitioner requests revival for unintentional abandonment.

³ The “Director shall cause an examination to be made of the application,” 35 U.S.C. § 131, in a manner consistent with all of the PTO's legal obligations.

In addition to all the above grounds, the Director should implement and ensure compliance with the President's instructions, as discussed in § VI starting at page 35. The PTO has been delinquent in implementing instructions from the President. The PTO has neglected to provide the "training" that the President instructed agencies to give their employees. PTO operations can be made remarkably more efficient if applicants and examiners know what to expect of each other, and the President's instructions require that the PTO establish these bilaterally-disclosed expectations. The Director should instruct the examining corps that unless a rule exists in written form in a document having force of law, the PTO acts illegally in imposing any requirement against applicants. The Director should instruct the examining corps that if a 37 C.F.R. regulation or Federal Circuit case states a rule binding the conduct of the PTO or defining a legal term that affects the scope of the PTO's duties, the PTO has no discretion whatsoever to depart. If the rule binding PTO conduct exists in the MPEP, then a PTO employee must seek pre-clearance to depart.

II. This Petition is timely

A. Several issues could not be presented earlier because of failures and untimely action by senior PTO officials; this Petition is filed within two months of the PTO's latest action

Section § III.B of this paper shows that senior officials of the PTO failed to comply with the law. Such charges should not be lightly made, and could not be responsibly made, until fully investigated. The PTO supplied the last fact required to establish the illegality of the PTO's conduct only in late September 2009, less than two months before filing of this petition.

As will be discussed further in § III.B of this paper, the PTO is obligated to make certain filings with the White House Office of Management and Budget pursuant to the Paperwork Reduction Act. This attorney obtained and diligently reviewed OMB's files for any evidence that such filings had been made, and found none. To confirm this absence and to conclusively "prove a negative," this attorney made several inquiries of numerous offices in the PTO, to identify whether and when required filings had ever been made. The PTO delayed its response to each inquiry, often over a month. After many delays and failures by the PTO to answer the precise issues relevant to the Paperwork Act, the PTO's last reply on September 24, 2009 (also in Exhibit C) confirmed that the sources this attorney had consulted were the correct and complete

files that should have been searched, and that indeed, the PTO had *never* made the required filings, let alone obtained approval. It was not until recently that Petitioner could confidently state that the PTO simply ignored the law.

Because this paper could not responsibly be filed until that investigation was complete, it should be considered timely.

B. Several issues arise under statutes that forbid the PTO from imposing any deadline; these statutes cannot be abrogated by PTO Rule

Several of the grounds set forth below assert rights arising under statutes or Presidential directives that may not be abrogated or limited by PTO rule. For example, the issue discussed in § III.B arises under the Paperwork Reduction Act, which expressly bars the PTO from imposing any deadline, 44 U.S.C. § 3512(c) (“The protection provided by [§ 3512] may be raised in the form of a complete defense, bar, or otherwise *at any time* during the agency administrative process”), and that the Act’s protections apply “notwithstanding any other provision of law.” Likewise, 5 U.S.C. § 552(a)(2) provides that “a person may not *in any manner* be ... adversely affected by ... [a] staff manual or instruction” issued without certain procedural requirements, requirements that the PTO never even attempted. The grounds raised in §§ III.B, III.D, III.E, and IV.C arise under law that is superior to any rule promulgated by the PTO. The PTO may not rely on any time limit in 37 C.F.R. to dismiss these grounds as untimely.

C. The PTO lacks authority to impose any deadline for No-Fee § 1.181(a) Petitions, and thus the grounds in §§ III and IV of this Petition may not be considered untimely

The PTO lacks authority to impose any requirement for form or deadline for the § 1.181(a) issues raised §§ III and IV of this petition, because the PTO has never sought—let alone obtained—clearance under the Paperwork Reduction Act for such petitions.⁴ Of the grounds raised herein, the PTO only has Paperwork clearance for petitions to revive for unintentional abandonment (§ VII), and that ground has no two-month deadline. Unless the PTO can answer the five Paperwork questions posed in § III.B at page 15 to show that it has

⁴ The only possibilities appear to be ICR submissions 200707-0651-005, Table 3, rows 31 and 32, and 200804-0651-002, Table 3, line 1, neither of which request OMB clearance for “supervisory authority” petitions under 37 C.F.R. § 1.181(a) or (c).

Paperwork clearance for § 1.181(a) petitions, the PTO may not dismiss any § 1.181(a) ground as untimely.

III. The Love memo was not legally promulgated—it violates the U.S. Constitution, the Administrative Procedure Act, the Paperwork Reduction Act, and Executive Orders and directives from the President—and may not be enforced against applicants

A. Facts: time line for the Love memo

The Love memo was apparently signed on April 25, 2007.

Two revised editions of the MPEP were published in September 2007 and July 2008.

The Love memo was not incorporated into these revisions of the MPEP. The Foreword to the MPEP states as follows:

Foreword

... Orders and Notices still in force which relate to the subject matter included in this Manual are incorporated in the text. Orders and Notices, or portions thereof, relating to the examiners' duties and functions *which have been omitted or not incorporated in the text may be considered obsolete.*

Not only did the PTO not incorporate the Love memo into the MPEP, apparently the PTO kept the Love memo totally secret from the public. After receiving the April 14, 2008 Action (and others much like it in other applications at around the same time), this attorney made several detailed searches of the PTO's web site between late 2008 and into February 2009 to find any PTO document setting out the restriction principles that appeared in the Office Action. No document was found, and this attorney assumed that the Examiner was simply making up new grounds for restriction (in T.C. 3690, examiner modification of MPEP form paragraphs is frequent, at least one instance in perhaps a majority of all Office Actions). The Internet Wayback Machine (www.archive.org) confirms that the Love memo was not available to the public at any time during 2008 for which the Wayback machine has records. See Exhibit E.

The first time this attorney found any publication of the Love memo or anything relating to its content was in late March or early April 2009.

The undersigned attorney obtained all of the PTO's potentially-relevant Paperwork Reduction filings since 2003 from OMB. The most pertinent papers from the OMB file for 2006-09 are included as Exhibit F and Exhibit G to this paper. None of these papers reflect any attempt by the PTO to seek, let alone obtain, White House approval for the modifications to

restriction information collections reflected in the Love memo, or for any other revisions to restriction information collections, since at least 2003.⁵

This attorney telephoned a Technology Center Director in early July 2009, asking whether the PTO considered the Love memo to remain in effect, in view of four specific issues: (a) failure to obtain clearance under the Paperwork Reduction Act, (b) failure to obtain clearance under the President's *Good Guidance Bulletin*, (c) failure to publish any notice in the Federal Register as required by the Administrative Procedure Act, and (d) the Foreword to the MPEP. The Technology Center Director returned the phone call over three weeks later, on August 5, 2009:⁶

... I talked to Rob Clarke and Cathleen Fonda in our [Office of Patent Legal Administration] policy shop. ... You are right, the Manual has been revised. However, Chapter 800 has not been revised. So as a result, the [Love memo] does control and represents current Office policy.

Neither any attempt to comply or any exemption from the Paperwork Act, the APA, the *Good Guidance Bulletin*, or the MPEP Foreword was identified.

This attorney followed up by telephone calls starting in May 2009 and by email to Robert Clarke on August 21, 2009. This attorney requested identification of any filing that the PTO had

⁵ The PTO's most-recent request for approval under the Paperwork Reduction Act, covering all "patent processing" activities between initial filing and issue (<http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0651-0031>), was filed with the Office of Management and Budget on April 24, 2008. (http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200707-0651-005). The PTO gained only limited approval—indeed, approvals that had been granted were retroactively revoked by the White House, because of massive irregularities in the PTO's 2006, 2007 and 2008 filings. <http://www.reginfo.gov/public/do/DownloadDocument?documentID=44055&version=4>. The PTO's most recent Federal Register Notice on restriction practice, 72 Fed.Reg. 44992, 44999 (Aug. 10, 2007) stated that the PTO was not seeking OMB approval under the Paperwork Reduction Act for any revisions to restriction practice. The PTO's currently-approved information requests in 0651-0031 are listed in the July 1, 2009 Notice of Action letter, http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200707-0651-005#. No information collections relating to restriction are approved, save some related cover sheets. No filing relating to divisional applications, <http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0651-0032>, seeks clearance for the additional divisional filings that would be required under the Love memo. Thus, none of these filings could possibly cover any modification to restriction information collection of the Love memo.

The PTO's filings before June 2006 are not available on the web site. The undersigned attorney obtained copies of the PTO's filings back to 2003 from OMB. No filings relating to the Love memo or any other modification to restriction information collections are reflected in the OMB files.

⁶ The undersigned attorney attributes no blame to the Technology Center Director, he/she is only the messenger. The PTO legal officer who gave legal advice that ignores the law was apparently Mr. Clarke. He's the one who ought to know better.

ever made seeking approval for the modified information collection embodied in Love memo. No reply was received until September 24, 2009, when Jennifer McDowell provided the email reply set forth in Exhibit C.

Note from these replies that no one in the PTO has been able to make any good faith averment that the PTO ever attempted to even minimal compliance with the Paperwork Reduction Act or any of the other laws that govern rule making, with respect to the Love memo.⁷ Thus, unless something relevant has escaped both this attorney's diligent search and the attention of the people in the PTO most likely to know, the PTO has never sought, let alone obtained, White House Paperwork approval for the Love memo.

The Office of Management and Budget directed the PTO to remove all rule-change related requests for clearance in early 2008,⁸ so it appears that even if the PTO *had* filed a request for clearance of the Love memo, that clearance was revoked. See Exhibit F.

On October 22, 2009, this attorney again diligently reviewed and searched the PTO's web site, and found that as of October 22, 2009, there are apparently no links that lead to the Love memo. If one has prior knowledge of the URL, one can get to the Love memo, but there is apparently no path to the Love memo from the www.uspto.gov home page. There is likewise no accessible index that leads to the Love memo.

⁷ Ms. McDowell's email contains a number of faulty statements. For example:

- She states that the Paperwork Reduction Act only applies as a "defense to enforcement actions." The statute says otherwise: "The protection provided by [the Paperwork Reduction Act] may be raised in the form of a complete defense, bar, or otherwise at any time during the agency administrative process..." 5 C.F.R. § 1320.6(c) clarifies that the Act applies to an application for "receipt of a benefit." Her statement that the Act is limited to "enforcement proceedings" is simply wrong.
- She avoids answering the question. The question asks "please identify the ICR submission number and the table line within that submission." An ICR submission number is designated by 6 digits, dash, 4 digits, dash, 3 digits, and a table line number is a number between 1 and 100 or so. See, *e.g.*, footnote 4. Whatever question Ms. McDowell answered, it was not the question asked.
- She avoids answering the question. The Love memo, the subject of the inquiry, was never incorporated into the MPEP. Her statement "the MPEP has been reviewed by OIRA" has nothing to do with the question that was asked.
- She avoids addressing the question, by failing to address the precise modified information collection. She states only that 0651-0031 covers some "associated" activities, but Ms. McDowell carefully avoids any statement about the precise information collection that is the subject of the question.

All in all, Ms. McDowell's email appears to be a concession that the PTO has never obtained OMB clearance for the precise information collection involved.

⁸ See footnote 5.

B. The PTO has no authorization under the Paperwork Reduction Act for any modification to restriction information collections since at least 2003

The Paperwork Reduction Act, 44 U.S.C. § 3501-3519,⁹ requires the PTO to request and obtain approval from the White House Office of Management and Budget before it may enforce any rule requiring any submission of information to the PTO.¹⁰ The procedural steps that the PTO must follow are set out in 44 U.S.C. § 3507 (“An agency shall not conduct or sponsor the collection of information unless in advance of the adoption or revision ... the agency has...” followed the steps for obtaining White House approval). 44 U.S.C. § 3512 provides that the PTO may not enforce any requirement, or penalize any applicant, if the PTO failed to complete those steps and obtain OMB approval.

As described in the time line at page 10, after diligent search and inquiry with the PTO staff most likely to know, it seems clear that the PTO never even *sought* the required clearance, let alone obtained it. The two people within the PTO most knowledgeable about the issue have only been able to aver that *if* the PTO ever sought clearance, then the right place to look for it would be under OMB control number 0651-0031. But no document filed within control number

⁹ The text of the Act is available at <http://www.archives.gov/federal-register/laws/paperwork-reduction/>, and the text of OMB's implementing regulations for agencies (5 C.F.R. Part 1320, especially §§ 1320.5, 1320.8, 1320.9, and 1320.11) is at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title05/5cfr1320_main_02.tpl.

¹⁰ The term “collection of information” is defined as follows, 5 C.F.R. § 1320.3(c)

(c) Collection of information means ... the obtaining, causing to be obtained, soliciting, or requiring the disclosure to an agency... of information by or for an agency by means of identical questions posed to, or identical reporting, recordkeeping, or disclosure requirements imposed on, ten or more persons, whether such collection of information is mandatory, voluntary, or required to obtain or retain a benefit. “Collection of information” includes any requirement or request for persons to obtain, maintain, retain, report, or publicly disclose information. As used in this Part, “collection of information” refers to the act of collecting or disclosing information, to the information to be collected or disclosed, to a plan and/or an instrument calling for the collection or disclosure of information, or any of these, as appropriate.

(1) A “collection of information” may be in any form or format, including the use of ... rules or regulations; planning requirements; circulars; directives; instructions; bulletins...

OMB (the agency charged with administering the Paperwork Reduction Act, and thus the agency whose interpretation controls) interprets the term “collection of information” broadly enough to cover written arguments, elections, and divisional applications that the Love memo purports to require.

0651-0031 corresponds to the Love memo, let alone any compliance with the other requirements of the Act, and no one in the PTO has been able to even suggest that such a filing exists.

Since the PTO has no valid OMB approval for the Love memo,¹¹ it cannot “display” that approval in the manner required by the Paperwork Reduction Act.

In such situations, the Paperwork Reduction Act provides as follows:

44 U.S.C. § 3512 Public protection

(a) Notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information that is subject to this subchapter if –

(1) the collection of information does not display a valid control number assigned by the Director in accordance with this subchapter; or

(2) the agency fails to inform the person who is to respond to the collection of information that such person is not required to respond to the collection of information unless it displays a valid control number.

(b) The protection provided by this section may be raised in the form of a complete defense, bar, or otherwise at any time during the agency administrative process or judicial action applicable thereto.

Regulations promulgated by the Executive Office of the President, and applicable to all federal agencies, provide as follows:¹²

5 C.F.R. § 1320.6 Public protection.

(c) Whenever an agency has imposed a collection of information as a means for proving or satisfying a condition for the receipt of a benefit or the avoidance of a penalty, and the collection of information does not display a currently valid OMB control number or inform the potential persons who are to respond to the collection of information, as prescribed in Sec. 1320.5(b), *the agency shall not treat a person's failure to comply*, in and of itself, as grounds for withholding the benefit or imposing the penalty. The agency shall instead permit respondents to prove or satisfy the legal conditions in any other reasonable manner. ...

¹¹ A “control number” covers only the specific information collections for which the PTO made filings required by 44 U.S.C. § 3506(c)(2)(A) and § 3507(a). A control number “is not a nose of wax, which may be turned and twisted in any direction, by merely referring to the [number], so as to make it include something more than, or something different from, what [the agency originally applied for].” Rather, the PTO must apply for a new control number (or extension to an existing control number) *every* time it makes a “substantive or material modification to a collection of information.” § 3507(h)(3). It is the PTO’s obligation to maintain an inventory of approved information collections, 44 U.S.C. § 3506(c)(1)(B), so that when the public asks questions such as those posed in Petitioner’s email, the PTO can answer the specific question. Since Ms. McDowell was unable to answer the specific questions posed (see footnote 7), it appears that the PTO broke the “inventory” law, too.

¹² http://edocket.access.gpo.gov/cfr_2002/janqtr/pdf/5cfr1320.6.pdf

(d) Whenever a member of the public is protected from imposition of a penalty under this section for failure to comply with a collection of information, such penalty may not be imposed by an agency directly, by an agency through judicial process, or by any other person through administrative or judicial process.

The law forbids the PTO from taking any action to enforce the Love memo.

If any restriction is adhered to in future, the PTO must identify—for both the paper filed to elect claims, and for the incremental divisional applications to be filed under the Love memo—each of the following five items:

- Where and when the PTO published objective estimates of burden of the Love memo (the election paper *and* the *incremental* number of filings of divisional applications), and sought public comment, as required by 44 U.S.C. § 3506(c)(2)(A) and (B).
- The OMB “valid control number” applicable to the precise information collections embodied by the Love memo. Note that mere identification of a control number is not responsive to this question, if that control number has not been granted to cover the two precise information collections embodied in the Love memo.
- For precisely the modification to an information collection embodied in the Love memo, either (a) the OMB ICR submission number¹³ in which that control number was applied for, and the line item number in the Information Collection Supporting Statement for that submission, or (b) the line item in the current OMB “Notice of Action” or currently-approved information collection inventory.
- An indication where the control number is “displayed” in the manner required by 44 U.S.C. § 3512, with respect to the two precise information collections.
- Where the PTO informed the public that it is not required to comply with the modified information collections specified in the Love memo, unless the PTO displays a valid control number..

44 U.S.C. §§ 3507 and 3512 and 5 C.F.R. § 1320.6 provide that if any one of these ten questions (five questions, applicable to both the election paper and to any divisional application) is not answered, the PTO cannot enforce restriction information collections as set forth in the Love memo. Absent an answer to any one of the ten questions, the Love memo and the Examiner's paper issued pursuant thereto were both unenforceable when issued, and the PTO may not penalize Petitioner in any way for “failure to comply.”

¹³ An “ICR submission number” is 6 digits, dash, 4 digits, dash, 3 digits. The relevant OMB submissions are listed at <http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0651-0031>. Note that approvals for ICR submissions 200512-0651-002 (12/22/2005), 200606-0651-001 (6/5/2006) and 200703-0651-001 (3/13/2007) were revoked in April 2008, as documented at <http://www.reginfo.gov/public/do/DownloadDocument?documentID=44055&version=4>. This leaves no submission in the relevant time period that could conceivably be applicable.

On the record as it exists today, because the PTO failed to complete its obligations under the Paperwork Reduction Act, the PTO is required by § 1320.6(c) to permit applicants to provide the required information, that is, claims, "in any reasonable manner." The claims now pending are filed in the manner provided by statute. The claims are presented in a "reasonable" form, and the appropriate fees have been paid. The PTO has no authority to impose any penalty for failure to comply with the Love memo.

If the PTO wishes to enforce the Love memo, it will have to run the Love memo through the entire process specified by the Paperwork Reduction Act and OMB's Information Collection Regulations.¹⁴ This Petitioner eagerly wishes to see the application move forward, within whatever rules the PTO has validly promulgated, but asks that the PTO only impose such requirements as are validly promulgated.

C. The Love memo violated an Executive Order of the President of the United States and an equivalent directive from the Executive Office of the President

1. Agencies may not bind the public through guidance

In January 2007, the President ordered all agencies that they may not treat guidance manuals (such as the MPEP) as binding against the public, only against their own employees.¹⁵ If an agency wants to bind the public, it must use rule making procedures, not guidance. The President's *Good Guidance Bulletin* reads as follows, in relevant part:

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

The preamble to the Bulletin elaborates:

¹⁴ Petitioner notes that several other very burdensome modifications to information collections were smuggled past OMB review in MPEP 8th Ed. Rev. 3 (August 2005). Those were not cleared either, and are likewise unenforceable.

¹⁵ Executive Office of the President, "Final Bulletin for Agency Good Guidance Practices," OMB Memorandum M-07-07, <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf> (Jan. 18, 2007), 72 Fed. Reg. 3432 (Jan. 25, 2007).

This Bulletin on "Agency Good Guidance Practices" is to ensure that guidance documents of Executive Branch . . . agencies are . . . not improperly treated as legally binding requirements.¹⁶

The Department of Commerce has instructed the PTO that the MPEP and revisions thereto are subject to the President's Bulletin.¹⁷

Thus, even if the PTO had some historical misunderstanding of its power to bind the public through the MPEP and examiner memoranda, the President instructed the PTO that the PTO is no longer authorized to do so. Any further reliance on the Love memo (or any other examiner memorandum, or the MPEP) to the detriment of applicants violates these instructions from the President.

2. The PTO failed to comply with procedures required by the *Good Guidance Bulletin*

The President's *Good Guidance Bulletin* requires that amendments to the MPEP be circulated for notice and comment at the time that they are published.¹⁸ The Love memo was not circulated for notice and comment at any time, and thus may not be enforced.

3. The PTO unlawfully confuses the public by failing to clearly identify which guidance documents are in effect and which are not

The President's *Good Guidance Bulletin* requires that agencies clearly inform the public which guidance documents are still in effect, and which are not, so that the public is not left guessing:

III. Public Access and Feedback for Significant Guidance Documents.

1. Internet Access:

a. Each agency shall maintain on its website -- or as a link on an agency's website to the electronic list posted on a component or subagency's website -- a current list of its significant guidance documents in effect. The list shall include the name of each significant guidance document, any document identification number, and issuance and revision dates. The agency shall provide a link from the current list to each significant guidance document that is in effect. New significant guidance documents and their website links shall be added promptly to this list, no later than 30 days from the date of issuance.

b. The list shall identify significant guidance documents that have been added, revised or withdrawn in the past year.

¹⁶ *Good Guidance Bulletin*, Preamble, 72 Fed. Reg. at 3433 col. 1-2; [.../m07-07.pdf](#) at page 4.

¹⁷ Department of Commerce, Office of the Chief Information Officer, Significant Guidance Documents Currently in Effect, http://ocio.os.doc.gov/PROD01_003151.

¹⁸ *Good Guidance Bulletin*, § IV.

No such web page is apparent on the PTO's web site. For some period of time, there was a list of "memoranda to the Examining Corps," but that page lacked the required information to remove the public's uncertainty as to which guidance is still in effect and which is not. And as of October 22, 2009, even that minimal but inadequate page is apparently inaccessible from the www.uspto.gov home page.

The PTO has still not given the public any notice that Chapter 800 of the MPEP as published in July 2008 is in anything less than full force and effect. The Love memo departs from the published MPEP, and is simply void.

4. The PTO failed to comply with an Executive Order

Executive Order 13,422, which was in effect from January 2007 through January 2009, required that agencies follow certain procedures before issuing memoranda like the Love memo. The Executive Order reads as follows:¹⁹

Sec. 9. Significant Guidance Documents. Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with advance notification of any significant guidance documents. Each agency shall take such steps as are necessary for its Regulatory Policy Officer to ensure the agency's compliance with the requirements of this section. Upon the request of the Administrator, for each matter identified as, or determined by the Administrator to be, a significant guidance document, the issuing agency shall provide to OIRA the content of the draft guidance document, together with a brief explanation of the need for the guidance document and how it will meet that need. The OIRA Administrator shall notify the agency when additional consultation will be required before issuance of the significant guidance document.

There is no suggestion at OMB's web site that the PTO ever complied with this provision of the Executive Order.

D. The Love memo violates multiple provisions of the Administrative Procedure Act and were unconstitutional

5 U.S.C. § 552(a) provides that the PTO may not enforce any rule until it has published it in the Federal Register, or that the person affected had personal knowledge. Likewise, the Due Process Clause of the U.S. Constitution forbids agencies from enforcing unpublished rules. The PTO neglected all of these requirements until at least late March 2009, and is in breach of this obligation as of October 27, 2009. The Love memo is unenforceable.

¹⁹ Executive Order 12866 of September 30, 1993, as amended by E.O. 13258 of February 26, 2002 and E.O. 13422 of January 18, 2007, Regulatory Planning and Review, http://www.whitehouse.gov/omb/inforeg/eo12866/eo12866_amended_01-2007.pdf

1. Facts: the Love memo was not published as required

Through much of 2008 and into February 2009, this attorney diligently searched all available resources to find any PTO document that would support the restriction requirements that were being raised by several examiners. No such document was available. After the PTO disclosed the existence of the Love memo in April 2009, this attorney checked the Internet Wayback machine, www.archive.org, and confirmed that the Love memo was not available to the public during 2008. On October 22, 2009, this attorney again reviewed the PTO's web site, and there are apparently no links that lead from the www.uspto.gov home page to the Love memo. It was apparently only available to PTO "insiders." Documents reflecting this search are presented as Exhibit E.

Further, for most of 2008 and early 2009, the PTO had a "robots.txt" file on its web site that prevented internet search engines from crawling and indexing uspto.gov.

2. The PTO violated publication and notice requirements arising under the Administrative Procedure Act and Constitution

Both the Administrative Procedure Act and the due process clause of the Fifth Amendment to the United States Constitution forbid government agencies from relying on secret rules.²⁰ Agencies may only enforce rules that are published in way that gives the public an opportunity to comply with them. There are two very practical reasons for this.

²⁰ *Lightfoot v. District of Columbia*, 339 F.Supp.2d 78, 88-89 (D.D.C. 2004) (emphasis added, footnotes, quotations and citations omitted) presents the Constitutional analysis as follows:

If Due Process is to mean anything, it is a fundamental guarantee that stakeholders are provided both sufficient notice and fair procedures when governmental discretion mandates the abrogation of their rights or privileges. The central purpose of the Due Process clause is to ensure the *accountability* of the government and its administrative agencies to its citizenry: while discretion is certainly permitted, administrators must provide a public framework for principled decision-making and create clear boundaries for that discretion. "Courts should require administrative officers to articulate the standards and principles that govern their discretionary decisions in as much detail as possible." ... Due Process is best achieved when the integrity of the administrative process is maintained through a framework of publicly available rules and guidelines that provide an opportunity for comment and criticism. The idea that an administrative agency must provide a reasoned explanation using preordained standards serves a threefold purpose:

[1] enabling the court to give proper review to the administrative determination;
[2] helping to keep the administrative agency within proper authority and discretion, as well as helping to avoid and prevent arbitrary, discriminatory, and irrational action by the agency; and [3] informing the aggrieved person of the grounds of the administrative action so that he can plan his course of action ...

First, if any such legal principle exists, the principle is subject to conditions precedent, exceptions, attendant circumstances, context, or similar limitations. Without some reasonably precise, published, written statement of the legal principle, no applicant can determine whether the facts of a particular application fall within the legal principle thought to apply, and no applicant can amend the application in a way that precisely meets the legal principle.

Second, agencies are apt to act “arbitrarily, discriminatorily, and irrationally” if they do not have written statements of their legal standards, and that such irrationality is an unconstitutional violation of “due process of law.”²¹

Reflecting these common sense concerns for efficiency and fairness, the Administrative Procedure Act requires that all rules be published, and that the public be given notice of the existence of the rule by notice in the Federal Register. 5 U.S.C. §§ 552(a), 553(d). These provisions apply to all “rules,” whether those “rules” are stated in the Code of Federal Regulations or in documents such as the MPEP.²² For example, § 552 of the APA reads as follows (emphasis added):

... Due Process requires written standards whose availability provides notice to the interested public. *See, e.g., White v. Roughton*, 530 F.2d 750, 754 (7th Cir. 1976) (state welfare program's use of unwritten personal standards of eligibility struck down because “fair and consistent” application of eligibility requirements mandates “written standards and regulations”); *Holmes v. New York City Housing Auth.*, 398 F.2d 262, 265 (2d Cir. 1968) (“[d]ue process requires that selections among applications [in a housing program] be made in accordance with ascertainable standards”); *Martinez v. Ibarra*, 759 F.Supp. 664, 668 (D. Colo. 1991) (due process denied when the procedure for reviewing Medicaid application “is never articulated in clear, written standards” ...); *Baker-Chaput v. Cammett*, 406 F.Supp. 1134, 1140 (D. N.H. 1976) (“[T]he establishment of written, objective, and ascertainable standards is an elementary and intrinsic part of due process.”).

The D.C. Court of Appeals--in three major decisions--also has recognized the need for ascertainable, written standards in benefits programs and government decision-making. In *Miller v. District of Columbia Bd. of Appeals & Review*, 294 A.2d 365 (1972), the court highlighted “the danger of arbitrary administrative action based upon unarticulated and unannounced standards.” The court warned that “unless there are some standards relating the prior conduct of an applicant to the *particular* ... activity for which he seeks a license [to sell costume jewelry], the power to deny a license inevitably becomes an arbitrary, and therefore unlawful, exercise of judgment by one official....”

²¹ *Lightfoot v. District of Columbia*, 339 F.Supp.2d 78, 88-89 (D.D.C. 2004), quoted in footnote 20.

²² 5 U.S.C. § 551(4) define the term “rule” broadly. As the court explained in *Batterton v. Marshall*, 648 F.2d 694, 700–01 (D.C. Cir. 1980)

5 U.S.C. § 552. Public information; agency rules...

(a)(1) Each agency shall separately state and currently publish **in the Federal Register** for the guidance of the public—

...

(B) statements of the general course and method by which its functions are channeled and determined...

(C) rules of procedure. . . ;

Except to the extent that a person has actual and timely notice of the terms thereof, a person **may not in any manner be required to resort to, or be adversely affected by,** a matter required to be published in the Federal Register and not so published...

... A ... staff manual or instruction that affects a member of the public may be relied on, used, or cited as precedent by an agency against a party other than an agency only if—

(i) it has been indexed and either made available or published as provided by this paragraph; or

(ii) the party has actual and timely notice of the terms thereof.

First, the PTO cannot create rules on the fly by simply issuing a memorandum to examiners.

The law requires rule making procedures that protect the public; the PTO may not unilaterally waive those procedures by the mere expedient of not publishing its rule changes.²³

Second, if the PTO wishes to enforce the Love memo, the APA requires that the PTO do one of two things: (a) show that it published an appropriate notice in the Federal Register before April 14, 2008, or (b) show that a person associated with this application personally had “actual and timely notice,” before April 14, 2008.

The Administrative Procedure Act (APA), 5 U.S.C. §§ 551 *et seq.*, broadly defines an agency rule to include nearly every statement an agency may make:

(4) “rule” means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing (.)

5 U.S.C. § 551(4). The breadth of this definition cannot be gainsaid. The APA further defines “rule making” to mean “agency process for formulating, amending, or repealing a rule.” 5 U.S.C. § 551(5).

²³ *In re Nielsen*, 816 F.2d 1567, 1571, 2 USPQ2d 1525, 1527 (Fed. Cir. 1987) (“Before new requirements are imposed on ... the public, the requisite safeguards accompanying changes in administrative practice must be invoked. ... Such safeguards ensure the fair and consistent application of agency procedures.”).

The undersigned attorney searched all Federal Register notices since 2005 in April 2009 and again in August 2009, once in Lexis, and once at the Federal Register web site. No Federal Register notice was found giving the public any notice of the Love memo. In a telephone call to the Technology Center Director which was forwarded to Robert Clarke for handling, this attorney asked that the PTO identify any Federal Register publication. The Technology Center Director's phone message of August 5, 2009 (see page 11) silently concedes that no notice exists. Unless the PTO can show personal service on this petitioner or attorney, specifically drawing their attention to the specific provision the PTO wishes to enforce, the Love memo may not be given effect at any time before April 1, 2009 (even if the memo survives the other legal challenges raised in this petition).

Third, the PTO must show that the Love memo was "indexed." Because the PTO has a "robots.txt" file to block Google and similar search engines from indexing the PTO's web site, and the PTO provides no links to get to the Love memo, the memo fails this requirement, and cannot be enforced.

Fourth, "the USPTO must engage in notice and comment rule making when promulgating rules it is otherwise empowered to make." *Tafas v. Dudas*, 541 F.Supp.2d 805, 812, 86 USPQ2d 1623, 1628 (E.D. Va. 2008), *reaffirmed sub nom. Tafas v. Kappos*, App. No. 2008-1352, ___ F.3d ___, ___ USPQ2d ___ (Fed. Cir. Nov. 13, 2009). There was no notice-and-comment process for the Love memo. The Love memo may not be enforced.

3. The Love memo violates the APA by purporting to relieve the examiner from any duty to explain reasons

Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29, 48, 50 (1983) requires that an agency give an explanation for its action, The statement of reasons must satisfy these criteria:²⁴

[A]n agency must cogently explain why it has exercised its discretion in a given manner. . .

A "fundamental" requirement of administrative law is that an agency "set forth its reasons" for decision; an agency's failure to do so constitutes arbitrary and capricious agency action. That fundamental requirement is codified in [5 U.S.C. § 555(e)]. Section [555(e)] mandates that whenever an agency denies "a written application, petition, or

²⁴ *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 48, 50 (1983).

other request of an interested person made in connection with any agency proceeding,” the agency must provide “a brief statement of the grounds for denial,” unless the denial is “self-explanatory.” This requirement not only ensures the agency’s careful consideration of such requests, but also gives parties the opportunity to apprise the agency of any errors it may have made and, if the agency persists in its decision, facilitates judicial review. Although nothing more than a “brief statement” is necessary, the core requirement is that the agency explain “why it chose to do what it did.”

The statement of reasons must satisfy these criteria:²⁵

A court must set aside agency action it finds to be “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,” 5 U.S.C. § 706(2)(A). At a minimum, that standard requires the agency to “examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’”

MPEP § 808 restates this basic requirement that applies to all agencies to restriction requirements (emphasis added):

808 Reasons for Insisting Upon Restriction [R-3]

Every requirement to restrict has two aspects: (A) the *reasons (as distinguished from the mere statement of conclusion)* why each invention *as claimed* is either independent or distinct from the other(s); and (B) the *reasons why there would be a serious burden on the examiner if restriction is not required*, i.e., the reasons for insisting upon restriction therebetween as set forth in the following sections.

808.02 Establishing Burden [R-5]

...

Where the inventions as claimed are shown to be independent or distinct under the criteria of MPEP § 806.05(c) - § 806.06, the examiner, in order to establish reasons for insisting upon restriction, *must explain why there would be a serious burden* on the examiner if restriction is not required. Thus the examiner *must show by appropriate explanation one of the following*:

(A) **Separate classification thereof:** ...

(B) **A separate status in the art when they are classifiable together:** ...

(C) **A different field of search:**

Note that MPEP §§ 808 and 808.02 are merely direct application of the Administrative Procedure Act—the PTO has no discretion whatsoever to reduce the protections of § 808.02.²⁶

²⁵ *Tourus Records Inc. v. Drug Enforcement Admin.*, 259 F.3d 731, 736–37 (D.C. Cir. 2001) (citations, quotations, and footnotes omitted); *Moon v. U.S. Dep’t of Labor*, 727 F.2d 1315, 1318 (D.C. Cir. 1984) (“We cannot determine whether an agency has acted correctly unless we are told what factors are important and why they are relevant. Therefore, an agency must provide a reasoned explanation for its actions and articulate with some clarity the standards that governed its decision.”).

The Love memo breaks the law by purporting to authorize an examiner to provide a laundry list of five possible reasons (two of which are not mentioned anywhere in the MPEP), but keep hidden any identification of which one is thought to apply, and to keep hidden the facts to which that ground is applicable. Almost identical facts were considered by the Fourth Circuit,²⁷ when an ALJ issued a decision that referred to four possible grounds, but identified neither which of the four was applicable to the particular case, nor any facts to which one of the four might be applicable. The court vacated the ALJ, and ordered the ALJ to identify the particular ground and the particular facts to which the ground applied.

Here, is the text of the April 14, 2008 Action, which states the form paragraph from Love memo. Note that this form paragraph leaves it to the applicant to read the examiner's mind which ground applies, and to what facts:

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

²⁶ *Brown v. Apfel*, 11 Fed.Appx. 58, 59–60 (4th Cir. Mar. 29, 2001) (agency decision vacated when it failed to identify the evidence, inferences therefrom, or legal standards that were relied on in arriving at a decision).

²⁷ *Cook v. Heckler*, 783 F.2d 1168, 1173 (4th Cir. 1986).

The PTO issued no paper that comports with the requirements of the Administrative Procedure Act, and no obligation was imposed on Petitioner to elect. No abandonment may arise when Petitioner followed every enforceable law, and the breaches of law were the PTO's.

4. The PTO violated the Administrative Procedure Act by failing to follow its own "published rules" regarding examiner memoranda

The Love memo violates several provisions of the Administrative Procedure Act (APA). By statute, 5 U.S.C. § 552(a),²⁸ the PTO must have "published rules" for adopting "staff manuals and instructions to staff that affect a member of the public." The PTO's published rules state as follows, in the Foreword to the MPEP:

Foreword

... Orders and Notices still in force which relate to the subject matter included in this Manual are incorporated in the text. Orders and Notices, or portions thereof, relating to the examiners' duties and functions *which have been omitted or not incorporated in the text may be considered obsolete.*

The Love memo was signed in April 2007. The MPEP was revised and republished in September 2007 and July 2008. Therefore, the PTO's "published rules" render the Love memo obsolete as of September 2007, long before the Examiner's April 14, 2008 initial paper, and again in July 2008, before the Examiner's April 2009 Notice of Abandonment.

²⁸ 5 U.S.C. § 552(a)(2) reads as follows (emphasis added):

§ 552. Public information; agency rules, opinions, orders, records, and proceedings

(a)(2) Each agency, *in accordance with published rules*, shall make available for public inspection and copying--

...

(B) those statements of policy and interpretations which have been adopted by the agency and are not published in the Federal Register;

(C) administrative staff manuals and instructions to staff that affect a member of the public;

...

A ...staff manual or instruction that affects a member of the public may be relied on, used, or cited as precedent by an agency against a party other than an agency only if--

(i) it has been indexed and either made available or published as provided by this paragraph; or

(ii) the party has actual and timely notice of the terms thereof.

Mr. Clarke, speaking for OPLA through a T.C. Director (see page 11) attempted to create an *ad hoc* “chapter by chapter” exception to the MPEP. The PTO’s published rules specify that obsolescence occurs with respect to “this Manual,” not with respect to “those chapters of this Manual updated in this revision.” The PTO has offered no explanation for continuing vitality of the Love memo that comports with its “published rule,” thereby breaching § 552. Instead, the PTO only offers a plain declaration that the PTO refuses to follow its published rules, based on a made-up-on-the-fly excuse. But, as the Federal Circuit has reminded the PTO on several occasions, the PTO has no discretion to create on-the-fly exceptions to its written rules.²⁹ Mr. Clarke’s answer is a clear flouting of the law, unacceptable for a member of the Office of Patent Legal Administration or any other lawyer.

The President recently reminded agencies of this basic principle: “Each agency shall develop or have written procedures for the approval of significant guidance documents.”³⁰ By disregarding its existing “written procedures,” the PTO violated this instruction from the President.

The confusion sown by the PTO’s refusal to comply with its own published rules is compounded by the PTO’s failure to implement a notification requirement in the President’s *Good Guidance Bulletin*, discussed at § III.C.3 at page 17. The PTO gave no notice that it intended to abrogate major parts of Chapter 800. The public is left in a complete quandary—what documents are effective, and which are not?³¹

²⁹ *In re Nielsen*, 816 F.2d 1567, 1571, 2 USPQ2d 1525, 1527 (Fed. Cir. 1987) (“Before new requirements are imposed on ... the public, the requisite safeguards accompanying changes in administrative practice must be invoked. ... Such safeguards ensure the fair and consistent application of agency procedures.”); *Berkovitz v. U.S.*, 486 U.S. 531, 536 (1988) (“employees of regulatory agencies have no discretion to violate the command of ... regulations”); *see also* cases cited in footnotes 34 and 38.

³⁰ *Good Guidance Bulletin*, § II(1)(a).

³¹ An analogy between Soviet arbitrariness and agencies’ arbitrary procedure has been noted by the Supreme Court, *Shaughnessy v. U.S. ex rel Mezei*, 345 U.S. 206, 224–25 (1953) (Jackson, J., dissenting):

Procedural fairness, if not all that originally was meant by due process of law, is at least what it most uncompromisingly requires. Procedural due process is more elemental and less flexible than substantive due process. It yields less to the times, varies less with conditions... If it be conceded that [the agency’s end result was correct], does it matter what the procedure is? Only the untaught layman or the charlatan lawyer can answer that procedures matter not. Procedural fairness and regularity are of the indispensable essence of liberty. Severe substantive laws can be endured if they are fairly and impartially applied. Indeed, if put to the choice, one might well prefer to live

Unless the PTO can show a “published rule” that overrides the MPEP Foreword, and that it complied with various Executive Orders, the PTO violates § 552(a)(2) of the statute and instructions from the President by giving any continuing effect to the Love memo.

E. The Love Memo is an illegal retroactive rule making

This application was filed in May 14, 2002, and substantially amended in May 2008. Had the rules the PTO now seeks to impose been in effect at that time, the application would have been structured differently, or filed as several parallel applications, in order to prevent loss of patent term adjustment and increased cost that occur when divisional applications are filed.

The PTO lacks authority to change the rules in the middle of the game. The Supreme Court explained the general principle:³²

Retroactivity is not favored in the law. Thus, congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result. ... By the same principle, a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms. See *Brimstone R. Co. v. United States*, 276 U.S. 104, 122 (1928) (“The power to require readjustments for the past is drastic. It ... ought not to be extended so as to permit unreasonably harsh action without very plain words”). Even where some substantial justification for retroactive rulemaking is presented, courts should be reluctant to find such authority absent an express statutory grant.

An agency violates the proscription against retroactive rule making when “the new provision attaches new legal consequences to events completed before its enactment.”³³

Here, the Love memo changes the legal consequences—particularly the availability of patent term extension to compensate for the PTO’s already extensive delays—of the decision made to file the claims in a single application rather than in a voluntarily-divided set of applications.

If the PTO wishes to restrict at all, at best the law that applies is the law as it existed on May 14, 2002. Petitioner believes that no restriction can be raised under that standard, but the

under Soviet substantive law applied in good faith by our common-law procedures than under our substantive law enforced by Soviet procedural practices. Let it not be overlooked that due process of law is not for the sole benefit of an accused. It is the best insurance for the Government itself against those blunders which leave lasting stains on a system of justice but which are bound to occur on ex parte consideration.

³² *Bowen v. Georgetown University Hosp.*, 488 U.S. 204, 208-09 (1988).

³³ *Landgraf v. USI Film Products*, 511 U.S. 244, 269 n.23 (1994).

V. Petition for rulemaking—the MPEP should provide guidance to relieve applicants from any duty to reply to requirements that are procedurally inadequate

37 C.F.R. § 1.143 reads as follows:

§ 1.143 Reconsideration of requirement.

If the applicant disagrees with the requirement for restriction, he may request reconsideration and withdrawal or modification of the requirement, giving the reasons therefor. (See § 1.111). In requesting reconsideration the applicant must indicate a provisional election of one invention for prosecution, which invention shall be the one elected in the event the requirement becomes final. ...

The PTO should provide additional guidance, either by adding a sentence to §1.143 or by adding guidance to the MPEP, to cover situations where the examiner's paper is legally insufficient to create any obligation to reply. An applicant should have no duty to "indicate a provisional election" in response to a paper that was not validly issued:

- If the examiner's paper "short cuts" by omitting showings that are required by the MPEP (this happens all too regularly in T.C. 3690)
- If the examiner's paper exceeds the PTO's statutory authority, for example, by purporting to "restrict" an invention that is not claimed
- If the information collection lacks clearance under the Paperwork Reduction Act
- If the PTO neglected any of its legal duties under the Administrative Procedure Act, relevant Executive Orders, the Regulatory Flexibility Act, and the like
- If the claims were amended so that the stated grounds for restriction no longer apply
- If the examiner failed to "answer all material traversed" in a previous restriction paper

then the MPEP should make clear that the applicant has no duty to elect, and that "37 C.F.R. § 1.111(b) and all other law that would be applicable when an examiner goes outside of delegated authority: the May 14, 2008 paper "distinctly and specifically point[ing] out the supposed errors in the examiner's action," as required by § 1.111(b), is fully sufficient.

VI. The Director should (a) implement instructions from the President of the United States, and (b) remonstrate with examination staff to end a pervasive pattern of breaches of procedure

A. The Director is required to appoint a Good Guidance Officer

Good Guidance Bulletin § III(2)(b) requires that “Each agency shall designate an office (or offices) to receive and address complaints by the public that the agency is not following the procedures in this Bulletin or is improperly treating a significant guidance document as a binding requirement. The agency shall provide, on its website, the name and contact information for the office(s).”

Over the last two years, this attorney has emailed John Love, Magdalen Greenlief, and Linda Therkorn for the name of this office; none have responded. The name is not on the PTO's web site. The PTO has not met its obligations.

Petitioner again draws the PTO's attention to instructions from the President, and requests that the PTO appoint a Good Guidance officer, and post the name and contact information on the PTO's web site.

B. The Director is required to implement the training in Good Guidance Practices called for by the President

- The Director should instruct examiners that they only have authority to impose requirements against applicants that are stated in a document having “force of law.” The MPEP does not have force of law.⁴⁵ It therefore is not to be cited as law against applicants.⁴⁶ Examiners do not have authority to make up new laws on the fly. If a provision in the MPEP is challenged, the examiner must cite authority in order to maintain a position. For example, the treatment of “wherein” clauses stated in Chapter 2100 is simply wrong, and examiners should be instructed that the law does not permit them to rely on the MPEP for a patentability provision—if there is no Federal Circuit case, then it is not the law. The PTO must entertain applicants' arguments that do not meet the MPEP.⁴⁷
- The Director should instruct examiners that when the MPEP uses mandatory language applicable to the PTO or to examiners, like “must,” “the Office will,” and the like, that is mandatory, and examiners have *no authority* to depart, “without appropriate justification and

⁴⁵ For example, the MPEP does not meet (i) the requirements of 5 U.S.C. §§ 552(a), requiring publication and Federal Register notice for all rules, including any interpretative rules or rules guiding or binding the public published in the MPEP or other guidance, (ii) § 553, setting forth procedural prerequisites for rule making, or (iii) the Paperwork Reduction Act.

⁴⁶ The *Good Guidance Bulletin* has a few exceptions that are not relevant here.

⁴⁷ *Good Guidance Bulletin* § II(2)(h) (a guidance document may not “foreclose agency consideration of positions advanced by affected private parties”).

supervisory concurrence.”⁴⁸ Because the PTO has not implemented procedures required by the President,⁴⁹ as of today it appears that any variance from MPEP procedures must be pre-cleared in a “justification and concurrence” signed by the Director of the Office of Patent Legal Administration or Deputy Commissioner for Patent Examination Policy, so that the variance can be incorporated into future revisions of the MPEP. This problem extends from examiner to the head of the Office of Patent Legal Administration, as discussed at § VI.C at page 37

- The Director should instruct the examiners that requirements that the PTO placed on itself in the Code of Federal Regulations for the benefit of applicants may *never* be unilaterally waived by the PTO or attenuated by MPEP, unless there is no significant prejudice to the applicant or any third party.⁵⁰
- The Director should instruct examiners that unpublished procedures, or procedures improvised by individual examiners, necessarily lack clearance under the Paperwork Reduction Act and fail the rule making prerequisites of the Administrative Procedure Act, and therefore may not be enforced against applicants. The PTO is obligated to go through extensive public comment and regulatory approval processes, and examiners simply do not have the time, expertise, or authority to duplicate this effort or engage in independent rule making.

When examiners believe they have authority to carve out personal exceptions to the PTO's procedures or impose new requirements on applicants, only confusion and delay can result. The President's *Good Guidance Bulletin* is key to the efficiency improvements that the PTO seeks.

⁴⁸ *Good Guidance Bulletin* § II(1)(b).

⁴⁹ E.g., *Good Guidance Bulletin* § III(2)(b) (“Each agency shall designate an office (or offices) to receive and address complaints by the public that the agency is not following the procedures in this Bulletin or is improperly treating a significant guidance document as a binding requirement. The agency shall provide, on its website, the name and contact information for the office(s).”)

⁵⁰ The contrast between the PTO's authority to relax procedural requirements that apply to applicants and the non-waivability of procedural requirements that bind the PTO for to prevent prejudice to applicants is discussed in *City of Fredericksburg Virginia v. Federal Energy Comm'n*, 876 F.2d 1109, 1112 (4th Cir. 1989) (“[The Supreme Court] held that an administrative agency has discretion to relax or modify internal housekeeping regulations ... However, the exception announced ... does not apply if the agency regulations were intended ‘to confer important procedural benefits upon individuals’ or other third parties outside the agency. ... The applicability [of the discretion to relax regulations] thus turns on whether the regulation ... was designed to aid [the agency] or, instead, to benefit outside parties”); see also *American Farm Lines v. Black Ball Freight Service*, 397 U.S. 532, 539 (1970) (“It is always within the discretion of a court or an administrative agency to relax or modify its procedural rules adopted for the orderly transaction of business before it when in a given case the ends of justice require it. The action of either in such a case is not reviewable except upon a showing of substantial prejudice to the complaining party.”).

C. The Director should remonstrate with PTO personnel from top to bottom regarding respect for the rule of law

The anecdote set out at page 11 of his paper is symptomatic of one of the big problems that pervades PTO practice and leads to inefficiency and backlog. All too often, when a member of the public asks a PTO employee to follow the plain words of the law, the PTO employee makes up an on-the-fly exception. Applicants cannot rely on predictable procedures or written mechanisms for moving prosecution forward—PTO employees consistently improvise on-the-spot exceptions, leading to unwarranted delays.

The fact that the “chapter-by-chapter” excuse discussed at page 11 originated with the head of the Office of Patent Legal Administration is symptomatic of the pervasive disregard for the rule of law that infects almost all PTO proceedings, top to bottom. The Director should remonstrate with PTO employees, that written words directed to PTO employees mean what they say, and *no one*—not even the head of the Office of Patent Legal Administration—has authority to create one-off exceptions.⁵¹

VII. In the Alternative: Petition to revive for unintentional abandonment

In the alternative, and *only in the event that* the Director specifically makes findings denying each of the specific grounds raised in §§ III and IV and Exhibit B, *then* Petitioner petitions for revival of an unintentionally abandoned application. In particular, before reaching this issue, the Director must make express findings on all elements of the Paperwork Reduction Act issues listed in § III.B at page 15—the PTO is statutorily barred from imposing any penalty unless the PTO fully complied with the Act, and each and every other ground raised in §§ III and IV and Exhibit B. If any single ground is skipped, then the Director need not reach the following paragraph.

Only in the event that *each and every* ground set forth in §§ III and IV and Exhibit B are denied, and the PTO determines that breaches of law by the PTO are avoidable by applicants, then Petitioner avers that the entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 C.F.R. § 1.137(b) was unintentional. Since this application was filed on or after June 8, 1995, no terminal disclaimer is

⁵¹ See footnotes 29, 34, and 38

required. Petitioner notes that as now amended, the restriction requirement applies as follows. The claims were amended on May 14, 2008 to obviate any restriction requirement and to clearly bring them all within a group directed to "methods for making markets, making market maker quotations, and monitoring at least one security and automating the market making process." No one disputes that that group encompasses 1-5 7-39, 41-42, 44-75, 77-84, 87, 92-120, 124, 126, 127 are elected. Petitioner elects the invention claimed in that group. Only in the event that all grounds raised in §§ III and IV and Exhibit B of this petition are denied, kindly charge the "unintentional abandonment" fee to Deposit Account No. 50-3938, Order No. 01-1048.

VIII. Conclusion

The Love memo should be vacated.

The Examiner's papers of April 14, 2008, August 13, 2008 and April 27, 2009 should be vacated. The application is not abandoned.

Petitioner does not challenge the PTO's authority to divide applications, only the PTO's practice of raising restrictions under rules that have not been validly promulgated. Petitioner notes that any future restriction may only be imposed if the PTO can answer all ten questions raised under the Paperwork Reduction Act, in § III.B at page 13. In view of OMB's revocation of essentially all Paperwork clearances since December 2005 and the silence of PTO's filings on any update to restriction practice since at least January 2005, the latest modification to restriction practice that can possibly be valid is the version stated in MPEP Eighth Edition, Rev. 2, from May 2004. Similarly, this is the latest edition that does not raise issues of illegal retroactivity.

In the alternative, and *only* in the event that the Director denies each and every ground raised in §§ III and IV and Exhibit B, *then* Petitioner requests revival of the application as unavoidably or unintentionally abandoned, and requests that the fee therefor be charged to Deposit Account 50-3938, Order No. 01-1048.

Whatever the disposition of the above issues, the President instructs the PTO to implement the *Final Bulletin for Agency Good Guidance Practices*. Implementation of this directive from the President is now two years overdue, and implementation should begin forthwith. In particular, the Director should remonstrate with SPE's and examiners (especially in Tech Centers 3690) that they do not have authority to create personal exemptions from the

MPEP, and do not have authority to impose requirements against applicants above those stated in documents having force of law. They should be instructed that the law is not what they remember from training or arrive at by consensus or reason; the law is what exists in writing.

Kindly charge any additional fee, or credit any surplus, to Deposit Account No. 50-3938, Order No. 01-1048.

Respectfully submitted,

Dated: November 20, 2009

By: /David E. Boundy/
Registration No. 36,461

110 East 59th St.
New York, NY 10022
(212) 294-7848
(917) 677-8511 (FAX)

Exhibit A to
Petition to Vacate Examiner's Papers

**John Love, Memorandum to Patent Examining
Corps, "Changes to Restriction form
paragraphs" (April 25, 2007)**




UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MEMORANDUM

Date: April 25, 2007

To: Technology Center Directors
Patent Examining Corps

From: John Love 
Deputy Commissioner for Patent Examination Policy

Subject: Changes to Restriction form paragraphs

The purpose of this memorandum is to clarify Office policy with respect to communicating election of species requirements to applicants and with respect to establishing burden in the context of election of species requirements and restriction requirements.

Current form paragraphs 8.01 and 8.02 concerning election of species have caused confusion for some patent examiners and applicants. The current form paragraphs require an examiner to provide an explanation as to why the species are independent or distinct; the revised form paragraphs provide such explanation (i.e., "the mutually exclusive characteristics"). Using the revised form paragraphs, the examiner need only identify the species and identify the generic claim(s) (if present). However, as the Examiner Notes state, it is useful to describe the mutually exclusive characteristics of each species, if these characteristics are not readily apparent by the designation of the species by the figures or examples in the specification.

As noted in MPEP §§ 803 and 808.02, if the examination and search of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they are drawn to independent or distinct inventions, including species. To help ensure that an election of species requirement sets forth the requisite burden, the statement of search and examination burden is now incorporated directly into form paragraphs 8.01 and 8.02. These form paragraphs have been amended to include the three most common reasons for this burden in an election of species. In most cases at least two, if not all three, of these reasons will apply for patentably distinct species. If the applicant argues that the restriction is improper because there is no burden, the examiner should specify which one(s) of the reasons apply. The examiner should be able to readily identify with specificity which reason(s) apply when responding to applicant's arguments, since the search and FAOM will have been done.

New form paragraph 8.21 consolidates and replaces previous form paragraphs 8.21.01- 8.21.03 and 8.22. This new form paragraph will be for use at the end of all restriction requirements which require restrictions between inventions other than election of species, and lists the most common reasons for the search and examination burden.

The next revision of the MPEP will be amended to incorporate these changes. Examiners should seek assistance from knowledgeable TC personnel if questions arise.

Members of the MPEP Chapter 800 Review workgroup include:

TC 1600- Julie Burke, Christopher Low TC 1700- Gladys Corcoran
TC 2100- Pat Salce TC 2800- Hien Phan, Bill Baumeister
TC 2600- Ken Vanderpuye TC 3600- Terry Melius, Vinnie Millin
TC 3700- Tom Hughes OPLA- Kathleen Fonda, Karen Hastings

The following form paragraphs will be available as "custom form paragraphs" until the release of next OACS update in July 2007.

Amended form paragraphs 8.01, 8.02 and new form paragraph 8.21

¶ 8.01 Requiring an Election of Species; Species Claim(s) Present

This application contains claims directed to the following patentably distinct species [1]. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, [2] generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Examiner Note:

1. In bracket 1, identify the species from which an election is to be made. The species are preferably identified as the species of figures 1, 2, and 3, for example, or the species of examples I, II, and III, respectively. It would be useful to describe the mutually exclusive characteristics of each species if these characteristics are not readily apparent. Or, it may be useful to explain in more detail why the species are

independent or distinct using, for example only, the definition of independent or distinct inventions at MPEP § 802.01 or form paragraphs 8.14.01 or 8.20.02. However, it is not necessary to use form paragraphs 8.14.01 or 8.20.02 here.

2. In bracket 2 insert the appropriate generic claim information.
3. This form paragraph does not need to be followed by form paragraph 8.21.
4. If applicant traverses the requirement on the basis that there is no search burden, the examiner will explain specifically which reason(s) apply.

¶ 8.02 Requiring an Election of Species; No Species Claim Present

Claim [1] generic to the following disclosed patentably distinct species: [2]. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Examiner Note:

1. This form paragraph should be used for the election of requirement described in MPEP § 803.02 (Markush group) and MPEP § 808.01(a) where only generic claims are presented.
2. In bracket 2, clearly identify the species from which an election is to be made. The species may be identified as the species of figures 1, 2, and 3, for example, or the species of examples I, II, and III, respectively. It would be useful to describe the mutually exclusive characteristics of each species if these characteristics are not readily apparent. Or, it may be useful to explain in more detail why the species are

independent or distinct using, for example only, the definition of independent or distinct inventions at MPEP § 802.01 or form paragraphs 8.14.01 or 8.20.02. However, it is not necessary to use form paragraphs 8.14.01 or 8.20.02 here.

3. This form paragraph does not need to be followed by form paragraph 8.21.

4. If applicant traverses the requirement on the basis that there is no search burden, the examiner will explain specifically which reason(s) apply.

New form paragraph 8.21 replaces previous form paragraphs 8.21.01 - 8.21.03 and 8.22:

¶ **8.21 To Establish Burden AND Requirement for Election and Means for Traversal for all Restrictions, other than an Election of Species**

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Examiner Note:

1. THIS FORM PARAGRAPH MUST BE ADDED TO ALL RESTRICTION REQUIREMENTS **other than** those containing **only election of species**, with or without an action on the merits. This form paragraph only needs to be used once, after all restriction requirements are set out.

2. If applicant traverses the requirement on the basis that there is no search burden, the examiner will explain specifically which reason(s) apply.

Exhibit B to
Petition to Vacate Examiner's Papers

Summary of Legal Errors in the Love memo

<p>Process violations</p>	<p>Independent and Distinct Violations of Administrative Procedure Act (APA), Paperwork Reduction Act (PRA), and Good Guidance Principles (GGP)</p> <p>PRA violation #1: No valid OMB Control Number for paperwork burdens associated with MPEP language. (Only the burden of the transmittal form is approved.)</p> <p>APA violation #2: Unpublished until April 2009, 2 years after signature in April 2007. Constitutional violation #3: Unpublished until April 2009</p> <p>APA violation #4: No Federal Register notice.</p> <p>APA violation #5: PTO violated its own "published rules" in MPEP Foreword</p> <p>PRA violation #6: No valid OMB Control Number for most paperwork burdens associated with regulatory text. (Only the burden of the transmittal form is approved.)</p> <p>GGP violation #7: PTO violated its own "written rules" from MPEP Foreword</p> <p>APA violation #8: the Love memo is illegally retroactive</p> <p>APA violation #9: No public notice and comment for a substantive change, or change to long-standing interpretative rule.</p> <p>GGP violation #10: No written PTO procedures for issuing guidance. §II(1)(a).</p> <p>GGP violation #11: No public notice and comment, or reply to public comments received. §IV(1)(a-c).</p> <p>GGP violation #12: No reply to public comments. §IV(1)(d).</p> <p>GGP violation #13: Unpublished until April 2009, 2 years after issuance in April 2007. §III(1).</p> <p>GGP violation #14: No web page with "a current list of its significant guidance documents in effect," § III(a)(1)</p> <p>GGP violation #15: no web page with a list of "guidance documents that have been ... withdrawn in the past year", § III(a)(2), leaving the public unaware that pre-2007 MPEP was purportedly superseded</p> <p>GGP violation #16: No Guidance officer to "receive and address complaints by the public that the agency is not following the procedures" of the Good Guidance Bulletin. § III(2)(b)</p>
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<p>Both the pre-2007 MPEP and the Love memo exceed the limits on the PTO's authority to divide applications set by statute and regulation</p>	<p><i>Independent and Distinct Violations of Administrative Procedure Act (APA), Paperwork Reduction Act (PRA), and Good Guidance Principles (GGP)</i> STATUTORY AND REGULATORY LANGUAGE</p> <p>35 USC § 121</p> <p>“If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions.”</p> <p>37 CFR § 1.141(a)</p> <p>“Two or more independent and distinct inventions may not be claimed in one national application, ...”</p> <p>MPEP § 803</p> <p>“The claims of an application may properly be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent or distinct.”</p> <p><i>APA violation #17: The PTO cannot change regulations by guidance. (“And” and “or” are opposite logical operators.)</i></p> <p>LOVE MEMORANDUM (“Changes to Restriction form paragraphs” (4/25/07)-- consistent with MPEP § 803</p>
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<p>The Love memo triggers applicability of the APA and PRA by changing the substantive criteria that the PTO must show in order to require restriction</p>	<p><i>Independent and Distinct Violations of Administrative Procedure Act (APA), Paperwork Reduction Act (PRA), and Good Guidance Principles (GGP)</i> STATUTORY AND REGULATORY LANGUAGE</p> <p>[None.] MPEP § 803</p> <p>(A) “The inventions must be independent or distinct as claimed; and (B) There would be a serious burden on the examiner if restriction is not required.”</p> <p>LOVE MEMORANDUM (“Changes to Restriction form paragraphs” (4/25/07)</p> <p>(A) “The inventions must be independent or distinct as claimed (B) [T]here would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:</p> <p>(a) the inventions have acquired a separate status in the art in view of their different classification; (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter; (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries); (d) the prior art applicable to one invention would not likely be applicable to another invention; (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.”</p> <p><i>APA violation #18: Authorizes examiner to restrict without identifying specific grounds or facts, and without providing a “rational explanation” correlating the two</i> <i>PRA violation #19: Requires a greater number of papers filed to elect claims – no OMB ICR filing to obtain clearance for the additional responses</i> <i>PRA violation #20: Requires a greater number of divisional applications – no OMB ICR filing to obtain clearance for the additional responses</i> <i>GGP violation #21: Changes includes directive language binding the public. §(2)(h).</i></p>
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<p>What constitutes “serious burden on the Examiner,” and what showings must the examiner state in order to satisfy the requirement to show “serious search burden?”</p>	<p><i>Independent and Distinct Violations of Administrative Procedure Act (APA), Paperwork Reduction Act (PRA), and Good Guidance Principles (GGP)</i></p> <p>MPEP § 803: “[T]he examiner must show by appropriate explanation [one or more of the criteria set forth in §§ 808 (II) and 808.02].”</p> <p>MPEP § 808.01 “The particular reasons relied on by the examiner for holding that the inventions as claimed are either independent or distinct should be concisely stated. A mere statement of conclusion is inadequate. The reasons upon which the conclusion is based should be given.”</p> <p>MPEP § 808.02 “[I]n order to establish reasons for insisting upon restriction, [the Examiner] must explain why there would be a serious burden on the examiner if restriction is not required. Thus the examiner must show by appropriate explanation one of the following: (A) Separate classification thereof... (B) A separate status in the art when they are classifiable together... (C) A different field of search...”</p> <p>“Where ... the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among independent or related inventions.”</p> <p>LOVE MEMORANDUM (“Changes to Restriction form paragraphs” (4/25/07) Using the revised form paragraphs, the examiner need only identify the species and identify the generic claim(s) (if present). The examiner need not state any explanation.</p> <p>APA violation #22: <i>Changes substantive regulatory requirements (from the three criteria of MPEP § 808.02 to the five of the Love memo) without rule making procedure.</i> APA violation #23: <i>(Eliminates APA requirement that all agency decisions include “statement of grounds” and “rational connection between the facts found and the choice made.”.)</i> PRA violation #24: <i>PTO failed to file for Paperwork clearance for the additional responses triggered by the shift from three criteria to five</i> GGP violation #25: <i>Examiners may depart from guidance without supervisory approval. §11(2)(2)(b).</i></p>
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<p>What are an applicant's obligations and options?</p>	<p><i>Independent and Distinct Violations of Administrative Procedure Act (APA), Paperwork Reduction Act (PRA), and Good Guidance Principles (GGP)</i></p> <p>MPEP</p> <p>1. [Identify Examiner error and reply via a traverse paper]. <i>PRA violation #26: even for pre-existing MPEP standard, no valid OMB Control Number for burden associated with rebuttal paper.</i></p> <p>2. Election and filing of divisional [MPEP § 809.02(a)]. <i>PRA violation #27: even for pre-existing MPEP standard, No valid OMB Control Number for burden associated with election paper or divisional filings</i></p> <p>LOVE MEMORANDUM (“Changes to Restriction form paragraphs” (4/25/07) <i>PRA violation #28: Burden is ambiguous—because Love memo does not require identification of grounds or relevant facts,; public does not know what is required to rebut examiner’s determination.</i></p>
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Exhibit C to
Petition to Vacate Examiner's Papers

**Email Conversation with the PTO's Paperwork
Officials**

Boundy, David

From: Boundy, David
Sent: Friday, August 21, 2009 5:07 PM
To: 'Robert.Clarke@uspto.gov'
Cc: 'Nicholas_A._Fraser@omb.eop.gov'
Subject: Information Collection question

Attachments: Extract from OA showing non-MPEP restriction.pdf

Dear Mr. Clarke:

I have received a number of information collections substantially similar to the attached over the last 12 months or so.



Extract from OA
showing non-MP...

Based on my review, it appears that the PTO does not have a valid OMB Control Number for the modified information collection (an election of claims) requested in this paper. I also am unable to find any indication that the PTO ever sought clearance for the modified information collection (the additional divisional applications) that arise in the wake of such an election.

However, I may be wrong. If so, please identify the OMB Control Number that applies to providing elections of claims pursuant to the restriction rule set forth in this information collection. For each of these two information collection components, please identify the ICR submission number and the table line within that submission.

Thank you.

David E. Boundy
Vice President, Assistant General Counsel Intellectual Property
Cantor Fitzgerald LP

125 High Street, 26th Fl
Boston, MA 02110
(857) 413-2045 (no voice mail - use 212 number)
(646) 472 9737 (cell)

110 East 59th St
New York, NY 10022
(212) 294-7848
(917) 677-8511 (FAX)

Boundy, David

From: McDowell, Jennifer [Jennifer.McDowell@USPTO.GOV]
Sent: Thursday, September 24, 2009 7:56 AM
To: Boundy, David
Subject: RE: Information Collection questions

Yes, it is.

From: Boundy, David [mailto:DBoundy@cantor.com]
Sent: Wednesday, September 23, 2009 11:15 AM
To: McDowell, Jennifer
Subject: RE: Information Collection questions

Dear Ms. McDowell:

Thank you very much for your reply.

Could you please confirm that this is in reply to my email to Robert Clarke of Fri 8/21/2009 5:07 PM.

Thank you.

David E. Boundy
Vice President, Assistant General Counsel Intellectual Property
Cantor Fitzgerald LP

125 High Street, 26th Fl
Boston, MA 02110
(857) 413-2045 (no voice mail - use 212 number)
(646) 472 9737 (cell)

110 East 59th St
New York, NY 10022
(212) 294-7848
(917) 677-8511 (FAX)

From: McDowell, Jennifer [mailto:Jennifer.McDowell@USPTO.GOV]
Sent: Tuesday, September 22, 2009 4:07 PM
To: Boundy, David
Cc: 'Fraser, Nicholas A.'
Subject: Information Collection questions

Mr. Boundy,
I understand that you have recently contacted the USPTO. I am responding to your inquiries.

According to the White House Memorandum issued on March 4, 2009, the USPTO, like other federal agencies, remains obligated to seek review from OMB's Office of Information and Regulatory Affairs (OIRA) of significant policy and guidance documents. The memo makes clear that although President

9/30/2009

Obama revoked certain provision of Executive Order 12,866 relating to OIRA review, certain agency actions and documents remain subject to OIRA review. OMB has designated the Manual of Patent Examining Procedure as a significant guidance document, and the MPEP has been reviewed by OIRA.

Turning to your next question about redress for alleged violations of the Paperwork Reduction Act (PRA), you may contact OIRA if you believe that USPTO has not complied with the PRA. As you know, the PRA does not create a private right of action, but specifically serves as a defense to enforcement actions, by stating that "no person shall be subject to any penalty for failing to comply with a collection of information [...] if the collection of information does not display a current control number assigned by the Director [of the Office of Management and Budget.]"

Lastly, responses to Office actions, including responses to Office actions containing a requirement for restriction or for an election of species, are associated with the information collection under OMB control number 0651-0031. New applications, including new continuation applications, new divisional applications, or new continuation-in-part applications, are covered are associated with the information collection under OMB control number 0651-0032. The USPTO provides transmittal forms for responses to Office actions (PTO/SB/21) and for new applications (PTO/SB/05, PTO/SB/18, and PTO/SB/19), but does not provide a form for responses to Office actions or applications themselves.

Jennifer M. McDowell
Associate Counsel
Office of General Law

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E-mail transmission cannot be guaranteed to be secure or error-free. The sender
Although we routinely screen for viruses, addressees should check this e-mail a

For further important information, please see <http://www.cantor.com/legal/statement>

Exhibit D to
Email to Senior PTO Officials (Feb. 25, 2009)
Pages from the PTO's Web Site

Boundy, David

From: Boundy, David
Sent: Wednesday, February 25, 2009 12:36 PM
To: 'John.Doll@uspto.gov'; 'John.Love@uspto.gov'; 'James.Toupin@uspto.gov';
'Robert.Bahr@uspto.gov'; 'Magdalen.Greenlief@uspto.gov'
Subject: Revisions to MPEP

Dear Mr. Doll, Mr. Love, Mr. Toupin, Mr. Bahr, Ms. Greenlief:

I have been given materials that suggest that the PTO is planning a major and imminent revision of the MPEP. The materials I have suggest the following issues that I hope you will carefully consider before you go forward.

1. The materials I have qualify as a "rule" under the Administrative Procedure Act. 5 U.S.C. § 551(4); *Batterton v. Marshall*, 648 F.2d 694, 700-01 (D.C. Cir. 1980). Thus, at a minimum, a 30-day Federal Register notice would be required before enforcement can begin. I would also refer you to *Tafas v. Dudas*, 541 F.Supp.2d 805, 812, 86 USPQ2d 1623, 1628 (E.D. Va. 2008), which held that "the USPTO must engage in notice and comment rule making when promulgating rules it is otherwise empowered to make." The schedule information I have conflicts with these obligations under the APA and 35 U.S.C. § 2.

2. Rahm Emanuel and Peter Orszag have asked agencies not to publish rule making notices until an Obama appointee can review them. Rahm Emanuel, Memorandum for the Heads of Executive Departments and Agencies, Jan. 20, 2009, 74 Fed. Reg. 4435, <http://edocket.access.gpo.gov/2009/pdf/E9-1639.pdf> (Jan. 26, 2009); Peter Orszag, OMB Memorandum M-09-08, Implementation of Memorandum Concerning Regulatory Review (Jan. 21, 2009), http://www.whitehouse.gov/omb/assets/agencyinformation_memoranda_2009_pdf/m09-08.pdf. The schedule information I have conflicts with these instructions from the White House, and Mr. Orszag's request that rule making procedural requirements and public transparency be observed.

3. The materials I have are a "modification" of an "information collection," and therefore covered by the Paperwork Reduction Act. If the PTO publishes these amendments to the MPEP or distributes them to examiners, they will be unenforceable until they have gone through the process required by 44 U.S.C. § 3506 and § 3507. The PTO has never begun the Paperwork clearance process with respect to the materials I have, let alone completed it. (From the OMB files I have going back to late 2005, it appears that the PTO has never sought - let alone obtained - Paperwork clearance for **any** aspect of restriction practice - if my information is complete, any applicant could invoke the public protections of 44 U.S.C. § 3512 with respect to any restriction requirement. I suggest that the PTO might want to get current procedures on an enforceable footing before initiating a controversy by modifying them.)

4. The materials I have are "economically significant" amendments to guidance for purposes of the Final Bulletin on Agency Good Guidance Practices, OMB Memorandum M-07-07, <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf>. (Incidentally, I note that Mr. Love's office has regularly breached this set of instructions from OMB - perhaps this would be a good time to reevaluate the PTO's MPEP and examiner memorandum processes to ensure compliance going forward.)

5. When I received these materials, it explained a number of anomalous, non-MPEP-compliant papers I have received from examiners in the last few months. It is very curious that the PTO would be enforcing revised restriction rules that have **never** been published anywhere, let alone with the required notice in the Federal Register. Unpublished rules breach 5 U.S.C. § 552(a), § 553, and Constitutional due process, and OMB's Good Guidance Bulletin. Unpublished PTO practice that has never obtained OMB clearance also violates the Paperwork Reduction Act.

My information is partial, dated, and of unknown reliability. I apologize if I am misinformed. Kindly consider these issues carefully before acting. It would be very unfortunate for the PTO to publish something, and then have to publicly retract it.

Nonetheless, even if there is no new problem about to be created by an MPEP revision, there are a number of legal breaches already in daily progress, and I hope you will cure them with appropriate instructions to the examining corps, requests for Paperwork clearance, and the like. I suggest that the PTO should circulate a memorandum to the examining corps rescinding any previous instructions that have not been incorporated into the MPEP and not made public as required by the APA and OMB's Good Guidance Bulletin. A Federal Register notice should inform the public that restriction practice is unamended since 2006, and all restriction requirements relying on non-MPEP reasons like "the species are likely to raise different non-prior art issues under 35 U.S.C. 101 or 35 U.S.C. 112" were issued in error, are legally ineffective, and are withdrawn with no further action required by an applicant. A number of Paperwork requests for

approval are long overdue.

I am available to discuss any of these issues with you. Thank you.

David E. Boundy
Vice President, Assistant General Counsel Intellectual Property
Cantor Fitzgerald LP

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Exhibit E to

Petition to Vacate Examiner's Papers

Pages from the PTO's Web Site

United States Patent and Trademark Office

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Office of Patent Examination Policy

- [Office of Petitions \(#heading-1\)](#)
- [Office of Patent Legal Administration \(OPLA\) \(#heading-2\)](#)
- [Patent Cooperation Treaty Legal Administration \(#heading-3\)](#)
- [Manual of Patent Examining Procedure \(MPEP\) Staff \(#heading-4\)](#)

Office of Petitions

The Office of Petitions, under the authority of the Deputy Commissioner of Patent Examination (DCPEP), reviews and decides petitions, requests, and related inquiries, regarding the filing of patent applications, revival of abandoned applications, reinstatement of expired patents, withdrawal of patent applications from issue, small entity entitlement, review of previous decisions of the Technology Centers, suspension of regulations, and questions not specifically provided for by regulations.

[Further information about the Office of Petitions \(/about/offices/patents/pep/office_of_petitions.jsp\)](/about/offices/patents/pep/office_of_petitions.jsp)

Office of Patent Legal Administration (OPLA)

The mission of the Office of Patent Legal Administration (OPLA) is to assist in the development and administration of U.S. patent law, advise the USPTO on patent examination policy and formulate new regulations, policies, and procedures regarding patents.

The OPLA has the following responsibilities:

- Provides legal and policy guidance to the Commissioner for Patents, the Deputy Commissioner for Patent Operations, the Deputy Commissioner for Patent Resources and Planning, and the Deputy Commissioner for Patent Examination Policy.
- Assists in the development and implementation of patent law, provides means for its implementation, and formulates the accompanying regulations and practices.
- Monitors specialized programs such as reexamination, reissue and patent term extension; and assists in the efforts to negotiate the harmonization of patent laws and other international matters.
- Provides MPEP staff with suggested changes to the MPEP as a result of changes to the patent rules.
- Is also responsible for updating a majority of forms used by the patent examining corps and USPTO customers to reflect changes made to the patent rules and through policy initiatives.
- Legal advisors and special projects examiner provide staff assistance on special projects or studies as may be assigned by the Director of the OPLA, the Deputy Commissioner for Patent Examination Policy or the Commissioner for Patents. They also prepare reports or other documents as may be appropriate including studies and papers comparing US patent law and practices with the patent laws of other countries.
- Staff research case law, appropriate rules, facts-in-evidence, and other pertinent information; discuss policy implications with top USPTO management officials; compose USPTO decisions and either sign the decisions or have the final USPTO decision signed by the Deputy Commissioner for Patent Examination Policy or other top US Patent and Trademark Office management officials.
- Staff represent the USPTO and explain US patent law and Office policies and procedures in letters, phone calls, lectures and other contacts with members of the public and the patent bar.
- Staff decide various petitions and assists the Office of Petitions in deciding petitions, which have been delegated to that office for consideration.

>> [Presentations \(/patents/law/exam/presentation/index.jsp\)](/patents/law/exam/presentation/index.jsp)

Patent Cooperation Treaty Legal Administration

Provides legal and policy guidance on issues under the Patent Cooperation Treaty (PCT), including PCT rulemaking, international search and examination guidelines, petitions and training; provides education programs for users of PCT; and provides administrative oversight and coordinates the activities of the following functions: Patent Cooperation Treaty Legal Affairs, (PCTLA) which reviews and decides petitions relating to the PCT, assists with PCT Rules modifications, the legal standards for application format and electronic filing of international applications; Patent Cooperation Treaty Special Programs (PCTSP), which provides on all aspects of the PCT process; prepares training materials for PCT training classes for Patent Examining Corps professional and technical support staff, patent attorneys and agents, legal administrators, legal secretaries, and other members of the patent community; and provides current up-to-date PCT forms through the PCT Help Desk and through the PCT Home Page found on the United States Patent and Trademark Internet site; and the Inventor Assistance Center (IAC), which provides information and services to the public concerning any general questions regarding patenting examining policies and procedures, as well as other services provided by the United States Patent and Trademark Office and directs callers to the appropriate contact source; and mails or faxes information to customers as needed.

The Office of PCT Legal Administration is comprised of two branches

PCT Special Programs

The function of the PCT Special Programs Branch is to educate and assist the patent community with respect to the Patent Cooperation Treaty.

This branch is responsible for:

- Providing training courses to help patent applicants and practitioners file PCT applications
- Providing instruction to patent examiners at the USPTO concerning the search and examination of PCT applications.
- Providing direct assistance regarding PCT applications via the PCT Help Desk

PCT Legal Affairs

The PCT Legal Affairs Branch resolves legal issues relating to the Patent Cooperation Treaty. Such issues most often arise through petitions to the Commissioner in PCT international applications and in U.S. national stage applications submitted under 35 U.S.C. 371. This branch interprets and/or suggests changes to patent laws and rules and studies their effect on the Patent Cooperation Treaty and deals with other aspects of international patent law such as harmonization, the Patent Law Treaty, and electronic filing.

Manual of Patent Examining Procedure (MPEP) Staff

The **MPEP** staff organization works directly for the **Deputy Commissioner for Patent Examination Policy** and provides staff assistance in developing and formulating new guidelines, examining practices and procedures as well as revising existing guidelines, practices and procedures. The MPEP staff is responsible for updating the MPEP and the form paragraphs used by the examining corps. The MPEP staff is also responsible for ensuring that revised policies and procedures are appropriately disseminated to Office personnel through revisions to the MPEP, Federal Register or Official Gazette notices, or other official announcements. The MPEP staff also handles inquiries from Office personnel and the public requesting assistance in properly interpreting existing practices and procedures. [\(/about/offices/patents/pep/mpep_staff.jsp\)](/about/offices/patents/pep/mpep_staff.jsp)

[Further information about the MPEP staff \(/about/offices/patents/pep/mpep_staff.jsp\)](/about/offices/patents/pep/mpep_staff.jsp)

United States Patent and Trademark Office

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Recent Patent-Related Notices

TITLE*	OG CITE	OG DATE	FR CITE	FR DATE
* active hyperlinks in this column retrieve USPTO documents posted prior to publication in the OG or Fed. Reg.				
Notice of Change to Docketing of Requests for Continued Examination (signed 19 October 2009) [PDF]				
Changes to Practice for Continued Examination Filings, Patent Applications Containng Patentably Indistinct Claims, and Examination of Claims in Patent Applications (15Oct2009)			74 Fed. Reg.52686 [PDF]	14OCT2009
Additional Period for Comments on Interim Examination Instructions for Evaluating Patent Subject Matter Eligibility (09Oct2009)			74 Fed. Reg.52184 [PDF]	09OCT2009
Continuation of the Patent Prosecution Highway Pilot Program between the USPTO and DKPTO (signed 05 October 2009) [PDF]				
Continuation of the Patent Prosecution Highway Pilot Program between the USPTO and EPO (22Sep2009)	1347 OG 170	20OCT2009		
Request for Comments on Interim Examination Instructions for Evaluating Patent Subject Matter Eligibility (11Sep2009)	1347 OG 110	13OCT2009	74 Fed. Reg.47780 [PDF]	11SEP2009
Clarification of the Date of Decision of the Board of Patent Appeals and Interferences Under 37 CFR 1.304	1347 OG 48	06OCT2009		

(11Sep2009)				
Notice Concerning Calculation of the Patent Term Adjustment under 35 U.S.C. § 154(b)(1)(B) involving International Applications Entering the National Stage Pursuant to 35 U.S.C. § 371 (10Sep2009)	1347 OG 49	06OCT2009		
July 2009 Revision of Patent Cooperation Treaty Procedures; Final Rule (24Jun2009)	1344 OG 222	28JUL2009	74 Fed. Reg. 31372 [PDF]	01JUL2009
Patent Prosecution Highway Pilot Program between the United States Patent and Trademark Office and the National Board of Patents and Registration of Finland (25Jun2009)	1344 OG 165	21JUL2009		
Additional Period for Comments on Deferred Examination for Patent Applications; Request for comments; additional comment period (09Jun2009)	1344 OG 52	07JUL2009	74 Fed. Reg. 28473 [PDF]	16JUN2009
Sequence Listings and Tables Related Thereto in International Applications Filed in the United States Receiving Office (11Jun2009)	1344 OG 50	07JUL2009		
Electronic Exchange of Non-Participating Office Priority Documents Between the Japan Patent Office and the United States Patent and Trademark Office (03Jun2009)	1343 OG 348	30JUN2009		
Addition of World Intellectual Property Office as Participating Foreign Intellectual Property Office in Electronic Exchange of Priority Documents (01Jun2009)	1343 OG 347	30JUN2009		
Electronic Office Action (11May2009)	1343 OG 45	02JUN2009		
Patent Prosecution Highway Pilot Program between the United	1342 OG 100	12MAY2009		

States Patent and Trademark Office and the German Patent and Trade Mark Office (14Apr2009)				
Continuation of the Patent Prosecution Highway Pilot Program between the USPTO and IP Australia (13Apr2009)	1342 OG 99	12MAY2009		
Limited Competency of Certain International Searching Authorities With Respect to Applications Filed in the USPTO (13Mar2009)	1341 OG 51	07APR2009		
Extension of Time for Comments on Deferred Examination for Patent Applications; Request for comments; extension of comment period (03Mar2009)	1340 OG 262	31MAR2009	74 Fed. Reg. 10036 [PDF]	09MAR2009
Patent Prosecution Highway Pilot Program between the United States Patent and Trademark Office and the Intellectual Property Office of Singapore (29Jan2009)	1339 OG 160	24FEB2009		
Request for Comments and Notice of Roundtable on Deferred Examination for Patent Applications; Notice; Request for Comments (22Jan2009)	1339 OG 153	24FEB2009	74 Fed. Reg. 4946 [PDF]	28JAN2009
Notice Regarding Full Implementation of Patent Prosecution Highway Program between the United States Patent and Trademark Office and the Korean Intellectual Property Office (28Jan2009)	1339 OG 155	24FEB2009		
Closing of the United States Patent and Trademark Office on Friday, December 26, 2008 (22Dec2009)	1340 OG 200	24MAR2009		
Extension of the Patent Prosecution Highway Pilot Program between the USPTO and the	1338 OG 99	13JAN2009		

CIPO (22Dec2008)				
Patent Cooperation Treaty Update (18Dec2008)	1338 OG 61	13JAN2009		
Revised Requirements for Requesting Participation in the Patent Prosecution Highway Pilot Program in the USPTO (Between the USPTO and the EPO) (10Dec2008)	1338 OG 48	06JAN2009		
Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals; Delay of Effective and Applicability Dates (05Dec2008)			73 Fed. Reg. 74972 [PDF]	10DEC2008
Clarification of the Effective Date Provision in the Final Rule for Ex Parte Appeals; Interpretation and effective date clarification (20Nov2008)	1337 OG 44	02DEC2008	73 Fed. Reg. 70282 [PDF]	20NOV2008
Changes to Representation of Others Before the United States Patent and Trademark Office; Final Rule (17Nov2008)	1337 OG 107	09DEC2008	73 Fed. Reg. 67750 [PDF]	17NOV2008
Fiscal Year 2009 Changes to Patent Cooperation Treaty Transmittal and Search Fees; Final Rule (12Nov2008)	1337 OG 97	09DEC2008	73 Fed. Reg. 66754 [PDF]	12NOV2008
United States Patent and Trademark Office Bibliographic Information on Issued Patents and Published Patent Applications (21Oct2008)	1336 OG 204	25NOV2008		
Australian Patent Office to Act as International Searching Authority and International Preliminary Examining Authority for International Applications Received by the USPTO (31Oct2008)	1337 OG 265	23DEC2008		

Patent Prosecution Highway Pilot Program between the United States Patent and Trademark Office and the Danish Patent and Trademark Office (21Oct2008)	1336 OG 150	18NOV2008		
Addition of Korean Intellectual Property Office as Participating Foreign Intellectual Property Office in Electronic Exchange of Priority Documents and Further Procedural Information (14Oct2008)	1336 OG 94	11NOV2008		
Changes to Representation of Others Before the United States Patent and Trademark Office; Final Rule; Correction (09Oct2008)	1340 OG 257	31MAR2009	73 Fed. Reg. 59513 [PDF]	09OCT2008
Arrangement between IP Australia and the United States Patent and Trademark Office Concerning Action of the Australian Patent Office as an International Searching Authority and Preliminary Examining Authority under the Patent Cooperation International Treaty for Certain International Applications Received by the United States Patent and Trademark Office (24Sep2008)	1337 OG 261	23DEC2008		
Patent Prosecution Highway Pilot Program between the United States Patent and Trademark Office and European Patent Office (22Sep2008)	1335 OG 196	21OCT2008		
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Extension of the Patent Prosecution Highway Pilot Program Between the USPTO and the UKIPO (29Aug2008)	1336 OG 149	18NOV2008		
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Processing No Longer Required (27Aug2008)				
Changes to Representation of Others Before the United States Patent and Trademark Office; Final Rule (14Aug2008)	1334 OG 127	09SEP2008	73 Fed. Reg. 47650 [PDF]	14AUG2008
Revision of Patent Fees for Fiscal Year 2009: Final Rule (14Aug2008)	1334 OG 45	02SEP2008	73 Fed. Reg. 47534 [PDF]	14AUG2008
Changes to Practice for Documents Submitted to the United States Patent and Trademark Office, Notice of proposed rulemaking (06Aug2008)	1335 OG 55	07OCT2008	73 Fed. Reg. 45662 [PDF]	06AUG2008
Scope of Foreign Filing Licenses, Notice (23Jul2008)	1333 OG 159	19AUG2008	73 Fed. Reg. 42781 [PDF]	23JUL2008
Extension and Expansion of Pilot Concerning Public Submission of Peer Reviewed Prior Art (17Jul2008)	1333 OG 103	12AUG2008		
"Triway" Pilot Program among the United States Patent and Trademark Office, the European Patent Office, and the Japan Patent Office (14Jul2008)	1333 OG 50	05AUG2008		
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United States Postal Service Interruption and Emergency under 35 U.S.C. 21(a) (17Jun2008)	1332 OG 302	15JUL2008		
Fiscal Year 2009 Changes to Patent Cooperation Treaty Transmittal and Search Fees, Notice of proposed rulemaking (18Jun2008)	1332 OG 295	15JUL2008	73 Fed. Reg. 34672 [PDF]	18JUN2008
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Interferences in Ex Parte Appeals; Final Rule (10Jun2008)				
Revision of Patent Fees for Fiscal Year 2009, Proposed rule (29May2008)	1331 OG 97	24JUN2008	73 Fed. Reg. 31655 [PDF]	03JUN2008
Notice of Town Hall Meeting on the Protection of Industrial Designs (signed 28 May 2008) [PDF]				
Notice of Complex Work Unit Pilot Program Request for Voluntary Submission of Electronic Complex Work Unit Files (14Apr2008)	1330 OG 49	06MAY2008		
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WEB CAST RE: PUBLIC PAIR AND DATA-MINING REQUESTS WEB CAST (31Mar2008) [more information]	1329 OG 170	22APR2008		
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First Action Interview Pilot Program (24Mar2008)	1329 OG 159	22APR2008		
Change in Procedure for Requests to Withdraw from Representation In a Patent Application (13Mar2008)	1329 OG 99	08APR2008		
Examination of Patent Applications That Include Claims Containing Alternative Language; Proposed rule, request for comment on initial regulatory flexibility analysis (10Mar2008)	1329 OG 41	01APR2008	73 Fed. Reg. 12679 [PDF]	10MAR2008
Signatures No Longer Provided on Outgoing Correspondence from the Board of Patent Appeals and Interferences (18Mar2008)	1328 OG 140	18MAR2008		

Revision to the Time for Filing of a Biological Deposit and the Date of Availability of a Biological Deposit, Notice of proposed rulemaking (20Feb2008)	1328 OG 141	18MAR2008	73 Fed. Reg. 9254 [PDF]	20FEB2008
Termination of the United States Postal Service Interruption and Emergency under 35 U.S.C. 21(a) (15Feb2008)	1328 OG 95	11MAR2008		
Enhancement of Priority Document Exchange Program and USPTO Declaration Form (13Feb2008)	1328 OG 90	11MAR2008		
New Route Pilot Project between the United States Patent and Trademark Office and the Japan Patent Office (24Jan2008)	1332 OG 422	29JUL2008		
Duty of Disclosure Language Set Forth in Oaths or Declarations Filed in Nonprovisional Patent Applications (22Jan2008)	1327 OG 112	12FEB2008		
Patent Prosecution Highway Pilot Program between the United States Patent and Trademark Office and the Canadian Intellectual Property Office (14Jan2008)	1327 OG 45	05FEB2008		
Patent Prosecution Highway Pilot Program between the United States Patent and Trademark Office and the Korean Intellectual Property Office (14Jan2008)	1327 OG 49	05FEB2008		
Revised Requirements for Requesting Participation in the Patent Prosecution Highway Pilot Program in the USPTO (Between the USPTO and the UK IPO) (14Jan2008)	1327 OG 54	05FEB2008		
Notice Regarding Full Implementation of Patent Prosecution Highway Program between the United	1328 OG 44	04MAR2008		

States Patent and Trademark Office and the Japan Patent Office (signed 28 December 2007)				
Change in Publication Format of Patent and Trademark Office Notices and Changes in Display of Patent and Trademark Office Notices Electronic Official Gazette (signed 18 December 2007)	1326 OG 260	29JAN2008	72 Fed. Reg. 72999 [PDF]	26DEC2007
New Certification Requirements regarding the Export Administration Regulations in EFS-Web and Private PAIR (29 November 2007)	1326 OG 104	08JAN2008		
Closing of the United States Patent and Trademark Office on Monday, December 24, 2007 (signed 14 December 2007)	1326 OG 103	08JAN2008		
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April 2007 Revision of Patent Cooperation Treaty Procedures, Final rule; correction (11Oct2007)	1324 OG 22	06NOV2007	72 Fed. Reg. 57863 [PDF]	11OCT2007
Clarification of the Transitional Provisions Relating to Continuing Applications and Applications Containing Patentably Indistinct Claims (signed 10 October 2007)	1324 OG 20	06NOV2007		
Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc. (10Oct2007) [more information]	1324 OG 23	06NOV2007	72 Fed. Reg. 57526 [PDF]	10OCT2007
Revision of Patent Fees for Fiscal Year	1323 OG 160	23OCT2007	72 Fed. Reg. 55055 [PDF]	28SEP2007

2007, Final rule; correction (28Sep2007)				
April 2007 Revision of Patent Cooperation Treaty Procedures, Final rule (10Sep2007)	1323 OG xx	02OCT2007	72 Fed. Reg. 51559 [PDF]	10SEP2007
Patent Prosecution Highway Pilot Program between the United States Patent and Trademark Office and the United Kingdom Intellectual Property Office (signed 30 August 2007)	1322 OG 258	25SEP2007		
Revision of Patent Fees for Fiscal Year 2007, Final Rule (22Aug2007)	1321 OG 154	28AUG2007	72 Fed. Reg. 46899 [PDF]	22AUG2007
Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, Final rule (21Aug2007) [more information]	1322 OG 76	11SEP2007	72 Fed. Reg. 46716 [PDF]	21AUG2007
Electronic Signatures and Initials by Office Personnel Permitted in Application, Patent, and Reexamination Proceeding Matters (signed 20 August 2007)	1322 OG 73	11SEP2007		
Electronic Transfer of Priority Documents to the International Bureau (signed 13 August 2007)	1322 OG 30	04SEP2007		
Examination of Patent Applications That Include Claims Containing Alternative Language, Notice of proposed rule making (10Aug2007)	1322 OG 22	04SEP2007	72 Fed. Reg. 44992 [PDF]	10AUG2007
Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals (30 July 2007)	1321 OG 95	21AUG2007	72 Fed. Reg. 41472 [PDF]	30JUL2007
Addition of Japan Patent Office as Participating Foreign Intellectual Property	1320 OG 173	31JUL2007		

Office in Electronic Exchange of Priority Documents (signed 10 July 2007)				
Patent Cooperation Treaty Update (signed 28 June 2007; effective 01Aug2007)	1320 OG 116	24JUL2007		
Extension of the Patent Prosecution Highway Pilot Program between the USPTO and the JPO (signed 27 June 2007)	1320 OG 131	24JUL2007		
USPTO to Cease Supplying Paper Copies of Cited U.S. Patent References in International Applications	1320 OG 22	03JUL2007		
Simplification of the Electronic Exchange of Priority Documents (signed 04 June 2007)	1319 OG 150	26JUN2007		
Pilot Concerning Public Submission of Peer Reviewed Prior Art (signed 04 June 2007)	1319 OG 146	26JUN2007		
Electronic Notification of Outgoing Correspondence (e-Office Action) Update (signed 04 June 2007)	1319 OG 145	26JUN2007		
Revised Requirements for Requesting Participation in the Patent Prosecution Highway Pilot Program in the USPTO (signed 17 May 2007)	1319 OG 63	12JUN2007		
Electronic Exchange of Priority Documents (signed 23 April 2007)	1318 OG 116	15MAY2007		
Revisions and Technical Corrections Affecting Requirements for Ex Parte and Inter Partes Reexamination, Final rule (16 April 2007)	1318 OG 65	08MAY2007	72 Fed. Reg. 18892 [PDF]	16APR2007
Interim Procedures For Implementing The April 1, 2007, Changes To The Regulations Under The Patent Cooperation Treaty And Status Of Proposed Fee Changes (signed 30	1324 OG 104	20NOV2007		

March 2007)				
Changes to Representation of Others Before the United States Patent and Trademark Office, Supplemental notice of proposed rule making (28Feb2007)	1316 OG 123	27MAR2007	72 Fed. Reg. 9196 [PDF]	28FEB2007
Closing of the United States Patent and Trademark Office on Tuesday, January 2, 2007 (signed 28 February 2007)	1316 OG 123	27MAR2007		
Examination of Patent Applications Containing Nucleotide Sequences (signed 22 February 2007)	1316 OG 122	27MAR2007		
April 2007 Revision of Patent Cooperation Treaty Procedures, Notice of proposed rule making (16Feb2007)	1316 OG 59	13MAR2007	72 Fed. Reg. 7583 [PDF]	16FEB2007
Change in Procedure for Handling Nonprovisional Applications Having Omitted Items (signed 29 January 2007)	1315 OG 103	20FEB2007		
Changes to Facilitate Electronic Filing of Patent Correspondence, Final rule (23Jan2007)	1315 OG 57	13FEB2007	72 Fed. Reg. 2770 [PDF]	23JAN2007
Changes to Implement Priority Document Exchange Between Intellectual Property Offices, Final rule (16Jan2007)	1315 OG 63	13FEB2007	72 Fed. Reg. 1664 [PDF]	16JAN2007
Registration of patent attorneys and agents, OED Proposed and Revised Proposed Rules (12Feb2007) [PDF]				
Revised Requirements for Requesting Participation in the Patent Prosecution Highway Pilot Program in the USPTO (signed 03 January 2007)	1314 OG 1398	30JAN2007		
Electronic Notification of Outgoing Correspondence (e-Office Action) (signed 19 December	1314 OG 1321	16JAN2007		

United States Patent and Trademark Office

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Policy & Guides

The following policies, procedures, guides, tools and manuals are associated with the patent process.

NOTE: The information above was correct at the time of original publication. Some information may no longer be applicable. For example, amendments may have been made to the rules of practice since the original date of a publication, there may have been a change in any fees indicated, and certain references to publications may no longer be valid. Wherever there is a reference to a statute or rule, please check carefully whether the statute or rule in force at the date of publication of the advice has since been amended.

- [Patents Guidance \(#heading-1\)](#)
- [Tools & Manuals \(#heading-2\)](#)

Patents Guidance

- [Proposed Rule Changes to Focus the Patent Process in the 21st Century \(/patents/law/exam/changes/index.jsp\)](/patents/law/exam/changes/index.jsp)
- [Notices: Recent Patent-Related \(/patents/law/notices/index.jsp\)](/patents/law/notices/index.jsp) *pre-OG, OG & Federal Register*
- [Access to Published Patent Applications \(/patents/process/search/access.jsp\)](/patents/process/search/access.jsp)
- [Application Data Sheet \(ADS\) Guide \(/patents/resources/types/patappde.jsp\)](/patents/resources/types/patappde.jsp)
- [Business Methods Patents \(http://www.uspto.gov/web/menu/pbmethod/\)](http://www.uspto.gov/web/menu/pbmethod/)
- [Disclosure Document Program \(http://www.uspto.gov/web/offices/pac/disdo.html\)](http://www.uspto.gov/web/offices/pac/disdo.html)
- [Examination Guidelines for Computer-Related Inventions \(/patents/law/exam/mpep_examguide.jsp#com\)](/patents/law/exam/mpep_examguide.jsp#com) &
 - [Training Materials \(/patents/resources/types/comguide.jsp\)](/patents/resources/types/comguide.jsp)
- [General Information Concerning Patents \(/patents/resources/types/index.jsp\)](/patents/resources/types/index.jsp)
- [Types of Patents \(/patents/resources/types/types.jsp\)](/patents/resources/types/types.jsp)
 - [Provisional Patent Application \(/patents/resources/types/provapp.jsp\)](/patents/resources/types/provapp.jsp)
 - [Guide to Filing a Non-Provisional \(Utility\) Patent Application \(/patents/resources/types/utility.jsp\)](/patents/resources/types/utility.jsp)
 - [General Information about 35 U.S.C. § 161 Plant Patents \(/patents/resources/types/index.jsp\)](/patents/resources/types/index.jsp)
 - [Guide to Filing a Design Patent Application \(http://www.uspto.gov/web/offices/com/iip/pdf/brochure_05.pdf\)](http://www.uspto.gov/web/offices/com/iip/pdf/brochure_05.pdf)
 - [International Guidance \(/patents/init_events/pct/index.jsp\)](/patents/init_events/pct/index.jsp)
- [Revised Interim Utility Guidelines Training Materials \(http://www.uspto.gov/web/menu/utility.pdf\)](http://www.uspto.gov/web/menu/utility.pdf) (1999) [PDF]
- [Office of Patent Publication \(http://www.uspto.gov/web/patents/pubs/\)](http://www.uspto.gov/web/patents/pubs/)
- [Patent Business Goals \(PBG\) Final Rule Home Page \(/patents/resources/goals/index.jsp\)](/patents/resources/goals/index.jsp)
- [American Inventors Protection Act of 1999 \(AIPA\) Home Page \(/patents/law/aipa/index.jsp\)](/patents/law/aipa/index.jsp)
- [Provisional Application for Patent brochure \(/patents/resources/types/provapp.jsp\)](/patents/resources/types/provapp.jsp)
- [Restriction Practice - TC1600 \(http://www.uspto.gov/web/patents/restriction1600.htm\)](http://www.uspto.gov/web/patents/restriction1600.htm)
 - [Training Materials \(http://www.uspto.gov/web/patents/tc1600restrictionmaterials.pdf\)](http://www.uspto.gov/web/patents/tc1600restrictionmaterials.pdf) - TC1600
- [Written Description Training Materials \(http://www.uspto.gov/web/menu/written.pdf\)](http://www.uspto.gov/web/menu/written.pdf) [PDF]

Tools & Manuals

- **Classification:**
 - [Concordance, U.S. Patent Classification \(USPC\) to International Patent Classification \(IPC\) Eighth Edition \(http://www.uspto.gov/web/patents/classification/\)](http://www.uspto.gov/web/patents/classification/)
 - [Cross-Reference for Nanotechnology \(http://www.uspto.gov/web/patents/biochempharm/crossref.htm\)](http://www.uspto.gov/web/patents/biochempharm/crossref.htm)
 - [Examiner Handbook to the US Patent Classification System \(http://www.uspto.gov/web/offices/pac/dapp/sir/co/examhbk/index.html\)](http://www.uspto.gov/web/offices/pac/dapp/sir/co/examhbk/index.html)
 - [Manual of Patent Classification \(http://www.uspto.gov/web/patents/classification\)](http://www.uspto.gov/web/patents/classification)
 - [U.S. Patent Classification \(USPC\) Index \(http://www.uspto.gov/web/patents/classification/uspcindex/indextouspc.htm\)](http://www.uspto.gov/web/patents/classification/uspcindex/indextouspc.htm)
- [Forms \(/forms/index.jsp\)](/forms/index.jsp)
- [Manual of Patent Examining Procedure \(http://www.uspto.gov/web/offices/pac/mpep/index.htm\)](http://www.uspto.gov/web/offices/pac/mpep/index.htm)
- [Patent Laws, Consolidated \(http://www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf\)](http://www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf) [PDF]
- [Patent Rules, Consolidated \(http://www.uspto.gov/web/offices/pac/mpep/consolidated_rules.pdf\)](http://www.uspto.gov/web/offices/pac/mpep/consolidated_rules.pdf) [PDF]
- [Search Templates \(http://www.uspto.gov/web/patents/searchtemplates/searchtemplates.htm\)](http://www.uspto.gov/web/patents/searchtemplates/searchtemplates.htm)

Some contents linked to on this page require a plug-in for [PDF \(/faq/plugins/pdf.jsp\)](#) and [DOC \(/faq/plugins/office.jsp\)](#) files

Exhibit F to

Petition to Vacate Examiner's Papers

PTO's Filings at OMB For Information
Collection 0651-0031, 2006 to 2009

(excluding those designated "no material change"
and those revoked by OMB in April 2008)



OMB Control Number History

OMB Control Number:0651-0031

ICR Ref. No.	Request Type	Date Received By OIRA	Conclusion Date	Conclusion Action
200707-0651-005	Revision of a currently approved collection	09/26/2007	07/01/2009	Approved with change
200706-0651-004	No material or nonsubstantive change to a currently approved collection	06/22/2007	07/26/2007	Disapproved and continue
200703-0651-001	No material or nonsubstantive change to a currently approved collection	03/13/2007	03/30/2007	Approved without change
200606-0651-001	Emergency extension	02/13/2007	02/28/2007	Approved
200606-0651-001	Emergency extension	08/11/2006	08/21/2006	Approved
200606-0651-001	Revision of a currently approved collection	06/05/2006	07/12/2006	Approved without change
200603-0651-001	No material or nonsubstantive change to a currently approved collection	03/12/2006	03/12/2006	Approved without change
200512-0651-002	Revision of a currently approved collection	12/22/2005	02/22/2006	Approved without change
200509-0651-001	No material or nonsubstantive change to a currently approved collection	09/20/2005	09/20/2005	Approved without change
200506-0651-002	Revision of a currently approved collection	06/15/2005	08/29/2005	Approved without change
200407-0651-002	Revision of a currently approved collection	07/15/2004	10/12/2004	Approved without change
200406-0651-002	No material or nonsubstantive change to a currently approved collection	06/25/2004	06/25/2004	Approved without change
200401-0651-003	No material or nonsubstantive change to a currently approved collection	01/28/2004	01/28/2004	Approved without change
200309-0651-005	Revision of a currently approved collection	09/03/2003	12/19/2003	Approved with change
200304-0651-001	Revision of a currently approved collection	04/29/2003	07/14/2003	Approved without change
200202-0651-001	Emergency extension	12/20/2002	12/20/2002	Approved
200202-0651-001	Emergency extension	07/26/2002	07/26/2002	Approved
200202-0651-001	No material or nonsubstantive change to a currently approved collection	02/14/2002	02/14/2002	Approved without change
200106-0651-002	Revision of a currently approved collection	06/11/2001	10/16/2001	Approved without change
200004-0651-004	Revision of a currently approved collection	04/05/2000	08/01/2000	Approved without change
199908-0651-002	Revision of a currently approved collection	08/19/1999	10/26/1999	Approved without change
199812-0651-003	No material or nonsubstantive change to a currently approved collection	12/09/1998	12/09/1998	Approved without change
199812-0651-004	No material or nonsubstantive change to a currently approved collection	12/09/1998	12/09/1998	Approved without change
199707-0651-003	Revision of a currently approved collection	07/25/1997	09/24/1997	Approved without change
199701-0651-003	No material or nonsubstantive change to a currently approved collection	01/29/1997	01/29/1997	Approved without change
199607-0651-002	Reinstatement without change of a previously approved collection	07/26/1996	10/01/1996	Approved without change
199308-0651-004	No material or nonsubstantive change to a currently approved collection	08/01/1993	08/01/1993	Approved with change
199305-0651-004	New collection (Request for a new OMB Control Number)	05/14/1993	07/30/1993	Approved without change



Display additional information by clicking on the following: All [Brief and OIRA conclusion](#)
 [Abstract/Justification](#) [Legal Statutes](#) [Rulemaking](#) [FR Notices/Comments](#) [IC List](#) [Burden](#) [Misc.](#) [Certification](#)
[View Information Collection \(IC\) List](#) [View Supporting Statement and Other Documents](#)

Please note that the OMB number and expiration date may not have been determined when this Information Collection Request and associated Information Collection forms were submitted to OMB. The approved OMB number and expiration date may be found by clicking on the Notice of Action link below.

View ICR - OIRA Conclusion

OMB Control No: 0651-0031 ICR Reference No: 200707-0651-005
 Status: Active Previous ICR Reference No: [200703-0651-001](#)
 Agency/Subagency: DOC/PTO Agency Tracking No:
 Title: Patent Processing (Updating)
 Type of Information Collection: Revision of a currently approved collection
 Type of Review Request: Regular
 OIRA Conclusion Action: Approved with change Conclusion Date: 07/01/2009
[Retrieve Notice of Action \(NOA\)](#) Date Received in OIRA: 09/26/2007
 Terms of Clearance: Revised to correct collection list and supporting statement.

	Inventory as of this Action	Requested	Previously Approved
Expiration Date	07/31/2012	36 Months From Approved	06/30/2009
Responses	2,459,409	2,643,259	2,508,139
Time Burden (Hours)	2,893,322	3,632,456	3,724,791
Cost Burden (Dollars)	147,592,807	149,814,540	114,723,256

Abstract: This collection of information is required by 35 U.S.C. sec. 101 et.seq. and is administered through 37 CFR Part 1. During the pendency of a patent application or the period of enforceability of a patent, situations arise that require collection of information for the USPTO to further process the patent or application. This information can be used by the USPTO to continue the processing of the patent or application or to ensure that applicants are complying with the patent regulations. At the direction of OMB, this renewal is being resubmitted with all of the rule-related information removed from the collection pertaining to the notices of proposed rulemakings approved by OMB on 2/22/2006 (RIN 0651-AB94) and (RIN 0651-AB93) along with a change worksheet approved by OMB on 3/30/2007, revising the estimates for same. In total, 7 items are being removed.

Authorizing Statute(s): US Code: 35 USC 101 Name of Law: 37 CFR Part 1
Citations for New Statutory Requirements: None

Associated Rulemaking Information

RIN: **Stage of Rulemaking:** **Federal Register Citation:** **Date:**
 Not associated with rulemaking

Federal Register Notices & Comments

60-day Notice: **Federal Register Citation:** **Citation Date:**
 71 FR 103 05/30/2006
30-day Notice: **Federal Register Citation:** **Citation Date:**
 72 FR 180 09/18/2007

Did the Agency receive public comments on this ICR? No

Number of Information Collection (IC) in this ICR: [43](#)

IC Title	Form No.	Form Name
Applicant Initiated Interview Request Form	PTOL-413A	Applicant Initiated Interview Request Form
eIDS (Information Disclosure Statements) filed with no additional disclosure requirements	PTO/SB/08a, null	Information Disclosure Statement by Applicant
Information Disclosure Statements with no additional disclosure requirements	PTO/SB/08A, PTO/SB/08B	Information Disclosure Statement by Applicant, Information Disclosure Statement by Applicant

[Examination support document filed in certain nonprovisional applications covering the independent claims and the designated dependent claims \(proposed 37 CFR 1.75\(b\)\)](#)

[Electronic Filing System \(EFS\) Copy of Application for Publication](#)

[Copy of File Content Showing Redactions](#)

[Copy of the Applicant or Patentee's Record of the Application \(including copies of the correspondence, list of the correspondence, and statements verifying whether the record is complete or not\)](#)

PTO-2053-A/B,
PTO-2054-A/B,
PTO/2055-A/B

[Notice Under 37 CFR 1.251 - Pending Application](#), [Notice Under 37 CFR 1.251 - Abandoned Application](#), [Notice Under 37 CFR 1.251 - Patent](#)

[Request for Continued Examination \(RCE\) Transmittal](#)

PTO/SB/30

[Request for Continued Examination \(RCE\) Transmittal](#)

[Petitions under 37 CFR 1.17\(g\) include: Petitions to Access Assignment Records and Applications, Petition for Expungement/Return of Information, and Petition to Suspend Action in an Application](#)

[Petition for Extension of Time under 37 CFR 1.136\(a\)](#)

PTO/SB/22

[Petition for Extension of Time Under 37 CFR 1.136\(a\) FY 2006](#)

[Petition for Extension of Time under 37 CFR 1.136\(b\)](#)

PTO/SB/23

[Petition for Extension of Time Under 37 CFR 1.136\(b\)](#)

[Request for Corrected Filing Receipt \(electronic\)](#)

[Petitions under 37 CFR 1.17\(h\): Petition for Accepting Color Drawings/Photos, Petition for Entry of Model/Exhibit, Petition to Withdraw Application from Issue, and Petition to Defer Issue of Patent](#)

[Authorization To Permit Access to Application by Participating Offices Under 37 CFR 1.14\(h\)](#)

PTO/SB/39

[Authorization to Permit Access to Application by Participating Offices](#)

[Petition for Revival of an Application for Patent Abandoned Unavoidably](#)

PTO/SB/61

[Petition for Revival of an Application for Patent Abandoned Unavoidably Under 37 CFR 1.137\(a\)](#)

[Pre-Appeal Brief Request for Review](#)

PTO/SB/33

[Pre-Appeal Brief Request for Review](#)

[Request to Retrieve Electronic Priority Application\(s\) Under 37 CFR 1.55\(d\)](#)

PTO/SB/38

[Request to Retrieve Electronic Priority Application\(s\)](#)

[Petition for Express Abandonment to Obtain a Refund](#)

PTO/SB/24B

[Petition for Express Abandonment to Obtain a Refund](#)

[Petition to Make Special Under Accelerated Examination Program](#)

PTO/SB/28
EFS-Web

[Petition to Make Special under Accelerated Examination Program](#)

[Request for Deferral of Examination 37 CFR 1.103\(d\)](#)

PTO/SB/37

[Request for Deferral of Examination 37 CFR 1.103\(d\)](#)

[Non-publication Request](#)

PTO/SB/35

[Nonpublication Request under 35 U.S.C. 122\(b\)\(2\)\(B\)\(i\)](#)

[Request for Voluntary Publication or Republication EFS-Web](#)

[Request for Continued Examination \(RCE\) EFS-Web](#)

PTO/SB/30EFS

[Request for Continued Examination \(RCE\) Transmittal](#)

[Information Disclosure Citation in a Patent](#)

PTO/SB/42

[37 CFR 1.501 Information Disclosure Citation in a Patent](#)

[Petition for Request for Documents in a Form Other Than That Provided by 1.19](#)

[Request for Corrected Filing Receipt](#)

[Petition for Revival of an Application for Patent Abandoned Unintentionally](#)

PTO/SB/64

[Petition for Revival of an Application for Patent Abandoned Unintentionally Under](#)

[Request for Oral Hearing Before the Board of Patent Appeals and Interferences](#)

PTO/SB/32

[Request for Oral Hearing Before the Board of Patent Appeals and Interferences](#)

Processing Fee Under 37 CFR 1.17(i) Transmittal	PTO/SB/17i	Processing Fee under 37 CFR 1.17(i) Transmittal
Petition for Revival of an Application for Patent Abandoned for Failure to Notify the Office of a Foreign or International Filing	PTO/SB/64a	Petition for Revival of an Application for Patent Abandoned for Failure to Notify the Office of a Foreign or International Filing (37 CFR 1.137(f))
Request for First-Action Interview (Pilot Program)	PTOL-413C	Request for First-Action Interview (Pilot Program) - Draft form
Petition to Make Special Based on Age for Advancement of Examination under 37 CFR 1.102(c)(1)	PTO/SB/130 EFS-Web	Petition to Make Special Based on Age for Advancement of Examination under 37 CFR 1.102(c)(1)
Rescission of Previous Non-publication Request (35 U.S.C. 122(b)(B)(ii) and, if applicable, Notice of Foreign Filing (35 U.S.C. 122(b)(2)(B)(iii))	PTO/SB/36	Rescission of Previous Nonpublication Request (35 U.S.C. 122(b)(2)(B)(ii) and, if applicable, Notice of Foreign Filing (35 U.S.C. 122(b)(2)(B)(iii))
Request for Processing of Replacement Drawings to Include the Drawings in Any Patent Application Publication		
Express Abandonment under 37 CFR 1.138	PTO/SB/24	Express Abandonment Under 37 CFR 1.138
Petition for Express Abandonment to Avoid Publication Under 37 CFR 1.138(c)	PTO/SB/24A	Petition for Express Abandonment to Avoid Publication Under 37 CFR 1.138(c)
Disclaimers	PTO/SB/43, PTO/SB/63, PTO/SB/25, PTO/SB/62, PTO/SB/26	Disclaimer in Patent Under 37 CFR 1.321(a) , Terminal Disclaimer to Accompany Petition , Terminal Disclaimer to Obviate a Provisional Double Patenting Rejection over a Pending "Reference" Application , Terminal Disclaimer to Accompany Petition (Period Specified) , Terminal Disclaimer to Obviate a Double Patenting Rejection over a "Prior" Patent
Request for Expedited Examination of a Design Application	PTO/SB/27	Request for Expedited Examination of a Design Application (37 CFR 1.155)
Notice of Appeal	PTO/SB/31	Notice of Appeal from the Examiner to the Board of Patent Appeals and Interferences
Statement Under 37 CFR 3.73(b) Transmittal Form	PTO/SB/96 PTO/SB/21	Statement under 37 CFR 3.73(b) Transmittal Form
Requests to Access, Inspect and Copy	PTO/SB/67, PTO/SB/68	Power to Inspect/Copy , Request for Access to an Abandoned Application under 37 CFR 1.14
Deposit Account Order Form	PTO/SB/91	Deposit Account Order Form
Certificates of Mailing/Transmission	PTO/SB/97, PTO/SB/92	Certificate of Transmission under 37 CFR 1.8 , Certificate of Mailing under 37 CFR 1.8
Petition for a second continuation or continuation-in-part application showing why the amendment, argument, or evidence could not have been submitted prior to the close of prosecution		
Petition for a second request for continued examination showing why the amendment, argument, or evidence could not have been submitted prior to the close of prosecution in the application		

ICR Summary of Burden

	Total Approved	Previously Approved	Change Due to New Statute	Change Due to Agency Discretion	Change Due to Adjustment in Estimate	Change Due to Potential Violation of the PRA
Annual Number of Responses	2,459,409	2,508,139	0	11,100	-59,830	0
Annual Time Burden (Hours)	2,893,322	3,724,791	0	-261,104	-570,365	0

Annual Cost						
Burden	147,592,807	114,723,256	0	-687,947	33,557,498	0
(Dollars)						

Burden increases because of Program Change due to Agency Discretion: Yes

Burden Increase Due to: Miscellaneous Actions

Burden decreases because of Program Change due to Agency Discretion: Yes

Burden Reduction Due to: Miscellaneous Actions

Short Statement: The decrease in burden hours is due to a combination of the revised number of submissions, a re-estimation of the time it takes to complete some of the responses, and new requirements being added into the collection. The increase in costs is due to adjustments in responses and response times, the addition of new requirements into the collection and new EFS-Web submissions, and an adjustment for the current postage fees, increasing the recordkeeping costs, filing fees, and postage costs.

Annual Cost to Federal Government: \$7,320,402

Does this IC contain surveys, censuses, or employ statistical methods? No

Is the Supporting Statement intended to be a Privacy Impact Assessment required by the E-Government Act of 2002? No

Is this ICR related to the American Recovery and Reinvestment Act of 2009 (ARRA)? No

Agency Contact: Raul Tamayo 5712727728 Raul.Tamayo@uspto.gov

On behalf of this Federal agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9 and the related provisions of 5 CFR 1320.8(b)(3).

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

- (a) It is necessary for the proper performance of agency functions;
- (b) It avoids unnecessary duplication;
- (c) It reduces burden on small entities;
- (d) It uses plain, coherent, and unambiguous language that is understandable to respondents;
- (e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;
- (f) It indicates the retention periods for recordkeeping requirements;
- (g) It informs respondents of the information called for under 5 CFR 1320.8 (b)(3) about:
 - (i) Why the information is being collected;
 - (ii) Use of information;
 - (iii) Burden estimate;
 - (iv) Nature of response (voluntary, required for a benefit, or mandatory);
 - (v) Nature and extent of confidentiality; and
 - (vi) Need to display currently valid OMB control number;
- (h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected.
- (i) It uses effective and efficient statistical survey methodology (if applicable); and
- (j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of these provisions, identify the item by leaving the box unchecked and explain the reason in the Supporting Statement.

Certification Date: 09/26/2007

**SF-83 SUPPORTING STATEMENT
UNITED STATES PATENT AND TRADEMARK OFFICE
Patent Processing (Updating)
OMB Control Number 0651-0031**

A. JUSTIFICATION

1. Necessity of Information Collection

The United States Patent and Trademark Office (USPTO) is required by 35 U.S.C. § 131 et seq. to examine an application for patent and, when appropriate, issue a patent. Also, the USPTO is required to publish patent applications, with certain exceptions, promptly after the expiration of a period of eighteen months from the earliest filing date for which a benefit is sought under Title 35, United States Code (“eighteen-month publication”). Certain situations may arise that require additional information to be supplied in order for the USPTO to further process the patent or application. The USPTO administers the statutes through various sections of the rules of practice in 37 CFR Part 1.

During the processing for an application for a patent, the applicant or applicant’s representative may be required or desire to submit additional information to the USPTO concerning the examination of a specific application. The specific information required or that may be submitted includes: information disclosure statement and citation, examination support documents, requests for extension of time, the establishment of small entity status, abandonment and revival of abandoned applications, disclaimers, appeals, petitions, requests, expedited examination of design applications, transmittal forms, requests to inspect, copy and access patent applications, publication requests, certificates of mailing, transmittals, and submission of priority documents and amendments.

The new information being added into this collection since the previous renewal includes 3 proposed additions for notices of proposed rulemakings, 5 change worksheets, 7 new forms/requirements, and 8 electronic forms.

At the direction of OMB, this renewal is being resubmitted with all of the rule-related information removed from the collection pertaining to the notices of proposed rulemaking approved by OMB on 2/22/2006 entitled “Changes to Practice for the Examination of Claims in Patent Applications” (RIN 0651-AB94), and “Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims” (RIN 0651-AB93); along with a Change Worksheet approved by OMB on 3/30/2007 revising the estimates for same. The 7 items being removed are:

- Examination Support Document Transmittal
- Examination Support Document Listing of References

- Petition for a second continuation or continuation-in-part application showing why the amendment, argument, or evidence could not have been submitted prior to the close of prosecution in the prior-filed application (proposed 37 CFR 1.78(d)(1)(iv))
- Petition for a second request for continued examination showing why the amendment, argument, or evidence could not have been submitted prior to the close of prosecution in the application (proposed 37 CFR 1.114(f))
- Listing of Commonly Owned Applications and Patents 37 CFR 1.73(f)
- Listing of Commonly Owned Applications and Patents 37 CFR 1.73(f) EFS-Web
- Request for Streamlined Docketing Procedure

At the direction of OMB, this renewal is being resubmitted with all of the rule-related information removed from the collection pertaining to the notice of proposed rulemaking approved by OMB on 7/12/2006 entitled “Changes to Information Disclosure Statement Requirements and Other Related Matters” (RIN 0651-AB95).

Two information collections associated with Petitions under 37 CFR 1.17 (f) which were previously incorporated in 0651-0031 have been moved into a new ICR entitled Patent Petitions Charging the Fee under 37 CFR 1.17(f), with the burden calculations remaining the same as estimated previously in 0651-0031. See Federal Register Notice of May 30, 2006 (71 Fed Reg. 103).

Table 1 identifies the proposed statutory and regulatory provisions that require the USPTO to collect this information:

Table 1: Information Requirements for Patent Processing (Updating)

Requirement	Statute	Rule
Information Disclosure Statements and eIDS	35 U.S.C. § 2(b)(2)	37 CFR 1.56, 1.97 and 1.98
Transmittal Form	35 U.S.C. § 2(b)(2)	37 CFR 1.4; 1.5, 1.48, 1.111, 1.116, 1.121, 1.125, 1.133 and 1.291
Petitions for Extension of Time under 37 CFR 1.136(a) & (b)	35 U.S.C. §§ 2(b)(2), 41(a)(8), 131 and 132	37 CFR 1.136
Express Abandonment under 37 CFR 1.138	35 U.S.C. §§ 2(b)(2), 131 & 132	37 CFR 1.138
Petition for Express Abandonment to Avoid Publication under 1.138(c)	35 U.S.C. § 122(b)	37 CFR 1.38(c) and 1.211(a)(1)
Disclaimers	35 U.S.C. § 253	37 CFR 1.321
Request for Expedited Examination of a Design Application	35 U.S.C. § 2(b)(2)	37 CFR 1.155
Notice of Appeal	35 U.S.C. § 134	37 CFR 1.191
Information Disclosure Citation in a Patent	35 U.S.C. § 301	37 CFR 1.501
Petitions to Revive Unintentionally or Unavoidably Abandoned Applications	35 U.S.C. §§ 41(a)(7), 111, 133, 151 and 371(d)	37 CFR 1.137

Petition for Revival of an Application for Patent Abandoned for Failure to Notify the Office of a Foreign or International Filing	35 U.S.C. § 2(b)(2)	37 CFR 1.137 and 1.213
Requests to Access, Inspect and Copy	35 U.S.C. § 122	37 CFR 1.14
Deposit Account Order Form	35 U.S.C. § 2(b)(2)	37 CFR 1.25
Certificates of Mailing/Transmission	35 U.S.C. §§ 2(b)(2) and 21(a)	37 CFR 1.8
Statement under 37 CFR 3.73(b)	35 U.S.C. § 2(b)(2)	37 CFR 3.73(b)
Non-publication Request	35 U.S.C. § 122(b)(2)(B)(i)	37 CFR 1.213(a)
Rescission of Previous Non-publication Request (35 U.S.C. § 122(b)(2)(B)(ii)) and, if applicable, Notice of Foreign Filing (35 U.S.C. § 122(b)(2)(B)(iii))	35 U.S.C. §§ 122(b)(2)(B)(ii) and 122(b)(2)(B)(iii)	37 CFR 1.213(b)
Electronic Filing System (EFS) Copy of Application for Publication	35 U.S.C. §§ 122(b) and 122(b)(2)(B)(v)	37 CFR 1.215, 1.217, 1.219 and 1.221
Copy of File Content Showing Redactions	35 U.S.C. § 122(b)	37 CFR 1.217(d)
Copy of the Applicant or Patentee's Record of the Application (including copies of the correspondence, list of the correspondence, and statements verifying whether the record is complete or not)	35 U.S.C. § 2(b)(2)	37 CFR 1.251
Request for Continued Examination (RCE) Transmittal	35 U.S.C. § 132(b)	37 CFR 1.114
Request for Continued Examination (RCE) Transmittal EFS-Web	35 U.S.C. § 132(b)	37 CFR 1.114
Written request for an oral appeal hearing before the Board, filed in a separate paper from the appeal itself	35 U.S.C. § 134	37 CFR 1.194(b)
Request for Deferral of Examination 37 CFR 1.103(d)	35 U.S.C. §§ 2(b)(2) and 131	37 CFR 1.103(d)
Request for Voluntary Publication or Republication	35 U.S.C. § 2(b)(2)	37 CFR 1.221
Applicant Initiated Interview Request Form	35 U.S.C. § 2(b)(2)	37 CFR 1.133
Petition for Request for Documents in a Form Other Than That Provided by 1.19	35 U.S.C. §§ 2(b)(2), 131 and 132	37 CFR 1.19(i) and (j)
<u>Petitions under 37 CFR 1.17(g) include:</u> Petition to Access an Assignment Record Petition for Access to an Application Petition for Expungement and Return of Information Petition to Suspend Action in an Application	35 U.S.C. §§ 131 and 132	37 CFR 1.12, 1.14, 1.17(g), 1.59 and 1.102
<u>Petitions under 37 CFR 1.17(h) include:</u> Petition for Accepting Color Drawings or Photographs Petition for Entry of a Model or Exhibit Petition to Withdraw an Application from Issue Petition to Defer Issuance of a Patent	35 U.S.C. §§ 131 and 132	37 CFR 1.17(h), 1.84, 1.91, 1.103(d), 1.313 and 1.314
Request for Processing of Replacement Drawings to Include the Drawings in Any Patent Application Publication	35 U.S.C. §§ 2(b)(2), 131 and 132	37 CFR 1.215
Processing Fee under 37 CFR 1.17(i) Transmittal	35 U.S.C. § 2(b)(2)	37 CFR 1.17(i)
Request to Retrieve Electronic Priority Application(s) under 37 CFR 1.55(d)	35 U.S.C. § 2(b)(2)	37 CFR 1.155(d)
Authorization for Permit Access to Application by Participating Offices under 37 CFR 1.14(h)	35 U.S.C. § 2(b)(2)	37 CFR 1.14(h)

Petition for Express Abandonment to Obtain a Refund	35 U.S.C. § 4(d)(1)(D)	37 CFR 1.138(d)
Pre-Appeal Brief Request for Review	35 U.S.C. §§ 2(b)(2) and 134	37 CFR 41.32
Request for Corrected Filing Receipt	35 U.S.C. § 2(b)(2)	37 CFR 1.54, 1.76(a) and 1.48(a) and (c)
Request for Corrected Filing Receipt (electronic)	35 U.S.C. § 2(b)(2)	37 CFR 1.54, 1.76(a) and 1.48(a) and (c)
Petition to Make Special under Accelerated Examination Program	35 U.S.C. § 2(b)(2)	37 CFR 1.102
Request for First-Action Interview (Pilot Program)	35 U.S.C. § 2(b)	37 CFR 1.133
Petition to Make Special Based on Age for Advancement of Examination under 37 CFR 1.102(c)(1)	35 U.S.C. § 2(b)	37 CFR 1.102(c)(1)

2. Needs and Uses

The Information Quality Guidelines from Section 515 of Public Law 106-554, Treasury and General Government Appropriations Act for Fiscal Year 2001, apply to this information collection and comply with all applicable information quality guidelines, i.e., OMB and specific operating unit guidelines.

This proposed collection of information will result in information that will be collected, maintained, and used in a way consistent with all applicable OMB and USPTO Information Quality Guidelines.

Table 2 outlines how this information is used by the public and by the USPTO:

Table 2: Needs and Uses for Patent Processing (Updating)

Form and Function	Form #	Needs and Uses
Information Disclosure Statements (Ref. A)	PTO/SB/08a/08b and EFS-Web	<ul style="list-style-type: none"> Used by the applicant to meet the applicant's duty of disclosure under 37 CFR 1.56. Used by the USPTO when printing the patent document.
Transmittal Form (Ref. B)	PTO/SB/21	<ul style="list-style-type: none"> Used by the applicant to indicate what type of correspondence is being submitted. Used by the USPTO to determine the specific contents of the communication. Used by the USPTO to facilitate the routing of papers to the most appropriate USPTO locations.
Petitions for Extension of Time (Ref. C)	PTO/SB/22/23	<ul style="list-style-type: none"> Used by the applicant to request an extension of time. Used by the USPTO to determine whether the reason for requesting an extension is sufficient for granting it. Used by the USPTO to decide the correct fee, based upon the number of months of extension requested, and whether or not the applicant is entitled to small entity status.
Express Abandonment (Ref. D)	PTO/SB/24	<ul style="list-style-type: none"> Used by the applicant to expressly abandon an application. Used by the USPTO to determine whether the application is expressly abandoned. Used by the USPTO to determine whether an application has been expressly abandoned in favor of a continuation or divisional application.

Petition for express abandonment to avoid publication under 37 CFR 1.138(c) (Ref. E)	PTO/SB/24A	<ul style="list-style-type: none"> Used by the applicant to expressly request abandonment of an application to avoid publication of the application. Used by the USPTO to expressly abandon the application prior to its publication.
Disclaimers (Ref. F)	PTO/SB/25/26/43/62/63	<ul style="list-style-type: none"> Used by the applicant or assignee to disclaim the entire term or part of a term of a patent or a patent to be granted. Used by the USPTO to determine whether all owners have provided the required terminal disclaimer and to determine the length of the patent term to which the patentee is entitled. Used by the Certificate of Corrections branch of the USPTO for determining whether regulatory compliance has been met, for recording the disclaimer, and for providing the disclaimer data for printing.
Request for Expedited Examination of a Design Application (Ref. G)	PTO/SB/27	<ul style="list-style-type: none"> Used by the applicant to request expedited examination of a design application. Used by the USPTO to ensure that all of the required information to expedite examination is provided and to process the request.
Notice of Appeal (Ref. H)	PTO/SB/31	<ul style="list-style-type: none"> Used by the applicant to file a Notice of Appeal. Used by the USPTO to ensure that applicants comply with regulations when filing a Notice of Appeal.
Information Disclosure Citation (Ref. I)	PTO/SB/42	<ul style="list-style-type: none"> Informs the patent owner and the public that the patents or printed publications cited are in existence. Used by the examiner in subsequent reissue or reexamination proceedings.
Petitions to Revive Unintentionally or Unavoidably Abandoned Applications (Ref. J)	PTO/SB/61/64	<ul style="list-style-type: none"> Used by the applicant to request that applications that were unintentionally or unavoidably abandoned be revived. Used by the USPTO to ensure that applicants have included all the proper documentation and fees necessary to revive an unintentionally or unavoidably abandoned application.
Petition for Revival of an Application for Patent Abandoned for Failure to Notify the Office of a Foreign or International Filing (Ref. K)	PTO/SB/64a	<ul style="list-style-type: none"> Used by the applicant to revive an application for patent abandoned for failure to timely notify the office of a foreign or international filing. Used by the USPTO to revive an application for patent abandoned for failure to timely notify the office of a foreign or international filing.
Requests to Access, Inspect and Copy (Ref. L)	PTO/SB/67/68	<ul style="list-style-type: none"> Used by the public to request permission to inspect and/or make copies in accordance with regulations. Ensures that applications are maintained in confidence in accordance with regulations. Used by the USPTO to determine that the persons requesting permission to inspect and/or make copies are authorized to do so. Used by the USPTO to verify that the application requested is abandoned and that it has been referred to in the referenced U.S. patent.
Deposit Account Order Form (Ref. M)	PTO/SB/91	<ul style="list-style-type: none"> Used by the public to order goods or services using an established deposit account. Used by the USPTO to process orders for articles or services, and to identify the deposit account to which an order should be charged.
Certificate of Mailing/Transmission (Ref. N)	PTO/SB/92/97	<ul style="list-style-type: none"> Used by the applicant as evidence of the date for replies to actions by the USPTO. Used by the USPTO to determine the timeliness of replies by an applicant to actions by the USPTO.

Statement under 37 CFR 3.73(b) (Ref. O)	PTO/SB/96	<ul style="list-style-type: none"> Used by the applicant to show that this person has their authority to take actions on their behalf. Used by the USPTO to determine that the person signing has authority to take action on behalf of an assignee.
Non-publication Request (Ref. P)	PTO/SB/35	<ul style="list-style-type: none"> Used by the applicant to request that the USPTO not publish the application under 37 U.S.C. § 122(b). Used by the USPTO to determine whether the application should be published under 35 U.S.C § 122(b).
Notice of Rescission of Previous Non-publication Request (35 U.S.C. § 122 (b)(2)(B)(ii)) and, if applicable, Notice of Foreign Filing (35 U.S.C. § 122 (b)(2)(B)(iii)) (Ref. Q)	PTO/SB/36	<ul style="list-style-type: none"> Used by the applicant to rescind a previously filed request that the USPTO not publish the application under 35 U.S.C. § 122 (b)(2)(B)(ii). Used by the applicant to provide notice of a foreign or international filing required by 35 U.S.C. § 122 (b)(2)(B)(iii). Used by the USPTO to determine that the application is subject to eighteen-month publication.
Electronic filing system (EFS) copy of application for publication (Ref. R)	Electronic form via EFS	<ul style="list-style-type: none"> Used by the applicant to obtain publication of a version of the application different from the application as initially submitted to the USPTO. Used by the applicant to request publication of an application earlier than as provided for by eighteen-month publication or of an application that is not subject to eighteen-month publication. Used by the USPTO to create a publication document as part of the USPTO's publication of the application.
Copy of file content showing redactions	No Form	<ul style="list-style-type: none"> Used by the applicant to show redactions to USPTO actions/notices and the applicant's replies. Used by the USPTO to confirm what redactions are made to the copy of application file content that is provided to the public.
Copy of Applicant or Patentee's Record of the Application (including copies of the correspondence, list of the correspondence, and statements verifying whether the record is complete or not) Notice Under 37 CFR 1.251 – Pending Application (Ref. S) Notice Under 37 CFR 1.251 – Abandoned Application (Ref. T) Notice Under 37 CFR 1.251 – Patent (Ref. U)	PTO-2053-A/B PTO-2054-A/B PTO-2055-A/B	<ul style="list-style-type: none"> Used by the applicant to assist the USPTO in reconstructing a current copy of a missing patent or application file. Used by the USPTO to notify the applicant that the application or patent file is unlocatable and to request a copy of the applicant's or patentee's record of the application or patent file (including copies of the correspondence, list of the correspondence, and statements verifying whether the record is complete or not) in order to reconstruct the file of an unlocatable application or patent.
Request for Continued Examination (RCE) (Ref. V)	PTO/SB/30	<ul style="list-style-type: none"> Used by the applicant to request continued examination of a previously submitted application. Used by the USPTO to process and initiate continued examination of a previously submitted application.
Request for Continued Examination (RCE) EFS-Web (Ref. W)	PTO/SB/30EFS	<ul style="list-style-type: none"> Used by the applicant to request continued examination of a previously submitted application. Used by the USPTO to process and initiate continued examination of a previously submitted application.
Request for Oral Hearing Before the Board of Patent Appeals and Interferences (Ref. X)	PTO/SB/32	<ul style="list-style-type: none"> Used by the applicant to file a written request in a separate paper for an oral hearing before the Board. Used by the USPTO to process and consider the request for an oral appeal hearing.

Request for Deferral of Examination 37 CFR 1.103(d) (Ref. Y)	PTO/SB/37	<ul style="list-style-type: none"> Used by the applicant to request deferred examination of a patent application for up to three years from the earliest filing date for which a benefit is claimed. Used by the USPTO to process and consider this request for deferral of examination.
Request for Voluntary Publication or Republication	EFS-Web Only	<ul style="list-style-type: none"> Voluntary Publication: Used by the applicant to request publication of an application filed prior to November 29, 2000. Republishing: Used by the applicant to correct prior application publications containing material errors caused by the USPTO, or to correct other data, such as claims that previously published as part of an application publication. Used by the USPTO to publish an application filed prior to November 29, 2000, or to correct prior application publication errors.
Applicant Initiated Interview Request Form (Ref. Z)	PTOL/413A	<ul style="list-style-type: none"> Used by the applicant to request an interview. Used by the applicant to assist in the preparation of a written record of the interview. Used by the USPTO to allow the examiner to prepare in advance for an applicant initiated interview. Used by the USPTO to allow the examiner to focus on the issues to be discussed in the applicant initiated interview. Used by the USPTO to identify whether agreement has been reached.
Petition for Request for Documents in a Form Other Than That Provided by 1.19	No Form	<ul style="list-style-type: none"> Used by the applicant to obtain copies of documents that have been submitted in a form other than provided for by the rules of practice. Used by the USPTO to provide copies of documents that have been submitted in a form other than provided for by the rules of practice.
<u>Petitions under 37 CFR 1.17(g) include:</u> Petition to Access an Assignment Record Petition for Access to an Application Petition for Expungement and Return of Information Petition to Suspend Action in an Application	No Form	<ul style="list-style-type: none"> Used by the applicant to request access to an assignment record. Used by the applicant to request access to an application. Used by the applicant to request expungement and return of information. Used by the applicant to request to suspend action in an application. Used by the USPTO to grant access to an assignment record. Used by the USPTO to grant access to an application. Used by the USPTO to expunge and return information. Used by the USPTO to suspend action on an application.
<u>Petitions under 37 CFR 1.17(h) include:</u> Petition for Accepting Color Drawings or Photographs Petition for Entry of a Model or Exhibit Petition to Withdraw an Application from Issue Petition to Defer Issuance of a Patent	No Form	<ul style="list-style-type: none"> Used by an applicant to submit color drawings or photographs. Used by an applicant to submit a model or exhibit. Used by an applicant to request withdrawal of an application from issue. Used by an applicant to request permission to defer issuance of a patent. Used by the USPTO to accept color drawings or photographs from an applicant. Used by the USPTO to accept a model or exhibit. Used by the USPTO to withdraw an application from issue. Used by the USPTO to defer issuance of a patent.
Request for Processing of Replacement Drawings to Include the Drawings in Any Patent Application Publication	No Form	<ul style="list-style-type: none"> Used by applicants to request replacement drawings to be included as the drawings in any patent application publication. Used by the USPTO to process replacement drawings to be included as the drawings in any patent application publication.
Processing Fee under 37 CFR 1.17(i) Transmittal (Ref. AA)	PTO/SB/17i	<ul style="list-style-type: none"> Used by the applicant to identify the proper fee, and thus reduce the potential for any additional work due to mistakes in payment. Used by the USPTO to process the appropriate fees.

Request to Retrieve Electronic Priority Application(s) under 37 CFR 1.55(d) (Ref. BB)	PTO/SB/38	<ul style="list-style-type: none"> Used by the applicant to request that the USPTO retrieve priority documents from the other participating intellectual property offices. Used by the USPTO to retrieve priority documents from the other participating intellectual property offices.
Authorization for Permit Access to Application by Participating Offices under 37 CFR 1.14(h) (Ref. CC)	PTO/SB/39	<ul style="list-style-type: none"> Used by the applicant to authorize the USPTO to release confidential documents to other participating intellectual property offices that are important to the prosecution of the patent application. Used by the USPTO to properly release confidential documents to other participating intellectual property offices that are important to the prosecution of the patent application.
Petition for Express Abandonment to Obtain a Refund (Ref. DD)	PTO/SB/24B	<ul style="list-style-type: none"> Used by the applicant to expressly abandon the application for a refund of the search fee if recognized by an appropriate USPTO official prior to examination of the application. Used by the USPTO to expressly abandon the application and to refund the search fee to the applicant if recognized by an appropriate USPTO official prior to examination of the application.
Pre-Appeal Brief Request for Review (Ref. EE)	PTO/SB/33	<ul style="list-style-type: none"> Used by the applicant to request that a panel of examiners formally review the basis of the rejections in their application prior to filing an appeal brief. Used by the USPTO to determine whether an appeal should be maintained.
Request for Corrected Filing Receipt	No Form	<ul style="list-style-type: none"> Used by the applicant to request a corrected filing receipt. Used by the USPTO to correct errors in application data.
Request for Corrected Filing Receipt (electronic)	No Form (possibly capable through private PAIR)	<ul style="list-style-type: none"> Used by the applicant to electronically request a corrected filing receipt. Used by the USPTO to correct errors in application data.
Petition to Make Special under Accelerated Examination Program (Ref. FF)	PTO/SB/28 EFS-Web Only	<ul style="list-style-type: none"> Used by the applicant to assist in meeting the requirements necessary to request accelerated examination. Used by the applicant to increase the likelihood of a filing of a grantable application. Used by the USPTO to assist in the expeditious processing of the petitions to make special.
Request for First-Action Interview (Pilot Program) (Ref. GG)	PTOL-413C EFS-Web Only	<ul style="list-style-type: none"> Used by the applicant to request a first-action interview prior to the first Office action on the merits to advance prosecution of the application. Used by the USPTO to grant advancement of examination for the first Office action on the merits.
Petition to Make Special Based on Age for Advancement of Examination under 37 CFR 1.102(c)(1) (Ref. HH)	PTO/SB/130 EFS-Web Only	<ul style="list-style-type: none"> Used by the applicant to petition that an application be made special for advancement of examination by showing that the applicant is 65 year of age, or more. Used by the USPTO to assist in the expeditious processing of the petition to make special based on age.

3. Use of Information Technology

Generally, the USPTO does not use automated, electronic, mechanical, or other technologies to collect information for this collection. The USPTO allows applicants to use an electronic signature, which is consistent with international standards for electronic signatures, for patent application and reexamination proceeding documents

created with a word processor as well as the fillable forms that can be accessed through the USPTO website.

The USPTO's new web-based electronic filing system, EFS-Web, became available to the public on March 17, 2006. EFS-Web allows customers to file applications and associated documents through their standard web browser and does not require any significant client-side components. EFS-Web permits most patent applications and other patent-related documents to be submitted in portable document file (PDF) format. Accordingly, EFS-Web enables users to streamline processing and filing of patent correspondence, and to better integrate electronic filing into their current computer systems. EFS-Web offers many potential benefits to filers, including form validation to ensure that all required information has been included, immediate notification that a submission has been received, automated processing of requests, and avoidance of postage or other paper delivery costs.

Correspondence officially submitted via EFS-Web is accorded a "receipt date," which is the date the correspondence was received by the USPTO. After a successful submission, an acknowledgement receipt contains the receipt date, the time the correspondence was received at the USPTO, and a full listing of the correspondence submitted.

The USPTO provides restricted Internet access to patent application status for applicants and their designated representatives through the Patent Application Information Retrieval (PAIR) system, which is available at the USPTO website. PAIR provides USPTO customers with secure and immediate access to up-to-date application status and history information by the use of digital certificates, which maintain the confidentiality of the information transmitted electronically over the Internet. In addition to being sent to the customer, acknowledgement receipts for EFS-Web submissions will also be available in PAIR. The USPTO does not intend to disseminate any confidential application information to the general public electronically through PAIR or any other means. However, the general public may use PAIR to access non-private information regarding published applications and granted patents.

4. Efforts to Identify Duplication

This information is collected during the pendency of a patent application. It does not duplicate information or collection of data found elsewhere.

5. Minimizing the Burden to Small Entities

No significant impact is placed on small entities. Small entities simply need to identify themselves as such to obtain the benefits of small entity status.

Pursuant to 35 U.S.C. § 41(h)(1), the USPTO provides a fifty percent (50%) reduction in the fees charged under 35 U.S.C. § 41(a) and (b) for small entities. The USPTO's regulations concerning the payment of reduced patent fees by small entities are at

37 CFR 1.27 and 1.28, and reduced patent fees for small entity applicants are shown in 37 CFR 1.16, 1.17, 1.18 and 1.20.

6. Consequences of Less Frequent Collection

This information is collected only as required to process a patent application or enforceable patent, and is not collected elsewhere. Therefore, this collection of information could not be conducted less frequently. If this information were not collected, the USPTO would not be able to comply with the patent statute 35 U.S.C. § 131.

7. Special Circumstances in the Conduct of Information Collection

There are no special circumstances associated with this collection of information.

8. Consultation Outside the Agency

The 60-Day Notice was published in the Federal Register on May 30, 2006 (71 Fed Reg. 103). The comment period ended on July 31, 2006. No public comments were received.

The USPTO has long-standing relationships with groups from whom patent application data is collected, such as the American Intellectual Property Law Association (AIPLA), as well as patent bar associations, inventor groups, and users of our public facilities. Their views are expressed in regularly scheduled meetings and considered in developing proposals for information collection requirements. There have been no comments or concerns expressed by these or similar organizations concerning the time required to provide the information required under this program.

9. Payment or Gifts to Respondents

This information collection does not involve a payment or gift to any respondent.

10. Assurance of Confidentiality

Confidentiality of patent applications is governed by 35 U.S.C. § 122 and 37 CFR 1.14. Upon publication of an application or issuance of an application as a patent, the entire file contents of the application are available to the public (subject to the provisions for providing only a redacted copy of the filed contents). The disclosure of the invention in the application is the quid pro quo for the property right conferred by the patent grant, and the very means by which the patent statute achieves its constitutional objective of “promot[ing] the progress of science and useful arts.” The prosecution history contained in the application file is critical to determining the scope of the property right conferred by a patent grant.

To further define the boundaries of the confidentiality of patent applications in light of the eighteen-month publication of patent applications introduced under the American Inventors Protection Act of 1999, the USPTO amended 37 CFR 1.14 to maintain the confidentiality only of applications that have not been published as a U.S. patent application publication. 37 CFR 1.14 now provides that the public can obtain status information about the application, such as whether the application is pending, abandoned, or patented, whether the application has been published under 35 U.S.C. § 122(b), and the application “numerical identifier.” This information can be supplied to the public under certain conditions. The public can also receive copies of an application-as-filed and the file wrapper, as long as it meets certain criteria.

The confidentiality, security, integrity, authenticity, and non-repudiation of patent applications submitted electronically through EFS-Web is maintained using PKI technology and digital certificates for registered users. Applications electronically filed by non-registered users are protected using TLS or SSL protocols. The ePAVE submission software encrypts the electronic patent application package. The authorized filer electronically signs the application and then it is “digitally” signed using the digital certificates. Because ePAVE is also cryptographic software, it is subject to export and import restrictions of the United States. The license agreement informs those installing and using this software that they cannot export or import this software, nor can they be located in, under the control of, or a national or resident of countries that are under export or import restrictions.

11. Justification for Sensitive Questions

None of the required information is considered to be of a sensitive nature.

12. Estimate of Hour and Cost Burden to Respondents

Table 3 calculates the anticipated burden hours and costs of this information collection to the public, based on the following factors:

- **Respondent Calculation Factors**
The USPTO estimates that it will receive 2,459,409 responses to this information collection annually.
- **Burden Hour Calculation Factors**
The USPTO estimates that it will take the public an average of 1 minute, 48 seconds (0.03 hours) to 12 hours (12.0) to complete the collections of information described in this submission, depending on the nature of the information. This includes time to gather the necessary information, create the documents, and mail the completed request. The time estimates shown for the electronic forms in this collection are based on the average amount of time needed to complete and electronically file the associated form.
- **Cost Burden Calculation Factors**
The USPTO believes that both attorneys and paralegals will supply the information requested for this information collection. The professional rate of \$304 per hour used in

this submission to calculate the respondent cost burden is the median rate for associate attorneys in private firms as published in the 2005 report of the Committee on Economics of Legal Practice of the American Intellectual Property Law Association. This report summarized the results of a survey with data on hourly billing rates. The paraprofessional rate is \$90 per hour. These are fully loaded hourly rates.

Table 3: Burden Hour/Burden Cost to Respondents for Patent Processing (Updating)

Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (a) x (b) (c)	Rate (\$/hr) (d)	Total Cost (\$/hr) (c) x (d) (e)
Information Disclosure Statements with no additional disclosure requirements	2.00	273,300	546,600	\$304.00	\$166,166,400.00
eIDS (Information Disclosure Statements) filed with no additional disclosure requirements	2.00	68,450	136,900	\$304.00	\$41,617,600.00
Transmittal Form	2.00	1,039,500	2,079,000	\$90.00	\$187,110,000.00
Petition for Extension of Time under 37 CFR 1.136(a)	0.10	189,000	18,900	\$90.00	\$1,701,000.00
Petition for Extension of Time under 37 CFR 1.136(b)	0.50	54	27	\$304.00	\$8,208.00
Express Abandonment under 37 CFR 1.138	0.20	13,825	2,765	\$90.00	\$248,850.00
Petition for Express Abandonment to Avoid Publication Under 1.138(c)	0.20	500	100	\$90.00	\$9,000.00
Disclaimers	0.20	15,000	3,000	\$304.00	\$912,000.00
Request for Expedited Examination of a Design Application	0.10	130	13	\$304.00	\$3,952.00
Notice of Appeal	0.20	16,500	3,300	\$304.00	\$1,003,200.00
Information Disclosure Citation in a Patent	2.00	1,830	3,660	\$304.00	\$1,112,640.00
Petition for Revival of an Application for Patent Abandoned Unavoidably	8.00	585	4,680	\$304.00	\$1,422,720.00
Petition for Revival of an Application for Patent Abandoned Unintentionally	1.00	6,950	6,950	\$304.00	\$2,112,800.00
Petition for Revival of an Application for Patent Abandoned for Failure to Notify the Office of a Foreign or International Filing	1.00	2,400	2,400	\$304.00	\$729,600.00
Requests to Access, Inspect and Copy	0.20	18,650	3,730	\$90.00	\$335,700.00
Deposit Account Order Form	0.20	1,160	232	\$90.00	\$20,880.00
Certificates of Mailing/Transmission	0.03	590,000	17,700	\$90.00	\$1,593,000.00
Statement Under 37 CFR 3.73(b)	0.20	19,450	3,890	\$304.00	\$1,182,560.00
Non-publication Request	0.10	31,500	3,150	\$304.00	\$957,600.00
Rescission of Previous Non-publication Request (35 U.S.C. § 122(b)(2)(B)(ii)) and, if applicable, Notice of Foreign Filing (35 U.S.C. § 122(b)(2)(B)(iii))	0.10	525	53	\$304.00	\$16,112.00

Electronic Filing System (EFS) Copy of Application for Publication	2.50	1,000	2,500	\$90.00	\$225,000.00
Copy of File Content Showing Redactions	4.00	12	48	\$304.00	\$14,592.00
Copy of the Applicant or Patentee's Record of the Application (including copies of the correspondence, list of the correspondence, and statements verifying whether the record is complete or not)	1.00	235	235	\$90.00	\$21,150.00
Request for Continued Examination (RCE) Transmittal	0.20	54,300	10,860	\$304.00	\$3,301,440.00
Request for Continued Examination (RCE) Transmittal EFS-Web	0.20	1,700	340	\$304.00	\$103,360.00
Request for Oral Hearing Before the Board of Patent Appeals and Interferences	0.20	750	150	\$304.00	\$45,600.00
Request for Deferral of Examination 37 CFR 1.103(d)	0.20	53	11	\$304.00	\$3,344.00
Request for Voluntary Publication or Republication EFS-Web	0.20	1,400	280	\$90.00	\$25,200.00
Applicant Initiated Interview Request Form	0.35	1,600	560	\$304.00	\$170,240.00
Petition for Request for Documents in a Form Other Than That Provided by 1.19	1.00	50	50	\$90.00	\$4,500.00
<u>Petitions under 37 CFR 1.17(g) include:</u> Petition to Access an Assignment Record Petition for Access to an Application Petition for Expungement and Return of Information Petition to Suspend Action in an Application	2.00	3,600	7,200	\$304.00	\$2,188,800.00
<u>Petitions under 37 CFR 1.17(h) include:</u> Petition for Accepting Color Drawings or Photographs Petition for Entry of a Model or Exhibit Petition to Withdraw an Application from Issue Petition to Defer Issuance of a Patent	1.00	10,400	10,400	\$304.00	\$3,161,600.00
Request for Processing of Replacement Drawings to Include the Drawings in Any Patent Application Publication	1.00	50	50	\$90.00	\$4,500.00
Processing Fee Under 37 CFR 1.17(i) Transmittal	0.08	500	40	\$304.00	\$12,160.00
Request to Retrieve Electronic Priority Application(s) Under 37 CFR 1.55(d)	0.13	36,800	4,784	\$304.00	\$1,454,336.00
Authorization to Permit Access to Application by Participating Offices Under 37 CFR 1.14(h)	0.10	21,000	2,100	\$304.00	\$638,400.00
Petition for Express Abandonment to Obtain a Refund	0.20	3,000	600	\$304.00	\$182,400.00
Pre-Appeal Brief Request for Review	0.50	3,200	1,600	\$304.00	\$486,400.00
Request for Corrected Filing Receipt	0.08	25,000	2,000	\$90.00	\$180,000.00
Request for Corrected Filing Receipt (electronic)	0.08	2,050	164	\$90.00	\$14,760.00

Petition to Make Special Under Accelerated Examination Program	12.0	500	6,000	\$304.00	\$1,824,000.00
Request for First-Action Interview (Pilot Program)	2.50	1,000	2,500	\$304.00	\$760,000.00
Petition to Make Special Based on Age for Advancement of Examination under 37 CFR 1.102(c)(1) EFS-Web only	2.00	1,900	3,800	\$304.00	\$1,155,200.00
Total	- - - - -	2,459,409	2,893,322	- - - - -	\$424,240,804.00

13. Total Annualized Cost Burden

There are no maintenance or capital start-up costs associated with this submission. There are, however, non-hour costs due to record keeping requirements, filing fees and mailing costs that need to be added into the total annual non-hour cost burden.

A record keeping cost of \$7,020 is being added into this collection for the EFS-Web submissions. The applicant is strongly urged to retain a copy of the file submitted to the USPTO as evidence of authenticity in addition to keeping the acknowledgment receipt as clear evidence of the date the file was received by the USPTO. The USPTO estimates that it will take 5 seconds (0.001 hours) to print and retain a copy of the EFS-Web submissions and that approximately 78,000 submissions per year will use this option, for a total of 78 hours per year for printing this receipt. Using the paraprofessional rate of \$90 per hour, the USPTO estimates that the record keeping cost associated with this collection will be \$7,020 per year.

The minimum total annual filing fee/non-hour cost burden to respondents is outlined in Table 4 below:

Table 4: Filing Fees – Non-hour cost burden for Patent Processing (Updating)

Item	Responses (a)	Filing Fees (b)	Total Cost (a) x (b) (c)
Submission of an Information Disclosure Statement (IDS) under 37 CFR 1.97(c) or (d)	341,750	None	\$0
Transmittal Forms	1,039,500	None	\$0
One-month extension of time under 37 CFR 1.136(a)	60,270	\$120.00	\$7,232,400.00
One-month extension of time under 37 CFR 1.136(a) (small entity)	23,503	\$60.00	\$1,410,180.00
Two-month extension of time under 37 CFR 1.136(a)	31,225	\$450.00	\$14,051,250.00
Two-month extension of time under 37 CFR 1.136(a) (small entity)	12,891	\$225.00	\$2,900,475.00
Three-month extension of time under 37 CFR 1.136(a)	32,724	\$1,020.00	\$33,378,480.00
Three-month extension of time under 37 CFR 1.136(a) (small entity)	16,413	\$510.00	\$8,370,630.00

Four-month extension of time under 37 CFR 1.136(a)	3,370	\$1,590.00	\$5,358,300.00
Four-month extension of time under 37 CFR 1.136(a) (small entity)	2,267	\$795.00	\$1,802,265.00
Five-month extension of time under 37 CFR 1.136(a)	2,163	\$2,160.00	\$4,672,080.00
Five-month extension of time under 37 CFR 1.136(a) (small entity)	4,174	\$1,080.00	\$4,507,920.00
Extension of time under 37 CFR 1.136(b)	54	None	\$0
Express abandonment under 37 CFR 1.138	13,825	None	\$0
Petition for express abandonment to avoid publication under 37 CFR 1.138(c)	500	\$130.00	\$65,000.00
Statutory Disclaimer	11,250	\$130.00	\$1,462,500.00
Statutory Disclaimer (small entity)	3,750	\$65.00	\$243,750.00
Request for expedited examination of a design application	130	\$900.00	\$117,000.00
Notice of Appeal	12,570	\$500.00	\$6,285,000.00
Notice of Appeal (small entity)	3,930	\$250.00	\$982,500.00
Information Disclosure Citations	1,830	None	\$0
Petition to Revive Unavoidably Abandoned Application	250	\$500.00	\$125,000.00
Petition to Revive Unavoidably Abandoned Application (small entity)	335	\$250.00	\$83,750.00
Petition to Revive Unintentionally Abandoned Application	3,700	\$1,500.00	\$5,550,000.00
Petition to Revive Unintentionally Abandoned Application (small entity)	3,250	\$750.00	\$2,437,500.00
Petition for revival of an application for patent abandoned for failure to notify the office of a foreign or international filing	1,440	\$1,300.00	\$1,872,000.00
Petition for revival of an application for patent abandoned for failure to notify the office of a foreign or international filing – small entity	960	\$650.00	\$624,000.00
Requests to Access, Inspect and Copy	18,650	None	\$0
Deposit Account Order Form	1,160	None	\$0
Certificates of Mailing/Transmission	590,000	None	\$0
Statement under 37 CFR 3.73(b)	19,450	None	\$0
Non-publication request	31,500	None	\$0
Rescission of Non-publication request	525	None	\$0
Electronic Filing System (EFS) Copy of Application for Publication	1,000	None	\$0
Copy of File Content Showing Redactions	12	None	\$0
Copy of the Applicant or Patentee's Record of the Application (including copies of the correspondence, list of the correspondence, and statement verifying whether the record is complete or not)	235	None	\$0
Request for Continued Examination (RCE) Transmittal	43,500	\$790.00	\$34,365,000.00

Request for Continued Examination (RCE) Transmittal (small entity)	10,800	\$395.00	\$4,266,000.00
Request for Continued Examination (RCE) Transmittal EFS-Web	1,300	\$790.00	\$1,027,000.00
Request for Continued Examination (RCE) Transmittal (small entity) EFS-Web	400	\$395.00	\$158,000.00
Request for an Oral Hearing	600	\$1,000.00	\$600,000.00
Request for an Oral Hearing (small entity)	150	\$500.00	\$75,000.00
Processing Fee for Deferral of Examination	53	\$430.00	\$22,790.00
Request for Voluntary Publication or Republication	1,400	\$130.00	\$182,000.00
Applicant Initiated Interview Request Form	1,600	None	\$0
Petition for request for documents in a form other than that provided by 1.19	50	\$130.00	\$6,500.00
<u>Petitions under 37 CFR 1.17(g) include:</u> Petition to Access an Assignment Record Petition for Access to an Application Petition for Expungement and Return of Information Petition to Suspend Action in an Application	3,600	\$200.00	\$720,000.00
<u>Petitions under 37 CFR 1.17(h) include:</u> Petition for Accepting Color Drawings or Photographs Petition for Entry of a Model or Exhibit Petition to Withdraw an Application from Issue Petition to Defer Issuance of a Patent	10,400	\$130.00	\$1,352,000.00
Request for processing of replacement drawings to include the drawings in any patent application publication	50	\$130.00	\$6,500.00
Processing Fee under 37 CFR 1.17(i) Transmittal	500	\$130.00	\$65,000.00
Request to retrieve electronic priority application(s) under 37 CFR 1.55(d)	36,800	None	\$0
Authorization to permit access to application by participating offices under 37 CFR 1.17(h)	21,000	None	\$0
Petition for express abandonment to obtain a refund	3,000	None	\$0
Pre-Appeal Brief Request for Review (filed with the Notice of Appeal)	2,400	None	\$0
Pre-Appeal Brief Request for Review (filed later than the Notice of Appeal)	800	\$130.00	\$104,000.00
Correction Request Form	25,000	None	\$0
Correction Request Form (electronic)	2,050	None	\$0
Petition to Make Special Under Accelerated Examination Program	500	\$130.00	\$65,000.00
Request for First-Action Interview (Pilot Program)	1,000	None	\$0
Petition to Make Special Based on Age for Advancement of Examination under 37 CFR 1.102(c)(1)	1,900	None	\$0
Totals	2,459,409	- - - - -	\$146,546,770.00

There are mailing costs in the way of postage fees that also need to be added into the total annual non-hour cost burden for this collection. The public may submit the paper forms and petitions in this collection to the USPTO by mail through the United States Postal Service. All correspondence may include a certificate of mailing for each piece of correspondence enclosed, stating the date of deposit or transmission to the USPTO in order to receive credit for timely filing. The USPTO estimates that the average first-class postage for a mailed submission may amount to 58 cents. Postage for the certificates of mailing themselves are not calculated into this estimate as they are included with the individual pieces of correspondence that are being deposited with the United States Postal Service. The USPTO estimates that it will receive 1,791,409 responses per year subject to mailing costs, for a cost of \$1,039,017 annually in postage fees.

Therefore, the USPTO estimates that that the total annualized cost burden for this collection from record keeping costs (\$7,020), filing fees (\$146,546,770), and mailing costs (\$1,039,017) amounts to \$147,592,807.

14. Annual Cost to the Federal Government

The USPTO estimates that it takes a GS-5, step 1, between 1 minute 48 seconds (0.03 hours) and 4 hours to process the items in this collection. The hourly rate for a GS-5, step 1, is currently \$14.56 according to the U.S. Office of Personnel Management's (OPM's) wage chart, including locality pay for the Washington, DC area. When 30% is added to account for a fully loaded hourly rate (benefits and overhead), the rate per hour for a GS-5, step 1, is \$18.43 (\$14.56 + \$4.37).

Table 6 calculates the processing hours and costs of this information collection to the Federal Government:

Table 6: Burden Hour/Burden Cost to the Federal Government for Patent Processing (Updating)

Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (a) x (b) (c)	Rate (\$/hr) (d)	Total Cost (\$/hr) (c) x (d) (e)
Information Disclosure Statements and eIDS	0.30	341,750	102,525	\$18.43	\$1,889,536.00
Transmittal Form	0.10	1,039,500	103,950	\$18.43	\$1,915,799.00
Petition for Extension of Time under 37 CFR 1.136(a)	0.10	189,000	18,900	\$18.43	\$348,327.00
Petition for Extension of Time under 37 CFR 1.136(b)	0.20	54	11	\$18.43	\$203.00
Express Abandonment under 37 CFR 1.138	0.10	13,825	1,383	\$18.43	\$25,489.00
Petition for Express Abandonment to Avoid Publication under 37 CFR 1.138(c)	0.10	500	50	\$18.43	\$922.00
Disclaimers	0.20	15,000	3,000	\$18.43	\$55,290.00
Request for Expedited Examination of a Design Application	0.10	130	13	\$18.43	\$240.00

Notice of Appeal	0.10	16,500	1,650	\$18.43	\$30,410.00
Information Disclosure Citation in a Patent	0.10	1,830	183	\$18.43	\$3,373.00
Petition for Revival of an Application for Patent Abandoned Unavoidably or Unintentionally	0.30	7,535	2,261	\$18.43	\$41,670.00
Petition for Revival of an Application for Patent Abandoned for Failure to Notify the Office of a Foreign or International Filing	0.30	2,400	720	\$18.43	\$13,270.00
Requests to Access, Inspect and Copy	0.10	18,650	1,865	\$18.43	\$34,372.00
Deposit Account Order Form	0.20	1,160	232	\$18.43	\$4,276.00
Certificates of Mailing/Transmission	0.10	590,000	59,000	\$18.43	\$1,087,370.00
Statement under 37 CFR 3.37(b)	0.10	19,450	1,945	\$18.43	\$35,846.00
Non-publication Request	0.50	31,500	15,750	\$18.43	\$290,273.00
Rescission of Previous Non-publication Request (35 U.S.C. § 122(b)(2)(B)(ii)) and, if applicable, Notice of Foreign Filing (35 U.S.C. § 122(b)(2)(B)(iii))	0.50	525	263	\$18.43	\$4,847.00
Electronic Filing System (EFS) Copy of Application for Publication	0.25	1,000	250	\$18.43	\$4,608.00
Copy of File Content Showing Redactions	4.00	12	48	\$18.43	\$885.00
Copy of the Applicant or Patentee's Record of the Application (including copies of the correspondence, list of the correspondence, and statements verifying whether the record is complete or not)	1.00	235	235	\$18.43	\$4,331.00
Request for Continued Examination (RCE) Transmittal	0.60	54,300	32,580	\$18.43	\$600,449.00
Request for Continued Examination (RCE) Transmittal (small entity)	0.60	1,700	1,020	\$18.43	\$18,799.00
Request for Oral Hearing Before the Board of Patent Appeals and Interferences	0.10	750	75	\$18.43	\$1,382.00
Request for Deferral of Examination 37 CFR 1.103(d)	0.30	53	16	\$18.43	\$295.00
Request for Voluntary Publication or Republication	0.03	1,400	42	\$18.43	\$774.00
Applicant Initiated Interview Request Form	0.10	1,600	160	\$18.43	\$2,949.00
Petition for Request for Documents in a Form Other Than That Provided by 1.19	0.10	50	5	\$18.43	\$92.00
<u>Petitions under 37 CFR 1.17(g) include:</u> Petition to Access an Assignment Record Petition for Access to an Application Petition for Expungement and Return of Information Petition to Suspend Action in an Application	0.20	3,600	720	\$18.43	\$13,270.00

<u>Petitions under 37 CFR 1.17(h) include:</u> Petition for Accepting Color Drawings or Photographs Petition for Entry of a Model or Exhibit Petition to Withdraw an Application from Issue Petition to Defer Issuance of a Patent	0.10	10,400	1,040	\$18.43	\$19,167.00
Request for Processing of Replacement Drawings to Include the Drawings in Any Patent Application Publication	0.10	50	5	\$18.43	\$92.00
Processing Fee under 37 CFR 1.17(i) Transmittal	0.08	500	40	\$18.43	\$737.00
Request to Retrieve Electronic Priority Application(s) under 37 CFR 1.55(d)	0.05	36,800	1,840	\$18.43	\$33,911.00
Authorization for Permit Access to Application by Participating Offices under 37 CFR 1.14(h)	0.05	21,000	1,050	\$18.43	\$19,352.00
Petition for Express Abandonment to Obtain a Refund	0.10	3,000	300	\$18.43	\$5,529.00
Pre-Appeal Brief Request for Review	0.10	3,200	320	\$18.43	\$5,898.00
Request for Corrected Filing Receipt	0.08	25,000	2,000	\$18.43	\$36,860.00
Request for Corrected Filing Receipt (electronic)	0.08	2,050	164	\$18.43	\$3,023.00
Petition to Make Special under Accelerated Examination Program	0.50	500	250	\$18.43	\$4,608.00
Request for First-Action Interview (Pilot Program)	0.30	1,000	300	\$18.43	\$5,529.00
Petition to Make Special Based on Age for Advancement of Examination under 37 CFR 1.102(c)(1)	0.10	1,900	190	\$18.43	\$3,502.00
Total	- - - - -	2,459,409	292,301	- - - - -	\$5,387,113.00

15. Reason for Change in Burden

Summary of Changes Since the Previous Renewal

In the 2003 renewal of this collection the USPTO reported a total of 2,208,339 responses and 830,629 burden hours. Since that time, there have been numerous proposed additions due to rulemakings and change worksheets approved by OMB, along with an adjustment in responses and response times and the addition of new requirements into the collection, drastically affecting the response and burden hour totals.

The following changes have taken place since the previous renewal of this collection:

- July 2003 - Renewal approved by OMB with a total of 2,208,339 responses and 830,629 burden hours per year.
- December 2003 – OMB approved a proposed addition to the collection in conjunction with a proposed rulemaking, “Changes to Support Implementation of

the United States Patent and Trademark Office 21st Century Strategic Plan” (RIN 0651-AB64), that increased the responses by 7,450 and the burden hours by 22,600 annually.

- January 2004 – OMB approved a change worksheet that increased the time needed to complete the Transmittal Form, which in turn increased the burden by 1,871,100 hours.
- June 2004 – OMB approved a change worksheet adding 2 new fee transmittal forms into the collection, increasing the responses by 7,850 and the burden by 628 hours.
- October 2004 – OMB approved a proposed addition in conjunction with a proposed rulemaking, “Changes to Implement Priority Document Exchange between Intellectual Property Offices” (RIN 0651-AB75), that introduced two new forms into the collection, increasing the responses by 57,800 and the burden hours by 6,884 annually.
- August 2005 - OMB approved a proposed addition in conjunction with a proposed rulemaking, “Changes to Implement the Patent Search Fee Refund Provisions of the Consolidated Appropriations Act, 2005” (RIN 0651-AB79), that introduced one new form into the collection, increasing the responses by 3,000 and the burden hours by 600 per year.
- September 2005 - OMB approved a change worksheet that approved the USPTO altering the IDS form to allow users to file initial applications and follow-on submissions using PDF filed through EFS-Web. No change to responses or burden hours.
- February 2006 – OMB approved a change worksheet adding one new electronic form, Petition to Make Special Under Accelerated Examination Program, for an existing requirement, and increased the time from 1 hour to 12 hours. No change in the number of responses.
- March 2006 – OMB approved a change worksheet that changed the form numbers for the two priority document forms. No change in responses or burden hours.

With this renewal, the USPTO estimates the annual responses to be 2,459,409, with the annual burden hours at 2,893,322, a decrease of 48,730 responses and a decrease of 831,469 burden hours over the currently approved inventory.

The total annualized (non-hour) cost burden for this renewal of \$147,592,807 is an increase of \$32,869,551 from the currently approved total of \$114,723,256. The increase in costs is due to the various rulemakings and change worksheets in the past four years, along with an adjustment in responses and response times and the addition

of new EFS-Web submissions, increasing the recordkeeping costs, filing fees and postage costs.

Changes from the 60-Day Notice

The 60-Day Federal Register Notice, published in May 2006, reported that the USPTO estimated it would receive 2,604,029 responses resulting in 3,157,840 burden hours per year. Since that publication, there have been additional rulemakings and change worksheets submitted to OMB, along with adjustments in responses and response times and additions of new requirements into the collection, decreasing the responses by 144,620 and the burden hours by 264,518, resulting in the present 2,459,409 responses and 2,893,322 burden hours being reported for this submission.

The current annual (non-hour) cost proposed for this renewal of \$147,592,409 is a decrease of \$9,341,068 from the \$156,933,477 reported in the 60-Day Notice due to the adjustments mentioned above.

Change in Respondent Cost Burden

In 2003, the estimated hourly rate for attorneys was \$252. Using that rate, the reported burden hours yielded a respondent cost burden of \$153,236,424. For this renewal, the USPTO is using the current professional hourly rate of \$304. At this rate, the reported burden hours yield a respondent cost burden of \$424,240,804, which is an increase of \$271,004,380, due to the various rulemakings and change worksheets in the past four years, along with adjustments in responses and response times, and the addition of new requirements into the collection.

Changes in Response and Burden Hours

With this renewal, the number of responses decreased by 48,730, from 2,508,139 to 2,459,409, and the burden hours decreased by 831,469, from 3,724,791 to the present 2,893,322 per year. The decrease in burden hours is due to a combination of the revised number of submissions, a re-estimation of the time it takes to complete some of the responses, and new requirements being added into this collection. This decrease is due to both program changes and administrative adjustments, as follows:

- The USPTO believes that the number of Petitions for Express Abandonment to Avoid Publication Under 37 CFR 1.138(c) submitted per year will increase by 150 responses, from 350 to 500. **Therefore, this submission takes a burden increase of 30 hours as an administrative adjustment.**
- The USPTO believes that the time it takes to complete the Requests for Expedited Examination of a Design Application submitted per year will decrease by 6 minutes, from 12 to 6 minutes. **Therefore, this submission takes a burden decrease of 13 hours as an administrative adjustment.**

- The USPTO believes that the number of Petitions to Revive Unavoidably Abandoned Applications submitted per year will increase by 180 responses, from 405 to 585. **Therefore, this submission takes a burden increase of 1,440 hours as an administrative adjustment.**
- The USPTO believes that the number of Petitions to Revive Unintentionally Abandoned Applications submitted per year will increase by 2,415 responses, from 4535 to 6950. **Therefore, this submission takes a burden increase of 2,415 hours as an administrative adjustment.**
- The USPTO believes that the number of Certificates of Mailing/Transmission submitted per year will increase by 47,000 responses, from 543,000 to 590,000. **Therefore, this submission takes a burden increase of 1,410 hours as an administrative adjustment.**
- The USPTO believes that the number of Notices of Rescission of Previous Non-publication Request (35 U.S.C. § 122 (b)(2)(B)(ii)) and, if applicable, Notices of Foreign Filing (35 U.S.C. § 122 (b)(2)(B)(iii)) submitted per year will decrease by 1,575 responses, from 2,100 to 525. **Therefore, this submission takes a burden decrease of 157 hours as an administrative adjustment.**
- The USPTO believes that the number of Requests for Continued Examination (RCE) Transmittal submitted per year will increase by 28,300 responses, from 26,000 to 54,300. **Therefore, this submission takes a burden increase of 5,660 hours as an administrative adjustment.**
- For the last renewal, the Request for Voluntary Publication or Republication was noted as an annualized cost only. Since that time, it has come to the attention of the USPTO that this is an actual information requirement. There is no form associated with it but it can be selected via a radio-button on EFS-Web, and is coming into the collection as an expanded valid information requirement. The USPTO estimates that it will take 12 minutes to complete this form and that it will receive 1,400 responses per year. **Therefore, this submission takes a burden increase of 280 hours as a program change.**
- The USPTO believes that the number of Petitions under 37 CFR 1.17(f) submitted per year will decrease by 1,500 responses, from 4,800 to 3,300. **Therefore, this submission takes a burden decrease of 6,000 hours as an administrative adjustment.**
- The USPTO believes that the number of Petitions under 37 CFR 1.17(g) submitted per year will increase by 2850 responses, from 750 to 3,600. **Therefore, this submission takes a burden increase of 5,700 hours as an administrative adjustment.**

- The USPTO believes that the number of Petitions under 37 CFR 1.17(h) submitted per year will increase by 8,600 responses, from 1,800 to 10,400. **Therefore, this submission takes a burden increase of 8,600 hours as an administrative adjustment.**
- The USPTO believes that the number of Petition Fee under 37 CFR 1.17(f), (g) and (h) Transmittals submitted per year will increase by 9,950 responses, from 7,350 to 17,300. **Therefore, this submission takes a burden increase of 796 hours as an administrative adjustment.**
- A new electronic (EFS-Web) form is being added into the collection for the Requests for Continued Examination (RCE) Transmittal. The USPTO estimates that it will take 12 minutes to complete this form and it will receive 1,700 responses per year. **Therefore, this submission takes a burden increase of 340 hours as a program change.**
- A new form is being added in the collection entitled “Pre-Appeal Brief Request for Review.” The USPTO estimates that it will take 30 minutes to complete this form and that it will receive 3,200 responses per year. **Therefore, this submission takes a burden increase of 1,600 hours as a program change.**
- A new requirement is being added in the collection entitled “Request for Corrected Filing Receipt.” The USPTO estimates that it will take 5 minutes to complete this requirement and that it will receive 25,000 responses per year. **Therefore, this submission takes a burden increase of 2,000 hours as a program change.**
- A new requirement is being added in the collection entitled “Request for Corrected Filing Receipt (electronic).” The USPTO estimates that it will take 5 minutes to complete this requirement and that it will receive 2,050 responses per year. **Therefore, this submission takes a burden increase of 164 hours as a program change.**
- The USPTO believes that the number of Petitions to Make Special Under Accelerated Examination Program submitted per year will remain the same but the processing time will change, increasing the burden hours. **Therefore, this submission takes a burden increase of 500 hours as an administrative adjustment.**
- A new form is being added in the collection entitled “Request for First Action Interview (Pilot Program).” The USPTO estimates that it will take 2 hours and 30 minutes to complete this form and that it will receive 1,000 responses per year. **Therefore, this submission takes a burden increase of 2,500 hours as a program change.**

- A new form is being added in the collection entitled “Petition to Make Special Based on Age for Advancement of Examination under 37 CFR 1.102(c)(1).” The USPTO estimates that it will take 2 hours to complete this form and that it will receive 1,900 responses per year. **Therefore, this submission takes a burden increase of 3,800 hours as a program change.**

A total of 20,381 burden hours have been added to this collection as a result of administrative adjustments, along with an increase of 10,684 burden hours due to program changes. This results in a total net burden hour increase of 31,065 hours for this collection.

Changes in Annual (non-hour) Costs

For this renewal, the USPTO estimates that the total annual (non-hour) costs will increase by \$32,869,551, from \$114,723,256 currently on the OMB inventory to the present \$147,592,807. The increase in costs is due to adjustments in responses and response times, the addition of new requirements into the collection and new EFS-Web submissions, and an adjustment for the current postage fees, increasing the recordkeeping costs, filing fees and postage costs. **Therefore, the cost burden increase of \$33,557,498 due to administrative adjustments and a net decrease of \$687,947 due to program changes yield a total increase in annual (non-hour) cost burden of \$32,869,551 for the collection.**

16. Project Schedule

There is no plan to publish this information for statistical use. No special publication of the items discussed in this justification statement is planned. However, plant and utility patents granted are published weekly in the *Official Gazette of the United States Patent and Trademark Office*.

17. Display of Expiration Date of OMB Approval

The forms in this information collection will display the OMB Control Number and expiration date.

18. Exception to the Certificate Statement

This collection of information does not include any exceptions to the certificate statement.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection of information does not employ statistical methods.

References

- A. PTO/SB/08a/08b and EFS-Web Information Disclosure Statement by Applicant
- B. PTO/SB/21 Transmittal Form
- C. PTO/SB/22/23 Petitions for Extension of Time
- D. PTO/SB/24 Express Abandonment
- E. PTO/SB/24A Petition for Express Abandonment to Avoid Publication under 37 CFR 1.138(c)
- F. PTO/SB/25/26/43/62/63 Disclaimers
- G. PTO/SB/27 Request for Expedited Examination of a Design Application
- H. PTO/SB/31 Notice of Appeal
- I. PTO/SB/42 Information Disclosure Citation
- J. PTO/SB/61/64 Petitions to Revive Unintentionally or Unavoidably Abandoned Applications
- K. PTO/SB/64a Petition for Revival of an Application for Patent Abandoned for Failure to Notify the Office of a Foreign or International Filing
- L. PTO/SB/67/68 Requests to Access, Inspect and Copy
- M. PTO/SB/91 Deposit Account Order Form
- N. PTO/SB/92/97 Certificates of Mailing/Transmission
- O. PTO/SB/96 Statement under 37 CFR 3.73(b)
- P. PTO/SB/35 Non-publication Request
- Q. PTO/SB/36 Notice of Rescission of Previous Non-publication Request (35 U.S.C. § 122(b)(2)(B)(ii)) and, if applicable, Notice of Foreign Filing (35 U.S.C. § 122(b)(2)(B)(iii))
- R. Electronic form via EFS-Web Electronic filing system (EFS) copy of application for publication
- S. PTO-2053-A/B Notice Under 37 CFR 1.251-Pending Application
- T. PTO-2054-A/B Notice Under 37 CFR 1.251 – Abandoned Application
- U. PTO-2055-A/B Notice under 37 CFR 1.152 – Patent
- V. PTO/SB/30 Request for Continued Examination (RCE)
- W. PTO/SB/30EFS Request for Continued Examination (RCE) EFS-Web
- X. PTO/SB/32 Request for Oral Hearing Before the Board of Patent Appeals and Interferences
- Y. PTO/SB/37 Request for Deferral of Examination 37 CFR 1.103(d)
- Z. PTOL/413A Applicant Initiated Interview Request Form
- AA. PTO/SB/17i Processing Fee under 37 CFR 1.17i) Transmittal
- BB. PTO/SB/38 Request to Retrieve Electronic Priority Application(s) under 37 CFR 1.55(d)
- CC. PTO/SB/39 Authorization for Permit Access to Application by Participating Offices under 37 CFR 1.14(h)
- DD. PTO/SB/24B Petition for Express Abandonment to Obtain a Refund
- EE. PTO/SB/33 Pre-Appeal Brief Request for Review
- FF. PTO/SB/28 EFS-Web Petition to Make Special under Accelerated Examination Program
- GG. PTOL-413C EFS-Web Only Request for First-Action Interview (Pilot Program)
- HH. PTO/SB/130 EFS-Web Only Petition to Make Special Based on Age for Advancement of Examination under 37 CFR 1.102(c)(1)

NOTICE OF OFFICE OF MANAGEMENT AND BUDGET ACTION

Date 07/01/2009

Department of Commerce
Patent and Trademark Office
FOR CERTIFYING OFFICIAL: Suzanne Hilding
FOR CLEARANCE OFFICER: Diana Hynek

In accordance with the Paperwork Reduction Act, OMB has taken action on your request received 09/26/2007

ACTION REQUESTED: Revision of a currently approved collection
TYPE OF REVIEW REQUESTED: Regular
ICR REFERENCE NUMBER: 200707-0651-005
AGENCY ICR TRACKING NUMBER:
TITLE: Patent Processing (Updating)
LIST OF INFORMATION COLLECTIONS: See next page

OMB ACTION: Approved with change
OMB CONTROL NUMBER: 0651-0031

The agency is required to display the OMB Control Number and inform respondents of its legal significance in accordance with 5 CFR 1320.5(b).

EXPIRATION DATE: 07/31/2012

DISCONTINUE DATE:

BURDEN:	RESPONSES	HOURS	COSTS
Previous	2,508,139	3,724,791	114,723,256
New	2,459,409	2,893,322	147,592,807
Difference			
Change due to New Statute	0	0	0
Change due to Agency Discretion	11,100	-261,104	-687,947
Change due to Agency Adjustment	-59,830	-570,365	33,557,498
Change Due to Potential Violation of the PRA	0	0	0

TERMS OF CLEARANCE: Revised to correct collection list and supporting statement.

OMB Authorizing Official: Kevin F. Neyland
Deputy Administrator,
Office Of Information And Regulatory Affairs

List of ICs

IC Title	Form No.	Form Name	CFR Citation
Information Disclosure Statements with no additional disclosure requirements	PTO/SB/08A, PTO/SB/08B	Information Disclosure Statement by Applicant, Information Disclosure Statement by Applicant	37 CFR 1.98, 37 CFR 1.56, 37 CFR 1.97
eIDS (Information Disclosure Statements) filed with no additional disclosure requirements	PTO/SB/08a	Information Disclosure Statement by Applicant	37 CFR 1.56, 37 CFR 1.97, 37 CFR 1.98
Transmittal Form	PTO/SB/21	Transmittal Form	37 CFR 1.5, 37 CFR 1.4, 37 CFR 1.48, 37 CFR 1.111, 37 CFR 1.116, 37 CFR 1.121, 37 CFR 1.125, 37 CFR 1.133, 37 CFR 1.291
Petition for Extension of Time under 37 CFR 1.136(a)	PTO/SB/22	Petition for Extension of Time Under 37 CFR 1.136(a) FY 2006	37 CFR 1.136(a)
Petition for Extension of Time under 37 CFR 1.136(b)	PTO/SB/23	Petition for Extension of Time Under 37 CFR 1.136(b)	37 CFR 1.136(b)
Express Abandonment under 37 CFR 1.138	PTO/SB/24	Express Abandonment Under 37 CFR 1.138	37 CFR 1.138
Petition for Express Abandonment to Avoid Publication Under 37 CFR 1.138(c)	PTO/SB/24A	Petition for Express Abandonment to Avoid Publication Under 37 CFR 1.138(c)	37 CFR 1.138(c), 37 CFR 1.211(a)(1)
Disclaimers	PTO/SB/43, PTO/SB/62, PTO/SB/26, PTO/SB/25, PTO/SB/63	Disclaimer in Patent Under 37 CFR 1.321(a), Terminal Disclaimer to Accompany Petition (Period Specified), Terminal Disclaimer to Obviate a Double Patenting Rejection over a "Prior" Patent, Terminal Disclaimer to Obviate a Provisional Double Patenting Rejection over a Pending "Reference" Application, Terminal Disclaimer to Accompany Petition	37 CFR 1.321
Request for Expedited Examination of a Design Application	PTO/SB/27	Request for Expedited Examination of a Design Application (37 CFR 1.155)	37 CFR 1.155
Notice of Appeal	PTO/SB/31	Notice of Appeal from the Examiner to the Board of Patent Appeals and Interferences	37 CFR 1.191

List of ICs

IC Title	Form No.	Form Name	CFR Citation
Information Disclosure Citation in a Patent	PTO/SB/42	37 CFR 1.501 Information Disclosure Citation in a Patent	37 CFR 1.501
Petition for Revival of an Application for Patent Abandoned Unavoidably	PTO/SB/61	Petition for Revival of an Application for Patent Abandoned Unavoidably Under 37 CFR 1.137(a)	37 CFR 1.137
Petition for Revival of an Application for Patent Abandoned Unintentionally	PTO/SB/64	Petition for Revival of an Application for Patent Abandoned Unintentionally Under	37 CFR 1.137
Petition for Revival of an Application for Patent Abandoned for Failure to Notify the Office of a Foreign or International Filing	PTO/SB/64a	Petition for Revival of an Application for Patent Abandoned for Failure to Notify the Office of a Foreign or International Filing (37 CFR 1.137(f))	37 CFR 1.137, 37 CFR 1.213
Requests to Access, Inspect and Copy	PTO/SB/67, PTO/SB/68	Power to Inspect/Copy, Request for Access to an Abandoned Application under 37 CFR 1.14	37 CFR 1.14
Deposit Account Order Form	PTO/SB/91	Deposit Account Order Form	37 CFR 1.25
Certificates of Mailing/Transmission	PTO/SB/97, PTO/SB/92	Certificate of Transmission under 37 CFR 1.8, Certificate of Mailing under 37 CFR 1.8	37 CFR 1.8
Statement Under 37 CFR 3.73(b)	PTO/SB/96	Statement under 37 CFR 3.73(b)	37 CFR 3.73(b)
Non-publication Request	PTO/SB/35	Nonpublication Request under 35 U.S.C. 122(b)(2)(B)(i)	37 CFR 1.213(a)
Rescission of Previous Non-publication Request (35 U.S.C. 122(b)(B)(ii)) and, if applicable, Notice of Foreign Filing (35 U.S.C. 122(b)(2)(B)(iii))	PTO/SB/36	Rescission of Previous Nonpublication Request (35 U.S.C. 122(b)(2)(B)(ii)) and, if applicable, Notice of Foreign Filing (35 U.S.C. 122(b)(2)(B)(iii))	37 CFR 1.213(b)
Electronic Filing System (EFS) Copy of Application for Publication			37 CFR 1.215, 37 CFR 1.217, 37 CFR 1.219, 37 CFR 1.221
Copy of File Content Showing Redactions			37 CFR 1.217(d)

List of ICs

IC Title	Form No.	Form Name	CFR Citation
Copy of the Applicant or Patentee's Record of the Application (including copies of the correspondence, list of the correspondence, and statements verifying whether the record is complete or not)	PTO-2053-A/B, PTO-2054-A/B, PTO/2055-A/B	Notice Under 37 CFR 1.251 - Pending Application, Notice Under 37 CFR 1.251 - Abandoned Application, Notice Under 37 CFR 1.251 - Patent	37 CFR 1.251
Request for Continued Examination (RCE) Transmittal	PTO/SB/30	Request for Continued Examination (RCE) Transmittal	37 CFR 1.114
Request for Oral Hearing Before the Board of Patent Appeals and Interferences	PTO/SB/32	Request for Oral Hearing Before the Board of Patent Appeals and Interferences	37 CFR 1.194(b)
Request for Deferral of Examination 37 CFR 1.103(d)	PTO/SB/37	Request for Deferral of Examination 37 CFR 1.103(d)	37 CFR 1.103(d)
Request for Voluntary Publication or Republication EFS-Web			37 CFR 1.221
Applicant Initiated Interview Request Form	PTOL-413A	Applicant Initiated Interview Request Form	37 CFR 1.133
Petition for Request for Documents in a Form Other Than That Provided by 1.19			37 CFR 1.19(i) and (j)
Petitions under 37 CFR 1.17(g) include: Petitions to Access Assignment Records and Applications, Petition for Expungement/Return of Information, and Petition to Suspend Action in an Application			37 CFR 1.14, 37 CFR 1.12, 37 CFR 1.17(g), 37 CFR 1.59, 37 CFR 1.102
Petitions under 37 CFR 1.17(h): Petition for Accepting Color Drawings/Photos, Petition for Entry of Model/Exhibit, Petition to Withdraw Application from Issue, and Petition to Defer Issue of Patent			37 CFR 1.91, 37 CFR 1.103(d), 37 CFR 1.17(h), 37 CFR 1.313 and 1.314, 37 CFR 1.84
Request for Processing of Replacement Drawings to Include the Drawings in Any Patent Application Publication			37 CFR 1.215

List of ICs

IC Title	Form No.	Form Name	CFR Citation
Processing Fee Under 37 CFR 1.17(i) Transmittal	PTO/SB/17i	Processing Fee under 37 CFR 1.17(i) Transmittal	37 CFR 1.17(i)
Request to Retrieve Electronic Priority Application(s) Under 37 CFR 1.55(d)	PTO/SB/38	Request to Retrieve Electronic Priority Application(s)	37 CFR 1.155(d)
Authorization To Permit Access to Application by Participating Offices Under 37 CFR 1.14(h)	PTO/SB/39	Authorization to Permit Access to Application by Participating Offices	37 CFR 1.14(h)
Petition for Express Abandonment to Obtain a Refund	PTO/SB/24B	Petition for Express Abandonment to Obtain a Refund	37 CFR 1.138(d)
Pre-Appeal Brief Request for Review	PTO/SB/33	Pre-Appeal Brief Request for Review	37 CFR 41.32
Request for Corrected Filing Receipt			37 CFR 1.76(a), 37 CFR 1.48(a) and (c), 37 CFR 1.45
Request for Corrected Filing Receipt (electronic)			37 CFR 1.76(a), 37 CFR 1.54, 37 CFR 1,48(a) and (c)
Petition to Make Special Under Accelerated Examination Program	PTO/SB/28 EFS-Web	Petition to Make Special under Accelerated Examination Program	37 CFR 1.102
Request for First-Action Interview (Pilot Program)	PTOL-413C	Request for First-Action Interview (Pilot Program) - Draft form	37 CFR 1.133
Petition to Make Special Based on Age for Advancement of Examination under 37 CFR 1.102(c)(1)	PTO/SB/130 EFS-Web	Petition to Make Special Based on Age for Advancement of Examination under 37 CFR 1.102(c)(1)	37 CFR 1.102(c)(1)
Request for Continued Examination (RCE) EFS-Web	PTO/SB/30EFS	Request for Continued Examination (RCE) Transmittal	37 CFR 1.114

Exhibit G to

Petition to Vacate Examiner's Papers

PTO's Filings at OMB For Information
Collection 0651-0032, 2006 to 2009

(excluding those designated "no material change")



OMB Control Number History

OMB Control Number:0651-0032

ICR Ref. No.	Request Type	Date Received By OIRA	Conclusion Date	Conclusion Action
200702-0651-008	Revision of a currently approved collection	02/28/2007	06/05/2007	Approved without change
200509-0651-002	Emergency extension	01/16/2007	01/30/2007	Approved
200509-0651-002	Emergency extension	07/12/2006	07/12/2006	Approved
200509-0651-002	No material or nonsubstantive change to a currently approved collection	09/20/2005	09/20/2005	Approved without change
200506-0651-001	Revision of a currently approved collection	06/15/2005	08/29/2005	Approved without change
200309-0651-007	Revision of a currently approved collection	09/03/2003	12/22/2003	Approved with change
200304-0651-002	Revision of a currently approved collection	04/30/2003	07/14/2003	Approved without change
200106-0651-001	Emergency extension	12/20/2002	12/20/2002	Approved
200106-0651-001	Emergency extension	07/26/2002	07/26/2002	Approved
200106-0651-001	Revision of a currently approved collection	06/11/2001	08/28/2001	Approved without change
200004-0651-002	Revision of a currently approved collection	04/05/2000	08/07/2000	Approved without change
199908-0651-001	Revision of a currently approved collection	08/19/1999	10/26/1999	Approved without change
199906-0651-002	No material or nonsubstantive change to a currently approved collection	06/04/1999	06/04/1999	Approved without change
199807-0651-001	Revision of a currently approved collection	07/30/1998	09/25/1998	Approved without change
199707-0651-001	Revision of a currently approved collection	07/24/1997	09/24/1997	Approved without change
199605-0651-002	Revision of a currently approved collection	05/23/1996	08/01/1996	Approved without change
199506-0651-002	Revision of a currently approved collection	06/30/1995	09/29/1995	Approved without change
199308-0651-002	No material or nonsubstantive change to a currently approved collection	08/02/1993	08/02/1993	Approved with change
199305-0651-003	New collection (Request for a new OMB Control Number)	05/14/1993	07/30/1993	Approved without change



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Information Collection Review

EO 12866 Regulatory Review
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Information Collection Review
XML Reports



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[Abstract/Justification](#) [Legal Statutes](#) [Rulemaking](#) [FR Notices/Comments](#) [IC List](#) [Burden](#) [Misc.](#) [Certification](#)

[View Information Collection \(IC\) List](#)

[View Supporting Statement and Other Documents](#)

Please note that the OMB number and expiration date may not have been determined when this Information Collection Request and associated Information Collection forms were submitted to OMB. The approved OMB number and expiration date may be found by clicking on the Notice of Action link below.

View ICR - OIRA Conclusion

OMB Control No: 0651-0032

ICR Reference No: 200702-0651-008

Status: Active

Previous ICR Reference No: [200509-0651-002](#)

Agency/Subagency: DOC/PTO

Agency Tracking No:

Title: Initial Patent Applications

Type of Information Collection: Revision of a currently approved collection

Type of Review Request: Regular

OIRA Conclusion Action: Approved without change

Conclusion Date: 06/05/2007

[Retrieve Notice of Action \(NOA\)](#)

Date Received in OIRA: 02/28/2007

Terms of Clearance:

	Inventory as of this Action	Requested	Previously Approved
Expiration Date	06/30/2010	36 Months From Approved	06/30/2007
Responses	543,591	543,591	454,287
Time Burden (Hours)	10,677,624	10,677,624	4,171,568
Cost Burden (Dollars)	243,201,076	243,201,076	575,550,000

Abstract: This information collection is necessary to conduct a thorough examination of patent applications, in accordance with 35 U.S.C. 131 and 37 CFR 1.16 through 1.84. An applicant must provide sufficient information so the USPTO can properly examine the application to determine whether it meets the requirements outlined in the patent statutes and regulations. This collection covers new original utility, plant, design, provisional, continued prosecution applications (design) and provisional applications, in addition to petitions. The utility, design, and provisional applications can be filed electronically. Two new fees from the Consolidated Appropriations Act, 2005, five existing fees and surcharges previously overlooked, and one petition that was previously overlooked are being added to the collection at this time. The USPTO believes that the primary respondents to this information collection will be individuals or households.

Authorizing Statute(s): US Code: 35 USC 131 Name of Law: null

Citations for New Statutory Requirements: US Code: 35 USC 41(d)(1)(D) Name of Law: Consolidated Appropriations Act

Associated Rulemaking Information

RIN: **Stage of Rulemaking:** **Federal Register Citation:** **Date:**
Not associated with rulemaking

Federal Register Notices & Comments

60-day Notice: **Federal Register Citation:** **Citation Date:**
71 FR 53669 09/12/2006

30-day Notice: **Federal Register Citation:** **Citation Date:**
72 FR 8355 02/26/2007

Did the Agency receive public comments on this ICR? No

Number of Information Collection (IC) in this ICR: 18

IC Title	Form No.	Form Name
PTO/SB/02A and PTO/SB/02B, PTO/SB/02LR, PTO/SB/107, PTO/SB/106, PTO/SB/105, null, PTO/SB/101, PTO/SB/102, PTO/SB/05, PTO/SB/108, PTO/SB/104, PTO/SB/110, PTO/SB/17, PTO/SB/109, PTO/SB/103, PTO/SB/01, PTO/SB/04		Declaration - Additional Inventors-Supplemental Sheet and Declaration - Supplemental Priority Data Sheet, Declaration Supplemental Sheet for Legal Representatives (35 U.S.C 117) on Behalf of a Deceased or Incapacitated Inventor, Declaration and Power of Attorney for Patent Application - Russian Language Declaration, Declaration and Power of Attorney for Patent Application - Japanese Language Declaration, Declaration and Power of Attorney for Patent Application - French Language Declaration, Declaration and Power of Attorney for Patent Application - Chinese Language Declaration, Declaration and Power of Attorney for Patent Application - Dutch Language Declaration, Utility Patent Application Transmittal, Declaration and Power of Attorney for Patent Application, Declaration and Power of Attorney for Patent Application - Italian Language Declaration, Declaration and Power of Attorney for Patent Application, Fee Transmittal Form, Declaration and Power of Attorney for Patent Application, Declaration and Power of Attorney for Patent Application - German Language Declaration, Declaration for Utility or Design Patent Application (37 CFR 1.63), Supplemental Declaration for Utility or Design Patent Application (37 CFR 1.67)
Original New Utility Applications - No Application Data Sheet	PTO/SB/14, null, PTO/SB/01A, PTO/SB/17	Application Data Sheet 37 CFR 1.76, Declaration (37 CFR 1.63) for Utility or Design Application Using an Application Data Sheet (37 CFR 1.76), Fee Transmittal Form

Original New Plant Applications - Application Data Sheet	PTO/SB/03A, PTO/SB/17, PTO/SB/14	Declaration (37 CFR 1.63) for Plant Application Using an Application Data Sheet (37 CFR 1.76), Fee Transmittal Form, Application Data Sheet 37 CFR 1.76
Original New Design Applications - Application Data Sheet	PTO/SB/17, PTO/SB/01A, PTO/SB/14, null	Fee Transmittal Form, Declaration (37 CFR 1.63) for Utility or Design Application Using an Application Data Sheet (37 CFR 1.76), Application Data Sheet 37 CFR 1.76
	PTO/SB/103, PTO/SB/104, PTO/SB/02A and PTO/SB/02B, PTO/SB/108, PTO/SB/13/PCT, PTO/SB/107, PTO/SB/04, PTO/SB/101, PTO/SB/01, PTO/SB/102, PTO/SB/106, PTO/SB/110, PTO/SB/02LR, PTO/SB/105, PTO/SB/109	Declaration and Power of Attorney for Patent Application, Declaration and Power of Attorney for Patent Application - Italian Language Declaration, Declaration - Additional Inventors-Supplemental Sheet and Declaration - Supplemental Priority Data Sheet, Declaration and Power of Attorney for Patent Application - Swedish Language Declaration, Request for Filing a Continuation or Division of an International Application, Declaration and Power of Attorney for Patent Application - Russian Language Declaration, Supplemental Declaration for Utility or Design Patent Application (37 CFR 1.67), Declaration and Power of Attorney for Patent Application - Chinese Language Declaration, Declaration for Utility or Design Patent Application (37 CFR 1.63), Declaration and Power of Attorney for Patent Application, Declaration and Power of Attorney for Patent Application - Japanese Language Declaration, Declaration and Power of Attorney for Patent Application - Korean Language Declaration, Declaration Supplemental Sheet for Legal Representatives (35 U.S.C. 117) on Behalf of a Deceased or Incapacitated Inventor, Declaration and Power of Attorney for Patent Application - French Language Declaration, Declaration and Power of Attorney for Patent Application - Spanish Language Declaration
Utility Continuation/Divisional Applications	PTO/SB/17, PTO/SB/05	Fee Transmittal Form, Utility Patent Application Transmittal
Plant Continuation/Divisional Applications	PTO/SB/19, PTO/SB/17	Plant Patent Application Transmittal, Fee Transmittal Form
Design Continuation/Divisional Applications	PTO/SB/18, PTO/SB/17	Design Patent Application Transmittal, Fee Transmittal Form
Continued Prosecution Applications - Design (Request Transmittal and Receipt)	PTO/SB/29, PTO/SB/29A	For Design Applications Only: Continued Prosecution Application (CPA) Request Transmittal, For Design Applications Only Receipt for Facsimile Transmitted CPA

PTO/SB/104, PTO/SB/105, PTO/SB/106, PTO/SB/02A and PTO/SB/02B, PTO/SB/01, PTO/SB/04, PTO/SB/108, PTO/SB/109, PTO/SB/02LR, PTO/SB/102, PTO/SB/103, PTO/SB/101, PTO/SB/107, PTO/SB/110, PTO/SB/05, PTO/SB/17	Declaration and Power of Attorney for Patent Application , Declaration and Power of Attorney for Patent Application , Declaration and Power of Attorney for Patent Application - Japanese Language Declaration , Declaration - Additional Inventors - Supplemental Sheet and Declaration - Supplemental Priority Data Sheet , Declaration for Utility or Design Patent Application (37 CFR 1.63) , Supplemental Declaration for Utility or Design Patent Application (37 CFR 1.67) , Declaration and Power of Attorney for Patent Application , Declaration and Power of Attorney for Patent Application , Declaration Supplemental Sheet for Legal Representatives (35 U.S.C. 117) on Behalf of a Deceased or Incapacitated Inventor , Declaration and Power of Attorney for Patent Application , Declaration and Power of Attorney for Patent Application , Declaration and Power of Attorney for Patent Application - Chinese Language Declaration , Declaration and Power of Attorney for Patent Application , Declaration and Power of Attorney for Patent Application - Russian Language Declaration , Declaration and Power of Attorney for Patent Application , Utility Patent Application Transmittal , Fee Transmittal Form
PTO/SB/19, PTO/SB/17, PTO/SB/02LR, PTO/SB/03, PTO/SB/02A and PTO/SB/02B	Plant Patent Application Transmittal , Fee Transmittal Form , Declaration Supplemental Sheet for Legal Representatives (35 U.S.C. 117) on Behalf of a Deceased or Incapacitated Inventor , Plant Patent Application (35 U.S.C. 161) Declaration (37 CFR 1.63) , Declaration - Additional Inventors - Supplemental Sheet and Declaration - Supplemental Priority Data Sheet
PTO/SB/04, PTO/SB/02LR, PTO/SB/18, PTO/SB/17, PTO/SB/01, PTO/SB/02A and PTO/SB/02B	Supplemental Declaration for Utility or Design Patent Application (37 CFR 1.67) , Declaration Supplemental Sheet for Legal Representatives (35 U.S.C. 11) on Behalf of a Deceased or Incapacitated Inventor , Design Patent Application Transmittal , Fee Transmittal Form , Declaration for Utility or Design Patent Application (37 CFR 1.63) , Declaration - Additional Inventors - Supplemental Sheet and Declaration - Supplemental Priority Data Sheet
PTO/SB/16, null	Provisional Application for Patent Cover Sheet
	Petition to Accept Unintentionally Delayed Priority Claim
	Petition to Accept Non-Signing Inventors or Legal

[Representatives/Filing by Other Than All the Inventors or a Person not the Inventor](#)
[Petition under 37 CFR 1.6\(f\) to Accord the Application under 37 CFR 1.495\(b\) a National Stage Entry Date](#)

PTO/SB/02LR, [Declaration Supplemental Sheet for Legal Representatives \(35 U.S.C. 117\) on Behalf of a Deceased or Incapacitated Inventor](#), [Plant Patent Application Transmittal](#), [Declaration and Power of Attorney for Patent Application](#), [Fee Transmittal Forms](#), [Plant Patent Application \(35 U.S.C. 161\) Declaration \(37 CFR 1.63\)](#)
 PTO/SB/19,
 PTO/SB/109,
 PTO/SB/17,
 PTO/SB/03

PTO/SB/02LR, [Declaration Supplemental Sheet for Legal Representatives \(35 U.S.C. 117\) on Behalf of a Deceased or Incapacitated Inventor](#), [Declaration and Power of Attorney for Patent Application](#), [Declaration and Power of Attorney for Patent Application](#), [Design Patent Application Transmittal](#), [Fee Transmittal Form](#), [Declaration - Additional Inventors-Supplemental Sheet and Declaration - Supplemental Priority Data Sheet](#), [Supplemental Declaration for Utility or Design Patent Application \(37 CFR 1.67\)](#), [Declaration for Utility or Design Patent Application \(37 CFR 1.63\)](#)
 null, PTO/SB/02LR, [Declaration Supplemental Sheet for Legal Representatives \(35 U.S.C. 117\) on Behalf of a Deceased or Incapacitated Inventor](#), [Declaration and Power of Attorney for Patent Application](#), [Declaration and Power of Attorney for Patent Application](#), [Design Patent Application Transmittal](#), [Fee Transmittal Form](#), [Declaration - Additional Inventors-Supplemental Sheet and Declaration - Supplemental Priority Data Sheet](#), [Supplemental Declaration for Utility or Design Patent Application \(37 CFR 1.67\)](#), [Declaration for Utility or Design Patent Application \(37 CFR 1.63\)](#)
 PTO/SB/106,
 PTO/SB/105,
 PTO/SB/18,
 PTO/SB/17,
 PTO/SB/02A and
 PTO/SB/02B,
 PTO/SB/04,
 PTO/SB/01

[Original New Design Applications - No Application Data Sheet](#)

ICR Summary of Burden

	Total Approved	Previously Approved	Change Due to New Statute	Change Due to Agency Discretion	Change Due to Adjustment in Estimate	Change Due to Potential Violation of the PRA
Annual Number of Responses	543,591	454,287	0	10,678	78,626	0
Annual Time Burden (Hours)	10,677,624	4,171,568	0	53,390	6,452,666	0
Annual Cost Burden (Dollars)	243,201,076	575,550,000	2,090	1,260	-332,352,274	0

Burden increases because of Program Change due to Agency Discretion: Yes
Burden Increase Due to: Changing Regulations
Burden decreases because of Program Change due to Agency Discretion: No
Burden Reduction Due to:

Short Statement: The program change increases are due to a new application size fee introduced in the Consolidated Appropriations Act of 2005. Applicants can submit their design applications electronically through EFS-Web. The introduction of electronic filing for the design applications accounts for increases in the annual cost burden.

Annual Cost to Federal Government: \$8,936,439

Does this IC contain surveys, censuses, or employ statistical methods? No

Is the Supporting Statement intended to be a Privacy Impact Assessment required by the E-Government Act of 2002? No

Is this ICR related to the American Recovery and Reinvestment Act of 2009 (ARRA)? Uncollected

Agency Contact: Robert Clarke 571 272-7735 robert.clarke@uspto.gov

On behalf of this Federal agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9 and the related provisions of 5 CFR 1320.8(b)(3).

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

- (a) It is necessary for the proper performance of agency functions;
- (b) It avoids unnecessary duplication;
- (c) It reduces burden on small entities;
- (d) It uses plain, coherent, and unambiguous language that is understandable to respondents;
- (e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;
- (f) It indicates the retention periods for recordkeeping requirements;
- (g) It informs respondents of the information called for under 5 CFR 1320.8 (b)(3) about:
 - (i) Why the information is being collected;
 - (ii) Use of information;
 - (iii) Burden estimate;
 - (iv) Nature of response (voluntary, required for a benefit, or mandatory);
 - (v) Nature and extent of confidentiality; and
 - (vi) Need to display currently valid OMB control number;
- (h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected.
- (i) It uses effective and efficient statistical survey methodology (if applicable); and
- (j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of these provisions, identify the item by leaving the box unchecked and explain the reason in the Supporting Statement.

Certification Date: 02/28/2007

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**SF-83 SUPPORTING STATEMENT
PAPERWORK REDUCTION ACT – OMB CONTROL NUMBER 0651-0032
INITIAL PATENT APPLICATIONS**

A. JUSTIFICATION

1. Necessity of Information Collection

Article 1, Section 8, Clause 8 of the Constitution provides that Congress shall have the power...."[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." Congress has exercised this grant of power under the Constitution to enact the patent statute, Title 35, U.S.C., and to establish the United States Patent and Trademark Office (USPTO).

The USPTO is required by 35 U.S.C. § 131 to examine applications for patents. An applicant must provide sufficient information to allow the USPTO to properly examine the application to determine whether it meets the criteria set forth in the patent statute and regulations to be issued as a patent. The USPTO administers the statute through various rules in 37 CFR 1.16 through 1.84. The patent statute and regulations require that an application for patent (commonly referred to as an application package) include the following collections of information:

- (1) a specification containing a description of the invention and at least one claim defining the property right sought by the applicant;
- (2) a drawing(s) or photograph, where necessary, for an understanding of the invention;
- (3) an oath or declaration signed by the applicant; and
- (4) a filing fee.

Various types of patent applications are covered under this collection: new original utility, plant, design, and provisional applications; continuations/divisionals of international applications; continued prosecution applications (design); and continuation/divisional and continuation-in-part applications for the utility, plant, and design applications. In addition to these applications, this collection also contains petitions to accept unintentionally delayed priority claims, petitions to accept non-signing inventors or legal representatives/filing by other than all of the inventors or a person not the inventor, and petitions requesting that applications filed under 37 CFR 1.495(b) are accorded a national stage entry date.

Previously, applicants could only submit their new original utility and provisional applications to the USPTO electronically. Now new original design applications can be

filed electronically as well. The electronic options for the design applications are being submitted to OMB for review as part of this renewal.

In addition to the electronic design applications, this renewal submission also includes two new patent fees from the Consolidated Appropriations Act of 2005. One of the fees is a new filing fee of \$75 for small entities filing original utility applications electronically on or after December 8, 2004. The other fee is an application size fee that is paid for applications filed under 35 U.S.C. § 111 on or after December 8, 2004, in which the specification and the drawings exceed 100 sheets of paper.

The USPTO is taking this opportunity to add five other existing fees or surcharges and one petition that have been overlooked in previous renewals into the collection:

- Surcharges for the late filing of the fees, oaths, or declarations
- Surcharges for the late filing of the provisional application coversheets
- Fees for filing excess claims
- Fees for filing multiple dependent claims
- Fees for filing non-English specification
- Petition under 37 CFR 1.6(f) to accord an application under 37 CFR 1.495(b) a national stage entry date. As a result of reviewing the final rule notice, “Changes to Facilitate Electronic Filing of Patent Correspondence” (RIN 0651-AB92), the USPTO determined that this petition, an existing requirement that was mentioned in the rule, was overlooked in previous submissions and needed to be added into the collection as well.

In the previous submissions for this collection, the utility, design, and plant applications were grouped together, causing the response burden and fee tables to not line up with each other. Other difficulties arose once the USPTO started accepting electronically-filed applications for some but not all of the applications. In this renewal submission, the utility, design, and plant applications have been broken out separately, which allows the USPTO to show exactly how many of the different applications have been filed. The USPTO has also determined that the different types of utility, design, and plant applications have different estimated completion times. Previously, all of the applications had the same response time, so separating the applications results in a more accurate burden estimate. Separating the applications also makes it easier to account for the electronic filings since the utility, design, and provisional applications can be filed electronically, but not the plant applications. As a result of separating the applications, the response and fee burden tables can be more closely aligned.

Table 1 provides the specific statutes and regulations requiring the USPTO to collect the information for the patent applications and the petitions:

Table 1: Information Requirements to Determine Patentability

Requirement	Statute	Rule
Specification and claim	35 U.S.C. §§ 111 and 112	37 CFR 1.53 and 1.71 through 1.77

Drawing(s)	35 U.S.C. § 113	37 CFR 1.53 and 1.81 through 1.84
Declaration	35 U.S.C. §§ 25, 115, and 117	37 CFR 1.42, 1.43, 1.47, 1.53, and 1.63 through 1.69
Filing Fee	35 U.S.C. §§ 41 and 111	37 CFR 1.16 and 1.53
Continued Prosecution Application – Design (Request Transmittal and Receipt)	35 U.S.C. §§ 111, 120, and 121	37 CFR 1.53(d)
Petition to Accept Unintentionally Delayed Priority Claim	35 U.S.C. §§ 119(b), 119(e), and 120	37 CFR 1.55 and 1.78
Petition to Accept Non-Signing Inventors or Legal Representatives/Filing by Other Than All the Inventors or a Person Not the Inventor	35 U.S.C. §§ 116 through 118	37 CFR 1.42, 1.43, and 1.47
Petition under 37 CFR 1.6(f) to Accord the Application under 37 CFR 1.495(b) a National Stage Entry Date	35 U.S.C. § 371	37 CFR 1.6(f) and 1.495(b)

2. Needs and Uses

This information collection contains both paper and electronic forms. For the applications that are filed in paper, the USPTO provides various fee calculation and fee transmittal forms, application transmittal forms, and declaration forms. There are also forms to request the filing of a continuation or division of an international application and a request transmittal and receipt for transmitted facsimile for the continued prosecution applications. Some parts of the application, such as the specification and the drawings, do not have forms associated with them. The petitions covered in this information collection also do not have forms associated with them. There are 28 forms in this collection.

New original utility, provisional, and now design applications can be submitted electronically through the EFS-Web, which is an electronic filing system that is web-based and can be accessed from any web-enabled computer anywhere in the world. The documents that are submitted through EFS-Web are in the PDF (Portable Document Format) format. All of the key patent data is collected from the PDF documents, with a little data collected from the EFS-Web's standard web-based screens. Copies of the screens that the registered and unregistered users see when they file their applications through EFS-Web are attached (Attachment A). Since the majority of the information for the different applications is provided in the PDF attachments, copies of the specific electronically-filed applications are not attached to this submission. The information collected from the EFS-Web forms is processed automatically. In order to automatically process the data, the USPTO has started creating PDF web-based fillable forms, such as PTO/SB/14 The Application Data Sheet.

The Information Quality Guidelines from Section 515 of Public Law 106-554, Treasury and General Government Appropriations Act for Fiscal Year 2001, apply to this information collection and comply with all applicable information quality guidelines, *i.e.*, the OMB and specific operating unit guidelines.

This proposed collection of information will result in information that will be collected, maintained, and used in a way consistent with all applicable OMB and USPTO Information Quality Guidelines. (See Attachment B, the *USPTO Information Quality Guidelines*.)

Table 2 outlines how these collections of information are used by the public and by the USPTO:

Table 2: Needs and Uses of Information Collected to Determine Patentability

Form and Function	Form #	Needs and Uses
Specification (includes at least one claim) and Drawing(s)	No Form Associated	<ul style="list-style-type: none"> Used by the applicant to provide a description of the invention and of the property right sought by the applicant (the claim(s)). Used by the USPTO to examine an application for patent, and when appropriate, issue the application as a patent.
Patent Application Fee Determination Record (Substitute for Form PTO-875) (Attachment C)	PTO/SB/06	<u>Forms PTO/SB/06 and 07:</u> <ul style="list-style-type: none"> Used by the USPTO to determine the appropriate fees for small and non-small entities and for applications containing multiple dependent claims. NOTE: These forms are seldom used by applicants, but in the event that an applicant obtained these forms, their use would reduce fee calculation errors, especially in those applications containing multiple dependent claims.
Multiple Dependent Claim Fee Calculation Sheet (Substitute for Form PTO-1360; For Use with Form PTO/SB/06) (Attachment D)	PTO/SB/07	
Fee Transmittal Form (Attachment E)	PTO/SB/17	<ul style="list-style-type: none"> Used by applicants to determine fees. Used by the USPTO to verify applicant fee determination and to process the fee.
Utility Patent Application Transmittal (Attachment F)	PTO/SB/05	<u>Forms PTO/SB/05, 18, and 19:</u> <ul style="list-style-type: none"> Used by the applicant as a checklist to highlight information which may otherwise have been overlooked at the time of filing. Used by the applicant to provide identifying information about the submitted papers and himself/herself. Used by the USPTO to determine whether the submitted papers constitute an application for patent, whether it is a utility, plant, or design application.
Design Patent Application Transmittal (Attachment G)	PTO/SB/18	
Plant Patent Application Transmittal (Attachment H)	PTO/SB/19	
Declaration for Utility or Design Patent Application (37 CFR 1.63) (Attachment I)	PTO/SB/01	<u>Forms PTO/SB/01, 02A, 02B, 02LR, 03, and 04:</u> <ul style="list-style-type: none"> Assures that an applicant meets all of the requirements of 37 CFR 1.63 by providing the prerequisite language. Used by applicants to easily claim the benefit of an earlier application under 35 U.S.C. § 119 or 365. Enables the legal representative of a deceased inventor to file a patent application by signing the declaration on the behalf of a deceased or incapacitated inventor. Assures that an applicant will provide necessary information (most often overlooked). Used by the USPTO to determine whether the required information has been set forth in the declaration.
Declaration – Additional Inventors – Supplemental Sheet (Attachment J)	PTO/SB/02A	
Declaration – Supplemental Priority Data Sheet (Attachment J)	PTO/SB/02B	
Declaration Supplemental Sheet for Legal Representatives (35 U.S.C. §117) on Behalf of a Deceased or Incapacitated Inventor (Attachment K)	PTO/SB/02LR	
Plant Patent Application (35 U.S.C. 161) Declaration (37 CFR 1.63) (Attachment L)	PTO/SB/03	
Supplemental Declaration for Utility or Design Patent Application (37 CFR 1.67) (Attachment M)	PTO/SB/04	

Declaration and Power of Attorney for Patent Application (in various foreign languages) (Attachment N)	PTO/SB/101 through 110	<ul style="list-style-type: none"> • Perform the same functions as SB/01, 03, and 04. • Provide the applicant with a native (to the applicant) language version with English translation of the required declaration. Chinese, Dutch, German, Italian, French, Japanese, Russian, Swedish, Spanish, and Korean language declarations are available.
Application Data Sheet Form (Attachment O)	PTO/SB/14 and EFS-Web	<ul style="list-style-type: none"> • Provides applicant with a convenient manner to provide bibliographic information concerning the applicant and application that the applicant is either required, or desires, to provide to the USPTO. • Used by the USPTO to autoload data directly into USPTO databases, which reduces information capture errors caused by hand keying. • Used by the USPTO to provide a quick acknowledgment of the application and the information in USPTO records concerning the applicant and application.
Declaration (37 CFR 1.63) for Utility or Design Application Using an Application Data Sheet (37 CFR 1.76) (Attachment P) Declaration (37 CFR 1.63) for Plant Application Using an Application Data Sheet (37 CFR 1.76) (Attachment Q)	PTO/SB/01A PTO/SB/03A	<ul style="list-style-type: none"> • Provides applicant with a convenient manner to provide a declaration containing the minimal information that must be in the oath or declaration if the application also contains an application data sheet. • Used by the USPTO to process the declaration.
Request for Filing a Continuation or Division of an International Application (Attachment R)	PTO/SB/13/PCT	<ul style="list-style-type: none"> • Used by applicant to file a continuation or divisional of an international application. • Used by the USPTO to process a continuation or divisional of an international application.
For Design Applications Only: Continued Prosecution Application (CPA) Request Transmittal (Attachment S) For Design Applications Only: Receipt for Facsimile Transmitted CPA (Attachment T)	PTO/SB/29 PTO/SB/29A	<ul style="list-style-type: none"> • Used by the applicant to request additional examination of a previously submitted design application. • Used by the USPTO to process and initiate an additional examination of a previously submitted design application.
Provisional Application for Patent Cover Sheet – Paper and Electronic Filing (Attachment U)	PTO/SB/16 and EFS-Web	<ul style="list-style-type: none"> • Used by the applicant to file a provisional application with the USPTO. • Used by the applicant to include filing fees. • Used by the USPTO to identify provisional applications in order to promptly and properly process them. • Used by the USPTO to prepare the filing receipt. • Used by the USPTO to identify provisional applications that may require foreign filing licenses.
Petition to Accept Unintentionally Delayed Priority Claim	No Form Associated	<ul style="list-style-type: none"> • Used by the applicant to submit an unintentionally delayed priority claim to the USPTO. • Used by the USPTO to determine whether the applicant has included the documentation and fees necessary for the USPTO to accept unintentionally delayed priority claim under 35 U.S.C. §§ 119, 120, or 365.
Petition to Accept Non-Signing Inventors or Legal Representatives/Filing by Other Than All the Inventors or a Person Not the Inventor	No Form Associated	<ul style="list-style-type: none"> • Enables inventors or assignees who cannot locate or obtain signatures from an inventor or a legal representative of a deceased inventor to submit a patent application. • Used by the USPTO to ensure that the necessary information has been provided in support of the oath or declaration.

Petition under 37 CFR 1.6(f) to Accord the Application under 37 CFR 1.495(b) a National Stage Entry Date	No Form Associated	<ul style="list-style-type: none"> • Used by applicants to request a national stage entry date for applications filed under 37 CFR 1.495(b) • Used by the USPTO to assign applications filed under 37 CFR 1.495(b) a national stage entry date.
Electronic New Utility Patent Application	EFS-Web	<ul style="list-style-type: none"> • Used by filers to electronically file a new original utility application with the USPTO and to include the necessary filing fees. • Used by the USPTO to examine an application for patent, and when appropriate, issue the application as a patent.
Electronic New Design Application	EFS-Web	<ul style="list-style-type: none"> • Used by filers to electronically file a new original design application with the USPTO and to include the necessary filing fees. • Used by the USPTO to examine an application for patent, and when appropriate, issue the application as a patent.

3. Use of Information Technology

Currently, the USPTO does not generally use automated, mechanical, or other technological collection techniques to collect this information. The USPTO does, however, collect some of the patent application information electronically. In October 2000, the USPTO released the production version of the Electronic Filing System (EFS), which used two client-side components to create the patent applications: EFS-ABX for patent application specification authoring and ePAVE for form generation, validation, and submission to the USPTO. Because the percentage of electronic filings fell short of expectations, the USPTO requested feedback from the Intellectual Property (IP) community on how EFS could be improved. The agency found that the IP community wanted to file applications using the Adobe PDF (Portable Document Format) format that they use every day in their practice and that they did not want to download and install software on their computers in order to electronically file their applications.

Based on the response from the patent community, the USPTO developed EFS-Web, a web-based patent application filing system. EFS-Web was deployed in March 2006. The USPTO also incorporated the functionality of EFS-ABX and ePAVE into EFS-Web and integrated Private PAIR with the USPTO Portal and consequently stopped supporting EFS-ABX, ePAVE, and Entrust Direct software late in 2006.

EFS-Web is a web-based patent application and document submission system that allows applicants to file patent applications and documents without downloading special software or changing their documentation preparation tools or workflow processes. Applicants create their patent applications and associated documents using the tools and processes that they already use and then convert those documents into standard PDF files that are submitted through EFS-Web to the USPTO. EFS-Web uses standard web-based screens and prompts. Files are typically submitted through EFS-Web within minutes, depending on the speed of the Internet connection and the size of the PDF files. The USPTO has found that the time required for these submissions is significantly less than that typically required for submissions through the original EFS. In addition, EFS-Web automatically validates whether the PDF files and data can be accepted before they are actually submitted and alerts users if the application does not meet

USPTO standards so that the problems can be corrected before final submission to the USPTO.

Registered and unregistered users can file documents securely through EFS-Web, which is hosted on secure servers. The applications of registered users are protected using a Public Key Infrastructure (PKI) system and digital certificates which provide authentication and encryption security. For filers who are not registered, the applications are submitted to EFS-Web using Transport Layer Security (TLS) or Secure Socket Layer (SSL) protocol. Since EFS-Web has these security features in place, documents that are submitted through EFS-Web cannot be password protected or encrypted.

Registered users can file new utility, provisional, design, international applications for filing in the U.S. receiving office, and national stage applications under 35 U.S.C. § 371. They can also file follow-on documents for previously filed applications, pay the fees for existing patent applications, or file petitions to accept unintentionally delayed payment of maintenance fee in an expired patent (37 CFR 1.378(c) or pre-grant publication requests under 37 CFR 1.211 to 1.221 under the “Existing Application/Patent” option in EFS-Web. In addition, registered users can save their applications before submission so that they do not lose any information. They can view their saved submission packages under “My Workplace” as well as view their last 20 eFiling Acknowledgment Receipts.

Unregistered users cannot use all of the EFS-Web features. Unregistered users can file the same application types as the registered filers. They can file petitions to accept unintentionally delayed payment of maintenance fees in an expired patent (37 CFR 1.378(c)) , but they cannot file follow-on documents for previously filed applications, pay the fees for existing patent applications, or file the pre-grant publication requests under 37 CFR 1.211 to 1.221 options in “Existing Application/Patent.” Unregistered users must provide their contact information in order to proceed through the application process. They cannot access “My Workplace.”

After the application has been successfully submitted through EFS-Web, applicants will receive an acknowledgement receipt that lists the time and date stamp stating when the application was submitted to the USPTO, an application number, a confirmation number, and other critical information, such as the EFS ID, a listing of the files/documents associated with the submission, and page counts of the files/documents. This receipt is the legal equivalent of the post card receipt practice used for the patent application documents that are filed in paper and it is recommended that applicants print the electronic acknowledgement receipt to keep with their records.

EFS-Web uses the standard PDF file format (versions 1.1 to 1.6), which is readily available from commercial and free PDF converters. The form-fillable PDF forms do not need PDF creation software, only the latest free version of the Acrobat Reader (currently Adobe Reader 7.0.8 and above). The USPTO form-fillable PDF documents have version numbers; only version 2.0 and higher can be submitted through EFS-Web.

In addition to documents in the PDF format, EFS-Web also accepts PCT EASY .ZIP compressed files used to submit International PCT applications, and ASCII text files (.TXT) used to submit bio-sequence listings, computer program listings, large tables, etc. The .ZIP file must be created as part of the PCT-SAFE software package and can only be submitted as part of a new PCT application. The bio-sequence listing, computer program listing, and mega tables are the only attachments that can be submitted as text files.

The maximum size for EFS-Web submissions is 25 megabytes. Only 60 electronic files can be filed in any one submission. In cases where the application contains more than 60 files, the USPTO recommends that applicants break up the submission so that 60 or fewer files are submitted in the initial EFS-Web filing. The initial submission will be assigned an application number and any remaining electronic files can be filed as follow-on documents to the initial submission later that same day so that all of the files that actually make up the application will receive the same filing date.

The form-fillable PDF forms can be printed with data entered by the user; they can also be saved electronically with the data embedded and can be re-opened in order to modify the existing data. The form-fillable PDF forms enable the system to import and export data in XML format to and from document management systems and other databases. The information collected from the EFS-Web forms is processed automatically so the use of these forms accelerates the USPTO's processing of the patent applications and documents and increases the accuracy and timeliness of the data. This reduces the number of times that EFS-Web users have to redo their documents and reduces the need to file additional papers, such as the "Correction of Filing" forms. Use of these forms also enables the USPTO to process the requests in real time.

In order to be able to automatically process the data, the USPTO has started creating PDF web-based fillable forms, which are interactive forms with various field types and formatting-options that auto-load field information directly into the USPTO's systems. The USPTO plans to convert as many of the existing fillable forms into PDF web-based fillable forms for the EFS-Web as possible. Some EFS-Web forms will not auto-load data into the USPTO's systems and must be reviewed manually, but the majority of the forms will automatically load the data. The USPTO also has older PDF forms available through its website. Data entered into these forms will not be saved. If these older forms are submitted through EFS-Web, the data will not be automatically loaded into the USPTO's processing system. If an applicant creates their own form-fillable PDF document or modifies one of the USPTO's existing forms, the data from the individual fields will be accepted, however the data will not be auto loaded into the USPTO's processing systems.

There are many benefits to filing through EFS-Web that were not available previously. Users can access EFS-Web from any computer that can access the Web, regardless of their location. Since EFS-Web is hosted on the USPTO's secure servers and not on the individual's personal computer, USPTO staff can update EFS-Web without requiring any

action from the user. Applicants can submit fee payments and other requests in real time. The PDF forms can be passed around to multiple users for collaboration. Legal assistants or paralegals can submit applications through EFS-Web that have been previously reviewed by a registered practitioner without the responsible attorney or agent being present.

The PDF files that are submitted through EFS-Web should include either a handwritten signature in compliance with 37 CFR 1.4(d)(1) inserted before scanning the document or converting it to an image-based PDF form or an S-signature in compliance with 37 CFR 1.4(d)(2). When filing a new application through EFS-Web, a signed transmittal form or a signed Application Data Sheet is recommended for identification purposes; however, a signature is not required to obtain a filing date for new patent applications.

The PDF files that are submitted as part of the Patent Application Specification in EFS-Web are used to create the legal record of the application. The Official Record for applications filed through EFS-Web is a TIFF image of the original documents that are stored in the Image File Wrapper system. Applications and other documents submitted through EFS-Web are stored exactly as filed, for reference, in an independent location. The USPTO has created guidelines for the PDF documents to ensure that the application documents will be processed properly. Documents that do not conform to these guidelines may not be able to be processed by the USPTO.

EFS-Web integrates with Private Patent Application Information Retrieval (PAIR), the USPTO's online database that provides trusted filers with controlled access to non-published patent application information. Private PAIR also contains all of the information that the public can access in Public PAIR, such as bibliographic data, status, file history, PDF file images, continuity, foreign priority, patent term adjustments and extensions, text and TIFF images of published applications and patents, maintenance fees, and online ordering of copies. The form-fillable PDF forms submitted through EFS-Web allow the USPTO to extract the form data directly into Patent Application Locating and Monitoring (PALM), which is the main database used to process these forms. The data in PALM feeds directly into PAIR. Most new applications that are submitted electronically through EFS-Web can be viewed in Private PAIR within an hour after they are filed. Registered users can view and check on the status of their pending applications in Private PAIR, but unregistered users can only check on the status and the documents for patent and published applications as shown in PAIR.

4. Efforts to Identify Duplication

This information is collected only when an applicant (or representative) submits an application. The USPTO also collects information for petitions to accept unintentionally delayed priority claims, petitions to accept non-signing inventors or legal representatives/filing by other than all the inventors or a person not the inventor, and petitions to request that applications filed under 37 CFR 1.495(b) be assigned a national

stage entry date. This information is not collected elsewhere. Therefore, this collection does not create a duplication of effort or collection of data.

5. Minimizing the Burden to Small Entities

No significant impact is placed on small entities, as the rule (37 CFR 1.27) simply requires a small entity to identify itself as such to obtain the benefits of small entity status.

Pursuant to 35 U.S.C. § 41 (h)(1), the USPTO provides a fifty percent (50%) reduction in the fees charged under 35 U.S.C. § 41(a) and (b) for small entity applicants. The USPTO's regulations concerning the payment of reduced patent fees by small entities are at 37 CFR 1.27 and 1.28, and reduced patent fees for small entity applicants are shown in 37 CFR 1.16, 1.17, 1.18, and 1.20. In addition, the provisions of the Consolidated Appropriations Act of 2005 establish a filing fee of \$75 for small entities filing original utility applications electronically on or after December 8, 2004.

6. Consequences of Less Frequent Collection

This information is collected only when an applicant (or representative) submits an application. The USPTO also collects information for petitions to accept unintentionally delayed priority claims, petitions to accept non-signing inventors or legal representatives/filing by other than all the inventors or a person not the inventor, and petitions to request that applications filed under 37 CFR 1.495(b) be assigned a national stage entry date. This information is not collected elsewhere. Therefore, this collection of information could not be conducted less frequently and the USPTO could not examine an application or issue a patent as required by the patent statute (35 U.S.C. § 131) if this information was not collected.

7. Special Circumstances in the Conduct of Information Collection

There are no special circumstances associated with this collection of information.

8. Consultation Outside the Agency

The 60-Day Federal Register Notice was published on September 12, 2006 (Vol. 71, No. 176) (Attachment V). The public comment period ended on November 13, 2006. No comments were received from the public.

In addition, the USPTO consults with the Public Advisory Committees, which were created by statute in the American Inventors Protection Act of 1999 to advise the Under Secretary of Commerce for Intellectual Property and Director of the USPTO on the management of the patent and trademark operations. The Advisory Committees consist of United States citizens chosen to represent the interests of the diverse users of the USPTO. The Advisory Committees review the policies, goals, performance,

budget, and user fees of the patent and trademark operations, respectively, and advise the Director on these matters.

The USPTO has long-standing relationships with patent bar associations, inventor groups, and users of our public facilities. Their views are expressed in regularly scheduled meetings and considered in developing proposals for information collection requirements. The USPTO also meets regularly with groups from whom patent application data is collected, such as the American Intellectual Property Law Association.

9. Payment or Gifts to Respondents

This information collection does not involve a payment or gift to any respondent. Response to this information collection is necessary to obtain a patent.

10. Assurance of Confidentiality

Confidentiality of patent applications is governed by statute (35 U.S.C. § 122) and regulation (37 CFR 1.14). Upon publication of an application or issuance of an application as a patent, the entire file contents of the application is available to the public (subject to the provisions for providing only a redacted copy of the filed contents). The disclosure of the invention in the application is the quid pro quo for the property right conferred by the patent grant, and the very means by which the patent statute achieves its constitutional object of “promot[ing] the progress of science and useful arts.” The prosecution history contained in the application file is critical to determining the scope of the property right conferred by a patent grant.

To further define the boundaries of the confidentiality of patent applications in light of the eighteen-month publication of patent applications introduced under the American Inventors Protection Act of 1999, the USPTO amended 37 CFR 1.14 to maintain the confidentiality of applications that have not been published as a U.S. patent application. In the amended 37 CFR 1.14, the public can obtain status information about the application, such as whether the application is pending, abandoned, or patented, whether the application has been published under 35 U.S.C. § 122(b), and the application “numerical identifier.” This information can be supplied to the public under certain conditions. The public can also receive copies of an application-as-filed and the file wrapper, as long as it meets certain criteria.

Applications filed through EFS are maintained in confidence as required by 35 U.S.C. 122(a) until the application is published or a patent is issued. The confidentiality, security, integrity, authenticity, and non-repudiation of patent applications submitted electronically through EFS-Web is maintained using PKI technology and digital certificates for registered users. Applications electronically-filed by non-registered users are protected using TLS or SSL protocols. Currently, the USPTO is posting issued patents and application publications on its Internet Website. This information will not be released to the public unless it is part of an issued patent or application publication.

Patent applicants and/or their designated representatives can view the current status of their patent application through the Patent Application Information Retrieval (PAIR) system. Access to patent applications that are maintained in confidence under 35 U.S.C. § 122(a) is restricted to the patent applicant and/or their designated representatives by the use of digital certificates, which maintain the confidentiality and integrity of the information transmitted over the Internet. The public can view the status and history information for published applications and granted patents via PAIR.

11. Justification for Sensitive Questions

None of the required information is considered to be of a sensitive nature.

12. Estimate of Hour and Cost Burden to Respondents

Table 3 calculates the burden hours and costs of this information collection to the public, based on the following factors:

- **Respondent Calculation Factors**

Based on budgetary calculations, the USPTO projects that it will receive 543,591 responses per year (using FY 2007 projections as its baseline). The USPTO estimates that 37% of these responses will be submitted electronically. Table 3, column (b) shows the number of responses for the items in this collection.

- **Burden Hour Calculation Factors**

The USPTO estimates that it takes an average of 24 minutes to 30 hours to complete the applications and petitions in this information collection. At this time, new original utility, design, and provisional applications can be submitted electronically through EFS-Web. Since EFS-Web is still relatively new, the USPTO does not yet have a good indication of how much time is saved by filing applications or documents electronically via EFS-Web. Accordingly, the USPTO has estimated the same time to complete the electronically-filed applications as it does to complete those submitted in paper form. As experience with EFS-Web grows, the USPTO will reevaluate the time required for electronically-filed versus paper-filed applications and documents. Table 3, column (a) shows the time estimates for the items in this collection.

- **Cost Burden Calculation Factors**

The USPTO believes that associate attorneys will complete the items in this collection. The professional hourly rate of \$304 used to calculate the respondent cost burden is the median rate for associate attorneys in private firms as published in the 2005 report of the Committee on Economics of Legal Practice of the American Intellectual Property Law Association. This report summarized the results of a survey with data on hourly billing rates. This is a fully-loaded hourly rate.

Table 3: Burden Hour/Burden Cost to Respondents

Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a) x (b)	Rate (\$/hr) (d)	Total Cost (\$/hr) (e) (c) x (d)
Original New Utility Applications – No Application Data Sheet	30.0	116,000	3,480,000	\$304.00	\$1,057,920,000.00
Electronic Original New Utility Applications – No Application Data Sheet	30.0	116,000	3,480,000	\$304.00	\$1,057,920,000.00
Original New Plant Applications – No Application Data Sheet	7.0	1,115	7,805	\$304.00	\$2,372,720.00
Original New Design Applications – No Application Data Sheet	5.0	10,677	53,385	\$304.00	\$16,229,040.00
Electronic Original Design Applications – No Application Data Sheet	5.0	10,678	53,390	\$304.00	\$16,230,560.00
Original New Utility Applications – Application Data Sheet	29.8	29,000	864,200	\$304.00	\$262,716,800.00
Electronic Original New Utility Applications – Application Data Sheet	29.8	29,000	864,200	\$304.00	\$262,716,800.00
Original New Plant Applications – Application Data Sheet	6.8	285	1,938	\$304.00	\$589,152.00
Original New Design Applications – Application Data Sheet	4.8	2,672	12,826	\$304.00	\$3,899,104.00
Electronic New Design Applications – Application Data Sheet	4.8	2,673	12,830	\$304.00	\$3,900,320.00
Continuation/Divisional of an International Application – No Application Data Sheet	3.0	7,560	22,680	\$304.00	\$6,894,720.00
Utility Continuation/Divisional Applications	3.0	56,930	170,790	\$304.00	\$51,920,160.00
Plant Continuation/Divisional Applications	2.0	230	460	\$304.00	\$139,840.00
Design Continuation/Divisional Applications	1.0	750	750	\$304.00	\$228,000.00
Continued Prosecution Applications – Design (Request Transmittal and Receipt)	0.4	260	104	\$304.00	\$31,616.00
Utility Continuation-in-Part Applications	15.0	17,720	265,800	\$304.00	\$80,803,200.00
Plant Continuation-in-Part Applications	3.5	70	245	\$304.00	\$74,480.00
Design Continuation-in-Part Applications	2.5	480	1,200	\$304.00	\$364,800.00
Provisional Application for Patent Cover Sheet	10.0	96,680	966,800	\$304.00	\$293,907,200.00
Electronic Provisional Application for Patent Cover Sheet	10.0	41,490	414,900	\$304.00	\$126,129,600.00
Petition to Accept Unintentionally Delayed Priority Claim	1.0	920	920	\$304.00	\$279,680.00
Petition To Accept Non-Signing Inventors or Legal Representatives/Filing by Other Than All the Inventors or a Person not the Inventor	1.0	2,400	2,400	\$304.00	\$729,600.00

Petition under 37 CFR 1.6(f) to Accord the Application under 37 CFR 1.495(b) a National Stage Entry Date	0.5	1	1	\$304.00	\$304.00
Total	- - - -	543,591	10,677,624	- - - -	\$3,245,997,696.00

13. Total Annualized Cost Burden

There are capital start-up, postage, recordkeeping, and drawing costs associated with this information collection. This collection also has filing, search, examination, application size, excess and multiple dependent claims, and non-English specification fees and surcharges for the late filing of provisional applications, the filing, search, and examination fees, or the oath or declaration.

Capital Start-up Costs

Applicants who are submitting patent applications containing large computer program listings or mega tables can choose to submit them on Compact Disk-Read Only Memory (CD-ROM) or a Compact Disk-Recordable (CD-R), particularly if they choose not to or cannot submit their patent application through EFS-Web. Therefore, the costs for purchasing blank CD-R media (CDs), cases and labels for the CDs, and a padded mailing envelope for shipping the CD, are included in the annual (non-hour) costs for this collection. Blank CD-R media with plastic jewel cases can be purchased for approximately \$10 for 10 blank CDs, or about \$1 per disc. The average cost of software for labeling CDs, including blank labels and case inserts, is approximately \$20. Padded 8.5 x 11-inch mailing envelopes for shipping the CDs cost approximately \$12 for a package of 12, or about \$1 per envelope. In sum, the USPTO estimates that the total costs for the blank CD-R media, the software for labeling, the CDs, and the mailing envelope are approximately \$42 per year. The USPTO estimates that 3 patent applications will need to be submitted on CD per year, which when multiplied by \$42 results in \$126 in total costs. **Therefore, the USPTO estimates that the total capital start-up costs for this collection will be \$126 per year.**

Postage Costs

The applications, the petitions, and the oversized program listing/tables CD submissions may be submitted by mail through the United States Postal Service. The USPTO recommends that applicants file initial patent applications (which also include the continued prosecution, continuation and divisional, continuation-in-part, and provisional applications) by Express Mail to establish the filing date (otherwise the filing date of the application will be the date that it is received at the USPTO). The USPTO estimates that the average cost for sending an initial application by Express Mail will be \$18.80, and that customers filing documents associated with these initial applications may choose this option to mail their submissions to the USPTO. Therefore, the USPTO estimates that up to 340,429 submissions per year may be mailed to the USPTO at an average rate of \$18.80, for a postage cost of \$6,400,065 for the original new utility, plant, and design applications, the continuation/divisional of an international application,

utility, plant, and design continuation/divisional applications, the continued prosecution applications – design (request transmittal and receipt), utility, plant, and design continuation-in-part applications, and the provisional applications.

The petitions can be sent by first-class mail. The USPTO estimates that the average first-class postage cost for a mailed submission will be 63 cents, and that customers filing the petitions may choose to mail their submissions to the USPTO. Therefore, the USPTO estimates that up to 3,321 submissions per year may be mailed to the USPTO at an average first-class postage cost of 63 cents, for a total postage cost of \$2,092 per year for the petitions.

In the case of the oversized program listing/table CD submissions, the USPTO estimates that the average postage cost for these submissions will be 95 cents, to cover the costs of mailing the CD, the application transmittal form, and the cover letter. The USPTO estimates that 3 oversized program listing/table CD submissions will be received per year, for a postage cost of \$3 per year, for the oversized program listing/mega table CD submissions.

The total postage cost for this collection is \$6,402,160 per year.

Recordkeeping Costs

There are record keeping costs associated with the oversized program listing/mega table CD submissions and the electronic filing of new utility, design, and provisional applications. The USPTO advises applicants who submit applications with oversized computer program listings or tables on CD to retain a back-up copy of the CD and a printed copy of the application transmittal form for their records. The USPTO estimates that it will take an additional 5 minutes for the applicant to produce this back-up CD copy and 2 minutes to print the copy of the application transmittal form, for a total of 7 minutes (0.12 hours) for each oversized submission. The USPTO estimates that approximately 3 applications per year will be submitted with oversized computer program listings or tables, for a total of 0.36 hours per year for retaining the back-up CD and printed application transmittal form. The USPTO believes that these back-up copies will be prepared by paraprofessionals with an estimated hourly rate of \$90 per hour, for a recordkeeping cost for these back-up copies of \$32 per year.

In addition, the USPTO also strongly advises applicants who file their new utility, design, and provisional applications electronically to retain a copy of the file submitted to the USPTO as evidence of authenticity, in addition to keeping the acknowledgment receipt as clear evidence that the file was received by the USPTO on the date noted. The USPTO estimates that it will take 5 seconds (0.001 hours) to print and retain a copy of the acknowledgment receipt and that approximately 199,841 new submissions per year (145,000 utility, 13,351 design, and 41,490 provisional applications) will use this option, for a total of 200 hours per year. Using the paraprofessional rate of \$90 per hour, the USPTO estimates that the recordkeeping cost for retaining the acknowledgment receipt will be \$18,000 per year.

The total recordkeeping cost for this collection is \$18,032 per year.

Drawing Costs

Patent applicants can submit drawings with the utility, design, plant, and provisional applications. The actual cost of drawing production is variable, because some applicants produce their own drawings, while others contract the work out to various patent illustration firms. Applicants who produce their own drawings will need a graphics software package, in particular graphic software that can produce both 3D and 2D drawings. Commercial software packages such as TurboCAD 8.0 by ValuSoft can produce both 2D and 3D drawings. This particular software package costs \$79. Because the USPTO does not collect information to track how many applicants produce their own drawings, this software cost is provided only as an example and is not included in the burden estimate for this collection.

Inventors, attorneys, and practitioners can also hire various patent illustration services firms to create the utility, design, plant, and provisional drawings. For the purpose of estimating burden for this collection, the USPTO will consider all applicants to have their drawings prepared by these firms. Estimates for these drawings can vary greatly, depending on the number of figures that need to be produced, the total number of pages for the drawings, and the complexity of the drawings. Some firms use “per sheet” estimates to calculate the total costs, while others use hourly rates.

The utility, plant, and design continuation and divisional applications use the same drawings as the initial filings, so they are not included in these estimates. The continuation-in-part applications may use some of the same drawings as the initial applications and some new drawings may be submitted, so those numbers are included in these estimates. The drawings for the continued prosecution applications are also included in the estimates. There are no continuation, divisional, or continuation-in-part provisional applications.

The USPTO estimates that utility drawings can cost from \$40 to \$75 per sheet to produce. Using an average of this cost range, the USPTO estimates that it can cost \$58 per sheet to produce utility drawings and that on average, 11 sheets of drawings are submitted, for an average cost of \$638 to produce the utility drawings. Out of 307,720 utility applications submitted per year, the USPTO estimates that 91% or 280,025 applications will be submitted with drawings. The USPTO estimates that at least \$178,655,950 will be added to the total non-hour cost burden.

The USPTO estimates that design drawings can cost from \$50 to \$85 per sheet to produce. Using an average of this cost range, the USPTO estimates that it can cost \$68 per sheet to produce design drawings and that on average 4.8 sheets of drawings are submitted, for an average cost of \$326 to produce design drawings. Out of 27,440 design applications submitted per year, the USPTO estimates that 100% will be submitted with drawings. The USPTO estimates that at least \$8,945,440 will be added to the total non-hour cost burden.

Plant drawings are less complex to produce than utility and design drawings. The USPTO could not find costs from the various patent illustration firms that the agency researched for plant drawings. Based on this, the USPTO believes that the industry does not have a range of costs for these drawings and that the firms may charge clients their lowest rate for plant drawings. The lowest such rate that the USPTO found through research was \$35 per sheet. On average, 2 sheets of drawings are submitted per application, for an average cost of \$70 to produce plant drawings. Out of 1,470 plant applications submitted per year, the USPTO estimates that 100% will be submitted with drawings. The USPTO estimates that at least \$102,900 will be added to the total non-hour cost burden.

Provisional applications are also submitted with drawings. The USPTO could not find costs for the provisional drawings from the various patent illustration firms that the agency researched. Provisional applications permit the applicant to establish a patent filing date for his or her invention and to assess the marketability of that invention for one year. This allows the applicant to determine whether it will be economically feasible to market the invention without the higher cost of filing a non-provisional application. Applicants must submit a non-provisional application within 12 months after the filing date of the provisional application or else the provisional application will expire.

Based on these characteristics, the USPTO believes that patent illustration firms could charge between \$40 to \$75 per sheet to produce provisional drawings. Using an average of this cost range, the USPTO estimates that it can cost \$58 per sheet to produce these drawings. On average, 7.5 sheets of drawings are submitted per application, for an average cost of \$435 to produce provisional drawings. Out of 138,170 provisional applications submitted per year, the USPTO estimates that 78% or 107,773 applications will be submitted with drawings. The USPTO estimates that at least \$46,881,255 will be added to the total non-hour cost burden.

Based on these estimates for patent illustration firms producing drawings for utility, design, plant, and provisional applications, the USPTO estimates that at least \$234,585,545 will be added to the total non-hour cost burden.

There is also annual nonhour cost burden in the way of filing fees associated with this collection. The filing, search, and examination fees for the utility, plant, design, and provisional applications (including the continuation and divisional, continued prosecution, and continuation-in-part applications) are determined by which filing status (other entity or small entity) the applicant has selected. The filing fees for the electronically-filed new utility applications for small entities are \$75, but for the rest of the applications the fees are the same as those for the paper applications. The small entity status does not apply to the petition to accept delayed priority claims or to the petition to accept non-signing inventors or legal representatives/filing by other than all the inventors or a person not the inventor. The petition under 37 CFR 1.6(f) to accord the application under 37 CFR 1.495(b) a national stage entry date does not have a filing fee.

The total estimated filing costs of \$450,141,995 for this collection are calculated in the following tables.

Table 4 shows the annual filing, search, and examination fee cost burden for applicants filing the various applications and petitions. The USPTO estimates the cost burden associated with the various fees to be \$344,532,770.

Table 4: Filing, Search, and Examination Fees – Nonhour Cost Burden

Item	Responses (yr) (a)	Filing Fee	Search Fee	Examination Fee	Total Fee (b)	Total Non-Hour Cost Burden (yr) (a) x (b)
Original New Utility Applications – No Application Data Sheet – Other Entity	81,200	\$300.00	\$500.00	\$200.00	\$1,000.00	\$81,200,000.00
Original New Utility Applications – No Application Data Sheet – Small Entity	34,800	\$150.00	\$250.00	\$100.00	\$500.00	\$17,400,000.00
Electronic Original New Utility Applications – No Application Data Sheet – Other Entity	81,200	\$300.00	\$500.00	\$200.00	\$1,000.00	\$81,200,000.00
Electronic Original New Utility Applications – No Application Data Sheet – Small Entity	34,800	\$75.00	\$250.00	\$100.00	\$425.00	\$14,790,000.00
Original New Plant Applications – No Application Data Sheet – Other Entity	780	\$200.00	\$300.00	\$160.00	\$660.00	\$514,800.00
Original New Plant Applications – No Application Data Sheet – Small Entity	335	\$100.00	\$150.00	\$80.00	\$330.00	\$110,550.00
Original New Design Applications – No Application Data Sheet – Other Entity	5,232	\$200.00	\$100.00	\$130.00	\$430.00	\$2,249,760.00
Original New Design Applications – No Application Data Sheet – Small Entity	5,445	\$100.00	\$50.00	\$65.00	\$215.00	\$1,170,675.00
Electronic Original New Design Applications – No Application Data Sheet – Other Entity	5,232	\$200.00	\$100.00	\$130.00	\$430.00	\$2,249,760.00
Electronic Original New Design Applications – No Application Data Sheet – Small Entity	5,446	\$100.00	\$50.00	\$65.00	\$215.00	\$1,170,890.00
Original New Utility Applications – Application Data Sheet – Other Entity	20,300	\$300.00	\$500.00	\$200.00	\$1,000.00	\$20,300,000.00
Original New Utility Applications – Application Data Sheet – Small Entity	8,700	\$150.00	\$250.00	\$100.00	\$500.00	\$4,350,000.00
Electronic Original New Utility Applications – Application Data Sheet – Other Entity	20,300	\$300.00	\$500.00	\$200.00	\$1,000.00	\$20,300,000.00

Electronic Original New Utility Applications – Application Data Sheet – Small Entity	8,700	\$75.00	\$250.00	\$100.00	\$425.00	\$3,697,500.00
Original New Plant Applications – Application Data Sheet – Other Entity	200	\$200.00	\$300.00	\$160.00	\$660.00	\$132,000.00
Original New Plant Applications – Application Data Sheet – Small Entity	85	\$100.00	\$150.00	\$80.00	\$330.00	\$28,050.00
Original New Design Applications – Application Data Sheet – Other Entity	1,309	\$200.00	\$100.00	\$130.00	\$430.00	\$562,870.00
Original New Design Applications – Application Data Sheet – Small Entity	1,363	\$100.00	\$50.00	\$65.00	\$215.00	\$293,045.00
Electronic New Design Applications – Application Data Sheet – Other Entity	1,310	\$200.00	\$100.00	\$130.00	\$430.00	\$563,300.00
Electronic New Design Applications – Application Data Sheet – Small Entity	1,363	\$100.00	\$50.00	\$65.00	\$215.00	\$293,045.00
Continuation/Divisional of an International Application – No Application Data Sheet – Other Entity	5,990	\$300.00	\$500.00	\$200.00	\$1,000.00	\$5,990,000.00
Continuation/Divisional of an International Application – No Application Data Sheet – Small Entity	1,570	\$150.00	\$250.00	\$100.00	\$500.00	\$785,000.00
Utility Continuation/Divisional Applications – Other Entity	40,420	\$300.00	\$500.00	\$200.00	\$1,000.00	\$40,420,000.00
Utility Continuation/Divisional Applications – Small Entity	16,510	\$150.00	\$250.00	\$100.00	\$500.00	\$8,255,000.00
Plant Continuation/Divisional Applications – Other Entity	160	\$200.00	\$300.00	\$160.00	\$660.00	\$105,600.00
Plant Continuation/Divisional Applications – Small Entity	70	\$100.00	\$150.00	\$80.00	\$330.00	\$23,100.00
Design Continuation/Divisional Applications – Other Entity	365	\$200.00	\$100.00	\$130.00	\$430.00	\$156,950.00
Design Continuation/Divisional Applications – Small Entity	385	\$100.00	\$50.00	\$65.00	\$215.00	\$82,775.00
Continued Prosecution Applications – Design (Request Transmittal and Receipt) – Other Entity	125	\$200.00	\$100.00	\$130.00	\$430.00	\$53,750.00
Continued Prosecution Applications – Design (Request Transmittal and Receipt) – Small Entity	135	\$100.00	\$50.00	\$65.00	\$215.00	\$29,025.00
Utility Continuation-in-Part Applications – Other Entity	12,580	\$300.00	\$500.00	\$200.00	\$1,000.00	\$12,580,000.00

Utility Continuation-in-Part Applications – Small Entity	5,140	\$150.00	\$250.00	\$100.00	\$500.00	\$2,570,000.00
Plant Continuation-in-Part Applications – Other Entity	50	\$200.00	\$300.00	\$160.00	\$660.00	\$33,000.00
Plant Continuation-in-Part Applications – Small Entity	20	\$100.00	\$150.00	\$80.00	\$330.00	\$6,600.00
Design Continuation-in-Part Applications – Other Entity	235	\$200.00	\$100.00	\$130.00	\$430.00	\$101,050.00
Design Continuation-in-Part Applications – Small Entity	245	\$100.00	\$50.00	\$65.00	\$215.00	\$52,675.00
Provisional Application for Patent Cover Sheets – Other Entity	36,500	\$200.00	N/A	N/A	\$200.00	\$7,300,000.00
Provisional Application for Patent Cover Sheets – Small Entity	60,180	\$100.00	N/A	N/A	\$100.00	\$6,018,000.00
Electronic Provisional Application for Patent Cover Sheets – Other Entity	15,690	\$200.00	N/A	N/A	\$200.00	\$3,138,000.00
Electronic Provisional Application for Patent Cover Sheets – Small Entity	25,800	\$100.00	N/A	N/A	\$100.00	\$2,580,000.00
Petition to Accept Unintentionally Delayed Priority Claim	920	\$1,300.00	N/A	N/A	\$1,300.00	\$1,196,000.00
Petition to Accept Non-Signing Inventors or Legal Representatives/Filing by Other Than all the Inventors or a Person not the Inventor	2,400	\$200.00	N/A	N/A	\$200.00	\$480,000.00
Petition under 37 CFR 1.6(f) to accord the Application under 37 CFR 1.495(b) a National Stage Entry Date	1	N/A	N/A	N/A	N/A	\$00.00
Totals	543,591	-----	-----	-----	-----	\$344,532,770.00

Table 5 calculates the additional fees incurred when an application is filed with additional sheets or excess claims. The USPTO estimates that these fees apply to 311,905 of the 543,591 total applications filed per year. This table is a subset of Table 4 and adds an additional \$89,020,075 to the annualized (non-hour) costs shown in Table 4. It does not, however, change the number of responses. These fees are also determined by the filing status.

Table 5: Application Size and Excess Claims Fees – Nonhour Cost Burden

Item	Responses (yr) (a)	Filing Fee for Additional Sheets and Claims	Average Fee (b)	Total Non-Hour Cost Burden (yr) (a) x (b)
Provisional Application Size Fee for Each Provisional Application for Patent Cover Sheet, filed for Each Additional 50 Sheets Exceeding 100 Sheets – Other Entity	2,400	\$200.00 per each 50 sheets over 100	\$500.00	\$1,200,000.00
Provisional Application Size Fee for Each Provisional Application for Patent Cover Sheet, filed for Each Additional 50 Sheets Exceeding 100 Sheets – Small Entity	2,300	\$100.00 per each 50 sheets over 100	\$260.00	\$598,000.00
Utility and Plant Applications, with independent claims in excess of 3 – Other Entity	95,000	\$200.00 for each claim over 3	\$400.00	\$38,000,000.00
Utility and Plant Applications, with independent claims in excess of 3 – Small Entity	36,000	\$100.00 for each claim over 3	\$200.00	\$7,200,000.00
Utility and Plant Applications, filed with Claims in Excess of 20 – Other Entity	115,000	\$50.00 for each claim over 20	\$200.00	\$23,000,000.00
Utility and Plant Applications, filed with Claims in Excess of 20 – Small Entity	50,000	\$25.00 for each claim over 20	\$300.00	\$15,000,000.00
Utility Application Size Fee for Each Original New Utility Application, filed with each additional 50 sheets exceeding 100 sheets – Other Entity	7,500	\$250.00 for each additional 50 sheets over 100	\$425.00	\$3,187,500.00
Utility Application Size Fee for Each Original New Utility Application, filed with each additional 50 sheets exceeding 100 Sheets – Small Entity	3,500	\$125.00 for each additional 50 sheets over 100	\$225.00	\$787,500.00
Plant Application Size Fee for Each Original New Plant Application, filed with Each Additional 50 Sheets Exceeding 100 Sheets – Other Entity	25	\$250.00 for each additional 50 sheets over 100	\$275.00	\$6,875.00
Plant Application Size Fee for Each Original New Plant Application, filed with Each Additional 50 Sheets Exceeding 100 Sheets – Small Entity	10	\$125.00 for each additional 50 sheets over 100	\$265.00	\$2,650.00
Design Application Size Fee for Each Original New Design Application, filed for each Additional 50 Sheets that Exceeds 100 Sheets – Other Entity	110	\$250.00 for each additional 50 sheets over 100	\$265.00	\$29,150.00
Design Application Size Fee for Each Original New Design Application, filed for each Additional 50 Sheets that Exceeds 100 Sheets – Small Entity	60	\$125.00 for each additional 50 sheets over 100	\$140.00	\$8,400.00
Total	311,905	-----	-----	\$89,020,075.00

Table 6 calculates the surcharges and fees incurred when an application, the search or examination fee, or the oath or declaration is filed late, when the application is filed with multiple dependent claims, or when the application is filed with a non-English specification. The USPTO estimates that these fees apply to 123,040 of the 543,591 total applications filed per year. This table is a subset of Table 4 and adds an additional \$16,589,150 to the annualized (non-hour) costs shown in Table 4. It does not, however, change the number of responses. With the exception of the fee for the non-English specification, the remaining fees are determined by the filing status.

Table 6: Fees for Multiple Dependent Claims and Non-English Specifications and Surcharges for Late Filings

Item	Responses (yr) (a)	Surcharge Fee for Late Filing, Multiple Dependent Claims, or Non-English Specification Fees	Total Non-Hour Cost Burden (yr) (a) x (b)
Surcharge for Late Filing of Provisional Application for Patent Cover Sheets – Other Entity	3,910	\$50.00	\$195,500.00
Surcharge for Late Filing of Provisional Application for Patent Cover Sheets – Small Entity	5,650	\$25.00	\$141,250.00
Utility and Plant Applications, filed with Multiple Dependent Claims – Other Entity	8,000	\$360.00	\$2,880,000.00
Utility and Plant Applications, filed with Multiple Dependent Claims – Small Entity	3,600	\$180.00	\$648,000.00
Utility, Plant, and Design Applications, filed with a Surcharge for Late Filing, Search or Examination Fee, or Oath/Declaration – Other Entity	90,000	\$130.00	\$11,700,000.00
Utility, Plant, and Design Applications, filed with a Surcharge for Late Filing, Search, or Examination Fee, or Oath/Declaration – Small Entity	8,000	\$65.00	\$520,000.00
Non-English Specification	3,880	\$130.00	\$504,400.00
Totals	123,040	-----	\$16,589,150.00

The USPTO estimates that the total non-hour respondent cost burden for this collection, in the form of capital start-up, postage, recordkeeping, and drawing costs, in addition to the fees and surcharges, is \$691,147,858 per year.

14. Annual Cost to the Federal Government

The USPTO estimates that it takes a GS-5, step 1 approximately one hour to process original new utility, plant, and design applications, the continuations and divisionals of international applications, the continuation and divisional applications, and the continuation-in-part applications. The USPTO estimates that it takes a GS-5, step 1 approximately 36 minutes (0.6 hours) to process a continued prosecution application, and approximately 30 minutes (0.5 hours) to process a provisional application. The USPTO estimates that it takes a GS-5, step 1, 18 minutes (0.3 hours) to process the petitions to accept unintentionally delayed priority claims and to accept non-signing inventors or legal representatives, while it takes 6 minutes (0.1 hours) to process the petitions under 37 CFR 1.6(f) to accord the application under 37 CFR 1.495(b) a national stage entry date.

The current hourly rate for a GS-5, step 1 is \$14.56. When 30% is added to account for a fully loaded hourly rate (benefits and overhead), the cost per hour for a GS-5, step 1 is \$14.56 + \$4.37, for a rate of \$18.93.

Table 7 calculates the processing hours and costs of this information collection to the Federal Government:

Table 7: Burden Hour/Burden Cost to the Federal Government

Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a) x (b)	Rate (\$/hr) (d)	Total Cost (\$/hr) (e) (c) x (d)
Original New Utility Applications – No Application Data Sheet	1.0	116,000	116,000	\$18.93	\$2,195,880.00
Electronic Original New Utility Applications – No Application Data Sheet	1.0	116,000	116,000	\$18.93	\$2,195,880.00
Original New Plant Applications – No Application Data Sheet	1.0	1,115	1,115	\$18.93	\$21,107.00
Original New Design Applications – No Application Data Sheet	1.0	10,677	10,677	\$18.93	\$202,116.00
Electronic Original Design Applications – No Application Data Sheet	1.0	10,678	10,678	\$18.93	\$202,135.00
Original New Utility Applications – Application Data Sheet	1.0	29,000	29,000	\$18.93	\$548,970.00
Electronic Original New Utility Applications – Application Data Sheet	1.0	29,000	29,000	\$18.93	\$548,970.00
Original New Plant Applications – Application Data Sheet	1.0	285	285	\$18.93	\$5,395.00
Original New Design Applications – Application Data Sheet	1.0	2,672	2,672	\$18.93	\$50,581.00
Electronic New Design Applications – Application Data Sheet	1.0	2,673	2,673	\$18.93	\$50,600.00
Continuation/Divisional of an International Application – No Application Data Sheet	1.0	7,560	7,560	\$18.93	\$143,111.00
Utility Continuation/Divisional Applications	1.0	56,930	56,930	\$18.93	\$1,077,685.00
Plant Continuation/Divisional Applications	1.0	230	230	\$18.93	\$4,354.00
Design Continuation/Divisional Applications	1.0	750	750	\$18.93	\$14,198.00
Continued Prosecution Applications – Design (Request Transmittal and Receipt)	0.6	260	156	\$18.93	\$2,953.00
Utility Continuation-in-Part Applications	1.0	17,720	17,720	\$18.93	\$335,440.00
Plant Continuation-in-Part Applications	1.0	70	70	\$18.93	\$1,325.00
Design Continuation-in-Part Applications	1.0	480	480	\$18.93	\$9,086.00
Provisional Application for Patent Cover Sheet	0.5	96,680	48,340	\$18.93	\$915,076.00
Electronic Provisional Application for Patent Cover Sheet	0.5	41,490	20,745	\$18.93	\$392,703.00
Petition to Accept Unintentionally Delayed Priority Claim	0.3	920	276	\$18.93	\$5,225.00

Petition to Accept Non-Signing Inventors or Legal Representatives/Filing by Other Than All the Inventors or a Person Not the Inventor	0.3	2,400	720	\$18.93	\$13,630.00
Petition Under 37 CFR 1.6(f) to Accord the Application under 37 CFR 1.495(b) a National Stage Entry Date	0.1	1	1	\$18.93	\$19.00
Total	- - - -	543,591	472,078	- - - -	\$8,936,439.00

The USPTO’s total estimated cost for processing the information in this collection is estimated at \$8,936,439 per year.

15. Reason for Change in Burden

Summary of Changes Since the Previous Renewal

The OMB approved the renewal for this information collection on July 14, 2003, with 454,287 responses, 4,171,568 burden hours, and \$258,115,506 in annualized (non-hour) costs. On December 22, 2003, OMB approved the information collection package supporting the proposed rulemaking, “Changes to Support the Implementation of the United States Patent and Trademark Office 21st Century Plan (RIN 0651-AB64). This proposed rule did not impact the responses and burden hours for this collection, but it did increase the annualized (non-hour) cost burden to \$493,593,081. The OMB approved another information collection package supporting a proposed rulemaking, “Changes to Implement the Patent Search Fee Refund Provisions of the Consolidated Appropriations Act, 2005” (RIN-AB79) on August 29, 2005. This also did not impact the responses and burden hours, but it did increase the annualized (non-hour) cost burden to \$575,550,456. On September 20, 2005, OMB approved a change worksheet adding the EFS-Web version of the Application Data Sheet into the collection, but it did not change the total burden or annualized (non-hour) costs for this collection.

With this renewal, the USPTO estimates that the total burden and annualized (non-hour) costs for this collection will be 543,591 responses, 10,677,624 burden hours, and \$691,147,858 in annualized costs. This is an increase of 89,304 responses, 6,506,056 burden hours, and \$115,597,402 in annualized costs over the currently approved burden for this collection. The increases in the responses, burden hours, and annualized (non-hour) costs are due to both program changes and administrative adjustments.

Changes in Burden Estimates Since the 60-Day Federal Register Notice

In the 60-Day Federal Register Notice published on September 12, 2006 for this renewal, the USPTO reported that this collection would have an estimated 543,590 responses, 4,748,122 estimated burden hours, and \$1,443,429,088 in estimated respondent burden. The USPTO also estimated that there would be \$695,587,260 in capital start-up, postage, recordkeeping, and drawing costs and fees associated with this collection per year. After the publication of the 60-Day Notice, the USPTO determined that these reported estimates would need to be revised due to new

response and burden estimates and the addition of a previously overlooked requirement.

An existing requirement, Petition under 37 CFR 1.6(f) to Accord the Application under 37 CFR 1.495(b) a National Stage Entry Date,” that was previously overlooked, was added into the collection. The USPTO estimates that 1 petition will be submitted per year, and that this will increase the estimated number of responses reported for this collection in the 60-Day Federal Register Notice to 543,591.

The estimated annual burden hours have also increased due to reestimates of the amount of time that it takes the public to complete these applications. Previously, when the utility, design, and plant applications were grouped together, the estimated completion times for all of the applications in a particular group ranged from 10 hours and 45 minutes to 10 hours and 36 minutes. In the 60-Day Notice, the original estimated completion times were kept for the applications that are now reported separately. Since then, the USPTO has revised the completion times to more accurately reflect the amount of time that it takes to complete each type of application. The estimated completion times were revised for all of the applications except for the continued prosecution applications. The USPTO estimates that the petition under 37 CFR 1.6(f) will take 30 minutes to complete and that it will add 1 hour to the total burden hours. The USPTO estimates that 5,929,502 additional burden hours will be added to the collection per year, bringing the total burden hours to 10,677,624.

While the hourly rate used to calculate the total cost burden remains the same, the addition of the petition and the revised completion estimates also changed the total cost burden now reported for this collection. The USPTO estimates that the total cost burden will increase by \$1,802,568,608.

The USPTO now believes that applicants will file more of their applications electronically than was originally estimated. This has changed the percentage of applications filed electronically as opposed to paper filings, which in turn has decreased the postage costs and the fees associated with the applications and increased the recordkeeping costs. The USPTO estimates that the postage costs reported in the 60-Day Notice will decrease by \$1,190,717 per year and that the fees will decrease by \$3,254,355 per year. The USPTO estimates that the recordkeeping costs associated with the electronically-filed applications will increase by \$5,670.

Changes in Respondent Cost Burden

The respondent cost burden has increased since the previous renewal due to increased submissions and an increase in the hourly rate. The USPTO believes that all of these applications and petitions will be completed by associate attorneys. Based on figures provided by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association, the estimated hourly billing rate for the associate attorneys has increased from \$252 to \$304.

The total respondent cost burden for the currently approved information collection is \$1,051,234,914. With this renewal, the USPTO estimates that the total respondent cost burden will increase by \$2,194,762,782, to \$3,245,997,696 per year.

Changes in Responses and Burden Hours

The USPTO estimates that the number of responses submitted annually for this collection will increase by 89,304, from 454,287 to 543,591 responses. In addition, the USPTO estimates that the total burden hours for this collection will increase by 6,506,056 hours, from 4,171,568 hours to 10,677,624 burden hours per year. These changes are due to both program changes and administrative adjustments, as follows:

- The USPTO now accepts original design applications electronically through EFS-Web. The USPTO estimates that 13,351 design applications will be submitted electronically per year. As with the paper filings, the USPTO estimates that design applications without application data sheets that are filed electronically will take 5 hours to complete, while design applications with application data sheets that are filed electronically will take 4 hours and 48 minutes to complete. The USPTO estimates that the ability to file design applications electronically will add 66,220 burden hours to the collection per year. **Therefore, this collection takes a net burden increase of 66,220 hours as a program change.**
- While working on this renewal submission, the USPTO discovered a petition, Petition under 37 CFR 1.6(f) to Accord the Application under 37 CFR 1.495(b) a National Stage Entry Date, that needed to be added into this collection. This petition is an existing requirement that was overlooked in previous submissions. The USPTO estimates that 1 petition will be submitted per year and that it will increase the burden hours for this collection by 1 hour per year. The USPTO estimates that it will take 30 minutes to complete the petition. **Therefore, this collection takes a net burden increase of 1 hour as an administrative adjustment.**
- The USPTO believes that the number of provisional applications for patent cover sheets filed in paper per year will increase by 6,891 responses, from 89,789 to 96,680 responses per year, which will also increase the burden by 248,488 hours, from 718,312 to 966,800 burden hours per year. This is due to increased number of applications submitted and a reestimate of the amount of time that it takes to complete the application. **Therefore, this collection takes a net burden increase of 248,488 hours as an administrative adjustment.**
- The USPTO believes that more applicants will choose to submit their provisional applications for patent cover sheets electronically through EFS-Web. The USPTO estimates that the number of applications submitted electronically will increase by 40,850 responses, from 640 to 41,490 responses per year. The burden will also increase by 409,780 hours, from 5,120 to 414,900 burden hours per year. This is due to the increased number of provisional applications filed electronically and a reestimate of the amount of time that it takes to complete the application.

Therefore, this collection takes a net burden increase of 409,780 hours as an administrative adjustment.

- The USPTO believes that the number of petitions to accept unintentionally delayed priority claims filed per year will increase by 815 responses, from 105 to 920 responses per year, which in turn will increase the burden by 815 hours, from 105 to 920 burden hours per year. **Therefore, this collection takes a net burden increase of 815 hours as an administrative adjustment.**
- The USPTO believes that the number of petitions to accept non-signing inventors or legal representatives/filing by other than all the inventors or a person not the inventor will increase by 600 responses, from 1,800 to 2,400 responses per year and that in turn will increase the burden by 600 hours, from 1,800 to 2,400 burden hours per year. **Therefore, this collection takes a net burden increase of 600 hours as an administrative adjustment.**
- In the original EFS, applicants could not submit applications that were larger than 10 megabytes. Applications larger than 10 megabytes were copied onto a CD, which would then be mailed or hand delivered to the USPTO. In EFS-Web, the maximum size for the applications is 25 megabytes. A maximum of 60 electronic files can be filed in any one submission. If the application contains more than 60 files, the submission can be broken up so that 60 or fewer files are submitted in the initial EFS-Web filing, with the remainder of the files submitted later. With these changes, applicants no longer have to use the CDs to submit their oversized electronic applications. Consequently, the requirement for the CD submissions of oversized new utility and provisional applications that cannot be submitted electronically via EFS has been deleted from this collection. This deletes 3 responses and 1 burden hour per year from the total burden for this collection. **Therefore, this collection takes a net burden decrease of 1 hour as a program change.**
- In the previous renewal, the various new utility, plant, and design applications were all grouped together. In this renewal submission, the utility, design, and plant applications have been broken out separately, which allows the USPTO to show exactly how many of the different applications have been filed and makes it easier to account for the electronic filings. In addition, the USPTO determined that the different types of utility, design, and plant applications have different estimated completion times. Since the different types of applications were grouped together, they all had the same completion times. Separating the applications allows the USPTO to update the completion times to more accurately represent how much time it takes to complete these different types of applications. By comparing the total responses for the various utility, plant, and design applications in this submission against the application groupings in the currently approved collection, the USPTO estimates that the number of applications filed will increase by 26,802, from 361,687 to 388,489 responses per year. This in turn will increase the burden by 5,780,154 hours, from 3,446,125 to 9,226,279 burden hours per year. **Therefore, this**

collection takes a net burden increase of 5,780,154 hours as an administrative adjustment.

- The USPTO believes that fewer applicants will file continued prosecution applications – design (request transmittal and receipt) over the next 3 years. The USPTO estimates that the response will decrease by 3, from 263 to 260 responses per year, while the burden will decrease by 1 hour, from 105 to 104 burden hours per year. **Therefore, this collection takes a net burden reduction of 1 hour as an administrative adjustment.**

The USPTO estimates that the net total burden for this collection will increase by 6,506,056 hours, from 4,171,568 to 10,677,624 burden hours per year. The USPTO estimates that 1 hour will be reduced and 66,220 hours added to this collection as a result of program changes, for a net total increase of 66,219 burden hours per year. The USPTO estimates that 1 hour will be reduced and 6,439,838 hours added to this collection as a result of administrative adjustments, for a net total burden increase of 6,439,837 burden hours per year. **In sum, this information collection has a net burden increase of 6,506,056 hours per year, due to increases of 66,219 and 6,439,837 hours resulting from program changes and administrative adjustments, respectively.**

Changes in Annual (Non-Hour) Costs

For this renewal, the USPTO estimates that the annual (non-hour) costs for this collection will increase by \$115,597,402, from \$575,550,456 to \$691,147,858 per year. This change is due to both program changes and administrative adjustments, as follows:

- The USPTO believes that fewer provisional applications for patent cover sheets will be filed in paper and electronically by other entities during the next 3 years. This will reduce the fees associated with the provisional applications filed by other entities by \$4,030,600, from \$14,468,600 to \$10,438,000 per year. Conversely, the USPTO expects that small entities will file more provisional applications for patent cover sheets in paper and electronically. This will increase the fees associated with the provisional applications filed by small entities by \$6,789,400, from \$1,808,600 to \$8,598,000 per year. **Therefore, this collection has a net total increase of \$2,758,800 in annual (non-hour) fees due to an administrative adjustment.**
- The USPTO believes that fewer utility applications (including those filed with and without an application data sheet, continuation/divisional of an international application without an application data sheet, continuation/divisional, and continuation-in-part applications) will be filed in paper and electronically by other entities during the next 3 years. This will reduce the fees associated with the utility applications filed by other entities by \$11,147,000, from \$273,137,000 to \$261,990,000 per year. Conversely, the USPTO expects that small entities will file more utility applications. This will increase the fees associated with utility

applications filed by small entities by \$17,705,000, from \$34,142,500 to \$51,847,500 per year. **Therefore, this collection has a net total increase of \$6,558,000 in annual (non-hour) fee costs due to an administrative adjustment.**

- The USPTO believes that both small and other entities will file more plant applications (including those filed with and without an application data sheet, continuation/divisional, and continuation-in-part applications) during the next 3 years. This will increase the fees associated with the plant applications by \$383,460, from \$570,240 to \$953,700 per year. **Therefore, this collection has a net total increase of \$383,460 in annual (non-hour) costs due to an administrative adjustment.**
- The USPTO believes that fewer design applications (including those filed with and without an application data sheet, continuation/divisional, continued prosecution applications – design (request transmittal and receipt), and continuation-in-part applications) will be filed in paper and electronically by other entities during the next 3 years. This will reduce the fees associated with design applications filed by other entities by \$793,780, from \$6,731,220 to \$5,937,440. Conversely, the USPTO expects that small entities will file more design applications. This will increase the fees associated with design applications filed by small entities by \$2,250,620, from \$841,510 to \$3,092,130. **Therefore, this collection has a net total increase of \$1,456,840 in annual (non-hour) fee costs due to an administrative adjustment.**
- The USPTO believes that more petitions to accept unintentionally delayed priority claims will be filed during the next 3 years. This will increase the fees associated with this petition by \$1,059,500, from \$136,500 to \$1,196,000 per year. **Therefore, this collection has a net total increase of \$1,059,500 in annual (non-hour) costs due to an administrative adjustment.**
- The USPTO believes that more petitions to accept non-signing inventors or legal representatives/filing by other than all the inventors or a person not the inventor will be filed during the next 3 years. This will increase the fees associated with this petition by \$120,000, from \$360,000 to \$480,000 per year. **Therefore, this collection has a net total increase of \$120,000 in annual (non-hour) fee costs due to an administrative adjustment.**
- The Consolidated Appropriations Act, 2005 introduced a new application size fee for provisional, utility, plant, and design applications filed under 35 U.S.C. § 111 on or after December 8, 2004 that have specifications and drawings that exceed 100 sheets of paper. The fees vary for the different applications and are based on the filing status of the applicant. The USPTO estimates that these fees will apply to 15,905 of the total 543,591 total applications filed per year. This will increase the total fees associated with this collection by \$5,820,075. **Therefore, this collection has a net total increase of \$5,820,075 in annual (non-hour) fee costs due to a program change.**

- In addition to the filing, examination, search, and application size fees, there are also fees for excess claims, multiple dependent claims, surcharges for late filings, and fees for non-English specifications. While working on the renewal, it was discovered that these existing fees were not covered in the previous submissions of this collection. The fees vary for the different applications and are based on the filing status of the applicant (with the exception of the non-English specification). The USPTO estimates that these fees will apply to 419,040 of the total 543,591 total applications filed per year. This will increase the total fees associated with this collection by \$99,789,150. **Therefore, this collection has a net total increase of \$99,789,150 in annual (non-hour) fee costs due to an administrative adjustment.**
- Previously, applications filed electronically through EFS that exceeded 10 megabytes could only be submitted to the USPTO on a CD. Since then, a new web-based version of EFS called EFS-Web was released. In EFS-Web, the maximum size for the electronically-filed applications is 25 megabytes, the submission can contain up to 60 files, and applications that exceed 60 files can be broken down into groups of 60 files or less and filed through EFS-Web. Since EFS-Web can handle larger submissions than in the past, the USPTO does not foresee a need for applicants to file EFS-Web submissions on CD, although applications containing large computer program listings or mega tables may need to be submitted on CD. The USPTO now estimates that only 3 applications per year will need to be filed on CD, for a reduction of 3 responses. The USPTO estimates that this will reduce the capital start-up costs for this collection by \$126, from \$252 to \$126. **Therefore, this collection has a reduction of \$126 in annual (non-hour) capital start-up costs due to a program change.**
- The USPTO believes that more applicants will choose to submit their patent applications electronically through EFS-Web instead of submitting them in paper. The USPTO believes that this switch will reduce \$1,601,037 from the postage costs associated with this collection. This reduction offsets an increase of \$1,159 due to the addition of an overlooked requirement to the collection and increases in the postage fees. **Therefore, this collection takes a net burden reduction of \$1,599,878 in annual (non-hour) postage costs as an administrative adjustment.**
- For patent applications that are filed electronically through EFS-Web, the USPTO strongly recommends that applicants print and file a copy of the acknowledgement receipt as proof of when the application was accepted by EFS-Web. Previously, the USPTO only collected original new utility and provisional applications electronically, but now applicants also have the ability to file their original new design applications through EFS-Web. The USPTO estimates that this will increase the recordkeeping costs associated with this collection by \$1,170 per year. Since the USPTO believes that more applicants will choose to submit their patent applications electronically through EFS-Web instead of submitting them in paper, the USPTO estimates that an additional \$16,710 will be added to the recordkeeping costs. In addition, the USPTO

estimates that \$21 will be added as a result of an increase in the paraprofessional rate from \$30 to \$90 for the back-up copies of applications that contain oversized computer program listings or mega tables on CD. The USPTO estimates a net total burden increase of \$17,901 associated with the recordkeeping costs for this collection. **Therefore, this collection has a net burden increase of \$17,901 in annual (non-hour) recordkeeping costs, with \$1,170 due to a program change and \$16,731 due to an administrative adjustment.**

- Some of the utility, design, plant, and provisional applications are filed with drawings, which many applicants contract out to patent illustration firms. The USPTO believes that fewer utility applications with drawings will be filed over the next 3 years, but that more design, plant, and provisional applications containing drawings will be filed. Based on the projected increased submissions of the design, plant, and provisional applications, the USPTO estimates that \$18,800,502 will be added to the drawing costs. The USPTO expects that this increase, however, will be offset by the reduction in the drawing costs for the utility applications. The USPTO estimates that \$19,566,822 will be reduced from the drawing costs. Overall, the USPTO estimates that the net total reduction in the drawing costs for this collection will be \$766,320. **Therefore, this collection has a net total burden reduction of \$766,320 in annual (non-hour) drawing costs due to an administrative adjustment.**

The USPTO estimates that this submission will increase the total net burden in annual (non-hour) costs for this collection by \$115,597,402. The USPTO estimates that \$5,821,245 will be added to and \$126 reduced from this collection as a result of program changes, for a total net burden increase of \$5,821,119 in annual (non-hour) costs. The USPTO estimates that \$112,142,481 will be added to and \$2,366,198 reduced from this collection as a result of administrative changes, for a total net burden increase of \$109,776,283 in annual (non-hour) costs. **In sum, this information collection has a total net burden increase of \$115,597,402 in annual (non-hour) costs, due to increases of \$5,821,119 in program changes and \$109,776,283 in administrative adjustments.**

16. Project Schedule

There is no plan to publish this information for statistical use.

17. Display of Expiration Date of OMB Approval

The forms in this information collection will display the OMB Control Number and the OMB expiration date.

18. Exception to the Certificate Statement

This collection of information does not include any exceptions to the certificate statement.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection of information does not employ statistical methods.

LIST OF ATTACHMENTS

- A. EFS-Web screenshots for registered/unregistered users
- B. The USPTO Information Quality Guidelines
- C. PTO/SB/06 Patent Application Fee Determination Record (Substitute for Form PTO-875)
- D. PTO/SB/07 Multiple Dependent Claim Fee Calculation Sheet (Substitute for Form PTO-1360; For Use with Form PTO/SB/06)
- E. PTO/SB/17 Fee Transmittal Form
- F. PTO/SB/05 Utility Patent Application Transmittal
- G. PTO/SB/18 Design Patent Application Transmittal
- H. PTO/SB/19 Plant Patent Application Transmittal
- I. PTO/SB/01 Declaration for Utility or Design Patent Application (37 CFR 1.63)
- J. PTO/SB/02A Declaration – Additional Inventors – Supplemental Sheet and PTO/SB/02B Declaration – Supplemental Priority Data Sheet
- K. PTO/SB/02LR Declaration Supplemental Sheet for Legal Representatives (35 U.S.C. § 117) on Behalf of a Deceased or Incapacitated Inventor
- L. PTO/SB/03 Plant Patent Application (35 U.S.C. § 161) Declaration (37 CFR 1.63)
- M. PTO/SB/04 Supplemental Declaration for Utility or Design Patent Application (37 CFR 1.67)
- N. PTO/SB/101 through 110 Declaration and Power of Attorney for Patent Application (in various foreign languages)
- O. PTO/SB/14 Application Data Sheet Form
- P. PTO/SB/01A Declaration (37 CFR 1.63) for Utility or Design Application Using An Application Data Sheet (37 CFR 1.76)
- Q. PTO/SB/03A Declaration (37 CFR 1.63) for Plant Application Using an Application Data Sheet (37 CFR 1.76)
- R. PTO/SB/13/PCT Request for Filing a Continuation or Division of an International Application
- S. PTO/SB/29 For Design Applications Only: Continued Prosecution Application (CPA) Request Transmittal
- T. PTO/SB/29A For Design Applications Only: Receipt for Facsimile Transmitted CPA
- U. PTO/SB/16 Provisional Application for Patent Cover Sheet
- V. 60-Day Federal Register Notice published on September 12, 2006 (Vol. 71, No. 176)

NOTICE OF OFFICE OF MANAGEMENT AND BUDGET ACTION

Date 06/05/2007

Department of Commerce
Patent and Trademark Office
FOR CERTIFYING OFFICIAL: Barry West
FOR CLEARANCE OFFICER: Diana Hynek

In accordance with the Paperwork Reduction Act, OMB has taken action on your request received 02/28/2007

ACTION REQUESTED: Revision of a currently approved collection
TYPE OF REVIEW REQUESTED: Regular
ICR REFERENCE NUMBER: 200702-0651-008
AGENCY ICR TRACKING NUMBER:
TITLE: Initial Patent Applications
LIST OF INFORMATION COLLECTIONS: See next page

OMB ACTION: Approved without change
OMB CONTROL NUMBER: 0651-0032
The agency is required to display the OMB Control Number and inform respondents of its legal significance in accordance with 5 CFR 1320.5(b).

EXPIRATION DATE: 06/30/2010 DISCONTINUE DATE:

BURDEN:	RESPONSES	HOURS	COSTS
Previous	454,287	4,171,568	575,550,000
New	543,591	10,677,624	243,201,076
Difference			
Change due to New Statute	0	0	2,090
Change due to Agency Discretion	10,678	53,390	1,260
Change due to Agency Adjustment	78,626	6,452,666	-332,352,274
Change Due to Potential Violation of the PRA	0	0	0

TERMS OF CLEARANCE:

OMB Authorizing Official: John F. Morrall III
Acting Deputy Administrator,
Office Of Information And Regulatory Affairs

List of ICs

IC Title	Form No.	Form Name	CFR Citation
Original New Utility Applications - No Application Data Sheet	PTO/SB/102, PTO/SB/02A and PTO/SB/02B, PTO/SB/02LR, PTO/SB/107, PTO/SB/105, PTO/SB/106, PTO/SB/101, PTO/SB/108, PTO/SB/04, PTO/SB/01, PTO/SB/103, PTO/SB/109, PTO/SB/17, PTO/SB/110, PTO/SB/104, PTO/SB/05	Declaration and Power of Attorney for Patent Application - Dutch Language Declaration, Declaration - Additional Inventors-Supplemental Sheet and Declaration - Supplemental Priority Data Sheet, Declaration Supplemental Sheet for Legal Representatives (35 U.S.C 117) on Behalf of a Deceased or Incapacitated Inventor, Declaration and Power of Attorney for Patent Application - Russian Language Declaration, Declaration and Power of Attorney for Patent Application - French Language Declaration, Declaration and Power of Attorney for Patent Application - Japanese Language Declaration, Declaration and Power of Attorney for Patent Application - Chinese Language Declaration, Declaration and Power of Attorney for Patent Application, Supplemental Declaration for Utility or Design Patent Application (37 CFR 1.67), Declaration for Utility or Design Patent Application (37 CFR 1.63), Declaration and Power of Attorney for Patent Application - German Language Declaration, Declaration and Power of Attorney for Patent Application, Fee Transmittal Form, Declaration and Power of Attorney for Patent	37 CFR 1.42, 1.43, and 1.47, 37 CFR 1.63 through 1.69, 37 CFR 1.16, 37 CFR 1.71 through 1.77, 37 CFR 1.53, 37 CFR 1.81 through 1.84

List of ICs

IC Title	Form No.	Form Name	CFR Citation
		Application, Declaration and Power of Attorney for Patent Application - Italian Language Declaration, Utility Patent Application Transmittal	
Original New Plant Applications - No Application Data Sheet	PTO/SB/02LR, PTO/SB/19, PTO/SB/109, PTO/SB/17, PTO/SB/03	Declaration Supplemental Sheet for Legal Representatives (35 U.S.C. 117) on Behalf of a Deceased or Incapacitated Inventor, Plant Patent Application Transmittal, Declaration and Power of Attorney for Patent Application, Fee Transmittal Forms, Plant Patent Application (35 U.S.C. 161) Declaration (37 CFR 1.63)	37 CFR 1.53, 37 CFR 1.71 through 1.77, 37 CFR 1.81 through 1.84, 37 CFR 1.42, 1.43, 1.47, 37 CFR 1.63 through 1.69, 37 CFR 1.16
Original New Design Applications - No Application Data Sheet	PTO/SB/02LR, PTO/SB/106, PTO/SB/105, PTO/SB/18, PTO/SB/17, PTO/SB/02A and PTO/SB/02B, PTO/SB/04, PTO/SB/01	Declaration Supplemental Sheet for Legal Representatives (35 U.S.C. 117) on Behalf of a Deceased or Incapacitated Inventor, Declaration and Power of Attorney for Patent Application, Declaration and Power of Attorney for Patent Application, Design Patent Application Transmittal, Fee Transmittal Form, Declaration - Additional Inventors-Supplemental Sheet and Declaration - Supplemental Priority Data Sheet, Supplemental Declaration for Utility or Design Patent Application (37 CFR 1.67), Declaration for Utility or Design Patent Application (37 CFR 1.63)	37 CFR 1.53, 37 CFR 1.71 through 1.77, 37 CFR 1.82 through 1.84, 37 CFR 1.42, 1.43, 1.47, 37 CFR 1.63 through 1.69, 37 CFR 1.16
Original New Utility Applications - Application Data Sheet	PTO/SB/14, PTO/SB/01A, PTO/SB/17	Application Data Sheet 37 CFR 1.76, Declaration (37 CFR 1.63) for Utility or Design Application Using an Application Data Sheet (37 CFR 1.76), Fee Transmittal Form	37 CFR 1.63 through 1.69, 37 CFR 1.53, 37 CFR 1.71 through 1.77, 37 CFR 1.81 through 1.84, 37 CFR 1.42, 1.43, 1.47, 37 CFR 1.16

List of ICs

IC Title	Form No.	Form Name	CFR Citation
Original New Plant Applications - Application Data Sheet	PTO/SB/03A, PTO/SB/17, PTO/SB/14	Declaration (37 CFR 1.63) for Plant Application Using an Application Data Sheet (37 CFR 1.76), Fee Transmittal Form, Application Data Sheet 37 Cfr 1.76	37 CFR 1.53, 37 CFR 1.71 through 1.77, 37 CFR 1.16, 37 CFR 1.81 through 1.84, 37 CFR 1.42, 1.43, 1.47, 37 CFR 1.63 through 1.69
Original New Design Applications - Application Data Sheet	PTO/SB/17, PTO/SB/01A, PTO/SB/14	Fee Transmittal Form, Declaration (37 CFR 1.63) for Utility or Design Application Using an Application Data Sheet (37 CFR 1.76), Application Data Sheet 37 CFR 1.76	37 CFR 1.71 through 1.77, 37 CFR 1.81 through 1.84, 37 CFR 1.42, 1.43, 1.47, 37 CFR 1.53, 37 CFR 1.63 through 1.69, 37 CFR 1.16
Continuation/Divisional of an International Application - No Application Data Sheet	PTO/SB/101, PTO/SB/103, PTO/SB/104, PTO/SB/02A and PTO/SB/02B, PTO/SB/108, PTO/SB/13/PCT, PTO/SB/107, PTO/SB/04, PTO/SB/01, PTO/SB/102, PTO/SB/106, PTO/SB/110, PTO/SB/02LR, PTO/SB/105, PTO/SB/109	Declaration and Power of Attorney for Patent Application - Chinese Language Declaration, Declaration and Power of Attorney for Patent Application, Declaration and Power of Attorney for Patent Application - Italian Language Declaration, Declaration - Additional Inventors-Supplemental Sheet and Declaration - Supplemental Priority Data Sheet, Declaration and Power of Attorney for Patent Application - Swedish Language Declaration, Request for Filing a Continuation or Division of an International Application, Declaration and Power of Attorney for Patent Application - Russian Language Declaration, Supplemental Declaration for Utility or Design Patent Application (37 CFR 1.67), Declaration for Utility or Design Patent Application (37 CFR 1.63), Declaration and Power of Attorney for Patent Application, Declaration and Power of Attorney for Patent Application - Japanese Language Declaration, Declaration	37 CFR 1.53, 37 CFR 1.71 through 1.77, 37 CFR 1.81 through 1.84, 37 CFR 1.42, 1.43, 1.47, 37 CFR 1.63 through 1.69, 37 CFR 1.16

List of ICs

IC Title	Form No.	Form Name	CFR Citation
		and Power of Attorney for Patent Application - Korean Language Declaration, Declaration Supplemental Sheet for Legal Representatives (35 U.S.C. 117) on Behalf of a Deceased or Incapacitated Inventor, Declaration and Power of Attorney for Patent Application - French Language Declaration, Declaration and Power of Attorney for Patent Application - Spanish Language Declaration	
Utility Continuation/Divisional Applications	PTO/SB/17, PTO/SB/05	Fee Transmittal Form, Utility Patent Application Transmittal	37 CFR 1.71 through 1.77, 37 CFR 1.81 through 1.84, 37 CFR 1.42, 1.43, 1.47, 37 CFR 1.53, 37 CFR 1.63 through 1.69, 37 CFR 1.16
Plant Continuation/Divisional Applications	PTO/SB/19, PTO/SB/17	Plant Patent Application Transmittal, Fee Transmittal Form	37 CFR 1.71 through 1.77, 37 CFR 1.81 through 1.84, 37 CFR 1.42, 1.43, 1.47, 37 CFR 1.63 through 1.69, 37 CFR 1.53, 37 CFR 1.16
Design Continuation/Divisional Applications	PTO/SB/18, PTO/SB/17	Design Patent Application Transmittal, Fee Transmittal Form	37 CFR 1.53, 37 CFR 1.71 through 1.77, 37 CFR 1.81 through 1.84, 37 CFR 1.42, 1.43, 1.47, 37 CFR 1.63 through 1.69, 37 CFR 1.16
Utility Continuation-in-Part Applications	PTO/SB/104, PTO/SB/105, PTO/SB/106, PTO/SB/02A and PTO/SB/02B, PTO/SB/01, PTO/SB/04, PTO/SB/108, PTO/SB/109, PTO/SB/02LR, PTO/SB/102, PTO/SB/103, PTO/SB/101, PTO/SB/107, PTO/SB/110, PTO/SB/05, PTO/SB/17	Declaration and Power of Attorney for Patent Application, Declaration and Power of Attorney for Patent Application, Declaration and Power of Attorney for Patent Application - Japanese Language Declaration, Declaration - Additional Inventors - Supplemental Sheet and Declaration - Supplemental Priority Data Sheet, Declaration for Utility or Design Patent Application (37 CFR 1.63), Supplemental Declaration for Utility or Design Patent Application (37 CFR 1.67), Declaration and Power of	37 CFR 1.42, 1.43, 1.47, 37 CFR 1.63 through 1.69, 37 CFR 1.16, 37 CFR 1.71 through 1.77, 37 CFR 1.53, 37 CFR 1.81 through 1.84

List of ICs

IC Title	Form No.	Form Name	CFR Citation
		Attorney for Patent Application, Declaration and Power of Attorney for Patent Application, Declaration Supplemental Sheet for Legal Representatives (35 U.S.C. 117) on Behalf of a Deceased or Incapacitated Inventor, Declaration and Power of Attorney for Patent Application, Declaration and Power of Attorney for Patent Application, Declaration and Power of Attorney for Patent Application - Chinese Language Declaration, Declaration and Power of Attorney for Patent Application - Russian Language Declaration, Declaration and Power of Attorney for Patent Application, Utility Patent Application Transmittal, Fee Transmittal Form	
Plant Continuation-in-Part Applications	PTO/SB/19, PTO/SB/17, PTO/SB/02LR, PTO/SB/03, PTO/SB/02A and PTO/SB/02B	Plant Patent Application Transmittal, Fee Transmittal Form, Declaration Supplemental Sheet for Legal Representatives (35 U.S.C. 117) on Behalf of a Deceased or Incapacitated Inventor, Plant Patent Application (35 U.S.C. 161) Declaration (37 CFR 1.63), Declaration - Additional Inventors - Supplemental Sheet and Declaration - Supplemental Priority Data Sheet	37 CFR 1.53, 37 CFR 1.71 through 1.77, 37 CFR 1.81 through 1.84, 37 CFR 1.42, 1.43, 1.47, 37 CFR 1.63 through 1.69, 37 CFR 1.16
Design Continuation-in-Part Applications	PTO/SB/04, PTO/SB/02LR, PTO/SB/18, PTO/SB/17, PTO/SB/01, PTO/SB/02A and PTO/SB/02B	Supplemental Declaration for Utility or Design Patent Application (37 CFR 1.67), Declaration Supplemental Sheet for Legal Representatives (35 U.S.C. 11) on Behalf of a Deceased or Incapacitated	37 CFR 1.53, 37 CFR 1.71 through 1.77, 37 CFR 1.81 through 1.84, 37 CFR 1.42, 1.43, 1.47, 37 CFR 1.63 through 1.69, 37 CFR 1.16

List of ICs

IC Title	Form No.	Form Name	CFR Citation
		Inventor, Design Patent Application Transmittal, Fee Transmittal Form, Declaration for Utility or Design Patent Application (37 CFR 1.63), Declaration - Additional Inventors - Supplemental Sheet and Declaration - Supplemental Priority Data Sheet	
Provisional Application for Patent Cover Sheet	PTO/SB/16	Provisional Application for Patent Cover Sheet	37 CFR 1.53, 37 CFR 1.71 through 1.77, 37 CFR 1.81 through 1.84, 37 CFR 1.42, 1.43, 1.47, 37 CFR 1.63 through 1.69, 37 CFR 1.16
Petition to Accept Unintentionally Delayed Priority Claim			37 CFR 1.55, 37 CFR 1.78
Petition to Accept Non-Signing Inventors or Legal Representatives/Filing by Other Than All the Inventors or a Person not the Inventor			37 CFR 1.42, 37 CFR 1.43, 37 CFR 1.47
Petition under 37 CFR 1.6(f) to Accord the Application under 37 CFR 1.495(b) a National Stage Entry Date			37 CFR 1.6(f), 37 CFR 1.495(b)
Continued Prosecution Applications - Design (Request Transmittal and Receipt)	PTO/SB/29, PTO/SB/29A	For Design Applications Only: Continued Prosecution Application (CPA) Request Transmittal, For Design Applications Only Receipt for Facsimile Transmitted CPA	37 CFR 1.53(d)

Exhibit H to
Petition to Vacate Examiner's Papers

**Executive Office of the President, *Final Bulletin
for Agency Good Guidance Practices*, OMB
Memorandum M-07-07 (January 18, 2007)**



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

THE DIRECTOR

January 18, 2007

M-07-07

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS
AND AGENCIES

FROM: Rob Portman 

SUBJECT: Issuance of OMB's "Final Bulletin for Agency Good Guidance Practices"

The Office of Management and Budget (OMB) today issued a bulletin applicable to all departments and agencies entitled "Final Bulletin for Agency Good Guidance Practices." This Bulletin establishes policies and procedures for the development, issuance, and use of significant guidance documents by Executive Branch departments and agencies and is intended to increase the quality and transparency of agency guidance practices and the significant guidance documents produced through them.

This Bulletin is one aspect of a larger OMB effort to ensure and maximize the quality, utility, objectivity and integrity of information disseminated by Federal agencies, pursuant to the Information Quality Act.

This Bulletin has benefited from extensive public and agency comments received on a draft released by OMB on November 23, 2005.

If your staff has questions about this guidance, please contact Margaret Malanoski at (202) 395-3122 or Margaret_A_Malanoski@omb.eop.gov.

Attachment

OFFICE OF MANAGEMENT AND BUDGET

Final Bulletin for Agency Good Guidance Practices

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Final Bulletin.

SUMMARY: The Office of Management and Budget (OMB) is publishing a final Bulletin entitled, “Agency Good Guidance Practices,” which establishes policies and procedures for the development, issuance, and use of significant guidance documents by Executive Branch departments and agencies. This Bulletin is intended to increase the quality and transparency of agency guidance practices and the significant guidance documents produced through them.

On November 23, 2005, OMB proposed a draft Bulletin for public comment. 70 Fed. Reg. 71,866 (November 30, 2005). Upon request, OMB extended the public comment period from December 23, 2005 to January 9, 2006. 70 Fed. Reg. 76,333 (December 23, 2005). OMB received 31 comments on the proposal from diverse public and private stakeholders (see http://www.whitehouse.gov/omb/inforeg/good_guid/c-index.html) and input from Federal agencies. The final Bulletin includes refinements developed through the public comment process and interagency deliberations.

DATE: The effective date of this Bulletin is 180 days after its publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Margaret Malanoski, Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, N.W., New Executive Office Building, Room 10202, Washington, DC, 20503. Telephone (202) 395-3122.

SUPPLEMENTARY INFORMATION:

Introduction

As the scope and complexity of regulatory programs have grown, agencies increasingly have relied on guidance documents to inform the public and to provide direction to their staffs. As the impact of guidance documents on the public has grown, so too, has the need for good guidance practices -- clear and consistent agency practices for developing, issuing, and using guidance documents.

OMB is responsible both for promoting good management practices and for overseeing and coordinating the Administration’s regulatory policy. Since early in the

Bush Administration, OMB has been concerned about the proper development and use of agency guidance documents. In its 2002 draft annual Report to Congress on the Costs and Benefits of Regulations, OMB discussed this issue and solicited public comments regarding problematic guidance practices and specific examples of guidance documents in need of reform.¹ OMB has been particularly concerned that agency guidance practices should be more transparent, consistent and accountable. Such concerns also have been raised by other authorities, including Congress and the courts.²

In its 2002 Report to Congress, OMB recognized the enormous value of agency guidance documents in general. Well-designed guidance documents serve many important or even critical functions in regulatory programs.³ Agencies may provide helpful guidance to interpret existing law through an interpretive rule or to clarify how they tentatively will treat or enforce a governing legal norm through a policy statement. Guidance documents, used properly, can channel the discretion of agency employees, increase efficiency, and enhance fairness by providing the public clear notice of the line between permissible and impermissible conduct while ensuring equal treatment of similarly situated parties.

¹ U.S. Office of Management and Budget, Draft Report to Congress on the Costs and Benefits of Federal Regulations, 67 FR 15,014, 15,034-35 (March 28, 2002).

² See, e.g., Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 371(h) (establishing FDA good guidance practices as law); “Food and Drug Administration Modernization and Accountability Act of 1997,” S. Rep. 105-43, at 26 (1997) (raising concerns about public knowledge of, and access to, FDA guidance documents, lack of a systematic process for adoption of guidance documents and for allowing public input, and inconsistency in the use of guidance documents); House Committee on Government Reform, “Non-Binding Legal Effect of Agency Guidance Documents,” H. Rep. 106-1009 (106th Cong., 2d Sess. 2000) (criticizing “back-door” regulation); the Congressional Accountability for Regulatory Information Act, H.R. 3521, 106th Cong., § 4 (2000) (proposing to require agencies to notify the public of the non-binding effect of guidance documents) ; Gen. Elec. Co. v. EPA, 290 F.3d 377 (D.C. Cir. 2002) (striking down PCB risk assessment guidance as legislative rule requiring notice and comment); Appalachian Power Co. v. EPA, 208 F.3d 1015 (D.C. Cir. 2000) (striking down emissions monitoring guidance as legislative rule requiring notice and comment); Chamber of Commerce v. Dep’t of Labor, 174 F.3d 206 (D.C. Cir. 1999) (striking down OSHA Directive as legislative rule requiring notice and comment); Administrative Conference of the United States, Rec. 92-2, 1 C.F.R. 305.92-2 (1992) (agencies should afford the public a fair opportunity to challenge the legality or wisdom of policy statements and to suggest alternative choices); American Bar Association, Annual Report Including Proceedings of the Fifty-Eighth Annual Meeting, August 10-11, 1993, Vol. 118, No. 2, at 57 (“the American Bar Association recommends that: Before an agency adopts a nonlegislative rule that is likely to have a significant impact on the public, the agency provide an opportunity for members of the public to comment on the proposed rule and to recommend alternative policies or interpretations, provided that it is practical to do so; when nonlegislative rules are adopted without prior public participation, immediately following adoption, the agency afford the public an opportunity for post-adoption comment and give notice of this opportunity.”); 3 American Bar Association, “Recommendation on Federal Agency Web Pages” (August 2001) (agencies should maximize the availability and searchability of existing law and policy on their websites and include their governing statutes, rules and regulations, and all important policies, interpretations, and other like matters on which members of the public are likely to request).

³ See U.S. Office of Management and Budget, Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local and Tribal Entities, 72-74 (2002) (hereinafter “2002 Report to Congress”).

Experience has shown, however, that guidance documents also may be poorly designed or improperly implemented. At the same time, guidance documents may not receive the benefit of careful consideration accorded under the procedures for regulatory development and review.⁴ These procedures include: (1) internal agency review by a senior agency official; (2) public participation, including notice and comment under the Administrative Procedure Act (APA); (3) justification for the rule, including a statement of basis and purpose under the APA and various analyses under Executive Order 12866 (as further amended), the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act; (4) interagency review through OMB; (5) Congressional oversight; and (6) judicial review. Because it is procedurally easier to issue guidance documents, there also may be an incentive for regulators to issue guidance documents in lieu of regulations. As the D.C. Circuit observed in Appalachian Power:

The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in regulations. One guidance document may yield another and then another and so on. Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations.⁵

Concern about whether agencies are properly observing the notice-and-comment requirements of the APA has received significant attention. The courts, Congress, and other authorities have emphasized that rules which do not merely interpret existing law or announce tentative policy positions but which establish new policy positions that the agency treats as binding must comply with the APA's notice-and-comment requirements, regardless of how they initially are labeled.⁶ More general concerns also have been raised that agency guidance practices should be better informed and more transparent, fair and accountable.⁷ Poorly designed or misused guidance documents can impose significant costs or limit the freedom of the public. OMB has received comments raising these concerns and providing specific examples in response to its proposed Bulletin,⁸ its 2002

⁴ Id., at 72.

⁵ Appalachian Power, 208 F.3d at 1019.

⁶ See, e.g., Appalachian Power; Gen. Elec. Co.; Chamber of Commerce; House Committee on Government Reform, "Non-Binding Legal Effect of Agency Guidance Documents"; ACUS Rec. 92-2, supra note 2; Robert A. Anthony, "Interpretive Rules, Policy Statements, Guidances, Manuals and the Like – Should Federal Agencies Use Them to Bind the Public?" 41 Duke L.J. 1311 (1992).

⁷ See, e.g., note 2, supra.

⁸ U.S. Office of Management and Budget, "Proposed Bulletin for Good Guidance Practices," 70 FR 76,333

request for comments on problematic guidance⁹ and its other requests for regulatory reform nominations in 2001¹⁰ and 2004.¹¹ This Bulletin and recent amendments to Executive Order 12866 respond to these problems.¹²

This Bulletin on “Agency Good Guidance Practices” sets forth general policies and procedures for developing, issuing and using guidance documents. The purpose of Good Guidance Practices (GGP) is to ensure that guidance documents of Executive Branch departments and agencies are: developed with appropriate review and public participation, accessible and transparent to the public, of high quality, and not improperly treated as legally binding requirements. Moreover, GGP clarify what does and does not constitute a guidance document to provide greater clarity to the public. All offices in an agency should follow these policies and procedures.

There is a strong foundation for establishing standards for the initiation, development, and issuance of guidance documents to raise their quality and transparency. The former Administrative Conference of the United States (ACUS), for example, developed recommendations for the development and use of agency guidance documents.¹³ In 1997, the Food and Drug Administration (FDA) created a guidance document distilling its good guidance practices (GGP).¹⁴ Congress then established certain aspects of the 1997 GGP document as the law in the Food and Drug Administration Modernization Act of 1997 (FDAMA; Public Law No. 105-115).¹⁵ The FDAMA also directed FDA to evaluate the effectiveness of the 1997 GGP document and then to develop and issue regulations specifying FDA’s policies and procedures for the development, issuance, and use of guidance documents. FDA conducted an internal evaluation soliciting FDA employees’ views on the effectiveness of GGP and asking whether FDA employees had received complaints regarding the agency’s development,

(Dec. 23, 2005).

⁹ See note 1, supra.

¹⁰ U.S. Office of Management and Budget, Draft Report to Congress on the Costs and Benefits of Federal Regulations, 66 FR 22,041 (May 2, 2001).

¹¹ U.S. Office of Management and Budget, Draft Report to Congress on the Costs and Benefits of Federal Regulations, 69 FR 7,987 (Feb. 20, 2004); see also U.S. Office of Management and Budget, Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local and Tribal Entities 107-125 (2005).

¹² President Bush recently signed Executive Order 13422, “Further Amendment to Executive Order 12866 on Regulatory Planning and Review.” Among other things, E.O. 13422 addresses the potential need for interagency review of certain significant guidance documents by clarifying OMB’s authority to have advance notice of, and to review, agency guidance documents.

¹³ See, e.g., note 2, supra.

¹⁴ Notice, “The Food and Drug Administration’s Development, Issuance, and Use of Guidance Documents,” 62 FR 8961 (Feb. 27, 1997).

¹⁵ 21 U.S.C. § 371(h).

issuance, and use of guidance documents since the development of GGP. FDA found that its GGP had been beneficial and effective in standardizing the agency's procedures for development, issuance, and use of guidance documents, and that FDA employees had generally been following GGP.¹⁶ FDA then made some changes to its existing procedures to clarify its GGP.¹⁷ The provisions of the FDAMA and FDA's implementing regulations, as well as the ACUS recommendations, informed the development of this government-wide Bulletin.

Legal Authority for this Bulletin

This Bulletin is issued under statutory authority, Executive Order, and OMB's general authorities to oversee and coordinate the rulemaking process. In what is commonly known as the Information Quality Act, Congress directed OMB to issue guidelines to "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, utility, objectivity and integrity of information disseminated by Federal agencies."¹⁸ Moreover, Executive Order 13422, "Further Amendment to Executive Order 12866 on Regulatory Planning and Review," recently clarified OMB's authority to oversee agency guidance documents. As further amended, Executive Order 12866 affirms that "[c]oordinated review of agency rulemaking is necessary to ensure that regulations and guidance documents are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order," and the Order assigns that responsibility to OMB.¹⁹ E.O. 12866 also establishes OMB's Office of Information and Regulatory Affairs as "the repository of expertise concerning regulatory issues, including methodologies and procedures that affect more than one agency."²⁰ Finally, OMB has additional authorities to oversee the agencies in the administration of their programs.

The Requirements of the Final Bulletin and Response to Public Comments

A. Overview

¹⁶ See FDA, "Administrative Practices and Procedures; Good Guidance Practices," 65 FR 7321, 7322-23 (proposed Feb. 14, 2000).

¹⁷ 21 C.F.R. § 10.115; 65 FR 56,468 (Sept. 19, 2000).

¹⁸ Pub. L. No. 106-554, § 515(a) (2000). The Information Quality Act was developed as a supplement to the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq., which requires OMB, among other things, to "develop and oversee implementation of policies, principles, standards, and guidelines to -- (1) apply to Federal agency dissemination of public information, regardless of the form or format in which such information is disseminated; and (2) promote public access to public information and fulfill the purposes of this subchapter, including through the effective use of information technology." 44 U.S.C. § 3504(d).

¹⁹ Executive Order 12866, as further amended, § 2(b).

²⁰ Id.

This Bulletin establishes: a definition of a significant guidance document; standard elements for significant guidance documents; practices for developing and using significant guidance documents; requirements for agencies to enable the public to comment on significant guidance documents or request that they be created, reconsidered, modified or rescinded; and ways for making guidance documents available to the public. These requirements should be interpreted and implemented in a manner that, consistent with the goals of improving the quality, accountability and transparency of agency guidance documents, provides sufficient flexibility for agencies to take those actions necessary to accomplish their essential missions.

B. Definitions

Section I provides definitions for the purposes of this Bulletin. Several terms are identical to or based on those in FDA's GGP regulations, 21 C.F.R. § 10.115; the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq.; Executive Order 12866, as further amended; and OMB's Government-wide Information Quality Guidelines, 67 FR 8452 (Feb. 22, 2002).

Section I(1) provides that the term "Administrator" means the Administrator of the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget.

Section I(2) provides that the term "agency" has the same meaning as it has under the Paperwork Reduction Act, 44 U.S.C. § 3502(1), other than those entities considered to be independent agencies, as defined in 44 U.S.C. § 3502(5).

Section I(3) defines the term "guidance document" as an agency statement of general applicability and future effect, other than a regulatory action (as defined in Executive Order 12866, as further amended), that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue. This definition is used to comport with definitions used in Executive Order 12866, as further amended. Nothing in this Bulletin is intended to indicate that a guidance document can impose a legally binding requirement.

Guidance documents often come in a variety of formats and names, including interpretive memoranda, policy statements, guidances, manuals, circulars, memoranda, bulletins, advisories, and the like. Guidance documents include, but are not limited to, agency interpretations or policies that relate to: the design, production, manufacturing, control, remediation, testing, analysis or assessment of products and substances, and the processing, content, and evaluation/approval of submissions or applications, as well as compliance guides. Guidance documents do not include solely scientific research. Although a document that simply summarizes the protocol and conclusions of a specific research project (such as a clinical trial funded by the National Institutes of Health) would not qualify as a guidance document, such research may be the basis of a guidance

document (such as the HHS/USDA “Dietary Guidelines for Americans,” which provides guidance to Americans on what constitutes a healthy diet).

Some commenters raised the concern that the term “guidance document” reflected too narrow a focus on written materials alone. While the final Bulletin adopts the commonly used term “guidance document,” the definition is not limited only to written guidance materials and should not be so construed. OMB recognizes that agencies are experimenting with offering guidance in new and innovative formats, such as video or audio tapes, or interactive web-based software. The definition of “guidance document” encompasses all guidance materials, regardless of format. It is not the intent of this Bulletin to discourage the development of promising alternative means to offer guidance to the public and regulated entities.

A number of commenters raised concerns that the definition of “significant guidance document” in the proposed Bulletin was too broad in some respects. In particular, the proposed definition included guidance that set forth initial interpretations of statutory and regulatory requirements and changes in interpretation or policy. The definition in the proposed Bulletin was adapted from the definition of “Level 1 guidance documents” in FDA’s GGP regulations.

Upon consideration of the comments, the need for clarity, and the broad application of this Bulletin to diverse agencies, the definition of “significant guidance document” has been changed. Section I(4) defines the term “significant guidance document” as a guidance document disseminated to regulated entities or the general public that may reasonably be anticipated to: (i) Lead to 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; or (ii) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; or (iii) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (iv) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in Executive Order 12866, as further amended. Under the Bulletin, significant guidance documents include interpretive rules of general applicability and statements of general policy that have the effects described in Section I(4)(i) – (iv).

The general definition of “significant guidance document” in the final Bulletin adopts the definition in Executive Order 13422, which recently amended Executive Order 12866 to clarify OMB’s role in overseeing and coordinating significant guidance documents. This definition, in turn, closely tracks the general definition of “significant regulatory action” in E.O. 12866, as further amended. One advantage of this definition is that agencies have years of experience in the regulatory context applying the parallel definition of “significant regulatory action” under E.O. 12866, as further amended. However, a few important changes were made to the definition used in E.O. 12866, as further amended, to make it better suited for guidance. For example, in recognition of the non-binding nature of guidance the words “may reasonably be anticipated to” preface all

four prongs of the “significant guidance document” definition. This prefatory language makes clear that the impacts of guidance often will be more indirect and attenuated than binding legislative rules.

Section I(4) also clarifies what is not a “significant guidance document” under this Bulletin. For purposes of this Bulletin, documents that would not be considered significant guidance documents include: legal advisory opinions for internal Executive Branch use and not for release (such as Department of Justice Office of Legal Counsel opinions); briefs and other positions taken by agencies in investigations, pre-litigation, litigation, or other enforcement proceedings; speeches; editorials; media interviews; press materials; Congressional correspondence; guidances that pertain to a military or foreign affairs function of the United States (other than guidance on procurement or the import or export of non-defense articles and services); grant solicitations; warning letters; case or investigatory letters responding to complaints involving fact-specific determinations; purely internal agency policies; guidances that pertain to the use, operation or control of a government facility; and internal operational guidances directed solely to other federal agencies (including Office of Personnel Management personnel issuances, General Services Administration Federal Travel Regulation bulletins, and most of the National Archives and Records Administration’s records management bulletins). The Bulletin also exempts speeches of agency officials.

Information collections, discretionary grant application packages, and compliance monitoring reports also are not significant guidance documents. Though the Bulletin does not cover guidance documents that pertain to the use, operation, or control of a Federal facility, it does cover generally applicable instructions to contractors. Section I(4) also provides that an agency head, in consultation and concurrence with the OIRA Administrator, may exempt one or more categories of significant guidance documents from the requirements of the Bulletin.

The definition of guidance document covers agency statements of “general applicability” and “future effect,” and accordingly, the Bulletin does not cover documents that result from an adjudicative decision. We construe “future effects” as intended (and likely beneficial) impacts due to voluntary compliance with a guidance document. Moreover, since a significant guidance document is an agency statement of “general applicability,” correspondence such as opinion letters or letters of interpretation prepared for or in response to an inquiry from an individual person or entity would not be considered a significant guidance document, unless the correspondence is reasonably anticipated to have precedential effect and a substantial impact on regulated entities or the public. Thus, this Bulletin should not inhibit the beneficial practice of agencies providing informal guidance to help specific parties. If the agency compiles and publishes informal determinations to provide guidance to, and with a substantial impact on, regulated industries, then this Bulletin would apply. Guidance documents are considered “significant” when they have a broad and substantial impact on regulated entities, the public or other Federal agencies. For example, a guidance document that had a substantial impact on another Federal agency, by interfering with its ability to carry out

its mission or imposing substantial burdens, would be significant under Section I(4)(ii) and perhaps could trigger Section I(5) as well.

In general, guidance documents that concern routine matters would not be “significant.” Among an agency’s internal guidance documents, there are many categories that would not constitute significant guidance documents. There is a broad category of documents that may describe the agency’s day-to-day business. Though such documents might be of interest to the public, they do not fall within the definition of significant guidance documents for the purposes of this Bulletin. More generally, there are internal guidance documents that bind agency employees with respect to matters that do not directly or substantially impact regulated entities. For example, an agency may issue guidance to field offices directing them to maintain electronic data files of complaints regarding regulated entities.

Section I(5) states that the term “economically significant guidance document” means a significant guidance document that “may reasonably be anticipated to lead to” an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy or a sector of the economy. The relevant economic impacts include those that may be imposed by Federal agencies, state, or local governments, or foreign governments that affect the U.S. economy, as well as impacts that could arise from private sector conduct. The definition of economically significant guidance document tracks only the part of the definition of significant guidance document in Section I(4)(i) related to substantial economic impacts. This clarifies that the definition of “economically significant guidance document” includes only a relatively narrow category of significant guidance documents. This definition enables agencies to determine which interpretive rules of general applicability or statements of general policy might be so consequential as to merit advance notice-and-comment and a response-to-comments document – and which do not. Accordingly, the definition of economically significant guidance document includes economic impacts that rise to \$100 million in any one year or adversely affect the economy or a sector of the economy.

The definition of economically significant guidance document also departs in other ways from the language describing an economically significant regulatory action in Section 3(f)(1) of E.O. 12866, as further amended. A number of commenters on the proposed Bulletin raised questions about how a guidance document – which is not legally binding -- could have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy or a sector of the economy. As other commenters recognized, although guidance may not be legally binding, there are situations in which it may reasonably be anticipated that a guidance document could lead parties to alter their conduct in a manner that would have such an economically significant impact.

Guidance can have coercive effects or lead parties to alter their conduct. For example, under a statute or regulation that would allow a range of actions to be eligible

for a permit or other desired agency action, a guidance document might specify fast track treatment for a particular narrow form of behavior but subject other behavior to a burdensome application process with an uncertain likelihood of success. Even if not legally binding, such guidance could affect behavior in a way that might lead to an economically significant impact. Similarly, an agency might make a pronouncement about the conditions under which it believes a particular substance or product is unsafe. While not legally binding, such a statement could reasonably be anticipated to lead to changes in behavior by the private sector or governmental authorities such that it would lead to a significant economic effect. Unless the guidance document is exempted due to an emergency or other appropriate consideration, the agency should observe the notice-and-comment procedures of § IV.

In recognition of the non-binding nature of guidance documents, the Bulletin's definition of economically significant guidance document differs in key respects from the definition of an economically significant regulatory action in § 3(f)(1) of E.O. 12866, as further amended. First, as described above, the words "may reasonably be anticipated to" are included in the definition. Second, the definition of economically significant guidance document contemplates that the guidance document could "lead to" (as opposed to "have") an economically significant effect. This language makes clear that the impacts of guidance documents often will be more indirect and dependent on third-party decisions and conduct than is the case with binding legislative rules. This language also reflects a recognition that, as various commenters noted, guidance documents often will not be amenable to formal economic analysis of the kind that is prepared for an economically significant regulatory action. Accordingly, this Bulletin does not require agencies to conduct a formal regulatory impact analysis to guide their judgments about whether a guidance document is economically significant.

The definition of "economically significant guidance document" excludes guidance documents on Federal expenditures and receipts. Therefore, guidance documents on Federal budget expenditures (e.g., entitlement programs) and taxes (the administration or collection of taxes, tax credits, or duties) are not subject to the requirements for notice and comment and a response to comments document in § IV. However, if such guidance documents are "significant," then they are subject to the other requirements of this Bulletin, including the transparency and approval provisions.

Section I(6) states that the term "disseminated" means prepared by the agency and distributed to the public or regulated entities. Dissemination does not include distribution limited to government employees; intra- or interagency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law.²¹

²¹ See U.S. Office of Management and Budget's Government-wide Information Quality Guidelines, 67 FR 8452, 8454, 8460 (Feb. 22, 2002).

Consistent with Executive Order 12866, as further amended, Section I(7) defines the term “regulatory action” as any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final regulation, including notices of inquiry, advance notices of inquiry and notices of proposed rulemaking.

Section I(8) defines the term “regulation,” consistent with Executive Order 12866, as further amended, as an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.

C. Basic Agency Standards

Section II describes basic agency standards for significant guidance documents.

1. Agency Approval Procedures

Section II(1)(a) directs each agency to develop or have written procedures for the internal clearance of significant guidance documents no later than the effective date of this Bulletin. Those procedures should ensure that issuance of significant guidance documents is approved by appropriate agency officials. Currently at FDA the Director in a Center or an Office of Regulatory Affairs equivalent or higher approves a significant guidance document before it is distributed to the public in draft or final form. Depending on the nature of specific agency guidance documents, these procedures may require approval or concurrence by other components within an agency. For example, if guidance is provided on compliance with an agency regulation, we would anticipate that the agency’s approval procedures would ensure appropriate coordination with other agency components that have a stake in the regulation’s implementation, such as the General Counsel’s office and the component responsible for development and issuance of the regulation.

Section II(1)(b) states that agency employees should not depart from significant agency guidance documents without appropriate justification and supervisory concurrence. It is not the intent of this Bulletin to inhibit the flexibility needed by agency officials to depart appropriately from significant guidance documents by rigidly requiring concurrence only by very high-level officials. Section II(1)(a) also is not intended to bind an agency to exercise its discretion only in accordance with a general policy where the agency is within the range of discretion contemplated by the significant guidance document.

Agencies are to follow GGP when providing important policy direction on a broad scale. This includes when an agency communicates, informally or indirectly, new or different regulatory expectations to a broad public audience for the first time, including

regulatory expectations different from guidance issued prior to this Bulletin.²² This does not limit the agency’s ability to respond to questions as to how an established policy applies to a specific situation or to answer questions about areas that may lack established policy (although such questions may signal the need to develop guidance in that area). This requirement also does not apply to positions taken by agencies in litigation, pre-litigation, or investigations, or in any way affect their authority to communicate their views in court or other enforcement proceedings. This requirement also is not intended to restrict the authority of agency General Counsels or the Department of Justice Office of Legal Counsel to provide legal interpretations of statutory and regulatory requirements.

Agencies also should ensure consistent application of GGP. Employees involved in the development, issuance, or application of significant guidance documents should be trained regarding the agency's GGP, particularly the principles of Section II(2). In addition, agency offices should monitor the development, issuance and use of significant guidance documents to ensure that employees are following GGP.

2. Standard Elements

Section II(2) establishes basic requirements for significant guidance documents. They must: (i) Include the term “guidance” or its functional equivalent; (ii) Identify the agency(ies) or office(s) issuing the document; (iii) Identify the activity to which and the persons to whom the document applies; (iv) Include the date of issuance; (v) Note if it is a revision to a previously issued guidance document and, if so, identify the guidance that it replaces; (vi) Provide the title of the guidance and any document identification number, if one exists; and (vii) include the citation to the statutory provision or regulation (in Code of Federal Regulations format) which it applies to or interprets.

In implementing this Bulletin, particularly Section II(2)(e), agencies should be diligent to identify for the public whether there is previous guidance on an issue, and, if so, to clarify whether that guidance document is repealed by the new significant guidance document completely, and if not, to specify what provisions in the previous guidance document remain in effect. Superseded guidance documents that remain available for historical purposes should be stamped or otherwise prominently identified as superseded. Draft significant guidance documents that are being made available for pre-adoption notice and comment should include a prominent “draft” notation. As existing significant guidance documents are revised, they should be updated to comply with this Bulletin.

Finally, § II(2)(h) clarifies that, given their legally nonbinding nature, significant guidance documents should not include mandatory language such as “shall,” “must,”

²² See FDA’s Good Guidance Practices, 21 C.F.R. § 10.115(e): “*Can FDA use means other than a guidance document to communicate new agency policy or a new regulatory approach to a broad public audience?* The agency must not use documents or other means of communication that are excluded from the definition of guidance document to informally communicate new or different regulatory expectations to a broad public audience for the first time. These GGP’s must be followed whenever regulatory expectations that are not readily apparent from the statute or regulations are first communicated to a broad public audience.”

“required” or “requirement,” unless the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose consideration by the agency of positions advanced by affected private parties.²³ For example, a guidance document may explain how the agency believes a statute or regulation applies to certain regulated activities. Before a significant guidance document is issued or revised, it should be reviewed to ensure that improper mandatory language has not been used. As some commenters noted, while a guidance document cannot legally bind, agencies can appropriately bind their employees to abide by agency policy as a matter of their supervisory powers over such employees without undertaking pre-adoption notice and comment rulemaking. As a practical matter, agencies also may describe laws of nature, scientific principles, and technical requirements in mandatory terms so long as it is clear that the guidance document itself does not impose legally enforceable rights or obligations.

A significant guidance document should aim to communicate effectively to the public about the legal effect of the guidance and the consequences for the public of adopting an alternative approach. For example, a significant guidance document could be captioned with the following disclaimer under appropriate circumstances:

“This [draft] guidance, [when finalized, will] represent[s] the [Agency’s] current thinking on this topic. It does not create or confer any rights for or on any person or operate to bind the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach (you are not required to do so), you may contact the [Agency] staff responsible for implementing this guidance. If you cannot identify the appropriate [Agency] staff, call the appropriate number listed on the title page of this guidance.”

When an agency determines it would be appropriate, the agency should use this or a similar disclaimer. Agency staff should similarly describe the legal effect of significant guidance documents when speaking to the public about them.

D. Public Access and Feedback

Section III describes public access procedures related to the development and issuance of significant guidance documents.

1. Internet Access

²³ As the courts have held, see supra note 2, agencies need to follow statutory rulemaking requirements, such as those of the APA, to issue documents with legally binding effect, i.e., legislative rules. One benefit of GGP for an agency is that the agency’s review process will help to identify any draft guidance documents that instead should be promulgated through the rulemaking process.

Section III directs agencies to ensure that information about the existence of significant guidance documents and the significant guidance documents themselves are made available to the public in electronic form. Section III(1) enables the public to obtain from an agency's website a list of all of an agency's significant guidance documents. Under § III(1)(a), agencies will maintain a current electronic list of all significant guidance documents on their websites in a manner consistent with OMB policies for agency public websites and information dissemination.²⁴ To assist the public in locating such electronic lists, they should be maintained on an agency's website – or as a link on an agency's website to the electronic list posted on a component or subagency's website – in a quickly and easily identifiable manner (e.g., as part of or in close visual proximity to the agency's list of regulations and proposed regulations). New documents will be added to this list within 30 days from the date of issuance. The agency list of significant guidance documents will include: the name of the significant guidance document, any docket number, and issuance and revision dates. As agencies develop or revise significant guidance documents, they should organize and catalogue their significant guidance documents to ensure users can easily browse, search for, and retrieve significant guidance documents on their websites.

The agency shall provide a link from the list to each significant guidance document (including any appendices or attachments) that currently is in effect. Many recently issued guidance documents have been made available on the Internet, but there are some documents that are not now available in this way. Agencies should begin posting those significant guidance documents on their websites with the goal of making all of their significant guidance documents currently in effect publicly available on their websites by the effective date of this Bulletin.²⁵ Other requirements of this Bulletin, such as § II(2) (Standard Elements), apply only to significant guidance documents issued or amended after the effective date of the Bulletin. For such significant guidance documents (including economically significant guidance documents), agencies should provide, to the extent appropriate and feasible, a website link from the significant guidance document to the public comments filed on it. This would enable interested stakeholders and the general public to understand the various viewpoints on the significant guidance documents.

Under § III(1)(b), the significant guidance list will identify those significant guidance documents that were issued, revised or withdrawn within the past year. Agencies are encouraged, to the extent appropriate and feasible, to offer a listserve or

²⁴ U.S. Office of Management and Budget, Memorandum M-05-04, "Policies for Federal Agency Public Websites" (Dec. 17, 2004), available at: <http://www.whitehouse.gov/omb/memoranda/fy2005/m05-04.pdf>; U.S. Office of Management and Budget, Memorandum M-06-02, "Improving Public Access to and Dissemination of Government Information and Using the Federal Enterprise Architecture Data Reference Model" (Dec. 16, 2005), available at: <http://www.whitehouse.gov/omb/memoranda/fy2006/m06-02.pdf>

²⁵ In this regard, we note that under the Electronic Freedom of Information Act Amendments of 1996, agencies have been posting on their websites statements of general policy and interpretations of general applicability. See 5 U.S.C. § 552(a)(2).

similar mechanism for members of the public who would like to be notified by email each time an agency issues its annual update of significant guidance documents. To further assist users in better understanding agency guidance and its relationship to current or proposed Federal regulations, agencies also should link their significant guidance document lists to Regulations.gov.²⁶

2. Public Feedback

Section III(2) requires each agency to have adequate procedures for public comments on significant guidance documents and to address complaints regarding the development and use of significant guidance documents. Not later than 180 days from the publication of this Bulletin, each agency shall establish and clearly advertise on its website a means for the public to submit electronically comments on significant guidance documents, and to request electronically that significant guidance documents be issued, reconsidered, modified or rescinded. The public may state their view that specific guidance documents are “significant” or “economically significant” and therefore are subject to the applicable requirements of this Bulletin. At any time, the public also may request that an agency modify or rescind an existing significant guidance document. Such requests should specify why and how the significant guidance document should be rescinded or revised.

Public comments submitted under these procedures on significant guidance documents are for the benefit of the agency, and this Bulletin does not require a formal response to comments (of course, agencies must comply with any applicable statutory requirements to respond, and this Bulletin does not alter those requirements). In some cases, the agency, in consultation with the Administrator of OMB’s Office of Information and Regulatory Affairs, may in its discretion decide to address public comments by updating or altering the significant guidance document.

Although this Bulletin does not require agencies to provide notice and an opportunity for public comment on all significant guidance documents before they are adopted, it is often beneficial for an agency to do so when they determine that it is practical. Pre-adoption notice-and-comment can be most helpful for significant guidance documents that are particularly complex, novel, consequential, or controversial. Agencies also are encouraged to consider observing notice-and-comment procedures for interpretive significant guidance documents that effectively would extend the scope of the jurisdiction the agency will exercise, alter the obligations or liabilities of private parties, or modify the terms under which the agency will grant entitlements. As it does for legislative rules, providing pre-adoption opportunity for comment on significant guidance documents can increase the quality of the guidance and provide for greater public confidence in and acceptance of the ultimate agency judgments. For these reasons, agencies sometimes follow the notice-and-comment procedures of the APA even when doing so is not legally required.²⁷ Of course, where an agency provides for notice and

²⁶ Regulations.gov is available at <http://www.Regulations.gov/fdmspublic/component/main>.

²⁷ For example, in developing its guidelines for self-evaluation of compensation practices regarding systemic compensation discrimination, the Department of Labor provided for pre-adoption notice and

comment before adoption, it need not do so again upon issuance of the significant guidance document.²⁸

Many commenters expressed the desire for a better way to resolve concerns about agency guidance documents and adherence to good guidance practices. To help resolve public concerns over problematic guidance documents, § III(2)(b) requires each agency to designate an office (or offices) to receive and address complaints by the public that the agency is not following the procedures in this Bulletin or is improperly treating a guidance document as a binding requirement. The public also could turn to this office to request that the agency classify a guidance as “significant” or “economically significant” for purposes of this Bulletin. The agency shall provide the name and contact information for the office(s) on its website.

E. Notice and Comment on Economically Significant Guidance Documents

Under § IV, after the agency prepares a draft of an economically significant guidance document, the agency must publish a notice in the **Federal Register** announcing that the draft guidance document is available for comment. In a manner consistent with OMB policies for agency public websites and information dissemination, the agency must post the draft on its website, make it publicly available in hard copy, and ensure that persons with disabilities can reasonably access and comment on the guidance development process.²⁹ If the guidance document is not in a format that permits such electronic posting with reasonable efforts, the agency should notify the public how they can review the guidance document. When inviting public comments on the draft guidance document, the agency will propose a period of time for the receipt of comments and make the comments available to the public for review. The agency also may hold public meetings or workshops on a draft guidance document, or present it for review to an advisory committee or, as required or appropriate, to a peer review committee.³⁰ In some cases, the agency may, in its discretion, seek early public input even before it prepares the draft of an economically significant guidance document. For example, the agency could convene or participate in meetings or workshops.

opportunity for comment. See Office of Federal Contract Compliance Programs, “Guidelines for Self-Evaluation of Compensation Practices for Compliance with Nondiscrimination Requirements of Executive Order 11246 with Respect to Systemic Compensation Discrimination,” 69 FR 67,252 (Nov. 16, 2004).

²⁸ See, e.g., Office of Federal Procurement Policy Act, 41 U.S.C. § 418(b) (providing for pre-adoption notice and comment for procurement policies with a significant effect or cost).

²⁹ Federal agency public websites must be designed to make information and services fully available to individuals with disabilities. For additional information, see: <http://www.access-board.gov/index.htm>; see also Rehabilitation Act, 29 U.S.C. § 701, 794, 794d.

³⁰ See U.S. Office of Management and Budget, “Final Information Quality Bulletin for Peer Review,” 70 FR 2664 (Jan. 14, 2005).

After reviewing comments on a draft, the agency should incorporate suggested changes, when appropriate, into the final version of the economically significant guidance document. The agency then should publish a notice in the **Federal Register** announcing that the significant guidance document is available. The agency must post the significant guidance document on the Internet and make it available in hard copy. The agency also must prepare a robust response-to-comments document and make it publicly available. Though these procedures are similar to APA notice-and-comment requirements, this Bulletin in no way alters (nor is it intended to interpret) the APA requirements for legislative rules under 5 U.S.C. § 553.

Prior to or upon announcing the availability of the draft guidance document, the agency should establish a public docket. Public comments submitted on an economically significant guidance document should be sent to the agency's docket. The comments submitted should identify the docket number on the guidance document (if such a docket number exists), as well as the title of the document. Comments should be available to the public at the docket and, when feasible, on the Internet. Agencies should provide a link on their website from the guidance document to the public comments as well as the response to comments document.

After providing an opportunity for comment, an agency may decide, in its discretion, that it is appropriate to issue another draft of the significant guidance document. The agency may again solicit comment by publishing a notice in the **Federal Register**, posting a draft on the Internet and making the draft available in hard copy. The agency then would proceed to issue a final version of the guidance document in the manner described above. Copies of the **Federal Register** notices of availability should be available on the agency's website. In addition, the response-to-comments document should address the additional comments received on the revised draft.

An agency head, in consultation and concurrence with the OIRA Administrator, may identify a particular significant guidance document or class of guidance documents for which the procedures of this Section are not feasible and appropriate. Under § IV, the agency is not required to seek public comment before it implements an economically significant guidance document if prior public participation is not feasible or appropriate. It may not be feasible or appropriate for an agency to seek public comment before issuing an economically significant guidance document if there is a public health, safety, environmental or other emergency requiring immediate issuance of the guidance document, or there is a statutory requirement or court order that requires immediate issuance. Another type of situation is presented by guidance documents that, while important, are issued in a routine and frequent manner. For example, one commenter raised concerns that the National Weather Service not only frequently reports on weather and air conditions but also gives consumers guidance, such as heat advisories, on the best course of action to take in severe weather conditions. Even if such notices or advisories had an economically significant impact, subjecting them to the notice-and-comment

procedures of Section IV would not be feasible or appropriate. An agency may discuss with OMB other exceptions that are consistent with § IV(2).

Though economically significant guidance documents that fall under the exemption in § IV(2) are not required to undergo the full notice-and-comment procedures, the agency should: (a) publish a notice in the **Federal Register** announcing that the guidance document is available; (b) post the guidance document on the Internet and make it available in hard copy (or notify the public how they can review the guidance document if it is not in a format that permits such electronic posting with reasonable efforts); and (c) seek public comment when it issues or publishes the guidance document. If the agency receives comments on an excepted guidance document, the agency should review those comments and revise the guidance document when appropriate. However, the agency is not required to provide post-promulgation notice-and-comment if such procedures are not feasible or appropriate.

F. Emergencies

In emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow, the agency shall notify OIRA as soon as possible and, to the extent practicable, comply with this Bulletin. For those significant guidance documents that are governed by a statutory or court-imposed deadlines, the agency shall, to the extent practicable, schedule its proceedings so as to permit sufficient time to comply with this Bulletin.

G. Judicial Review

This Bulletin is intended to improve the internal management of the Executive Branch and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.³¹

H. Effective Date

The requirements of this Bulletin shall take effect 180 days after publication in the **Federal Register** except that agencies will have 210 days to comply with requirements for significant guidance documents promulgated on or before the date of publication of this Bulletin.

³¹ The provisions of this Bulletin, and an agency's compliance or noncompliance with the Bulletin's requirements, are not intended to, and should not, alter the deference that agency interpretations of laws and regulations should appropriately be given.

Bulletin for Agency Good Guidance Practices

I. Definitions.

For purposes of this Bulletin—

1. The term “Administrator” means the Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget (OIRA).

2. The term “agency” has the same meaning it has under the Paperwork Reduction Act, 44 U.S.C. § 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. § 3502(5).

3. The term “guidance document” means an agency statement of general applicability and future effect, other than a regulatory action (as defined in Executive Order 12866, as further amended, § 3(g)), that sets forth a policy on a statutory, regulatory or technical issue or an interpretation of a statutory or regulatory issue.

4. The term “significant guidance document” --

a. means (as defined in Executive Order 12866, as further amended, § 3(h)) a guidance document disseminated to regulated entities or the general public that may reasonably be anticipated to:

(i) Lead to 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;

(ii) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(iii) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(iv) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in Executive Order 12866, as further amended.

b. does not include legal advisory opinions for internal Executive Branch use and not for release (such as Department of Justice Office of Legal Counsel opinions); briefs and other positions taken by agencies in investigations, pre-litigation, litigation, or other enforcement proceedings (nor does this Bulletin in any other way affect an agency’s authority to communicate its views in court or in other enforcement proceedings); speeches; editorials; media interviews; press materials; Congressional correspondence; guidance documents that pertain to a military or foreign affairs function of the United States (other than guidance on procurement or the import or export of non-defense articles and services); grant solicitations; warning letters; case or investigatory letters responding to complaints involving fact-specific determinations; purely internal agency policies; guidance documents that pertain to the use, operation or control of a government facility; internal guidance documents directed solely to other Federal agencies; and any other category of significant guidance documents exempted by an agency head in consultation with the OIRA Administrator.

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

sector of the economy, except that economically significant guidance documents do not include guidance documents on Federal expenditures and receipts.

6. The term “disseminated” means prepared by the agency and distributed to the public or regulated entities. Dissemination does not include distribution limited to government employees; intra- or interagency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar laws.

7. The term “regulatory action” means any substantive action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final regulation, including notices of inquiry, advance notices of inquiry and notices of proposed rulemaking (see Executive Order 12866, as further amended, § 3).

8. The term “regulation” means an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency (see Executive Order 12866, as further amended, § 3).

II. Basic Agency Standards for Significant Guidance Documents.

1. Approval Procedures:

- a. Each agency shall develop or have written procedures for the approval of significant guidance documents. Those procedures shall ensure that the issuance of significant guidance documents is approved by appropriate senior agency officials.
- b. Agency employees should not depart from significant guidance documents without appropriate justification and supervisory concurrence.

2. Standard Elements: Each significant guidance document shall:

- a. Include the term “guidance” or its functional equivalent;
- b. Identify the agenc(ies) or office(s) issuing the document;
- c. Identify the activity to which and the persons to whom the significant guidance document applies;
- d. Include the date of issuance;
- e. Note if it is a revision to a previously issued guidance document and, if so, identify the document that it replaces;
- f. Provide the title of the document, and any document identification number, if one exists;
- g. Include the citation to the statutory provision or regulation (in Code of Federal Regulations format) which it applies to or interprets; and
- h. Not include mandatory language such as “shall,” “must,” “required” or “requirement,” unless the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose agency consideration of positions advanced by affected private parties.

III. Public Access and Feedback for Significant Guidance Documents.

1. Internet Access:

a. Each agency shall maintain on its website -- or as a link on an agency's website to the electronic list posted on a component or subagency's website -- a current list of its significant guidance documents in effect. The list shall include the name of each significant guidance document, any document identification number, and issuance and revision dates. The agency shall provide a link from the current list to each significant guidance document that is in effect. New significant guidance documents and their website links shall be added promptly to this list, no later than 30 days from the date of issuance.

b. The list shall identify significant guidance documents that have been added, revised or withdrawn in the past year.

2. Public Feedback:

a. Each agency shall establish and clearly advertise on its website a means for the public to submit comments electronically on significant guidance documents, and to submit a request electronically for issuance, reconsideration, modification, or rescission of significant guidance documents. Public comments under these procedures are for the benefit of the agency, and no formal response to comments by the agency is required by this Bulletin.

b. Each agency shall designate an office (or offices) to receive and address complaints by the public that the agency is not following the procedures in this Bulletin or is improperly treating a significant guidance document as a binding requirement. The agency shall provide, on its website, the name and contact information for the office(s).

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

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

a. Publish a notice in the **Federal Register** announcing that the draft document is available;

b. Post the draft document on the Internet and make it publicly available in hard copy (or notify the public how they can review the guidance document if it is not in a format that permits such electronic posting with reasonable efforts);

c. Invite public comment on the draft document; and

d. Prepare and post on the agency's website a response-to-comments document.

2. Exemptions: An agency head, in consultation with the OIRA Administrator, may identify a particular economically significant guidance document or category of such documents for which the procedures of this Section are not feasible or appropriate.

V. Emergencies.

In emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow, the agency shall notify OIRA as soon as possible and, to the extent practicable, comply with this Bulletin. For those significant guidance documents that are governed by a statutory or court-imposed deadline, the

agency shall, to the extent practicable, schedule its proceedings so as to permit sufficient time to comply with this Bulletin.

VI. Judicial Review.

This Bulletin is intended to improve the internal management of the Executive Branch and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.

VII. Effective Date.

The requirements of this Bulletin shall take effect 180 days after its publication in the **Federal Register** except that agencies will have 210 days to comply with requirements for significant guidance documents promulgated on or before the date of publication of this Bulletin.