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By Email regulatory_review_comments@uspto.gov

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Re: Improving Regulation and Regulatory Review (Docket No.: PTO–C–2011–0017), 76 Fed. Reg. 15891 (March 22, 2011)[1]

Dear Mr. Oettinger:

I write to comment on several aspects in which the PTO could improve its compliance with regulatory law, and improve its regulations.

As noted in § I.A below, the President instructed the PTO to provide 60 days for comment, not 30. This letter, filed within 60 days (plus weekends) of the Notice requesting comment, should be considered timely.

I. Question 5. How can the Office best encourage public participation in its rule making process? How can the Office best provide a forum for the open exchange of ideas among the Office, the intellectual property community, and the public in general?

A number of law already exist to "encourage public participation" and "provide a forum," however, the PTO's compliance with these laws in the last five years has been very problematic. Compliance with these laws would improve communications, the quality of the PTO's regulatory process, and the cost-benefit ratio of regulations that the PTO adopts.

A. The PTO should provide the full time that the President asks for comment periods, 60 days

Executive Order 13563 asks "To the extent feasible and permitted by law, each agency shall afford the public a meaningful opportunity to comment through the Internet

[1] http://edocket.access.gpo.gov/2011/pdf/2011-6660.pdf

on any proposed regulation, with a comment period that should generally be ***at least 60 days***."

60 days is important. Organizations such as AIPLA and ABA work in working groups. A group needs about a month to assemble ideas and prepare a first draft. Then, internal review periods take over a month. In order to meet the PTO's improperly-imposed 30 day comment period for this Notice, these two organizations materially altered the way they prepared their comments, and likely left out issues that would have been raised had they been able to follow their ordinary procedures.

Other agencies followed the 60-day instruction from the President for their comment periods for developing E.O. 13563 regulatory plans; others extended their original 30-day comment periods to 60 when asked. Even though this is not technically a "proposed regulation," 60 days to think and prepare is, if anything, even more important to the public, because the patent bar is less familiar with regulatory *process* than with patent law. The PTO should have followed the example of sister agencies. It is a sad irony that the PTO set a 30-day limit for this particular comment period, an irony that brings the PTO's poor regulatory practices into sharp focus.

B. The Patent Office consistently disregards statutes that require disclosure of facts in the rule making record at the time of a Notice of Proposed Rulemaking

Several laws require the PTO to make available much more data than has been the PTO's habit. Disclosure of all underlying factual information, documents, assumptions, computer models, and analytical methods is not only legally required, but is essential to "encourage public participation in its rule making process," because the public cannot meaningfully comment if the information is not available. The public is less inclined to participate if the public believes that "the fix is in." To "provide a forum for the open exchange of ideas among the Office, the intellectual property community, and the public in general" the PTO must make its underlying data and information available.

This request for comment is fairly typical. It arises out of the following requests by the President and by the Office of Management and Budget:

- Executive Order 13563, Improving Regulation and Regulatory Review, 76 Fed. Reg. 3821 (Jan. 21, 2011)
- President Obama's Memorandum on Regulatory Compliance of January 18, 2011, 76 Fed. Reg. 3825 (Jan. 21, 2011)
- President Obama's Memorandum on Regulatory Flexibility, Small Business, and Job Creation, 76 Fed. reg. 3827 (Jan. 21, 2011)
- Cass Sunstein, Administrator of the Office of Information and Regulatory Affairs, OMB Memorandum M-11-10, Memorandum for the Heads of Executive Departments and Agencies, and of Independent Regulatory Agencies, re Executive Order 13563, "Improving Regulation and Regulatory Review," http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-10.pdf

However, this Notice omits any mention of most of the relevant Presidential and OMB documents, and the five topics set forth in the PTO's notice do not fully cover all the issues that the President and OMB asked the PTO to seek comment about. Thus, the March 22 Notice fails to "best encourage public participation in its rule making process" and does not "best provide a forum for the open exchange of ideas among the Office, the intellectual property community, and the public in general."

This non-disclosure is symptomatic of many recent PTO rulemaking notices. A number of statutes and government-wide regulations require agencies to disclose the bases for their factual assertions at the time of a Notice of Proposed Rulemaking: The PTO seldom complies. For example, the recent Notice of Proposed Rulemaking, *Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals*; 75 Fed. Reg. 69828 (Nov. 15, 2010), the PTO presented several tables of estimated numbers of responses and time per response, but disclosed none of its underlying data assumptions, or analytical methods. I filed a request under the Freedom of Information Act and the PTO's Information Quality Guidelines; the PTO refused to disclose information that I know to be readily available to the PTO. The Office of General Counsel broke the law in failing to supplement the Notice of Proposed Rulemaking.

1. The Administrative Procedure Act requires disclosure

The Administrative Procedure Act has been interpreted by courts to require disclosure. The Third Circuit explained the need for a timely, well-maintained, integral record:[2]

> *In Texaco, Inc. v. Federal Power Commission,* 412 F.2d 740, 744 (3d Cir. 1969), we stated that one of the purposes of notice and comment rulemaking "was to give the public the opportunity to participate in the rulemaking process." Other courts have agreed. For example, in *Connecticut Light & Power Co. v. Nuclear Regulatory Commission,* 673 F.2d 525, 530 (D.C. Cir. 1982), the court noted in *dictum* that
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> > the purpose of the comment period is to allow interested members of the public to communicate information, concerns, and criticisms to the agency during the rule-making process.... In order to allow for useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules. To allow an agency to play hunt the peanut with technical information, hiding or disguising the information that it employs, is to condone a practice in which the agency treats what should be a genuine interchange as mere bureaucratic sport. An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary.
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> *See also Home Box Office, Inc. v. FCC,* 567 F.2d 9, 54 (D.C. Cir. 1977) ("[e]ven the possibility that there is here one administrative record for the public and this court and another for the [agency] and those 'in the know' is intolerable"). We believe a regulated party automatically suffers prejudice when members of the public who may submit comments are

[2] *Hanover Potato Prods. v Shalala*, 989 F.2d 123, 130 n.9 (3rd Cir. 1993); *see also Chocolate Mfrs' Ass'n of the U.S. v. Block*, 755 F.2d 1098, 1102-03 (4th Cir. 1985); *National Crushed Stone Ass'n v. EPA*, 601 F.2d 111, 117 (4th Cir. 1979), *reaff'd in relevant part* 643 F.2d 163 (4th Cir. 1981).

denied access to the complete public record.

2. The Paperwork Reduction Act requires disclosure

The Paperwork Reduction Act and regulations promulgated by OMB thereunder provide as follows:

> 44 U.S.C. § 3506(c)(3) With respect to the collection of information and the control of paperwork, each agency shall … certify (***and provide a record supporting such certification***, including public comments received by the agency) that each collection of information submitted to [OMB] for review under § 3507 [meets requirements for objective estimation and "reduces to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency"]

3. The e-Government Act requires disclosure

The e-Government Act of 2002 provides:

> (d) Electronic Docketing.-
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> (1) In general.-To the extent practicable, as determined by the agency in consultation with the Director, agencies shall ensure that a publicly accessible Federal Government website contains electronic dockets for rulemakings under [5 U.S.C. § 553].
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> (2) Information available.-Agency electronic dockets shall make publicly available online to the extent practicable, as determined by the agency in consultation with the Director-
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> (A) all submissions under [5 U.S.C. § 553(c)]; and
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> (B) other materials that by agency rule or practice are included in the rulemaking docket under [5 U.S.C. § 553(c)], whether or not submitted electronically.

4. The Information Quality Act and the PTO's implementing guidelines require disclosure

The Patent Office bound itself to Information Quality Guidelines[3] that require factual representations made in Notices of Proposed Rulemaking to meet requirements for transparency, reproducibility, and objectivity.

5. The PTO has *never* complied with its disclosure obligations concurrently with a Notice of Proposed Rulemaking

The Patent Office consistently neglects these obligations. The public is left largely in the dark as to the Office's basis for its factual assertions. For example, the PTO's most-recent Notice of Proposed Rulemaking (the Ex parte Appeal Rule NPRM of November 2010), and its concurrent submissions to OMB under the Paperwork Reduction Act, were accompanied by no disclosure whatsoever. A thorough analysis

[3] http://www.uspto.gov/web/offices/ac/ido/infoqualityguide.html

of the PTO's neglect of its obligations under the law were discussed in one of the public comment letters.[4]

For example, in the PTO's December 2009 submission to OMB in the Appeal Rule,[5] the PTO states that "The agency believes that it has objective factual support for its estimates." But the PTO does not ***disclose*** the basis for its time estimates. By confessing that the PTO ***has*** "objective factual support" but by refusing to ***produce*** or ***disclose*** that "objective basis," the PTO admitted that it broke the law.

C. Rule making notices and submissions to OMB should fairly and accurately state the public comment, and respond directly

The PTO's habit over 2006-2009 was to recharacterize public comments in Final Rule notices and in submissions to OMB, to respond only to the mischaracterized comment, and to avoid answering the precise issue raised. To consider one example:

- in the proceedings on the Appeal Rule from 2008 to 2009, Dr. Ron Katznelson and I made repeated requests for correction under the Information Quality Act, requesting that the PTO correct its *dissemination* of information in its rule making notices.
- The PTO repeatedly rewrote those comments as if they commented on information *to be collected*.[6]
- Both Dr. Katznelson and I repeatedly drew this error to the PTO's attention, and asked the PTO to respond to the comments that we presented, not as the PTO recharacterized it.

We all make honest mistakes. Honest people correct their honest mistakes when they are pointed out. The PTO's recharacterization of comments is so pervasive (at least during 2006-09) and the PTO is so resistant to correcting its mistakes, that it seems impossible to attribute the error to honest mistake. The mischaracterization appears to be an intentional effort to mislead OMB and the Small Business Administration in their review of PTO regulatory actions. Both OMB and SBA-Advocacy are *ex parte* tribunals. The PTO is reminded of Virginia State Bar Ethical Rule 3.3(c),[7] which requires the PTO to fairly present public comments to OMB and SBA in reviews under Executive Order 12,866, the Paperwork Reduction Act, and the Regulatory Flexibility Act.

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[4] http://www.uspto.gov/ip/boards/bpai/procedures/rules/rule_comment_nov2010_belzer.pdf

[5] Supporting Statement for Appeal Rule, 0651-0063, December 4, 2009, at http://www.reginfo.gov/public/do/DownloadDocument?documentID=89627&version=2 at page

[6] See, e.g., PTO's Supporting Statement to OMB, 0651-0063, Dec. 4, 2009, at http://www.reginfo.gov/public/do/DownloadDocument?documentID=89627&version=2 at pages 11-12.

[7] http://www.vsb.org/pro-guidelines/index.php/rules/advocate/rule3-3/

II. Question 1. What is the best way for the office to identify which of its significant regulations should be modified, streamlined, expanded, or repealed? What process should the Office use to select rules for review and how should it prioritize such review?

One good place to start is to take the Paperwork Reduction Act, Regulatory Flexibility Act, and Executive Order 12,866 seriously. All three require the PTO to evaluate its rules for effect on the public, objectively estimate the economic effects and burdens, and to regulate accordingly.

The PTO continues to violate these requirements, by providing only estimates based on "staff" with no underlying data, no transparency, and no ability to reproduce the PTO's estimates.

III. Question 2. What can the Office, relative to its regulation process, do to reduce burdens and maintain flexibility for the public while promoting its missions?

A. Compliance with rule making procedure

The PTO could sharply reduce its regulatory cost by simply following existing law governing agency rule making. The PTO's compliance with basic rule making law was shockingly poor from 2006-2009. Though it has improved somewhat in 2010, it is far below the standard that, for example, the PTO requires of applicants.

1. A rule-making time line

To give the PTO the benefit of doubt, we assume that the PTO's 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 distinguishing intent from incompetence in the event of future breaches, here is a synopsis of 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.

0. Some agencies can promulgate rules through adjudication (for example, the NLRB), some cannot. 35 U.S.C. § 2(b)(2)(B) places the PTO in the latter category. When the PTO wants to bind the public or impose additional Paperwork burden, the PTO must use rulemaking procedure. The PTO may not promulgate rules through decisions of the Board of Patent Appeals,[8] through Decisions of the Petitions Office, through memoranda to the examining corps, or by publication in the MPEP.

[8] The current attempt to revise restriction practice through the Love and Bahr memoranda, and through *Ex parte DeGrado*, 10/801,951, request for briefing (BPAI May 9, 2011), are all illegal.

1. When the PTO begins to develop a rule, the PTO must file with OMB to put the rule on the "Regulatory Agenda."[9]
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"[10] to evaluate the following:[11]
   (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 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,[12] then the PTO must prepare a Regulatory Impact Analysis under OMB Circular A-4 before the PTO publishes a Notice of Proposed Rulemaking.[13]

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[9] 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).

[10] 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.

[11] 44 U.S.C. § 3506(c)(2) and 5 C.F.R. § 1320.8(d)(1).

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

5. Any rule[14] 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.[15] As part of this submission, the PTO must certify or demonstrate (depending on the setting), and provide a record in support of the certification,[16] that:
   (a) the information to be collected "is necessary for the proper performance of the functions of the agency";[17]
   (b) the agency is not seeking "unnecessarily duplicative" collection of "information otherwise reasonably accessible to the agency";[18]
   (c) the agency "has taken every reasonable step to ensure that the proposed collection of information … is the least burdensome necessary";[19] and
   (d) the regulations are "written using plain, coherent, and unambiguous terminology."[20]
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

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(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.

[13] Executive Order 12,866 is available at http://www.whitehouse.gov/omb/inforeg/eo12866/ index_eo12866.html. Circular A-4 is at http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf.

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

[15] 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.

[16] 44 U.S.C. § 3506(c)(3) and 5 C.F.R. § 1320.9.

[17] 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…").

[18] 44 U.S.C. § 3506(c)(3)(B) and 5 C.F.R. § 1320.5(d)(1)(ii).

[19] 44 U.S.C. § 3506(c)(2)(A)(iv) and 5 C.F.R. § 1320.5(d)(1)(i).

[20] 44 U.S.C. § 3506(c)(3)(D) and 5 C.F.R. § 1320.9(d).

sector of $100 million per year,[21] then the PTO must prepare an unfunded mandates analysis, before publishing a Notice of Proposed Rulemaking.[22]

(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";[23]

(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."[24] 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.[25]

7. The PTO should "seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation."[26] 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);[27] or

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[21] Adjusted for inflation, relative to 1995.

[22] 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.

[23] 2 U.S.C. § 1535(a).

[24] 2 U.S.C. § 1534(a).

[25] 2 U.S.C. § 1532.

[26] Executive Order 12,866 § 6(a).

[27] *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).

(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;[28] or

(d) an amendment reverses or repeals any previous rule;[29] 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*,[30] then the rule requires notice and comment.

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;[31]

(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;[32]

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[28] 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.

[29] 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).

[30] 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).

[31] 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 dockets for rulemakings under [5 U.S.C. § 553]. … Agency electronic dockets shall make publicly available online …other materials that by agency rule or practice are included in the rulemaking docket under [5 U.S.C. § 553(c)]"); *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.'").

(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;[33]

(z) because information disseminated in a Paperwork Reduction Act submission to OMB (step 5) or a Notice of Proposed Rulemaking (step 8) is "influential" information, the PTO must observe OMB Information Quality Guidelines and the PTO's own Information Quality Guidelines.[34]

9. The PTO must receive comments from the public and from OMB for the required amount of time (usually 30 days under the APA,[35] 60 days for any rule covered by the Paperwork Reduction Act,[36] 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.[37]
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.[38]
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

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[32] 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).

[33] 5 U.S.C. §§ 603 and 605.

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

[35] 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);

[36] 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").

[37] 44 U.S.C. § 3507(d)(4)(D) and 5 C.F.R. § 1320.11(h)(2).

[38] Executive Order 12,866 § 6(b).

a "major rule," the submission must occur at least 60 days before the PTO's proposed effective date.[39]

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.[40] OMB must approve or disapprove the information collections embodied in the rule within 60 days of the submission.[41] 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.[42]
15. All rules must be published in some form before the PTO may enforce.[43]
    (a) All rules of general applicability and legal effect must be published in the Code of Federal Regulations.[44]
    (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.[45]
    (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.[46]
    (e) An interpretative rule, or a legislative rule that "recognizes an exemption or relieves a restriction," may take effect immediately on publication.[47]
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;[48]

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[39] 5 U.S.C. § 801–808.

[40] 5 C.F.R. § 1320.11(h).

[41] 5 U.S.C. § 3507(b) and § 3507(d)(4).

[42] 5 U.S.C. §§ 604 and 605.

[43] 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).

[44] 44 U.S.C. § 1510, 1 C.F.R. § 8.1.

[45] 5 U.S.C. § 552(a)(1).

[46] 5 U.S.C. § 553(d).

[47] 5 U.S.C. § 553(d)(1) and (2).

(b) The final rule notice must include supporting explanation and factual data sufficient to satisfy *State Farm* criteria for "arbitrary and capricious."[49]

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*.[50] 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, a "robust response to comments document," and inclusion on the PTO's web page listing 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."[51]

2. 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 the full range of costs in consideration of any rule or regulatory action: For example, the PTO has made several attempts to amend restriction rules in recent years, and in each case has failed to account for the full range of costs that would arise. To take restriction as one prototypical example, any modification to restriction practice would require consideration of all the following:

- Attorney fees. For example, in the *Markush* IRFA, the PTO conceded that attorney fees for a divisional are typically over $10,000.[52] The PTO admitted that the *Markush* rule would have required several tens of thousands of additional applications. Yet the PTO certified to the Small Business Administration that the *Markush* rule would have had "no substantial economic impact" and to OMB that the regulatory burdens were essentially zero.
- Burdens on inventors or clients. Often, in the context of restriction requirements, choosing among species requires deep analysis by the client.
- Costs of analyzing information. The Paperwork Reduction Act requires that the PTO include the cost of ***analyzing*** any requirement raised, and *choosing* from among the options.

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[48] 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*.

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

[50] See footnote 30.

[51] Executive Order 12,866 § 5.

[52] 73 Fed.Reg. at 12681 col. 3.

- 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 totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim." *In re Weber*, 580 F.2d 455, 458, 198 USPQ 328, 331 (CCPA 1978). Any revision to restriction practice requires that this loss be accounted for.
- 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.

These costs must be accounted for in any Paperwork Reduction Act, Regulatory Flexibility Act, Executive Order 12,866, or Good Guidance filing.

IV. Question 3. How can the Office ensure that its significant regulations promote innovation and competition in the most effective and least burdensome way? How can these Office regulations be improved to accomplish this?

Again, the answer is simple: follow existing law. The PTO cannot ensure that its regulatory structure is effective and non-burdensome if the PTO continues its pattern of regulating based on naked "belief" of agency staff, when existing law requires the PTO to obtain and use objective information.

The PTO should review all regulations for points at which the PTO violated basic regulatory principles or law:

- a regulation in 37 C.F.R. or the MPEP that exceeds the PTO's statutory authority
- a regulation in the MPEP or other guidance that was promulgated without observance of rule making procedural law
- a regulation that imposes burdens or economic effects that violate the regulatory principles of Executive Order 12866

A. Recent memoranda to examiners demonstrate the PTO's pervasive breach of regulatory processes

To take one example, In April 2007[53] and January 2010,[54] the PTO issued two memoranda substantially amending restriction practice. For example, these two memoranda permitted examiners to restrict on grounds that have no relationship whatsoever to "independence" or "distinctness" of inventions:

- 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.

The PTO violated multiple laws in promulgating these two memoranda:

- The April 2007 memorandum was kept entirely hidden from the public until mid-2009. Agencies violate constitutional due process and 5 U.S.C. § 552 when they promulgate secret rules.
- The PTO violated 5 U.S.C. § 552(a) by never publishing a notice in the Federal Register giving notice of these two memoranda.
- The PTO violated, and continues to violate, its own written standards for effect of memoranda to examiners, by continuing to enforce these memoranda after new versions of the MPEP were published, without incorporating these memoranda into the text. This is a violation of both § 552 of the Administrative Procedure Act and the *Good Guidance Directive*.
- The PTO never followed the requirements of 35 U.S.C. § 2(b)(ii)(B) and 5 U.S.C. § 553 for promulgating rules of this nature.[55]
- The PTO never made any of the analyses or filings required under the Paperwork Reduction Act or Information Quality Rule, and thus the Love and Bahr memoranda were never enforceable.

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

[54] 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

[55] *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).

- These two memoranda both violate § 555 of the Administrative Procedure Act by purporting to permit examiners to restrict without making any showings, by merely inserting boilerplate into form paragraphs, without a "statement of grounds" and "rational connection between the facts found and the choice made."

The process that led to these two memoranda should be reviewed, much as the FAA reviews a plane crash. For the PTO to break this many laws, twice, there must have been multiple failures of the PTO's rule making procedural processes. The PTO should identify where these failures occurred, and create processes to reduce the likelihood of future failure.

B. The PTO imposes unnecessary burdens by refusing to implement *Good Guidance Practices*

In 2007, the Executive Office of the President issued the *Bulletin on Agency Good Guidance Practices*,[56]as an implementing guideline under the Information Quality Act, and OMB's general authorities to oversee and coordinate the rulemaking process. The *Good Guidance Directive* is intended to increase the quality and transparency of agency guidance practices and the significant guidance documents produced through them.

Guidance documents, such as the MPEP and examiner guidelines, are helpful when they interpret existing law through an interpretive rule or clarify how the agency tentatively will treat or enforce a governing legal norm. 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

The Patent Office has not implemented the *Good Guidance Directive*—indeed, in a recent decision[57] on a petition, signed by Robert Bahr (the Acting Assistant Commissioner for Examination Policy), the Office formally refused to implement these instructions from the President.

The *Good Guidance Directive*, and the administrative law that it reminds agencies of and relies on, require as follows:

1. The PTO has only such authority to issue rules that bind applicants as Congress delegated to the PTO (35 U.S.C. § 2 and 3, and similar statutes), and only when the PTO observes the procedural laws that govern rule making, including 5 U.S.C. § 553, 44 U.S.C. § 3501-3518, 5 C.F.R. Part 1320, Executive Order 12,866, and presidential directives issued pursuant thereto. The PTO may not issue regulations that purport to bind the public by slipping them into the MPEP, without full rule making

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[56] 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).

[57] Robert Bahr, Acting Assistant Commissioner for Examination Policy, 10/890,602, Decision on Petition (Nov. 3, 2010).

procedure.. An agency may not rely solely on a guidance document as a statement of law, and may "not[rely on a guidance document to] foreclose agency consideration of positions advanced by affected private parties."[58] The PTO should make clear to all personnel that when an applicant challenges a statement of law in the MPEP or other guidance, the PTO must cite a document that carries force of law if it is to maintain its position.

2. The PTO has plenary authority to issue instructions to its examining personnel, 5 U.S.C. § 301. Once issued, those instructions are binding on examiners, and applicants are entitled to rely on them.[59] The PTO should institute a process for clearing waiver requests, and instruct examiners that they lack authority to carve out personal exceptions to 37 C.F.R. regulations or the MPEP.

3. The PTO should maintain a current list of its significant guidance documents, including the effective status, name, issuance, revision, and withdrawal date, to remove ambiguity as to current status of guidance documents.[60]

4. The PTO should designate an office (or offices) to receive and address complaints that the PTO is not following proper procedures relating to its guidance documents, or is improperly treating a guidance document as a binding requirement. The PTO should provide, on its website, the name and contact information for the office(s).[61]

5. The PTO should review its guidance documents, including the MPEP, to remove any language that implies a binding requirement on applicants.

6. The PTO should provide training to the examining corps regarding the asymmetric binding effect of agency guidance documents such as the MPEP:[62]

- Guidance documents, such as the MPEP, may not asserted as law to adversely effect applicants, or to foreclose agency consideration of positions

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[58] *Good Guidance Directive*, § II(2)(h); *Paralyzed Veterans of America v. West*, 138 F.3d 1434, 1436 (Fed Cir 1998); *Drake v. Honeywell, Inc.*, 797 F.2d 603,607 (8th Cir. l986) ("Being in nature hortatory, rather than mandatory, interpretive rules can never be violated."); *Cubanski v. Heckler*, 781 F.2d 1421, 1426 (9th Cir. 1986) ("an interpretive rule is one issued without delegated legislative power. … Such rules are essentially hortatory and instructional in that they go more 'to what the administrative officer thinks the statute or regulation means.'").

[59] *In re Kaghan*, 387 F.2d 398, 401, 156 USPQ 130, 132 (CCPA 1967) ("we feel that an applicant should be entitled to rely not only on the statutes and Rules of Practice but also on the provisions of the MPEP in the prosecution of his patent application.").

[60] *Good Guidance Directive* § III(1).

[61] *Good Guidance Directive* § III(2)(b).

[62] *Good Guidance Directive* Preamble § C(1)

advanced by affected private parties,[63] except insofar as they restate statutory or regulatory requirements, or fall within the narrow permissible scope for interpretative rules.

- Examiners should not depart from written instructions governing examiner conduct without appropriate justification and supervisory concurrence.[64]

A large fraction of the PTO's backlog arises because applicants have no predictable way to advance an application, because the PTO provides far too little enforcement oversight to ensure compliance with the MPEP. Both the PTO and applicants would be immensely happier with each other, and more efficient, if everyone had a common understanding of the legal effect of guidance documents, and if examiners were informed, unequivocally, that they are obligated to comply, and that PTO management will enforce.

V. Conclusion

Regulations exist to maximize benefit for all parties. The law of regulation is no exception—the PTO, the applicant public, and competitors of patentees can only realize the benefits of PTO regulations if the PTO follows that rule making law.

Sincerely,
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[63] 5 U.S.C. § 552(a); 44 U.S.C. § 3507(a) and § 3512; 5 C.F.R. § 1320.6; *Good Guidance Directive* § II(2)(h).

[64] *Good Guidance Directive* § II(1)(b); *Service v. Dulles*, 354 U.S. 363, 374–76 (1957) (agency action that departed from unpublished agency staff manual was void); *In re Kaghan*, 387 F.2d 398, 401, 156 USPQ 130, 132 (CCPA 1967) ("we feel that an applicant should be entitled to rely not only on the statutes and Rules of Practice but also on the provisions of the MPEP in the prosecution of his patent application.").