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By Email

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Re: Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals (RIN 0651-AC37), 75 Fed. Reg. 69828 (Nov. 15, 2010)

Re: Information Collection Request for Control Number 0651-AC37, ICR Ref. 201010-0651-001 (Nov. 15, 2010)¹

Dear APJ Horner:

I take this opportunity to comment on the Notice of Proposed Rulemaking (NPRM) published on Nov. 15, 2010, and the associated Paperwork Reduction Act Supporting Statement² filed at OMB on November 15, 2010. Also, because PTO's Paperwork Reduction Act ICR filing Ref. No. 200809-0651-003 of December 3, 2009³

¹ http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201010-0651-001

² Supporting Statement, OMB Control Number 0651-0063, RIN 0651-AC37 <http://www.reginfo.gov/public/do/DownloadDocument?documentID=212768&version=0> (Nov. 15, 2010)

³ Supporting Statement, OMB Control Number 0651-0063, Ref. 200809-0651-003 <http://www.reginfo.gov/public/do/DownloadDocument?documentID=89627&version=2> (Dec. 3, 2009)

was not accompanied by public notice or an opportunity to comment and it contains related issues, I comment on that as well.

In general, this NPRM is a welcome change. The *content* of the proposed rule is extremely encouraging, and raises only a few difficulties. This NPRM clearly reflects the PTO's new approach of working collaboratively with applicants.

However, on issues of rule making procedure and administrative practice, this NPRM remains problematic. Again, it is an improvement over its predecessors, but it fails to comply with simple black-and-white steps, and communicates continued resistance to the importance of procedural law. Important laws, including the Administrative Procedure Act, the Regulatory Flexibility Act, the Paperwork Reduction Act, the e-Government Act, and longstanding internal governmental procedures such as Executive Order 12,866, are not properly obeyed. PTO's noncompliance with these laws and procedures has been brought to the Office's attention repeatedly, including in three previous rounds of this precise rule making. Public comments are either silently ignored or recharacterized to avoid being responsive. Facts that require "objective support" and a "record" are asserted based on naked "belief" by the Office. A judgment of the United States District Court for the Eastern District of Virginia relating to the PTO's rule making duties is neither mentioned nor obeyed.

The Board is one place in the Office that has the highest obligation to act as "persons of competent legal knowledge," 35 U.S.C. § 6(a), with full respect for the rule of law, and careful observance of procedure. This NPRM does not live up to that standard. This Notice continues to reflect limited knowledge or respect for established statutory and administrative procedure and requirements for evidentiary support. The skepticism that the PTO has created in the Patent bar over the last six years will not be ameliorated until the PTO and the Board make clear that it respects procedural laws that protect the inventing public as much as it respects those laws that limit the issuance of patents.

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Most of my comments on the rule itself (as opposed to rule making procedure) fall into two general categories:

- Options reduce costs. If the rules provide applicants with multiple options, each applicant will choose the lowest-cost option for the case at hand. Any command-and-control regulation that limits options will increase costs, no matter how well-meaning the PTO may be in choosing a one-size-fits-all procedure or rule.
- Careful observance of procedure reduces costs and improves PTO decision making. Predictable compliance by the PTO with procedural law reduces costs by increasing predictability, which will improve the reliability and quality of all PTO processes. The application of procedural rules only against applicants, and never against examiners, increases costs by creating unpredictability and distrust, and it is arbitrarily unfair.

I. The PTO should permit appeal of less than all claims, without requiring cancellation of non-appealed claims

I genuinely appreciate that proposed Bd. R. 41.31(c) reflects an attempt to pull back from the extreme position that the PTO took in *In re Ghuman*, that rejected claims will be cancelled if not appealed. However, proposed Bd. R. 41.31(c) goes too far in the opposite direction, replacing one command-and-control regulation with another. The proposal for Bd. R. 41.31(c) would significantly increase the paperwork burden and non-burden hour costs of filing an appeal, thus indirectly reducing the expected value of intellectual property and reducing the number of appeals. The Board may intend this latter result, but presumably it does not intend the former. Ironically, for the smaller number of appeals that would still be filed, proposed Bd. R. 41.31(c) would unwittingly increase the burden on the Board, which would have to devote scarce resources to matters that do not necessarily warrant the Board's attention. Instead of reducing the Board's workload, this provision would increase it.

Rather than amending Bd.R. 41.33(c) as proposed, Rule 41.37(c)(1)(vi) should be amended as follows to codify the pre-*Ghuman* status quo, and preserve options (with new text underlined):

(vi) *Grounds of rejection to be reviewed on appeal.* The appeal brief may include a concise statement of each ground of rejection presented for review, which may identify rejections that are not appealed. If this section is omitted, the Board will presume that all

rejections of all claims are appealed. Any grounds of rejection that are pending and rejected but either not identified here as appealed, or identified here as not appealed, such claims will remain pending, rejected, and unaffected by the appeal.

The NPRM suggests that review of all claims is “presumed,” but identifies no procedure for rebutting the presumption. The NPRM states “the proposed rule would require cancellation of any non-appealed claims by filing an amendment.” That’s not a presumption; that’s *Ghuman* by another name. There is no good reason to go this far, when a lower-burden alternative exists, permitting an appellant to leave rejected claims unappealed, as under current law.

Applicants have valid reasons for appealing some claims and not others. For example:

- An appellant may choose to appeal only dependent claims, but leave the independent claim pending during the appeal, so that dependent claims found allowable can be amended into independent form at the conclusion of the appeal
- Unappealed claims may be left pending so that they can be amended to depend on allowable claims at the conclusion of the appeal, once it is clear which claims are allowable and which are not.
- Unappealed claims may be maintained to be pursued in an RCE or divisional at the conclusion of the appeal, hopefully after the Board has decided some issue that is more easily presented in the appeal in some claims than in others
- In each case, leaving claims pending in the application (though rejected and not involved in the appeal), relieves applicants of making choices based on an unforeseeable future, and relieves the Office from taking actions that need not be taken.

Leaving claims unappealed, pending, rejected, and simply *ignored* by the appeal saves work for both appellants and the Board, enabling both to focus on the most important questions.

There are a number of additional problems with any proposal that involve a reduction in options for handling of claims that are rejected but do not support an appeal, especially any proposal that requires or presumes cancellation of claims.

First, PTO rules and Federal Circuit authority have long provided that Board adjudications have no *res judicata* effect.⁴ Proposed Bd. R. 41.31(c) sharply attenuates the protections of that precedent, by requiring the appellant to conclusively accept an adverse effect, when unappealed claims under current law simply stand rejected but subject to all the options for future cure of the rejection.

Second, the NPRM identifies no statute that grants the PTO the authority to cancel claims or deem claims cancelled, or most disturbingly, require cancellation of claims as a *quid pro quo* for exercising the right of review granted by § 134. Canceling claims is “substantive” by any definition. Any rule that would require cancellation of claims would be a “substantive” rule that is beyond the PTO’s authority.⁵ Proposed Bd. R. 41.31(c) is not only unwise, but *ultra vires*.

Third, under the facts that the PTO admits in the Supporting Statement, this rule violates the Paperwork Reduction Act for lack of practical utility.⁶ Neither the NPRM nor the Supporting Statement identify **any** value or efficiency (i.e., “practical utility”) that accrues to either the Office or to appellants from rescinding the existing right to leave some claims pending, rejected, and unappealed. However, the November 2010 Supporting Statement acknowledges that this change would **increase** burden. An increase in burden with no practical utility, particularly when a lower-burden alternative

⁴ “[P]recedent has long supported the right of an applicant to file a continuation application despite an unappealed adverse Board decision, and to have that application examined on the merits.” *In re Kaghan*, 387 F.2d 398, 401, 156 USPQ 130, 132 (1967). “Where the Patent Office has reconsidered its position on patentability in light of new arguments or evidence submitted by the applicant, the Office is not forbidden by principles of preclusion to allow previously rejected claims.” *Abbott Laboratories v. TorPharm Inc.*, 300 F.3d 1367, 1379, 63 USPQ2d 1929, 1936–37 (Fed. Cir. 2002), *citing See In re Craig*, 411 F.2d 1333, 1335–36, 162 USPQ 157, 159 (1969).

⁵ *Cooper Technologies Co. v. Dudas*, 536 F.3d 1330, 1336, 87 USPQ2d 1705, 1709 (Fed. Cir. 2008) (“To comply with § 2(b)(2)(A), a Patent Office rule must be ‘procedural’—*i.e.*, it must ‘govern the conduct of proceedings in the Office.’ ... We have also previously held that 35 U.S.C. § 2(b)(2) does not authorize the Patent Office to issue ‘substantive’ rules.”)

⁶ *Practical utility* is defined in 44 U.S.C. § 3502(11) and 5 C.F.R. § 1320.3(l).

exists and has been part of the PTO's rules for decades, is incompatible with the Paperwork Reduction Act.⁷

Likewise, the NPRM identifies no practical utility to the Board from adjudicating rejections that the appellant does not want to appeal. The Board's resources are conserved if appellants can designate claims that are unappealed, and leave their status unchanged until the appeal is decided. Why should the Board choose to make a larger workload for itself? Options create savings for all parties; removing options creates costs.

This is the position I recommended in my comments on the ANPRM,⁸ a position consistent with case law.⁹ Claims that are rejected and unappealed have long been, and should remain, exactly that: pending, rejected, and unappealed. I identified the benefits and efficiencies of allowing claims to stand pending, rejected, and unappealed, noted the costs and burdens to both the public and to the Office of requiring cancellation before the appeal is complete, and identified documents that disproved many of the factual premises on which any "cancellation" proposal rested. I drew the Office's

⁷ *Dole v. United Steelworkers of America*, 494 U.S. 26, 32 (1990) (under the Paperwork Reduction Act, "Agencies are also required to minimize the burden on the public to the extent practicable. See 44 U.S.C. § 3507(a)(1)"). Agency heads must "certify (and provide a record supporting such certification, including public comments received by the agency) that each collection of information...reduces to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency, including with respect to small entities,..." 44 U.S.C. § 3507(a)(1)(d).

⁸ <http://www.uspto.gov/patents/law/comments/boundy12jan2010.pdf> at pages 4-5. The complete comment letter is incorporated here as Attachment A.

⁹ *In re Dollinger*, 474 F.2d 1027, 1031-32, 177 USPQ 201, 204-05 (CCPA 1973) is one clear example of the PTO's long-standing practice of permitting claims to remain pending, rejected, and not standing for adjudication in the appeal. The PTO's Notice of Dec. 14, 2009, *Procedure for Treating Rejected Claims That Are Not Being Appealed, Request for Comments* misstated a number of material historical facts.

AIPLA's comment states that it relies heavily on the facts that were provided by the PTO in the December 2009 Notice. While AIPLA deserves great respect, its comments are expressly based on influential information disseminated by the PTO that does not satisfy applicable Information Quality requirements of both OMB and PTO. AIPLA's comments based on factual misapprehensions disseminated by the PTO should not be binding on the public.

attention to probable violations of the Office's authority under the Patent Act, the Paperwork Reduction Act, and the Administrative Procedure Act.¹⁰

I am concerned that this rule may be a reincarnation of *In re Ghuman* and the proposal circulated in December 2009.¹¹ In that notice, the PTO acknowledged that it was attempting to regulate solely for its own convenience. In view of this history, the PTO must fully explain how any rule that would require cancellation of claims is a valid exercise of the Office's statutory authority, which of course is limited to procedural rule making.

The Board's rules should maintain the long-standing option to leave some claims pending, rejecting, and unappealed, with no *res judicata* effect.

II. Balances between late new grounds of rejection, remand, and appellants' ability to reply

"New grounds of rejection" are a necessary evil, and have to be permitted in advisory actions, decisions on Pre-Appeals, Examiner's Answers, and in final Board decision. However, the PTO must likewise recognize that "new grounds" arising after a final Action and any time during appeal almost always arise because of deficiencies during § 130/§ 131 examination phase, and inadequate compliance with 37 C.F.R. § 1.104.. It is thus essential that applicants always have a forum for responding to new grounds, irrespective of when during the process they are raised. This is not just a moral obligation, it's a legal one. The Patent Act, 35 U.S.C. § 102, states that grant of a patent is an "entitlement," a property right subject to full Constitutional procedural due process protections.

¹⁰ *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 80 (2d Cir. 2006) (an "agency [proposing to change the *status quo*] must consider reasonably obvious alternatives and, if it rejects those alternatives, it must give reasons for the rejection..."); *Home Box Office Inc. v. Fed Communications Comm'n*, 567 F.2d 9, 35–36 (D.C. Cir. 1977) ("the opportunity to comment is meaningless unless the agency responds to significant points raised by the public.").

¹¹ Procedure for Treating Rejected Claims That Are Not Being Appealed, Request for Comments (no RIN docket number), 74 Fed. Reg. 66097 (Dec. 14, 2009).

Applicants and the Board face similar problems stemming from the same source. Often, the first Action on the merits is extremely vague, merely hinting at some possible ground of rejection, never presenting a full analysis addressing all *prima facie* elements of any specific ground of rejection as required by MPEP Chapter 2100. This makes a substantive, targeted reply impossible. The first *bona fide* consideration of legally required issues may not come until appeal. These problems arise because supervisors generally are unwilling to require examiners to adhere to the procedural instructions to examiners in MPEP Chapter 2100. This problem is exacerbated by the Office's stated policy that an examiner's failure to adhere to Chapter 2100 is neither petitionable nor appealable. A substantial fraction of appeals to the Board would go away if the PTO insisted that examiners adhere to Chapter 2100 except under extraordinary circumstances. The PTO ought to attack the underlying problem that causes the Board to be overwhelmed with cases that should (and could) have been resolved by examiners.

A. Appellants should have the right to submit new evidence, including affidavit evidence, in reply to any "new ground of rejection" raised in the Examiner's Answer or Board decision, while maintaining the appeal

The NPRM proposes to rescind the Supplementary Examiner's Answer of 37 C.F.R. § 41.43. This would be a serious mistake. A Supplementary Answer is the appropriate vehicle for "ensuring that the Board has the benefit of the examiner's final evaluation of the weight and sufficiency of any evidence relied upon by appellants prior to the Board rendering a decision on appeal" (75 Fed. Reg. 69832 at col. 1) while ensuring that applicants have a fair opportunity to get a timely final adjudication.

A Supplementary Answer forces the examiner to reconsider the case—potentially resulting in withdrawal of the rejections, saving effort for the Board and time for the applicant. A good Supplementary Answer may also force the appellant to reconsider the appeal, again saving work for the Board. And for those cases in which a Supplementary Answer reaches the Board, the Board benefits from the analysis in the

Supplementary Answer. Is the Board indirectly expressing no confidence in the quality of Supplementary Answers, proposing to do away with them because they are unhelpful? If so, relieving examiners of the obligation to consider cases more carefully is not the solution; establishing and enforcing high quality standards, and properly rewarding excellence, is far more likely to succeed.

B. Affidavits should be admitted if they tip the balance on any rejection, not only if they dispose of all rejections

37 C.F.R. § 41.33(d)(1), apparently unamended in this NPRM, reads as follows:

(d)(1) An affidavit or other evidence filed after the date of filing an appeal pursuant to § 41.31(a)(1) through (a)(3) and prior to the date of filing a brief pursuant to § 41.37 may be admitted if the examiner determines that the affidavit or other evidence overcomes all rejections under appeal and that a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented has been made.

Affidavits and evidence responding to new grounds should be admitted on the same standard as Federal Rule 401, “any tendency to make the existence of any fact that is of consequence to the determination of the appeal more probable or less probable than it would be without the evidence.” The only information that should not be admissible is information that is either superfluous or irrelevant. Moreover, any information responds to a new ground of rejection raised in the final Action or at any later time must be admissible to ensure that the Board’s procedures are consistent with Constitutional due process requirements.

Why should admissibility be contingent on an examiner’s determination *of a legal issue*? This is an obvious conflict of interest. Such a rule would allow an examiner to exclude an affidavit that is embarrassing to the examiner, demonstrates non- or malfeasance, or simply forces the examiner to do the work of writing a careful reply. The evidence should come in, and the Board should then decide whether the evidence results in allowance.

The PTO has no good ground—certainly none that comports with the Paperwork Reduction Act’s requirement to *minimize* burden on the public—to restrict affidavits to “all or nothing.”

C. The definition of “new ground” stated in the NPRM is incomplete, and should be expanded and corrected in several respects

The definition of “new grounds” given at 75 Fed.Reg. 69838-39 is too narrow in several respects.

First, the proposed guidance on “new ground of rejection” (75 Fed.Reg. at 69838-39) treats many of the cited Federal Circuit cases as if they were decided ad hoc, with no statement of reasons or general rule. The proposed guidance asks individual examiners to “identify the example below that is most analogous to the situation at hand” (75 Fed. Reg. at 69838 col. 3), without giving them any guidance as to *which attributes of the fact pattern* the Federal Circuit considered relevant. However, the Federal Circuit has at least a dozen cases to define the term “new ground of rejection,” often using words like “any” or “always” to make clear that the reasoning of these cases applies broadly. The PTO cannot both adhere to case law and narrowly isolate these fact patterns, as the PTO attempts here. Failure to present the full breadth of the Federal Circuit’s holdings is both contrary to law and counterproductive to the PTO’s goal of efficiently examining applications.

The PTO should comply with the Office of Management and Budget’s government-wide directive on the use of guidance. As OMB makes clear, the purpose of guidance directed to agency personnel is to “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.”¹² It is not to impose regulatory burdens on applicants or alter their substantive rights through some unaccountable back channel. Moreover, the NPRM identifies no reason to deny examiners the clearer guidance and broader categories of “new grounds” given by the Federal Circuit. Keeping examiners

¹² Office of Management and Budget, *Final Bulletin for Agency Good Guidance Practices*, Introduction, OMB Memorandum M-07-07, <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf> at page 2 (Jan. 18, 2007), 72 Fed. Reg. 3432, 3432 col. 3 (Jan. 25, 2007).

in the dark cannot improve the efficiency of patent examination, nor would it reduce the burdens on the Board.

Second, I am puzzled that this NPRM specifically carves out “final rejections under Rule 1.113” and new grounds in decisions of the Board under § 41.50(b) from the definition of “new ground” (75 Fed.Reg. 69838 col. 1). Where the words have a plain meaning, and “the text of the regulation” is the same,¹³ and the regulation addresses the same concerns for administrative due process,¹⁴ the Supreme Court’s *Chevron* jurisprudence leaves the PTO no discretion to define the term “new ground of rejection” contrary to its text, or differently in different contexts, or to carve away procedural protections. The *procedural consequences* of a “new ground of rejection” may differ depending on procedural posture, but the NPRM identifies no canon of regulatory construction that suggests that any different *definition* should apply, and no strand of *Chevron* jurisprudence that leaves the PTO any discretion to even make the attempt to attempt to redefine “new ground of rejection” differently in different contexts. The NPRM’s stated reason has no grounding in any law for construction of a statute or regulation, and thus it invites litigation that ultimately will require the Board to rewrite its rules of practice yet again.

Prosecution can only be closed when “the record reflects the results of a proceeding in the PTO during which the applicant has been afforded an opportunity to bring forth the facts thought necessary to support his or her position.”¹⁵ The Federal Circuit explained in *Hyatt v. Dudas* that the definition of “new ground” that I discuss here was dictated by “the text of the regulation,” and dictated by “the fact that the PTO bears

¹³ *Hyatt v. Dudas*, 551 F.3d 1307, 1313, 89 USPQ2d 1465, 1468 (Fed. Cir. 2008).

¹⁴ *In re Waymouth*, 486 F.2d 1058, 1061, 179 USPQ 627, 629 (CCPA 1973).

¹⁵ *In re Gartside*, 203 F.3d 1305, 1316, 53 USPQ2d 1769, 1774–75 (Fed. Cir. 2000).

the initial burden ... of presenting a *prima facie* case of unpatentability.”¹⁶ The court’s holdings, based on the “text of the regulation”¹⁷ and “administrative due process”¹⁸ leave no room for any attempted carve-out or less-capacious meaning in contexts other than an Examiner’s Answer. The NPRM appears to be an attempt to relitigate issues that have already been decided, repeatedly. Indeed, the NPRM repeats many of the same arguments that the Federal Circuit has called “plainly erroneous and inconsistent with the text of the regulation.”¹⁹

Third, a clear and correct definition of “new ground of rejection” in the context of final rejection and § 41.50(b) is a duty of the Patent Office under the Paperwork Reduction Act.²⁰ Agency rules containing paperwork burdens must be “written using plain, coherent, and unambiguous terminology.” It is especially disturbing that the Board proposes to replace the Federal Circuit’s interpretation of the term “new ground of rejection” with language that is obtuse, illogical, and vague.

Fourth, the NPRM attempts to rewrite case law. The Federal Circuit in *In re De Blauwe*, 736 F.2d 699, 706 n.9, 222 USPQ 191, 197 n.9 (Fed. Cir. 1984) states that where the Office advances “a position or rationale new to the proceedings, an applicant **must** be afforded an opportunity to respond to that position or rationale by submission of contradicting evidence.” The NPRM proposes to decimate this directive: “A ‘position or rationale new to the proceedings’—even if based on evidence previously of record—**may** give rise to a new ground of rejection.” Attempting to rewrite case law reflects

¹⁶ *Hyatt v. Dudas*, 551 F.3d 1307, 1312–13, 89 USPQ2d 1465, 1468–69 (Fed. Cir. 2008) (in the context of “written description,” rejecting the PTO’s contention that “ground of rejection” is limited to “merely the statutory section”).

¹⁷ *Hyatt*, 551 F.3d at 1313, 89 USPQ2d at 1469.

¹⁸ *In re Kronig*, 539 F.2d 1300, 1303, 190 USPQ 425, 426 (CCPA 1976).

¹⁹ *Hyatt v. Dudas*, 551 F.3d 1307, 1312–13, 89 USPQ2d 1465, 1469 (Fed. Cir. 2008).

²⁰ 44 U.S.C. § 3506(c)(3)(D).

poorly on whether the authors of the NPRM possess the “competent legal knowledge” expected of them.

Fifth, the NPRM overlooks the uniform definition of the term “new ground” consistently applied for 25 years’ Federal Circuit case law. Though there are several linguistic formulations, all are essentially the same—*any* change in the reasoning that is large enough to change the replies that are material and relevant is a “new ground of rejection:”

- any “position or rationale new to the proceedings”²¹
- any change in “the precise reason” for the rejection²²
- any change in thrust that changes the way an appellant would react must be accompanied by a fair opportunity to advance that reaction²³

The NPRM attempts to replace this clear, broad test with a handful of pinpoint fact patterns.²⁴

²¹ *In re DeBlauwe*, 736 F.2d 699, 706 n. 9, 222 USPQ 191, 197 n.9 (Fed. Cir. 1984) (interpreting the term “new ground” in 37 C.F.R. § 1.196(b), now § 41.50(b): “Where the board makes a decision advancing a position or rationale new to the proceedings, an applicant must be afforded an opportunity to respond to that position or rationale” to the full extent permitted by the rules relevant to the procedural stage, citing 37 C.F.R. § 1.196(b)); *In re Eynde*, 480 F.2d 1364, 1370–71, 178 USPQ 470, 474 (CCPA 1973) (“We do agree with appellants that where the board advances a position or rationale new to the proceedings... the appellant must be afforded an opportunity to respond to that position or rationale” [to the full extent permitted by the relevant rule]. This court so held in *In re Moore*, [444 F.2d 572, 170 USPQ 260 (CCPA 1971)], and we expressly reaffirm that view. The board’s refusal to consider evidence which responds to such a new rationale is error.”).

²² *Hyatt v. Dudas*, 551 F.3d 1307, 1312–13, 89 USPQ2d 1465, 1468–69 (Fed. Cir. 2008) (“a ‘ground of rejection’ ... is not merely the statutory requirement for patentability that a claim fails to meet but also the precise reason why the claim fails that requirement”).

²³ *In re Kronig*, 539 F.2d 1300, 1302–03, 190 USPQ 425, 426 (CCPA 1976) (“the ultimate criterion of whether a rejection is considered ‘new’ in a decision by the board is whether appellants have had fair opportunity to react to the thrust of the rejection. We agree with this general proposition, for otherwise appellants could be deprived of the administrative due process rights”); *In re Weymouth*, 486 F.2d 1058, 1060–61, 179 USPQ 627, 629 (CCPA 1973) (different rationale for “written description” rejection of the identical claim language, “the bases of their rejections were wholly different, necessitating different responses by appellants” and required “opportunity to provide a different and appropriate response”), *modified on rehearing* 489 F.2d 1297, 180 USPQ 453 (CCPA 1974); *see also In re Carreira*, 532 F.2d 1356, 1360 (CCPA 1976) (Miller, J., concurring)

Fifth, the definition in the PTO's proposed guidance overlooks several broader classes of acts that constitute "new grounds" defined in case law:

- designating a new "particular part relied on" or relying on a "different portion" of a reference, is a new ground of rejection,²⁵ unless the new portion "goes no farther than, and merely elaborates on" the old portion because new facts in the new portion do not relate to the claim.²⁶
- A new reference, even one offered to back up a previous assertion of official notice or "well-known prior art," is always a new ground of rejection.²⁷
- A new reference offered to show "level of skill in the art" or "motivation to modify" or "motivation to combine" is a new ground.²⁸
- A new factual finding or inference, even one drawn from the identical portions of existing references, or a new application of the law to the identical facts, is a new ground of rejection.²⁹

²⁴ *Hyatt v. Dudas*, 551 F.3d 1307, 1312–13, 89 USPQ2d 1465, 1468–69 (Fed. Cir. 2008) (in the context of "written description," rejecting the PTO's contention that "ground of rejection" is limited to "merely the statutory section").

²⁵ *In re Wiechert*, 370 F.2d 927, 933, 152 USPQ 247, 251–52 (CCPA 1967) ("An applicant's attention and response are naturally focused on that portion of the reference which is specifically pointed out by the examiner. ... [W]hen a rejection is factually based on an entirely different portion of an existing reference the appellant should be afforded an opportunity to make a showing of unobviousness vis-à-vis such portion of the reference").

²⁶ *In re DBC*, 545 F.3d 1373, 1382 n.5, 89 USPQ2d 1123, 1130 n.5 (Fed. Cir. 2007) (when a new portion "goes no farther than" the originally cited abstract, the new portion is not a new ground of rejection)

²⁷ *In re Ahlert*, 424 F.2d 1088, 1092 n. 4, 165 USPQ 418, 421 n. 4 (CCPA 1970) (commenting on a new reference to buttress an assertion of official notice, "it is not uncommon for the board itself to cite new references, in which case a new ground of rejection is *always* stated," emphasis added); *but see In re Boon*, 439 F.2d 724, 727, 169 USPQ 231, 234 (CCPA 1971) (exception: a new reference is not a new ground, when (a) the new reference is a standard reference work (like Webster's Dictionary), (b) the fact noticed "plays a minor role," and (c) the applicant has had at least one prior opportunity (apparently before the final action) "to challenge either the correctness of the fact asserted or the notoriety or repute of the reference cited in support of the assertion").

²⁸ *Ex parte Mathur*, Appeal No. 95-4103, <http://des.uspto.gov/Foia/ReterivePdf?system=BPAI&fInm=fd954103> at 7, 9–10, 15–16, 1996 WL 1795838 at *3–4, 6 (BPAI Jun. 26, 1996) (unpublished) (new references offered by the examiner to support "level of skill in the art" but not directly applied, and relied upon by the Board to support "motivation to combine" the original references, were "new grounds of rejection").

- A new finding of fact, supporting position, or rationale is a new ground, even if it is simply offered to buttress a previous analysis or inference.³⁰
- A new application of the law to the facts is a new ground, if the “basic thrust” differs.³¹
- A new claim interpretation is a new ground.³²

Sixth, the guidance promised in the NPRM should expressly caution against several ploys that are regularly practiced by Technology Center Directors and the

²⁹ *In re Kumar*, 418 F.3d 1361, 1368, 76 USPQ2d 1048, 1052 (Fed. Cir. 2005) (“In calculating the overlapping values, the Board found facts not found by the examiner regarding the differences between the prior art and the claimed invention, which in fairness required an opportunity for response.”); *In re Moore*, 444 F.2d 572, 574–75, 170 USPQ 260, 263 (CCPA 1971) (*any* new “finding of a new fact,” even from the same reference, even solely in support of an alternative to the preexisting rationale, requires that the applicant be given an opportunity to respond), *reaffirmed by In re Eynde*, 480 F.2d at 1364, 1370–71, 178 USPQ 470, 474 (CCPA 1973); *In re Meyer*, 599 F.2d 1028, 1031, 202 USPQ 175, 179 (CCPA 1979) (holding that the Board’s § 102 rejection is a “new ground of rejection” even though based on the same art as the examiner’s § 103 rejection).

³⁰ *In re Kumar*, 418 F.3d 1361, 1367–68, 76 USPQ2d 1048, 1051 (Fed. Cir. 2005) (a new calculation applied to a reference is not “simply an additional explanation of the Board’s decision,” it is a new ground of rejection, “the Board found facts not found by the examiner regarding the differences between the prior art and the claimed invention, which in fairness required an opportunity for response”); *In re Waymouth*, 486 F.2d 1058, 1061, 179 USPQ 627, 629 (CCPA 1973) (“merely advanc[ing] ‘an additional reason’ for affirming the examiner” is a “new rejection”), *modified* 489 F.2d 1297, 180 USPQ 453 (CCPA 1974); *Moore*, 444 F.2d at 574–75, 170 USPQ at 263, *reaffirmed by In re Eynde*, 480 F.2d at 1364, 1370–71, 178 USPQ 470, 474 (CCPA 1973).

³¹ *Ex parte Mattel Inc.*, Appeal No. 1999-2373, <http://www.uspto.gov/go/dcom/bpai/decisions/fd992373.pdf> at 13–14, 23–24, 2003 WL 22282332 at *6, *10 (BPAI Oct. 29, 1999) (unpublished) (different analysis of claims 10 and 11, on the same Adachi and Kimura references, is a new ground of rejection); *Ex parte Coe*, Appeal No. 95-4526, <http://www.uspto.gov/go/dcom/bpai/decisions/fd954526.pdf> at 13–14, 16, 1995 WL 1747721 at *5 (BPAI May 28, 1998) (unpublished) (a different analysis of the same two references, Sukiennik and Nosaki, of the same claim, claim 4, is a “new ground of rejection”).

³² *Ex parte American Academy of Science*, remand in Appeal No. 1998-1483, App. Ser. No. 90/003,463, <http://www.uspto.gov/go/dcom/bpai/decisions/rc981483.pdf>, 2003 WL 23014678 at *2 (BPAI Mar. 9, 1999) (unpublished) (“We admit that our introduction of new definitions, while legally correct, has dramatically changed the issues under Section 102 as argued by appellant and the examiner. Therefore, we agree with appellant that the affirmance of the rejections under Section 102 should be designated a new ground of rejection.”).

Petitions Office to deny “premature final rejection” petition decisions. The following examples are within the definition of “new ground:”³³

- A new finding of fact is a new ground, even if designated “official notice”³⁴
- Any position or rationale new to the proceedings is a new ground, even if that new position or rationale is “simply an additional explanation of the Board’s decision,” or a response to an applicant’s argument.³⁵
- An examiner’s silence in an earlier paper can lead to a finding of a “new ground of rejection” if subsequent events make relevant any reply issue that an applicant would have raised had the examiner not been silent.³⁶

³³ *In re Kumar*, 418 F.3d 1361, 1367, 76 USPQ2d 1048, 1051 (Fed. Cir. 2005); *In re Ahlert*, 424 F.2d 1088, 1098, 165 USPQ 418, 421 (CCPA 1970) (newly “found facts ... regarding the differences between the prior art and the claimed invention,” even if cast as “official notice,” “in fairness required an opportunity for response”); *In re Bulina*, 362 F.2d 555, 558–59, 150 USPQ 110, 113 (CCPA 1966). The difference cuts both ways—when a new single-reference § 102 rejection is based on the identical portions of one reference from a multi-reference § 103 combination, that shift is not a “new ground.”

³⁴ *Hyatt v. Dudas*, 551 F.3d 1307, 1312–13, 89 USPQ2d 1465, 1468–69 (Fed. Cir. 2008) (in the context of § 112 ¶ 1 rejections of claims with differing language, rejecting PTO’s contention that “ground of rejection” is limited to the statutory ground, without regard to the facts or reasoning applied); *In re Kumar*, 418 F.3d 1361, 1367, 76 USPQ2d 1048, 1051 (Fed. Cir. 2005) (new inferences drawn from the same art, cast as “official notice,” were nonetheless new grounds).

³⁵ *In re DeBlauwe*, 736 F.2d 699, 705–06, 222 USPQ 191, 196–97 (Fed. Cir. 1984) (when an applicant has argued a point, the examiner and Board are obligated to respond to those arguments, and their new response requires giving an applicant a new opportunity to respond); *In re Kumar*, 418 F.3d 1361, 1367, 76 USPQ2d 1048, 1051–52 (Fed. Cir. 2005) (“Although the PTO argues that the calculations the Board included in its decision were not new evidence, but simply an additional explanation..., these values ... had not previously been identified by the examiner or the Board. Kumar was entitled to respond to these calculations, and the Board committed procedural error in refusing to consider the evidence proffered in response.”); *In re Waymouth*, 486 F.2d 1058, 1061, 179 USPQ 627, 629 (CCPA 1974) (rejecting the PTO’s argument that new grounds are exempt when the Board “merely advanced ‘an additional reason’”—different rationale is a new ground), *modified on rehearing* 489 F.2d 1297, 180 USPQ 453 (CCPA 1974).

³⁶ *Ex parte Mathur*, Appeal No. 95-4103, <http://des.uspto.gov/Foia/RetrievePdf?system=BPAI&fNm=fd954103> at 20–21, 1996 WL 1795838 at *9 (BPAI Jun. 26, 1996) (unpublished) explains as follows:

The examiner did not notify appellants that the arguments premised upon so-called unexpected properties were deficient since they were not supported by objective evidence. As set forth in *In re De Blauwe*, 736 F.2d 699, 705–06, 222 USPQ 191, 197 (Fed. Cir. 1984), if the examiner had previously pointed this out

- The number of claims in an application does not change any threshold for recognizing a “new ground of rejection.” A number of recent petitions decisions have suggested that applications with larger-than-normal numbers of claims lose the protections against “new grounds of rejection.”

Administrative due process requires the PTO to give applicants a fair opportunity to react to the thrust of any new ground³⁷ that should have been raised earlier (37 C.F.R. § 1.104 (examination shall be “complete”) regardless of the time or context in which the examiner’s “new position or rationale” arises. For example, if the examiner introduces the new ground in response to an applicant’s showing that an old ground of rejection is weak or untenable, any shift or buttressing is still a “new ground,” and the applicant must be given full opportunity to reply.³⁸

Notably, the PTO has litigated the test for “new ground” repeatedly, and has lost almost all of these cases. (Even when the PTO wins a “new ground” issue on the facts, the PTO has repeatedly lost on its attempts to advance the legal tests put forth in the Notice.) It’s time for the PTO to accept the judgments of the Federal Circuit, that the plain meaning of the term “new ground of rejection” is far broader than senior PTO staff wants it to be.

to appellants, “appellants would, at least, have had notice and would have had an opportunity to file objective evidence” (footnote omitted). The examiner’s failure to put appellants on notice as to the lack of objective evidence in support of their argument concerning unexpected properties constitutes a second separate reason to denominate our affirmance of the examiner’s decision as a new ground of rejection under 37 C.F.R. § 1.196(b) [now § 41.50(b)].

See also quote from *In re DeBlauwe* in footnote 35.

³⁷ *Kronig*, 539 F.2d at 1303, 190 USPQ at 426.

³⁸ *In re Eynde*, 480 F.2d 1364, 1371, 178 USPQ 470, 475 (CCPA 1973) (even though Board’s new rationale, based on the Eynde patent, was in response to arguments made in the appeal Reply Brief, it was nonetheless a “new ground”), *reaffirmed by Kronig*, 539 F.2d at 1303, 190 USPQ at 427; *Ex parte Kozek*, Appeal No. 95-4678, <http://des.uspto.gov/Foia/RetrievePdf?system=BPAI&fINm=fd954678> at 7–9, 1995 WL 1747751 at *3–4 (BPAI Sep. 16, 1997) (unpublished) (expressly acknowledging that appellant’s argument overcomes the examiner’s stated reasons, but entering a “new ground of rejection” based on a different analysis of the identical references).

D. The middle sentence of proposed § 41.39(a)(2) should be removed because it appears to limit new ground of rejection, not emphasize a particular example among many

Proposed 37 C.F.R. § 41.39(a)(2) should be amended as follows:

~~(2) An examiner's answer may include a new ground of rejection. For purposes of the examiner's answer, any rejection that relies upon any new evidence not relied upon in the Office action from which the appeal is taken (as modified by any advisory action) shall be designated by the primary examiner as a new ground of rejection. An examiner's answer that includes a new ground of rejection must be approved by the Director.~~

The middle sentence will be interpreted by examiners to imply that *only* a "rejection that relies upon any new evidence not relied upon in the Office action" is a new ground that needs to be designated or approved. To avoid this misunderstanding, the second sentence should be removed to make clear that *any* new ground, under the Federal Circuit's definition I provide in § II.C, requires supervisory approval, and should trigger the rights outlined in § 41.39(b).

I also note that the current version of this rule is freely ignored. In my experience, perhaps a quarter of all Examiners' Answers include "new grounds" with no signature of any supervisory authority, much less the Director. The Rule should make clear that any such Examiner's Answer must be personally signed by the T.C. Director, or whomever is named as the approving official.

E. Rights arising out of new grounds of rejection should not be conditioned on the PTO's "designation"

Both current and proposed Bd. R. 41.39(b) and proposed B.R. 41.50(d) provide appellants with options arising with a new ground of rejection, but the options are conditioned on the PTO "designating" the new ground. These options must attach to the nature of the PTO's action (i.e., whether it meets the definition of "new ground"), not whether the Examiner or the Board designated it as such. Permitting the Examiner or the Board to use arbitrary distinctions of their own choosing to overrule facts destroys the legitimacy of the rule.

First, as I discussed above, in § II.C at page 12, the PTO has had significant difficulty in acknowledging Federal Circuit authority defining the term “new ground of rejection.” For example, in the December 2008 ANPRM, the PTO stated:

Where a newly cited reference is added in the examiner’s answer merely as evidence of the prior statement made by the examiner as to what is “well-known’ in the art which was challenged for the first time in the appeal brief, the citation of the reference in the examiner’s answer would not ordinarily constitute a new ground of rejection within the meaning of Bd.R. 41.39(a)(2) and 41.39(b). 74 Fed.Reg. at 67994 col. 3.

This is incompatible with Federal Circuit law. In *In re Ahlert*, a 1970 case that considered virtually the same facts posed in the ANPRM, the court noted, “it is not uncommon for the board itself to cite new references, in which case a new ground of rejection is **always** stated.”³⁹ Despite this settled case law, the PTO repeated this error three times in the PTO’s 2007 and 2008 Appeals Rule Making notices, and each time I brought the error to the Board’s attention in public comment letters.⁴⁰ I am pleased to note that past erroneous statements of law are absent from this NPRM, the PTO still fails to acknowledge the clear “always” holding of *Ahlert*.

If senior PTO legal staff have difficulty adhering to Federal Circuit precedent, it will be very difficult to expect that examiners will voluntarily limit their own compensation by reading the case law more carefully. Even ironclad regulatory text may not be sufficient, as there are numerous examples (many cited here) in which ironclad regulatory text has been ignored by senior PTO legal staff. A procedural right conditioned on either an examiner’s designation or on the petitions process, when both

³⁹ *In re Ahlert*, 424 F.2d 1088, 1092 n. 4, 165 USPQ 418, 421 n. 4 (CCPA 1970) (emphasis added).

⁴⁰ <http://www.uspto.gov/web/offices/pac/dapp/opla/comments/bpai/boundy.pdf> at Attachment F (pages 75-80); <http://www.reginfo.gov/public/do/DownloadDocument?documentID=87036&version=0> at page 31;

are decided by nonlawyers who lack the legal skills to accurately quote, let alone accurately synthesize, case law, is for all practical purposes no right at all.

The PTO has two choices: present a fair, accurate, and complete synthesis of the law of “new ground of rejection” in guidance, make it applicable in all contexts, and enforce it, or else rescind final rejection practice, and allow free amendment and new evidence on appeal. If the PTO will not honor the half of the compact prosecution bargain that benefits applicants, the PTO should rescind the half of the regulations that encumber applicants.

F. The Board should continue to have the power to remand

Like new grounds, remands are a necessary evil and sometimes the best available remedy for inadequate fact-finding and incomplete examination procedure by the examiner. MPEP §§ 1211, 1211.01, 1211.02. Putting too high a hurdle before the power of a Board panel to remand is, in many cases, incompatible with “secur[ing] the just, speedy, and inexpensive resolution of every proceeding before the Board.” 37 C.F.R. § 41.1(b).

Oftentimes, the examiner's statement of a rejection is insufficient for the Board to decide the matter. Instead, the Board is often forced to develop the record on its own and to base the Decision on Appeal on new grounds.⁴¹ Instead of acting as both inquisitor and primary finder of fact, in a setting where an applicant has almost no ability

⁴¹ *E.g.*, *Ex parte Daleiden*, Appeal 2007-1003, <http://des.uspto.gov/Foia/RetrievePdf?system=BPAI&fNm=fd2007100303-14-2007> at 2, 2007 WL 774805 at 1 (BPAI Mar. 14, 2007) (remanding because examiner failed to respond to arguments in the Appeal Brief); *Ex parte Rozzi*, 63 USPQ2d 1196, 1200-03 (BPAI 2002) (remanding without decision because of a host of examiner omissions and procedural errors); *Ex parte Gambogi*, 62 USPQ2d 1209, 1212 (BPAI 2001) (“We decline to tell an examiner precisely how to set out a rejection.”); *Ex parte Jones*, 62 USPQ2d 1206, 1208 (BPAI 2001) (refusing to adjudicate an issue that the examiner has not developed); *Ex parte Schricker*, 56 USPQ2d 1723, 1725 (BPAI 2000) (“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 1999) (noting that the appeal is “not ripe” because of omissions and defects in the examiner's analysis).

to provide alternative insights or correct errors,⁴² the Board should be permitted to vacate the rejections and to remand the application back to the examiner with instructions that the examiner more fully develop the record.

It is essential to accompany sound procedural rules with effective management incentives. Thus, when the Board issues a remand, the examiner should lose the counts that were granted for Actions that were too incomplete to advance examination. Similarly, examiners should not get additional counts for new grounds of rejection that should have been made earlier. Without these incentives, examiners will continue to shift their examination responsibilities to the Board.⁴³

The Board must retain jurisdiction after vacature so that patent term adjustment protections remain in place. Applicants should not be penalized for incomplete examination. Such errors should never chargeable to the appellant.

Further, a too-strict rule will lead to strategic behavior by APJs. The recent restructuring of Board compensation metrics, which do not give credit for remands, should be sufficient incentive to deter excessive reliance on remand authority. Of course, PTO must monitor how the policy works in practice, as I discuss in § II.H below.

⁴² *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 811, 229 USPQ 478, 479 (1986) (Supreme Court remands for clarification due to the “lack [of] an adequate explanation of the basis for the Court of Appeals’ judgment”—when the underlying decision is procedurally incomplete, fair substantive review is impossible); *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”—vacating 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”).

⁴³ A fair incentive scheme also would reward Examiners when their positions are legitimately affirmed. PTO management should track Examiners’ performance with respect to appeals to identify both extremes: those most in need of remedial training, and those whose performance is exemplary.

G. Instead of limiting remands, the Board should curb its workload by publishing standards for remand requests that will be routinely granted

The Board could remarkably cut down its workload, and improve efficiency of examination, by publishing criteria on which an appeal will be remanded *per se*. The Board has frequently noted that it is stymied when examiners fail to fully state grounds of rejection; appellants find this no less frustrating and inefficient. An appellant that believes that it will be more productive to have an examination by an examiner that is compelled to follow procedure than to wait through the Board's backlog should have a quick option to get that examination. The Board should amend Chapter 1200 of the MPEP to provide that an appeal will be summarily remanded, perhaps as early as before an appeal brief is filed, if an applicant makes a showing of any of the following breaches of examination procedure:

- The obligation to “answer all material traversed” is absolute, and no rejection may be made final, or survive Pre-Appeal, if any material traversed is left unanswered.⁴⁴
- 37 C.F.R. § 1.104(c)(2) has two separate requirements for rejections over prior art: particular parts relied on must be designated “as nearly as practicable,” and (for any § 102 reference that shows anything more than the claim, and for all § 103 rejections) “clearly explain” the pertinence of that prior art. This has several components:
 - All anticipation and obviousness rejections must include a limitation-by-limitation mapping to the prior art.
 - The Office Action must consider each rejected claim limitation-by-limitation. Paragraph-by-paragraph is insufficient.
 - The mapping must identify a specific item in the reference by name or reference numeral. A designation of a chunk of text, in hopes that the applicant can reconstruct the examiner's thinking, is insufficient. (The

⁴⁴ 5 U.S.C. § 555(e) (agency decision must include a “brief statement of grounds”); *Mulloy v United States*, 398 US 410, 418 (1970) (“Since the petitioner presented a nonfrivolous, *prima facie* claim for a change in the [agency decision] based on new factual allegations which were not conclusively refuted by other information in his file, it was an abuse of discretion for the board not to reopen [the decision], thus depriving him of his right to an administrative appeal.”)..

common practice in 3690 and 3710, of designating large chunks (sometimes over a page) is not sufficient.)⁴⁵

- If claim interpretation is an issue, the examiner must acknowledge that the claim interpretation is disputed, state the claim interpretation applied, and supply a reason to show that that interpretation is “reasonable” in light of the factors specified at MPEP § 2112 *et seq.* A mere statement that certain claim language reads on a portion of a reference is not sufficient; the interpretation and comparison steps must be separate and stated expressly.⁴⁶

All anticipation rejections must satisfy this list for final rejection, to forward a Pre-Appeal to the Board, and for an Examiner’s Answer:

- All elements must be shown explicitly or inherently.
 - The burden of proof is on the examiner. If a reference can fairly be read two ways, the reading favoring the applicant is the applicable reading.
 - All reliance on inherency must include “a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art” in compliance with MPEP § 2112.
 - Official notice is never applicable to anticipation.

All obviousness rejections must satisfy this list for final rejection, to forward a Pre-Appeal to the Board, and for an Examiner’s Answer:

- Every obviousness rejection must either use one of the MPEP § 2143 seven rationales, or bear the personal signature of a T.C. Director. Individual examiners do not have authority to depart.
- The Office Action must show that all elements are known or suggested in the art. The examining corps (at least 3690 and 3710) need to be reminded that “suggested” requires some affirmative statement in a reference pointing specifically in the direction of the claim element. Examiner explanation alone is never sufficient to meet a claim limitation (except for “species within disclosed genus” of MPEP § 2144.08).

⁴⁵ Incidentally, the Office would do well to publish Pre-Grant Publications in column and line number format – the paragraph number format has led to a noticeable decline in care and precision in examiners’ consideration of references.

⁴⁶ See *In re Baker Hughes, Inc.*, 215 F.3d 1297, 1301, 55 USPQ2d 1149, 1152 (Fed. Cir. 2000) (“claim construction by the PTO is a question of law that we review *de novo*”); *Ex parte Ogawa*, Appeal No. 95-1628, <http://des.uspto.gov/Foia/ReterivePdf?system=BPAI&fInm=fd951628>, 1997 WL 1897874 at *1 (BPAI Oct. 24, 1997).

- The Office Action must make some showing corresponding to “motivation to combine,” whether that showing is designated “use of known technique to improve similar devices,” “improve similar devices,” “ready for improvement to yield predictable results,” “design need or market pressure,” design incentives or other market forces, or the like—all of the *KSR* tests include some corresponding showing.
- The Office Action must make some showing corresponding to “reasonable expectation of success,” whether that showing is designated “predictable results,” “predictable solutions,” “anticipated success,” “variations [that] are predictable to one of ordinary skill in the art,” or the like—all of the *KSR* tests include some corresponding showing.
- When an applicant makes a request for a reference or affidavit under 37 C.F.R. § 1.104(d)(2), the examiner must come forward with one or the other (or else a showing that the item requested is a legal conclusion rather than a fact). Commonly, at least in 3690 and 3710, examiners either totally ignore such requests, or give a more emphatic and longer explanation based solely on examiner opinion. Neither is permissible.
- All assertions of Official notice must make a showing of “such instant and unquestionable *demonstration* as to defy dispute,” and include “*specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge*. ... The applicant should be *presented with the explicit basis on which the examiner regards the matter as subject to official notice* so as to adequately traverse the rejection.” MPEP § 2144.03(B).
- The reason or rationale must be specific to the references and the claim, not boilerplate like “reduces cost and improves functionality.”
- It is *never* allowable to use the phrase “because it would have been obvious” within an obviousness rejection. The law nowhere authorizes circular reasoning. Obviousness is established by showing all *prima facie* elements: all elements, motivation, success. “Because it would have been obvious” has no place in any Office Action.
- After identifying a claim element that is absent from the art, it is *never* allowable to create it by examiner reasoning, except for the species-within-disclosed-genus test of MPEP § 2144.08. All tests for obviousness require, at the least, that all elements be known.
- “Inherency” is applicable in anticipation, but plays only a limited role in obviousness. “Inherency” may never be relied on to meet direct claim language in an obviousness rejection.

H. Remands by any other name should be curbed

Instead of restricting the Board’s ability to issue remands, the PTO should take a more proactive approach in reviewing and policing individual APJs. An example of possible abuse is discussed below. The following data represents Decisions on Appeal authored⁴⁷ by APJ James D. Thomas in calendar year 2010. These data were retrieved using Westlaw and the BPAI’s own web portal⁴⁸ through December 1, 2010.⁴⁹

These decisions have the following pattern:

	Thomas		BPAI ⁵⁰		Thomas/BPAI
	N	%	N	%	Ratio of Percentages
Affirmed ⁵¹	43	62%	3565	49%	1.3
Affirmed-in-part	0	0%	1044	14%	0.0
“Reversed”	26	38%	2158	30%	1.3
Remands/Other	0	0%	545	8% ⁵²	0.0
Total	69	100%	7312	100%	

In comparison to the overall percentages for all BPAI decisions, APJ Thomas appears to reverse somewhat more frequently than his peers and, unlike his peers, he issues no remands. However, a deeper consideration of APJ Thomas’ decisions tells a very different story.

In only 7 of the 26 Thomas Decisions listed in PAIR as being "BPAI Decision—Examiner Reversed" were the rejections made by the examiner *actually* reversed by

⁴⁷ Decisions that were not authored by APJ Thomas are not included in these data.

⁴⁸ <http://des.uspto.gov/Foia/BPAIReadingRoom.jsp>

⁴⁹ Although the Patent Office is required to publish these Decisions, certain Decisions authored by APJ Thomas in CY2010 have not been published. The data discussed herein only relates to the published Decisions.

⁵⁰ See http://www.uspto.gov/ip/boards/bpai/stats/receipts/fy2010sep_e.jsp.

⁵¹ These includes 3 Decisions on Requests for Rehearings.

⁵² Includes Panel Remands, Administrative Remands, and Dismissed. In CY2010, only 4 Panel Remands were issued.

APJ Thomas. In the other 19 decisions (73%),⁵³ Thomas rendered *no decision on the merits*. His rejections were “reversed pro forma” (a disposition apparently improvised by APJ Thomas) or vacated. In most of these 19, APJ Thomas entered new grounds of rejection and rendered no opinion on the pending rejections.

Of the 19 Decisions in which APJ Thomas raised a new ground of rejection:

- 16 included a rejection under 35 U.S.C. § 101
- 5 of the Decisions included a rejection under 35 U.S.C. § 112 ¶ 2
- 2 included a rejection under 35 U.S.C. § 112 ¶ 1.^{54,55}

Of these 19 applications in which a new ground of rejection was entered, 2 were subsequently allowed, 2 are awaiting examiner action after the amendment, and 12 are in active prosecution. Of the 13 applications in which the examiner’s rejection was vacated but not actually reversed and the examiner issued a new Office Action after Applicant’s amendment, the examiner maintained the art rejections that were the issue on appeal in 11 of those applications.⁵⁶ Therefore, with the exception of only a single instance, the examiners of these applications treated the Decision, in which the examiner was ostensibly “reversed,” as a Panel Remand instead of a reversal.

⁵³ Most of these are not available on the Board’s web page of decisions, they have to be dug out of the file wrappers one by one—it seems these decisions were not run through the normal machinery.

⁵⁴ 4 of the Decisions included multiple new rejections.

⁵⁵ Normally, remands for issues such as 35 U.S.C. § 101 and the second paragraph of 35 U.S.C. § 112 are considered an Administrative Remand and handled by an Administrator and not a full panel of APJs. See, e.g., Appeal No. 2009-2845, in which an Administrative Remand was mailed on April 17, 2009 to have the examiner determine whether claims 1-5 fall within one of the statutory categories recited in 35 U.S.C. § 101; and Appeal No. 2009-012658, in which an Administrative Remand was mailed on April 16, 2010 to have the examiner address issues under 35 U.S.C. § 101 and the second paragraph of 35 U.S.C. § 112.

⁵⁶ In the other 2 applications, Applicants substantively amended the claims in one of the applications, and in the other application, the examiner considered the art rejections to be overcome.

Revising the prior chart based to reflect the actual effect of the decisions rendered by APJ Thomas (instead of how these Decisions were characterized by the APJ in PAIR), yields the following data:

	Thomas		BPAI		Thomas/ BPAI
	N	%	N	%	Ratio of Percentages
Affirmed	43	62%	3565	49%	1.3
Affirmed-in-part	0	0%	1044	14%	0.0
Reversed	10 ⁵⁷	14%	2158	30%	0.5
Remands/Other	16	23%	545	8%	2.9
Total	69	100%	7312	100%	

When APJ Thomas' percentages are compared to the BPAI's averages, we see that Thomas' rate of reversal is not 30% greater than the BPAI average; it is half as great. Instead of issuing no remands at all, APJ Thomas issues remands at almost three times the BPAI's average rate. Because Board members get no credit for remands, APJ Thomas gets production counts by misclassifying remands as "reversed pro forma."

Of the 7,312 appeals disposed of by the Board in FY2010, the Board issued only four decisions formally designated as Panel Remands.⁵⁸ However, APJ Thomas alone has, in effect, issued 16 Panel Remands that were miscategorized as Reversals. As stated in 37 C.F.R. § 41.1(b), the rules associated with the appeal process are intended "to secure the just, speedy, and inexpensive resolution of every proceeding before the Board." The evidence shows, however, that APJ Thomas uses "reverse pro forma" to thwart the intent, if not the letter, of this rule.

⁵⁷ This number reflects the (7) full reversals plus (3) reversals in which a new grounds of rejection was indicated. If these (3) reversals in which new grounds of rejection were indicated are counted as a Remand/Other instead of Reversal, the percentages would be 10% Reversals and 28% Remands/Other.

⁵⁸ See http://www.uspto.gov/ip/boards/bpai/stats/receipts/fy2010sep_e.jsp

In nearly one quarter of the appeals handled by APJ Thomas, Applicants did not receive a decision on the matters presented to the BPAI on appeal. Instead, the issues went unaddressed, and the vast majority of these applicants bear additional costs continuing prosecution on the same issues, and often rebriefing an almost identical appeal to the BPAI. Not only does this violate the spirit and intent of 37 C.F.R. § 41.1(b), these actions violate 5 U.S.C. § 555(b), which requires that "[w]ith due regard for the convenience and necessity of the parties or their representatives and within a reasonable time, each agency shall proceed to conclude a matter presented to it" (emphasis added).

Although these data reflect a single APJ's actions, the type of actions taken by APJ Thomas have been ongoing for at some time.⁵⁹ Moreover, it appears that other APJs are now starting to employ similar techniques.⁶⁰ The Patent Office's goal of minimizing the number of appeals that transfer back-and-forth between the Board and the examiner is to be lauded. However, eliminating the Board's independent authority to remand an application to an examiner has no practical effect when APJs use other designations to achieve the same result as a remand, but without sacrificing production credit. APJ's sidestepped a previous attempt to discourage remands,⁶¹ and they are now sidestepping the latest attempt to rein in the practice by mischaracterizing remands

⁵⁹ See, e.g., Appeal No. 2008-0850, Appln. Ser. No 09/943,061, 2008 WL 3894053 (Aug. 20, 2008).

⁶⁰ See, e.g., Appeal No. 2009-005621 decided November 10, 2010 and authored by Debra Stevens; Appeal No. 2009-003870 decided October 22, 2010 and authored by Eric Grimes; Appeal No. 2009-007332 decided October 5, 2010 and authored by St. John Courtenay III.

⁶¹ See email memo from James T. Moore to all BPAI judges dated May 7, 2009, in which it was stated that remands were considered "not normally efficient mechanisms for securing the 'just, speedy, and inexpensive' resolution of an appeal before the Board" and required approval of the Vice Chief Judge before productivity credit will be provided for such a remand. The memo is reproduced at <http://www.patentlyo.com/patent/2009/05/bpai-shuts-down-dissent-in-favor-of-efficiency.html>

in a manner that *gains* the production credit that a remand designation denies them, but without being candid about it.

As I noted in the previous section regarding examiners, effective management of the Board's scarce resources requires devising incentives that are compatible with the behavior the Director seeks to encourage. If the problem in the past was that APJs issued too many remands—i.e., they failed to adjudicate cases that were ripe—denying them production credits for remands predictably created perverse new incentives. First, as shown above, it encouraged APJs to misclassify the remands they issued in ways that preserved production credits. Second, it may have biased how APJ's applied the law. For example, if the facts of a particular appeal argued for a remand, the prospect of being denied production credit *for the legitimate work involved in reviewing an appeal to reach that conclusion* could lead APJs to find some ground to reverse or affirm in part, thereby permitting a different classification than a self-punitive remand.

I. Examiner's Answers should be presented in a single integrated document

Proposed Bd.R. 41.39(a)(1) proposes to relieve the examiner of having to prepare an integrated statement of the grounds of rejection, but instead proposes to shift to the appellant the task of assembling the examiner's thoughts out of the last Action, all advisory actions (up to five in one case), and any written decision on Pre-Appeal.

This is a very bad idea, one that will harm both the Board and appellants.

One of the key functions of an Examiner's Answer is to force the examiner to rethink the entire case, and consolidate thoughts into a coherent single set of thoughts. An Examiner's Answer forces the examiner to take a consistent position on all issues. The proposal thus unwittingly encourages low-quality examination. During § 131/§ 132 examination, applicants are frequently confronted with a second Action that is merely a copy of the first action, and a "response to remarks" appended apparently with no thought to the original first action, so that the "response" section states positions that

are incompatible with the position in the copied earlier Action. This problem should not be allowed to propagate further. If this proposal is adopted, appellants and the Board will be confronted with a hodge-podge of previously filed papers amended by disconnected notes.

MPEP § 1207.02(A)(9)(c) and (d)(1) require that an Examiner's Answer "point[] out where all of the specific limitations recited in the rejected claims are found in the prior art relied upon in the rejection." In my experience, this is seldom honored. This requirement should be moved from the MPEP to 37 C.F.R. § 41.39 to make clear that appellants have a clear right to a complete statement of the grounds of rejection. Obviously this should be in the final Action, and no later than an Examiner's Answer.⁶²

J. The rules should make clear that "new grounds of rejection" at any stage of appeal are measured against the examiner's last action, not the immediately-preceding paper

The CCPA long ago suggested (though without definitively holding) that one should look to the final rejection to determine which are "new grounds" as late as the Board's final decision, and that the term is not a mere increment against the previous paper.⁶³

If we are to look to the final rejection, rather than the answer, to see what rejections are *involved* in the appeal, that is where we should look to see what grounds of rejection the examiner has *specified*.

⁶² As the Board has noted elsewhere, Examiners should provide a complete statement of the grounds of rejection during examination, not just in the Examiner's Answer. *Ex parte Govindan*, Appeal No. 2001-0758, <http://des.uspto.gov/Foia/RetrievePdf?system=BPAI&fINm=fd010758> at 5, 2002 WL 32334569 at *3 (BPAI Nov. 15, 2002) (unpublished) ("for meaningful appellate review to occur, the examiner must present a full and reasoned explanation of the rejection. ... We would further emphasize what should be self-evident: the examiner must present a full and reasoned explanation of the rejection *in the statement of the rejection*" (emphasis in original)).

⁶³ *In re Bush*, 296 F.2d 491, 496, 131 USPQ 263, 266 (CCPA 1961) (emphasis the court's).

Later cases suggest that the Federal Circuit still feels the same way.⁶⁴

This follows from basic examination procedure. One set of procedural rules applies during § 1.104/§ 1.111 examination, when the examiner bears the burden of proving nonpatentability, claims are freely amended, and evidence is freely adduced. A narrower set of rules applies during appeal, but those narrower rules only make sense if the PTO fully carried out its half during § 1.104/§ 1.111 examination. If the examiner failed to follow the procedures for § 1.104/§ 1.111 examination, and the Petitions Office and T.C. Directors continue to assert their views (as stated repeatedly throughout Chapter 2100) that there are no enforceable procedures to compel complete examination, then appeal provides the only remedy for the substantive errors that arise out of haphazard procedure. The Board's rules should be structured to ameliorate the costs and disadvantages imposed on applicants by examiner nonfeasance.

III. The proposed “waiver” provisions are problematic and inconsistent with law

The Board is not an Article III court of appeals, nor is the Board to be an arm of the Solicitor's Office—i.e., an advocate for unpatentability. Instead, the Board is an administrative adjudication tribunal governed by 5 U.S.C. § 555; it has an obligation to

⁶⁴ *E.g.*, *In re McDaniel*, 293 F.2d 1379, 1385, 63 USPQ2d 1462, 1466 (Fed. Cir. 2002) (reminding the PTO that the “statutory mandate that the Board review ‘adverse decisions of the examiners upon applications for patents,’ 35 U.S.C. § 6(b)”, and it may not affirm or reverse issues that first arise during appeal, at least when the Office closes access to procedural rights to respond with amendments, affidavits, arguments, etc.); *In re Oetiker*, 977 F.2d 1443, 1445–46, 24 USPQ2d 13443, 1444 (Fed. Cir. 1992) (contrasting approval of the examiner's introduction of new grounds during “initial examination” while the applicant had an opportunity to respond, against disapproval of the Office's introduction of new grounds while an applicant's opportunities to respond are closed); *In re De Blauwe*, 736 F.2d 699, 706 n. 9, 222 USPQ 191, 197 n.9 (Fed. Cir. 1984) (“[W]here the board advances a position or rationale new to the proceedings, as it is empowered to do and quite capable of doing, the appellant must be afforded an opportunity to respond to that position or rationale by the submission of contradicting evidence. ... The board's refusal to consider evidence which responds to such a new rationale is error.”).

adjudicate *de novo*.⁶⁵ The Board is part of the fact-development stage of agency proceedings, and is under a special obligation to perform duties in a “fair, impartial, and equitable”⁶⁶ manner. See 35 U.S.C. § 3(a)(2)(A).

In an Article III court proceeding, district court rules force the parties to fully disclose their positions early, for example through expert reports (Fed.R.Civ.P. 26) and the like. In an Article III proceeding, parties are never sandbagged with new positions late in the game, because the rules against doing so are bilateral and enforced.

In contrast, the PTO reminds applicants throughout Chapter 2100 of the MPEP that it will not compel examiners to fully disclose and develop their positions before appeal. The statistics in the NPRM prove the point—the Board affirms about 15% of appealed rejections.⁶⁷

Article III standards for “waiver,” which are founded on the presumption that the scales of justice are procedurally balanced, are clearly inappropriate unless and until the PTO adopts—and follows—balanced procedures. They are otherwise incompatible with the Director’s duty to ensure that the PTO operates in a “fair, impartial, and equitable manner,”⁶⁸ incompatible with the statutory entitlement to grant of patents that are authorized under the law, 35 U.S.C. §§ 102 and 132. The Board should be taking as many opportunities to grant patents that are required to be granted under the statute as it takes to deny those that are not.

A. The proposed waiver is beyond the authority of the PTO

The proposed waiver is a shift of the burden of proof, by purporting to relieve the PTO of the burden of showing some element of unpatentability or foreclosing a showing

⁶⁵ *Ex parte Frye*, 94 USPQ2d 1072, 1075 (BPAI 2010) (*en banc*, precedential)

⁶⁶ 35 U.S.C. § 3(a)(2)(A) (Director shall provide policy direction and management supervision, and shall perform his duties in a “fair, impartial, and equitable manner.”)

⁶⁷ But for the cost of appeal, more applications would be appealed and result in reversal.

⁶⁸ 35 U.S.C. § 35 U.S.C. § 3(a)(2)(A).

of patentability. But “the assignment of the burden of proof is a rule of substantive law,”⁶⁹ and the PTO lacks statutory authority to issue substantive rules.⁷⁰ Thus the Board lacks authority to impose a waiver rule unless it can prove that such a rule does not shift the burden of proof.

B. The Board should have all powers that tend to help “conclude a matter presented to it”

The NPRM proposes to revise Bd.R. 41.50(c) to remove the Board’s power to suggest how a claim may be amended to overcome a rejection and proposes to add new language to the rule explaining the procedure by which appellants can seek review of a panel’s failure to designate a decision as containing a new ground of rejection.

This is facially incompatible with the Board’s and PTO’s obligation under 5 U.S.C. § 555(b), which requires that “within a reasonable time, each agency shall proceed to conclude a matter presented to it” (emphasis added). The Board should not by rule forego opportunities to suggest how prosecution can be concluded.

C. The analysis of “waiver” in the NPRM is incorrect—the Board is not an Article III court

For the same reasons, the various “waiver” provisions should not be adopted. The Board may take the position that it cannot investigate every ground for allowance that an appellant does not raise, and appellants that leave arguments unargued do so at their own risk, but it seems incompatible with the Board’s role as a fair and neutral arbiter for the Board to grant itself every power to raise new rejections without prompting by the examiner, with limited opportunity to rebut, and to simultaneously state that the Board will not consider clear grounds for reversal that it recognizes.

⁶⁹ *Director, Office of Workers’ Compensation Programs, Dep’t of Labor v. Greenwich Collieries*, 512 U.S. 267, 271, 275–81 (1994).

⁷⁰ *Cooper Technologies Co. v. Dudas*, 536 F.3d 1330, 1336, 87 USPQ2d 1705, 1709 (Fed. Cir. 2008) (“To comply with § 2(b)(2)(A), a Patent Office rule must be ‘procedural’—*i.e.*, it must ‘govern the conduct of proceedings in the Office.’ ... We have also previously held that 35 U.S.C. § 2(b)(2) does not authorize the Patent Office to issue ‘substantive’ rules.”)

D. The proposed waiver rule and the Board's "new ground" rule are incompatible with each other

This fact pattern recurs often: a claim has three limitations, and any two of those limitations can be read on a reference, but not all three simultaneously. An examiner might read two (e.g., A and B), and the error is in limitation C. An appellant will argue limitation C. The Board, under its new ground authority, might then read A and C onto the reference, and make an error with respect to limitation B. If the rules provide that the mismatch on limitation B is waived, then the appellant has no way to seek correction of the Board's error.

The rules have to be symmetric not for mere subjective fairness, but to avoid objective errors by the Board.

IV. Board jurisdiction

A. A "restatement" of the Scope of "Appealable Subject Matter" Might Reduce the Propensity of Applicants to File Appeals

A "restatement of the law" of the Board's § 134 jurisdiction would be immensely helpful to appeals, and more importantly, to efficient examination and reduction of the Board's backlog.

Unfortunately, the examining operation has a very different opinion of jurisdictional scope of appealable subject matter than the Board, and the lack of agreement leaves a large "no man's land" of *procedural* issues underlying rejections of claims where examiners operate with no supervision or oversight from either the Board or the Director. For example, a number of Tech Center SPRE's and Tech Center Directors believe that "premature final rejection" is an appealable issue because it relates to claims, and thus examiners have little constraint or guidance.

Most statements of the Board's jurisdiction are very difficult to locate. For example, statements of the Board's jurisdiction are found in unpublished decisions, and intermediate appeals decisions that are not searchable on the Board's web page or decisions that have never been made public. I have attempted to collect the public and

non-public statements of the Board's jurisdiction of which I am aware in a way that could be added to MPEP § 1201. That proposed "Restatement" is presented as Attachment B to this letter. I urge that it—or something much like it—be incorporated into the MPEP.

The Board should not, and cannot, be the primary entity enforcing proper application of the law during examination. Rather, PTO management, having exerted great and careful effort to produce Chapter 2100 of the MPEP, should enforce it by requiring examiners to set forth findings on all *prima facie* issues required by the MPEP. Once an examiner states a position, if the examiner has erred, the applicant can identify and diagnose the error—whether it lies with applicant or examiner—and resolve the issue. The problem is the pervasive *silence* of the examining operation, and frequent application of "rules" that have no basis in any written document. Clarifying the scope of the Board's jurisdiction will appropriately define the breadth of management's duty to "manage and direct" the examining operation. 35 U.S.C. § 3(b)(2)(A). That will be more efficient for all concerned, and save the Board from its backlog problem.

B. The PTO has not considered how existing laws and regulations have created or contributed to the problem it is trying to solve

Executive Order 12,866⁷¹ requires every agency, for every rulemaking, to "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." § 1(b)(2). The NPRM reveals no evidence of such introspection.

From outside the PTO, the problem the Office seeks to solve lies squarely with existing laws and regulations, or rather, senior career managers' incorrect interpretations of these laws:

⁷¹ William J. Clinton, 1993. Executive Order 12866--Regulatory Planning and Review (58 Fed. Reg. 51735-51744),

- 35 U.S.C. § 3(b)(2)(A) defines the PTO's duty to "manage and direct" "all aspects" of examination," but senior career managers incorrectly believe that "all aspects" excludes those aspects that are inconvenient to manage
- 35 U.S.C. §§ 131 and 132 defines the PTO's duty to "cause an examination to be made" and "state reasons," but senior career managers incorrectly believe that any issue relating to claims is outside the procedural supervisory duty of the Director.

The proposed Appeal Rules might be unnecessary if the Petitions Office implemented longstanding Federal Circuit law requiring the Director and Commissioner to oversee discretionary and procedural acts of examiners, even when they relate to claims. The Petitions Office also refuses to abide by the Federal Circuit's instructions that applicants are "entitled to rely" on the MPEP⁷²

Attorneys read the MPEP and know that it states rules that they are "entitled to rely" on to predict the Office's future course, and their ethical obligations to clients limits their ability to surrender property rights that the Office is legally obligated to provide. When an examiner refuses to comply with the MPEP, extended prosecution and appeal are the result.

I suggest that a far more effective approach to reduce the number and increase the efficiency of appeals would be to implement procedures by which applicants could ensure procedurally complete examination in the first instance, thereby removing much of the need for either continuations or appeals. As I note in § IV.A, above, that could be achieved by a clear statement of the limits of the Board's jurisdiction (thereby clarifying the obligation of petitions officials to decide non-appealable petitions under 37 C.F.R. § 1.181(a)(1)), and the obligation of line management to "cause an examination to be made" under 35 U.S.C. § 131.

⁷² *In re Kaghan*, 387 F.2d 398, 847-48, 156 USPQ2d 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").

C. Jurisdiction should transfer after review of the Reply Brief by the examiner

The NPRM starts from a worthy goal, to "minimize the number of appeals that transfer back-and-forth between the Board and the examiner." To accomplish this, the NPRM proposes that "Examiner[s] would no longer be required to acknowledge receipt of the reply brief." It is hard to see how much benefit would accrue from eliminating this very minor task. If the PTO seriously believes that acknowledgement is superfluous, however, it is hard for applicants to argue provided that they have some other form of assurance of receipt. What is far more important from the applicant's perspective is that the examiner actually *consider the arguments presented* in the reply brief.

V. Comments on the Information Collection Rule (ICR) Notice and Supporting Statement

I congratulate the PTO for filing a draft Supporting Statement⁷³ with OMB "on or before" the date of the Notice of Proposed Rulemaking containing the 60-day notice for the ICR revision that would be required for a final rule.⁷⁴ The public is capable of providing informed comment on much more of the ICR than is typically the case.

A. The PTO's burden estimates lack "objective support," and they appear to significantly understate likely burden

The Paperwork Reduction Act and its implementing rule require agencies to provide objectively supported burden estimates⁷⁵ that are unbiased.⁷⁶ The PTO has

⁷³ Supporting Statement, OMB Control Number 0651-0063, RIN 0651-AC37
<http://www.reginfo.gov/public/do/DownloadDocument?documentID=212768&version=0>

⁷⁴ The 60-day notice and draft Supporting Statement are required by 44 U.S.C. § 3506 and 5 C.F.R. § 1320.11.

⁷⁵ 44 U.S.C. § 3506(c)(1)(A)(iv) and 5 C.F.R. § 1320.8(a)(4).

⁷⁶ Office of Management and Budget. 2002. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication. 67 Fed. Reg. 8452-8460; Graham JD. 2002. *Memorandum for the President's Management Council: Executive Branch Implementation of the Information Quality Law*, http://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/pmc_graham_100402.pdf.

committed to provide unbiased estimates,⁷⁷ and in this ICR the PTO repeatedly certifies in its Supporting Statements to have done so. Unfortunately, the Supporting Statement does not live up to these requirements, commitments, and certifications.

1. No objective support provided for estimates of burden-hours

The record at OMB discloses no “objective support” for the PTO’s burden-hour estimates. Changes in these estimates are listed on pages 14-16, but the PTO discloses no basis for them, either. The claimed time savings of three hours per Appeal Brief is unsupported, as were the 2008 and 2009 “estimates” (30 and 34 hours, respectively). In our experience, the number of hours required to prepare a Reply Brief is about three times what PTO assumes—again, based on no objective support. All of PTO’s unit burden-hour estimates appear to be arbitrary.

2. No objective support for estimates of the numbers of responses

No objective support is provided for the PTO’s estimated numbers of Appeal Briefs, Reply Briefs, and other information collection. Contrary to recent experience *and the Board’s* intentions, these estimates are flat over the requested approval period. I note that the PTO has proposed an upward “administrative adjustment” of 55% in the number of Reply Briefs expected. This increase is said to be “[b]ased on current projections,” the foundation for which is not disclosed.

3. Bias and error in estimates of hourly rates

As it has in several previous ICRs, the PTO assumes an hourly rate for patent counsel of \$325 per hour. This figure is known to be biased, for it is the median rather than the mean of the asymmetric distribution from which it comes. The source of the distribution is the AIPLA’s 2009 economic survey, a data source that commenters have

⁷⁷ U.S. Patent and Trademark Office. 2002. *Information Quality Guidelines* (<http://www.uspto.gov/web/offices/ac/ido/ifoqualityguide.html>)

previously noted does not meet applicable information quality standards because, among other things, it has an overwhelming nonresponse bias defect.⁷⁸

The PTO also ignores what it surely knows: appeals are typically prepared by more senior attorneys, who bill at rates higher than the average for all patent attorneys.

4. Information collections the PTO refuses to count

The ICR does not include any estimated burden for oral hearings; indeed, it does not even acknowledge them as part of the burden. But they are included; the definition of burden is broad, encompassing “time, effort, or financial resources expended by persons to generate, maintain, or provide information” including “transmitting, *or otherwise disclosing* the information,”⁷⁹ which an oral hearing certainly does. Similarly, oral communications are expressly included in OMB’s regulatory definitions of “information”⁸⁰ and “collection of information,”⁸¹ so the PTO has no legal justification for excluding them from the ICR.

What is most disconcerting about having to recite this litany of technical errors is that they have been noted numerous times by commenters on previous PRA notices. To date, the PTO has neither refuted these commenters nor made corrections. It is a reasonable inference that the Office has no intention of complying with the PRA unless OMB, which has sole authority to enforce the Act, compels it to do so.

⁷⁸ Richard B. Belzer, *Letter to Raul Tamayo RE: Request for Comments on Methodology for Conducting an Independent Study of the Burden of Patent-Related Paperwork* (75 Fed. Reg. 8649)(2010), at http://www.uspto.gov/patents/announce/prs_study_regchkbk.pdf.

⁷⁹ 44 U.S.C. § 3502(2)(F).

⁸⁰ 5 C.F.R. § 1320.3(h).

⁸¹ 5 C.F.R. § 1320.3(c)(1).

VI. Problematic compliance and noncompliance with statutory and Executive Order requirements for rule making

A. The PTO offers no explanation for its continued defiance of *Tafas v. Dudas*

This NPRM is subject to the Administrative Procedure Act in all respects, contrary to the PTO's statement at 75 Fed. Reg. 69843, col. 2.

The United States District Court for the Eastern District of Virginia, held that "the structure of [35 U.S.C. § 2(b)(2)] makes it clear that the USPTO must engage in notice and comment rule making when promulgating rules it is otherwise empowered to make—namely, procedural rules."⁸² When the PTO moved to dismiss the subsequent appeal to the Federal Circuit for mootness, the PTO irrevocably committed itself to this opinion—the assertion of mootness carried with it a statement "*with assurance* that there is *no* reasonable expectation that the alleged violation will recur."⁸³ When a federal agency asserts mootness, it is "only because" the agency ceases all "offending conduct" by accepting the request.⁸⁴ The Federal Circuit accepted the PTO's acquiescence to mootness. Further, the Federal Circuit denied the PTO's request to vacate the District Court's decision.⁸⁵

The NPRM does not even acknowledge that the *Tafas* case ever existed, stating at 75 Fed. Reg. 69843, col. 2:

these rule changes involve rules of agency practice and procedure under 5 U.S.C. 553(b)(A), and prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553(b)(A) (or any other law). ...

Because the proposed rule is procedural, it is not required to be published for notice and comment. ...

⁸² *Tafas v. Dudas*, 541 F.Supp.2d 805, 812, 86 USPQ2d 1623, 1628 (E.D. Va. 2008), *reinstated sub nom. Tafas v. Kappos*, 586 F.3d 1369, 1371, 92 USPQ2d 1693, 1694 (Fed. Cir. 2009) (granting PTO's motion to dismiss the appeal on grounds of mootness, and holding that district court decision is reinstated).

⁸³ *County of Los Angeles v. Davis*, 440 U.S. 625, 631 (1979).

⁸⁴ *Adarand Constructors Inc. v. Slater*, 528 U.S. 216, 221–22 (2000).

⁸⁵ *Tafas v. Kappos*, 586 F.3d 1369, 1371, 92 USPQ2d 1693, 1694 (Fed. Cir. 2009).

The NPRM simply ignores *Tafas*, with no comment, no attempt to distinguish, and no explanation. If the PTO believes that *Tafas* does not apply, then it should clearly say so and provide a reasoned legal defense for the position.

The NPRM continues as follows:

Merck & Co. v. Kessler, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996) (the rules of practice promulgated under the authority of former 35 U.S.C. 6(a) (now in 35 U.S.C. 2(b)(2)) are not substantive rules to which the notice and comment requirements of the Administrative Procedure Act apply);

This is legal error. *Merck* considered the difference between interpretative and legislative rules (under the alternative name sometimes used, “substantive” rules). The interpretative/legislative distinction in *Merck* is entirely irrelevant to the procedural/substantive distinction that matters here, or the procedural rules in this NPRM. Second, *Merck* is *entirely silent* with respect to notice and comment—the representation that *Merck* held that “the notice and comment requirements of the Administrative Procedure Act [do not] apply” to procedural rules constitutes a gross misreading of the case.

As in the case of paperwork burden mentioned above, this defect in the PTO’s administrative procedure has been raised numerous times in previous public comments. The PTO has neither refuted the legal argument presented nor changed its practices. Thus, it is a reasonable inference that the Office has no intention of complying with the law unless a *second* court compels it to do so.

B. The PTO’s position on notice and comment appears to be an effort to evade the Regulatory Flexibility Act

A strategic reason for the PTO’s refusal to adhere to the holding in *Tafas* (§ VI.A at page 42) is that acknowledging the requirement for notice and comment would trigger applicability of the Regulatory Flexibility Act, a procedural law the PTO appears determined to evade. The RFA clearly applies in this rule making because notice and comment is required by the Patent Act. The PTO has a legal obligation to prepare an Initial Regulatory Flexibility Analysis. If it fails to do so, any final rule will be easily challenged as improperly issued.

C. The NPRM is not accompanied by the disclosure of data, facts, and other supporting documents required by the Administrative Procedure Act, Paperwork Reduction Act, E-Government Act, and Information Quality Act

An agency must disclose all material facts in the Notice of Proposed Rulemaking. The agency must make its evidence available in a publicly-available rule making file at the time of the Notice of Proposed Rulemaking, so that the public has fair notice and meaningful opportunity to comment and challenge the agency's basis.⁸⁶ Release of summary information is insufficient to meet an agency's duty to disclose its models, data, and assumptions.⁸⁷ Further, the E-Government Act of 2002 requires the PTO to make this information available on the agency's web site at about the time of the NPRM.⁸⁸

At the very least, the documents underlying the numbers in these two tables should have been made available:

⁸⁶ *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); *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.’”).

⁸⁷ *Washington Trollers Ass'n v. Kreps*, 645 F.2d 684 (9th Cir. 1981) (high-level summary, without underlying model or data to “enable an interested or affected party to comment intelligently,” is arbitrary and capricious).

⁸⁸ E-Government Act of 2002, Pub.L. 107-347 (Dec. 17, 2002), § 206(d), codified in notes to 44 U.S.C. § 3501 (“To the extent practicable, as determined by the agency in consultation with the Director, agencies shall ensure that a publicly accessible Federal Government website contains electronic dockets for rulemakings under [5 U.S.C. § 553]. ... Agency electronic dockets shall make publicly available online ... other materials that by agency rule or practice are included in the rulemaking docket under [5 U.S.C. § 553(c)]”).

PRE-APPEAL BRIEF CONFERENCE EFFECTS: ACTIONS IN RESPONSE TO REQUEST FOR PRE-APPEAL BRIEF REVIEW

FY	Number of requests	Frequency of requests (percent)	Proceed to board (percent)	Prosecution reopened (percent)	All rejections withdrawn (percent)	Defective request (percent)
06	6,525	24	55	37	5	3
07	7,240	25	56	38	4	2
08	8,255	27	59	37	2	2
09	9,967	30	56	39	3	2
10	12,019	34	56	38	5	1

APPEAL CONFERENCE EFFECTS: ACTIONS IN RESPONSE TO APPEAL BRIEF

FY	Examiner's answer (percent)	Prosecution reopened (percent)	All rejections withdrawn (percent)	Other action (percent)
98	58	12	29	1
99	52	15	32	1
00	46	21	32	1
01	40	25	34	1
02	38	26	34	1
03	38	29	31	1
04	39	32	27	2
05	39	35	24	2
06	49	30	19	2
07	56	28	14	2
08	59	28	12	1
09	56	27	16	1
10	59	23	17	1

D. The PTO breached its obligation under the Paperwork Reduction Act to “consult with members of the public” to develop its burden estimates

5 C.F.R. § 1320.8(d)(1) requires the PTO to consult with the public either before an NPRM to minimize burden and validate burden estimates, or in the NPRM itself:

§ 1320.8 Agency collection of information responsibilities.

(d)(1) Before an agency submits a collection of information to OMB for approval, and except as provided in paragraphs (d)(3) and (d)(4) of this section, the agency shall provide 60-day notice in the Federal Register, *and otherwise consult with members of the public* and affected agencies concerning each proposed collection of information...

The PTO did not “otherwise consult.” I have contacted most of the chairs and vice-chairs for the Patent Office committees of the AIPLA, ABA-IPL and AIPLA, and none had been contacted before November 15, 2010, let alone “consulted” on the required issues.

VII. The Board's continued enforcement of regulatory requirements above the 2004 Rules is a breach of the Paperwork Reduction Act and OMB's terms of clearance

On December 22, 2008, the Executive Office of the President specifically instructed the Board, in an individualized letter—not a general letter to the entire executive branch, but a letter directed solely to the PTO on issues of Board procedure—that the PTO is to enforce *only* the 2004 rules, with no additional duties or reduction in rights of appellants.⁸⁹

The PTO—and particularly the Board—continue to defy presidential authority, in several respects. The continuing pattern of the Board acting in excess of the Board's legal authority is deeply troubling, and should cease forthwith.

A. Board intake clerks continue to enforce unwritten rules

As late as November 2010, Board intake clerks continue to enforce a requirement for “mapping” of claims,⁹⁰ when all that is required under the 2004 version of 37 C.F.R. § 41.37(c)(1)(v) is “A concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which shall refer to the specification by page and line number, and to the drawing, if any, by reference characters.” Rule 41.37(c) states no further requirement for “mapping,” or to treat each claim separately in the Summary.

⁸⁹ <http://www.reginfo.gov/public/do/DownloadNOA?requestID=216727> (Dec. 22, 2009) (“TERMS OF CLEARANCE: [Appeal rules are cleared subject to PTO's modification of request for clearance] to limit it to the current rule [37 CFR 41.1 et seq. (2004)].”).

⁹⁰ 11/927,240, Notification of Non-Compliant Appeal Brief (Nov. 5, 2010) (“Section V Summary of Claimed Subject Matter must identify and map all independent claims...”)

B. Illegal constraints on the contents of Reply Briefs

The 2004 version of Appeal Rule 41.41(c)(1)(vi) permits applicants to raise arguments in *either* the appeal brief or a reply brief.⁹¹ However, the 2008 Appeal Rule would have taken away this right by requiring all arguments to be raised in the appeal brief or be forever waived.⁹²

This change, had it been enacted, would have included significant new paperwork burdens that required prior OMB approval to be enforceable. The 2008 Appeal Rule never became effective because OMB declined to approve the information collections contained therein.

Nonetheless, the Board is enforcing this provision of the 2008 Appeal Rule (and possibly other provisions) as if the rule had been approved by OMB and not stayed. In *Ex parte Borden*,⁹³ the Board cites Rule 37(c)(1)(vii) disingenuously to make it appear as if the 2004 and 2008 rules are the same. The Board used an ellipsis to hide the bold text of the 2004 rule text, shown below inside square brackets:

Any arguments or authorities not included in the brief **[or a reply brief filed pursuant to §41.41]** will be refused consideration by the Board, unless good cause is shown.

It is this hidden text that confers the right to raise arguments in a reply brief, the very thing the Board has denied in *Ex parte Borden*. Strikingly, *Borden* was issued only **two weeks** after OMB set the terms of clearance for enforceability of the 2004 appeal rules.

⁹¹ The 2004 version of Rule 41.37 (which governs appeal briefs) states, “Any arguments or authorities not included in the brief *or a reply brief filed pursuant to §41.41* will be refused consideration by the Board, unless good cause is shown” (emphasis added).

⁹² The 2008 version of Rule 41.37 states in part, “The ‘argument’ shall explain why the examiner erred as to each ground of rejection to be reviewed. Any explanation must address all points made by the examiner with which the appellant disagrees. Any finding made or conclusion reached by the examiner that is not challenged will be presumed to be correct.” The 2008 version of rule 41.41 (which governs reply briefs) states, “Any arguments raised in the reply brief which are not responsive to points made in the examiner’s answer will not be considered and will be treated as waived.”

⁹³ *Ex parte Borden*, Appeal No. 2008-004312, 93 USPQ2d 1473, 1474-75 (BPAI Jan 7, 2010) (<http://www.uspto.gov/ip/boards/bpai/decisions/inform/fd08004312.pdf>.)

A search of Board actions reveals 77 instances in which it has cited *Ex parte Borden*, presumably for the purpose of supporting the proposition that argument no longer can be raised in a reply brief. The Board is ignoring the indefinite stay of the 2008 Appeal rule, and ignoring the absence of a valid OMB Control Number for the related information collections—presumably in the hope that no applicant will learn of these defects and file a legal challenge under the APA and PRA.⁹⁴

The Board's action in *Ex parte Borden*, and probably many of the subsequent 77 cases, is vulnerable to legal challenge under the Administrative Procedure Act. The Board also is subject to challenge via the PRA's public protection provisions. It must be "reasonable"⁹⁵ *per se* for an applicant to provide information in the manner prescribed by the 2004 Appeal Rule (i.e., in a reply brief). The Board's refusal to consider information in a reply brief constitutes a penalty for which 44 U.S.C. § 3512 provides an affirmative defense and remedy.

The holding is only one of several problematic aspects of *Borden*. The body of the *Borden* opinion at page 4 misquotes the text of § 41.37(c)(1)(vii) by replacing the words "or reply brief" with ellipses, to excise reply briefs from the protections given appellants by that rule. Misquotation by ellipses, to change the meaning of a text, was identified as sanctionable conduct by the Federal Circuit in *Precision Specialty Metals Inc. v. U.S.*, 315 F.3d 1346 (Fed. Cir. 2003).

VIII. Conclusion

I am greatly encouraged by fresh winds in the PTO over the last few months, and by the overall tenor of this rule package. However, the PTO's—and especially the

⁹⁴ This is not difficult to fathom. In 2007, it became clear that the Board was unskilled in administrative law and unfamiliar with the PRA. The Board has long believed that its actions are exempt from the APA. Its unfamiliarity with the PRA is amply illustrated by its failure to secure OMB approval of its information collections despite the existence of these procedures since 1981.

⁹⁵ 5 C.F.R. § 1320.6(c) states: "The agency shall instead permit respondents to prove or satisfy the legal conditions in any other reasonable manner."

Board's—lack of concern for procedural law raises continuing concern. Procedural law exists so that the public and agency know what to expect of each other—good fences make good neighbors. Even though only a few patent lawyers know the procedural law, they all have a gut feel for the notions of fairness that are reflected in the law, and know when the PTO is acting unfairly (even if they can't identify the legal breach). The PTO's new relationship with applicants will sour if the PTO fails to take seriously the formal procedural law and the informal fairness that the law embodies.

Sincerely,

/s/ David E. Boundy

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Attachment A

Boundy Letter of January 10, 2010

David E. Boundy
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New York, NY 10022

January 12, 2010

By Email

Ms Joni Y. Chang
PatentPractice@uspto.gov
Office of Patent Legal Administration
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Cc: Nicholas A. Fraser, Desk Officer for Patent and Trademark Office, Office of Information and Regulatory Affairs, Office of Management and Budget, Nicholas_A._Fraser@omb.eop.gov (Executive Order 12,866 and Paperwork Reduction issues in introductory paragraphs and in §§ III.C, III.D, and III.E starting at page 10)

Re: Procedure for Treating Rejected Claims That Are Not Being Appealed, Request for Comments (no RIN docket number), 74 Fed. Reg. 66097 (Dec. 14, 2009)

Dear Ms. Chang:

This Notice presents four big issues and a host of smaller ones:

- The regulatory effect of the Notice is unambiguously and uniformly negative on the public. The Notice identifies no benefit to either the public or to the Office, but does acknowledge several adverse effects and costs. The PTO does not address these new economic effects or burdens in the manner required by **Executive Order 12,866** or the **Final Bulletin for Agency Good Guidance Practices**, and the Notice ignores a lower-burden alternative, the procedure that prevailed for decades until May 2008.
- The Notice creates new information collection burdens that require clearance under the **Paperwork Reduction Act**, but contains no estimate of either number of responses or cost per response, and does not commence the process to obtain OMB clearance for those burdens. The PTO has information in its database that would permit the PTO to estimate burden as required by the Act, but the PTO did not disclose the data it has.

- The disagreement among various parts of the PTO that the Notice seeks to correct arose out of the Board's breach of a directive from the Executive Office of the President, the *Final Bulletin for Agency Good Guidance Practices*, and *ultra vires* breach of a policy determination made by the Office that was binding on the Board. The Notice does nothing to acknowledge, let alone cure, those two breaches.
- The Notice will *increase* the workload for the Board—in the future, appellants will appeal claims that would not have been appealed under today's regulations, in order to avoid the adverse effects of the Notice

The Notice proposes to change the procedure that prevailed before 2008, where unappealed claims were “withdrawn from the appeal” but remained pending. This pre-2008 procedure is simple to administer, and is predictable because it is the procedure used by every other judicial or administrative tribunal for almost every issue. The “withdrawn from the appeal” procedure is dictated by current 37 C.F.R. Part 41, and is the only option that appears to be consistent with various provisions of administrative law that bind the PTO. The Administrative Procedure Act, the Paperwork Reduction Act, and two directives of the President point to the proper resolution: the PTO should recognize that *Ex parte Ghuman*, 88 USPQ2d 1478 (BPAI 2008), the purported basis for the Notice, violated administrative law, and should be vacated. The rest of the MPEP should be conformed to “withdrawn from the appeal” procedure.

This Notice is deeply disappointing for its numerous violations of administrative law. Winds of change in fall 2009 raised hopes that the PTO had finally begun to respect its obligations under the Paperwork Reduction Act, Executive Order 12,866, and the Administrative Procedure Act, which operate to protect applicants from PTO overreaching. Instead, this Notice baldly ignores these laws, and other procedural laws that govern the PTO. Strikingly, the Notice ***never mentions*** any of the procedural laws that govern the PTO—which calls into question the PTO's commitment to comply with administrative rule making law. The Notice identifies ***no problem*** with pre-2008 procedure, ***no identified benefit to either applicants or the PTO*** from the proposal, and nothing about the proposed procedure that improves on pre-2008 procedure. The proposal admits that applicants will lose significant rights and may be subject to

additional “information collections” under the Paperwork Reduction Act, but identifies no beneficial *quid pro quo*, indeed, no benefit to *anyone*.

Strikingly, the pre-2008 procedure that the Notice displaces was the *simplest* procedure for the Office (the Office literally had to do *nothing*); under the Notice, the Board proposes to cancel claims, nearly the most-severe expropriation that could be imposed, even if the PTO has to *go out of its way to do so*. The Notice also fails to recognize the adaptive responses that applicants will take—claims that go unappealed today will be appealed in the future—which will increase the Board’s workload.

The Director should exercise his authority to vacate *Ghuman*.¹ The rest of the MPEP should be conformed to pre-2008 “withdrawn from the appeal” procedure. If the PTO believes a change from “withdrawn from the appeal” is warranted, the PTO must observe the laws that govern administrative rule making: at the very least the PTO must identify a problem, and make a cost-benefit showing vis-à-vis that problem. In all likelihood, the PTO will find that there is no alternative to pre-2008 “withdrawn from the appeal” procedure that is consistent with the Paperwork Reduction Act and Executive Order 12,866, and will decide to amend or vacate all written documents (including *Ghuman*) that conflict with “withdrawn from the appeal.”

I. **Pre-2008 “withdrawn from the appeal” procedure—established, sensible, legal, simple, predictable**

Column 2 of the Notice correctly states that until May 2008, “non-appealed rejected claims were considered ***withdrawn from the appeal***.” Those claims remained pending, though rejected. This is the simplest possible way to handle the matter: the Board needs to do literally *nothing*. Any issue not argued stands as decided by the

¹ The Director has such authority over the Board. For example, 37 C.F.R. Part 41 issues on the authority of the Director, not the Board. The Director has issued orders in the past overruling the Board to oversee the Board’s compliance with PTO regulations, e.g., *In re Oku*, 25 USPQ2d 1155, 1157 (Comm’r Pats. & TM 1992) (Director has jurisdiction to review “the important question of whether the Board followed PTO regulations established by the [Director]. In appropriate circumstances the [Director] may exercise his supervisory authority” over actions of the Board).

examiner, with whatever *res judicata* effect applies to examiner decisions, no more, no less.² At the conclusion of the appeal, unappealed claims have exactly the same status they had at the beginning of the appeal. This mirrors that procedure before all other tribunals: an uncontested issue is just that, and is not an admission or waiver of any other issue.

In August 2005, MPEP § 1205.02 was amended to largely track the “withdrawn from the appeal” procedure, and now reads as follows:

1205.02 Appeal Brief Content [R-3]

...If a ground of rejection stated by the examiner is not addressed in the appellant’s brief, that ground of rejection will be summarily sustained by the Board

MPEP § 1205.02 is *almost* correct: when unappealed claims are “withdrawn from the appeal,” the Board is to take *no action at all*, not even “summarily sustain.” The claims remain *pending in the application*, though rejected and not appealed, and emerge at the end of the appeal in the same posture as they entered, for whatever further prosecution the applicant and examiner see fit.

There are several important conveniences for the PTO and for applicants that flow from pre-2008 procedure that simply leaves the claims pending, rejected, and withdrawn from the appeal. First, if the unappealed claims have dependent claims that **are** appealed, the dependent claims are in formally-sufficient form, and there is no need for the appellant to file a gratuitous amendment to put the claims in independent form. Second, because the claims are withdrawn from the appeal, the Board has the simplest possible task: do **nothing**. Neither *Ghuman* nor the Notice identifies any benefit to the PTO to requiring more. Third, the unappealed claims can reenter prosecution at the conclusion of the appeal, with only minimal procedural fuss, for example, a Rule 312

² “[P]recedent has long supported the right of an applicant to file a continuation application despite an unappealed adverse Board decision, and to have that application examined on the merits.” *In re Kagan*, 387 F.2d 398, 401, 156 USPQ 130, 132 (1967). “Where the Patent Office has reconsidered its position on patentability in light of new arguments or evidence submitted by the applicant, the Office is not forbidden by principles of preclusion to allow previously rejected claims.” *Abbott Laboratories v. TorPharm Inc.*, 300 F.3d 1367, 1379, 63 USPQ2d 1929, 1936–37 (Fed. Cir. 2002), *citing* *In re Craig*, 411 F.2d 1333, 1335–36, 162 USPQ 157, 159 (1969).

amendment to make them dependent on allowed claims. Most important, applicants are not forced to choose based on an unforeseeable future or to file a gratuitous amendment to claims whose rejections might be affirmed.

“Withdrawn from the appeal” is stated in the plain text of 37 C.F.R. § 41.37. § 41.37 carefully makes clear that appellants have the right to appeal some claims and not others. *E.g.*, § 41.37(c)(1)(iii) requires two separate designations, “status of all the claims in the proceeding (*e.g.*, rejected, allowed...)” and “an identification of those claims that are being appealed...” § 41.37 clarifies that “rejected” and “appealed” are not coextensive. If § 41.37 required that all rejected claims be either appealed or cancelled, then the two separate status identifications required in § 41.37(c)(1)(iii) would be superfluous. Any attempt to make them coextensive is inconsistent with the language, and to the degree it burdens applicants, that attempt would be illegal.

As will emerge below, it is hard to conceive of any other procedure that could possibly be consistent with the Office’s duties under the Paperwork Reduction Act and Executive Order 12,866, or consistent with the *text* of Part 41, without the PTO exceeding its authority.

II. The Board exceeded its authority when it issued *Ghuman* without observance of procedural law

“Withdrawn from the appeal,” or its close analog MPEP § 1205.02, is more than common sense. The procedural rights in favor of applicants are legally binding on the Board, under several provisions of administrative law.

First, the Board was required to obtain intra-agency pre-clearance of any departure from the MPEP, pursuant to a directive Bulletin from the Executive Office of the President.³

Second, the *Ghuman* decision is inconsistent with the Federal Circuit’s decisions in *Kaghan* and *Abbott Laboratories*, cited in footnote 2. The *Ghuman* panel did not

³ Executive Office of the President, *Final Bulletin for Agency Good Guidance Practices*, § II(1)(b), OMB Memorandum M-07-07, <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf> at page 20 (Jan. 18, 2007), 72 Fed. Reg. 3432, 3440 (Jan. 25, 2007).

explain how its ruling was consistent with Federal Circuit precedent. Indeed, the *Ghuman* panel cited no statutory or Federal Circuit authority whatsoever—it appears that the Board believed it was writing on a clean slate, and had no obligation to consider any law other than its own precedent. But that is beyond the Board’s authority.⁴

Third, the *Ghuman* panel relied on MPEP § 1215.03 to support its power to cancel or order cancellation of claims. The *Ghuman* panel violated one of the most basic principles of administrative law: the MPEP is a guidance document, and was not issued with the procedures required by statute before the PTO can bind or adversely affect the public. Without those procedures, the MPEP cannot bind or adversely affect on the public.⁵ Under administrative law statutes⁶ and express instructions from the Executive Office of the President,⁷ ***the MPEP may not be cited adversely to applicants.*** The *Ghuman* decision was illegal when it was issued. *Ghuman* is an error to correct, not to propagate.

Fourth, provisions of agency guidance documents that run in favor of the public, such as MPEP § 1205.02, are binding throughout the agency.⁸ Interpretative rules,

⁴ Just last week, the Federal Circuit “remind[ed] ... the Board that they must follow judicial precedent instead of 37 C.F.R. § 41.200(b) ... because the PTO lacks the substantive rulemaking authority to administratively set aside judicial precedent.” *Koninklijke Philips Electronics N.V. v. Cardiac Science Operating Co.*, App. 2009-1241 at p. 17 (Fed. Cir. 2010).

⁵ 5 U.S.C. § 552(a) (an agency “may not adversely affect” any member of the public based on documents such as the MPEP). To be sure, the MPEP is ***binding on Office personnel*** (including the Board) to the degree it operates in favor of applicants, as a “housekeeping” rule for internal agency operations. 5 U.S.C. § 301, also known as the “housekeeping statute” (“The head of an Executive department ... may prescribe regulations for the government of his department, the conduct of its employees...”)

⁶ *E.g.*, 5 U.S.C. §§ 552(a) and 553, 44 U.S.C. §§ 3506 and 3507, etc.

⁷ *Good Guidance Bulletin*, footnote 3, *passim* (reiterating over and over again that guidance documents are *not* to be treated as binding on the public, and the agency is required to have established procedures for handling complaints from the public when the agency illegally does so).

⁸ *Morton v. Ruiz*, 415 U.S. 199, 235 (1974) (“Where the rights of the individuals are affected, it is incumbent upon agencies to follow their own procedures.”); *Vitarelli v. Seaton*, 359 U.S. 535, 546-47 (1959) (Frankfurter, J. concurring) (“An executive agency must be rigorously held to the standards by which it professes its action to be judged ...”).

such MPEP § 1205.02, are binding on an agency, including the agency's ALJs.⁹ The *Ghuman* panel had no discretion to silently ignore MPEP § 1205.02. If the panel disagreed with the PTO's determination to grant procedural rights to applicants and state them in the MPEP, then the panel was obligated to work through the MPEP revision process, including the Paperwork Reduction Act, not to casually ignore published procedures.¹⁰

In a prior case, the Board identified its basis for refusing to be bound by the authority of the Director, or follow pronouncements of policy-making offices of the PTO.¹¹ Judge Barrett, in *Ex parte Bilski*,¹² wrote:

The Board is not bound by [the § 101 Interim Guidelines]⁸

⁸ From the movie *Pirates of the Caribbean* (Disney 2003):

Elizabeth: You have to take me to shore! According to the Code of the Order of the Brethren.

Barbossa: First, your return to shore was not part of our negotiations nor our agreement, so I 'must' do nothin'. And secondly, you must be a pirate for the pirate's code to apply, and you're not. And thirdly, the code is more what you call guidelines than actual rules. Welcome aboard the Black Pearl, Miss Turner.

⁹ *Yale-New Haven Hospital v. Leavitt*, 470 F.3d 71, 80 (2nd Cir. 2006) ("An interpretative rule binds an agency's employees, including its ALJs"); Kenneth C. Davis & Richard J. Pierce, Jr., *ADMINISTRATIVE LAW* § 6.3 (3d ed. 1996 & Supp.1997).

¹⁰ *Atchison, Topeka and Santa Fe Ry. v. Wichita Board of Trade*, 412 U.S. 800, 805–08 (1973) ("Whatever the ground for the departure from prior norms, ..., it must be clearly set forth so that the reviewing court may understand the basis for the agency's action and so may judge the consistency of that action with the agency's mandate."); *Ramaprakash v. Federal Aviation Admin.*, 346 F.3d 1121, 1124 (D.C. Cir. 2003) (Roberts, J.) (an agency departing from its precedent must provide "a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored.").

¹¹ The Board was wrong. *Service v. Dulles*, 354 U.S. 363, 374–76 (1957) (agency manual was binding, and violation of that manual was ground for setting aside agency action); *Yale-New Haven Hospital v. Leavitt*, 470 F.3d 71, 80 (2nd Cir. 2006) (addressing an agency staff manual: "An interpretative rule binds an agency's employees, including its ALJs,"); *Good Guidance Bulletin*, footnote 3.

¹² *Ex parte Bilski*, <http://www.uspto.gov/ip/boards/bpai/decisions/inform/fd022257.pdf>, 2006 WL 4080055 at *35 (BPAI Sep. 26, 2006) (informative)

The *Bilski* panel did not explain why a statement of a *fictional pirate*—a paradigmatic scofflaw—should be followed as if it were law. The *Bilski* panel did not explain why it neglected to consult any administrative law treatise or any primary authority¹³ to determine whether the Board was obligated to follow the PTO’s published policy determinations, or whether the Board is bound by instructions issued with the authority of the Director.

Illegal acts of two rogue panels of the Board (*Bilski* footnote 8 and *Ghuman*) should not mature into PTO policy, especially where the policy proposed in the Notice imposes costs on the public with no identified benefit to anyone.

III. Breaches of procedural and substantive law

A. The proposal is a “rule” that requires APA procedure, including Notice and Comment, and requires compliance with the Regulatory Flexibility Act

The proposal in the Notice is unquestionably a “rule” for purposes of the Administrative Procedure Act.¹⁴ The Notice nowhere attempts to explain that the proposed procedure is anything other than an APA “rule” – it certainly identifies no exception to § 551(4). Yet, with that concession implied, the Notice inexplicably fails to follow the law that governs rule making.

¹³ See footnote 9.

¹⁴ *Batterton v. Marshall*, 648 F.2d 694, 700–01 (D.C. Cir. 1980), one of the key administrative law cases from the D.C. Circuit notes as follows:

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....

The PTO cannot engage in submarine rule making through mere Federal Register notice. The White House¹⁵ and several federal courts have repeatedly reminded the PTO in the last few years that the PTO cannot add burdens by rule or adjudication without full compliance with regulatory review procedure, cannot add burdens or requirements by stating requirements in the MPEP or other informal guidance documents, and is not permitted to circumvent various statutory rule making obligations.¹⁶

If the PTO wishes to implement the “procedure” set forth in the Notice without running directly contrary to a holding of the federal court with most-direct supervision of the PTO,¹⁷ the PTO will at the least have to run the proposal through notice and comment.

Because this is a rule that requires notice and comment, the PTO must also observe the Regulatory Flexibility Act, 5 U.S.C. §§ 603, 604, and Executive Order 13,272. The Notice reflects no acknowledgement of the existence of these laws, let alone any attempt to comply.

B. What is this Notice?

The Notice does not identify itself as an Advance Notice of Proposed Rulemaking, Notice of Proposed Rulemaking, Request for Comment on a Proposed Information Collection, or anything else. It contains none of the rule making discussion

¹⁵ <http://www.reginfo.gov/public/do/DownloadDocument?documentID=44055&version=4> (White House “directed” the PTO to withdraw the Continuations, Claims, and IDS rules from any request for approval)

¹⁶ *In re Donaldson Co.*, 16 F.3d 1189, 1194, 29 USPQ2d 1845, 1849 (Fed. Cir. 1994) (the mere fact that “the PTO may have failed to adhere to a statutory mandate over an extended period of time does not justify its continuing to do so.”); *Tafas v. Dudas*, 541 F.Supp.2d 805, 814–15, 86 USPQ2d 1623, 1630 (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”), *reinstated after PTO stipulation of acquiescence sub nom. Tafas v. Kappos*, 586 F.3d 1369, 1371, 92 USPQ2d 1693, 1694 (Fed. Cir. 2009)

¹⁷ *Tafas v. Dudas*, 541 F.Supp.2d at 814–15, 86 USPQ2d at 1630.

that would be required for a Notice at any stage of rule making proceedings. What is the current procedural status for this rule?

This Notice *could* have been an attempt to “consult with members of the public” as required by 5 C.F.R. § 1320.8(d)(1), but because the PTO disclosed none of the information required by § 1320.8(d)(1), there is nothing for the public to comment on. So it fails to serve even that role. So where are we?¹⁸

C. The Notice breaches Executive Order 12,866

Executive Order 12,866¹⁹ requires agencies to fully consider the consequences of rules, even rules stated outside of the Code of Federal Regulations (underline added)

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. ... Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits ..., 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 the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.

¹⁸ In passing, I have to observe that many of the errors that lead to the Board’s high appeal case load arise when PTO personnel fail to read the relevant law, or else make up exceptions on the fly. The improvisational nature of this Notice is symptomatic of the problems that pervade PTO proceedings. If we could all start with the understanding that (a) the law is what is written down in documents promulgated with appropriate procedure, (b) both applicants and the Office are obligated to follow the law as it exists in writing, (c) the Office may not impose requirements that do not exist in writing, and (d) the Office may not excuse itself on grounds that do not exist in writing, many problems and delays could be averted.

¹⁹ As amended in 2007, E.O. 12,866 may be found at http://www.whitehouse.gov/omb/inforeg/eo12866/eo12866_amended_01-2007.pdf. The Executive Order is currently under revision within the White House, and indications are that the revision will be closer to the 2007 version than the 1993 version. Going forward, the PTO would be well advised to use the 2007 version as its pole star, rather than the 1993 version discussed in this letter.

The Notice identifies no problem arising under the pre-2008 “withdrawn from the appeal” procedure—no inefficiency, no risk of error. The only issue identified in the Notice is an intra-PTO disagreement arising out of *Ghuman*’s departure from the PTO’s “withdrawn from the appeal” procedure.

(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..

Ghuman created the problem, and is an “existing regulation (or other law).” The President directs the PTO to abrogate *Ghuman*, not to add an additional regulatory burden. The Notice reflects no attempt by the PTO to follow the President’s instructions.

(6) Each agency shall assess both the costs and the benefits of the intended regulation and ... propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

The Notice does not identify any benefit of the proposed procedure vis-à-vis “withdrawn from the appeal,” either to applicants or to the PTO. The Notice’s only cost/benefit analysis of the proposed procedure, at least compared to “withdrawn from the appeal,” is to identify disadvantages and costs imposed on applicants. The Notice makes no attempt to justify the costs of the proposed procedure vis-à-vis “withdrawn from the appeal.” The Notice fails to acknowledge that the number of appealed claims will increase, or to evaluate the costs of those added appealed claims on the Board.

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

Nothing in the Notice reflects the PTO’s recognition of, let alone compliance with, this requirement of the Executive Order.

(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.

The Notice totally ignores the pre-2008 *status quo*, “withdrawn from the appeal,” as an alternative regulation. There is no “assessment,” evaluation, or cost/benefit comparison between the proposed procedure and “withdrawn from the appeal.”

(11) Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

The Notice reflects no consideration of the additional costs and disadvantages imposed on applicants by changing from “withdrawn from the appeal” to the proposed cancellation of claims, let alone an attempt to “tailor its regulations” to be no more burdensome than “withdrawn from the appeal.”

D. The December 2009 Notice neglects the PTO’s obligations under the Paperwork Reduction Act

The Notice unquestionably constitutes a “modification” of an “information collection” that is “sponsored” by the PTO, and the Notice’s only effect on burdens is to increase them. Thus, the Notice triggers obligations under the Paperwork Reduction Act, specifically 5 U.S.C. § 3507(h)(3) and 5 C.F.R. §§ 1320.5(g) and 1320.11. The Notice reflects no recognition by the PTO of its Paperwork obligations, let alone any attempt to comply. The PTO is already in breach of the law when it enforces *Ghuman* without Paperwork clearance, and will be in further breach if it fails to seek clearance for the proposal in the Notice.

On December 22, 2009, the White house granted the PTO Paperwork clearance for appeals, but on terms of clearance ***expressly limited to the 2004 rules.***²⁰ The PTO would be in breach of its terms of clearance if it attempted to modify appeals procedure without observing the requirements of 44 U.S.C. §§ 3506 and 3507, and 5 C.F.R. § 1320.11.

²⁰ <http://www.reginfo.gov/public/do/DownloadNOA?requestID=216727>

E. The Notice neglects to account for adaptive responses that will increase workload for the Board and Paperwork burden for the public

If unappealed claims will be abandoned, appellants will argue claims in the future that are not argued today.

The Notice will *increase* the workload on the Board.

It will also increase workload for appellants. The PTO must estimate this increase in burden, and seek clearance under the Paperwork Reduction Act.

F. The PTO has no statutory authority to act as proposed in the Notice

Canceling claims is a substantive act. The PTO has no authority to grant itself substantive authority by rule making, let alone by mere Federal Register notice.²¹ The Notice identifies no statute that grants the PTO authority to cancel claims, to “deem” claims cancelled, or to require applicants to cancel them. The Notice appears to be *ultra vires*.

G. The Notice compromises the new cooperation the PTO hopes to foster by failing to analyze the issues with legal or factual precision

Disturbingly, the Notice reflects an absence of care to ensure truthfulness or careful legal analysis. Parties only cooperate with each other when they trust each other to be truthful, accurate, and fair. Several statements in the Notice are simply wrong, reflect the PTO’s habitual lack of care to investigate facts and law before committing opinion to paper, and lack of concern for basic fairness. Careless assertions in Office Actions are a major cause of the PTO’s backlog and large appeal load; carelessness in a formal Federal Register Notice, and expropriating applicants’ rights with no identified benefit, does not foster trust in the PTO’s senior legal staff, and will delay building cooperation between the bar and the Office.

²¹ *Cooper Technologies Co. v. Dudas*, 536 F.3d 1330, 1336, 87 USPQ2d 1705, 1709 (Fed. Cir. 2008) (“To comply with § 2(b)(2)(A), a Patent Office rule must be ‘procedural’—*i.e.*, it must ‘govern the conduct of proceedings in the Office.’ ... We have also previously held that 35 U.S.C. § 2(b)(2) does not authorize the Patent Office to issue ‘substantive’ rules.”)

Column 2 of the notice states “There is no provision in 35 U.S.C. 134 or 37 C.F.R. 1.113 for an applicant to appeal only part of the examiner’s decision.” The inference that the PTO draws from absence reflects a profound misunderstanding of one of the most fundamental principles of American administrative law. 5 U.S.C. § 552(a), 5 U.S.C. § 553, 44 U.S.C. § 3512, and the President’s *Final Bulletin for Agency Good Guidance Practices* all make the same point, that if the PTO has not promulgated a rule with force of law to either require or forbid an act by an applicant, then the act is permitted and optional. As the Notice repeatedly concedes, Part 41 contains nothing to forbid appeals-in-part. Thus, an appeal-in-part is permitted and optional. The supposition behind the Notice, that applicants may act only where the PTO has extended a benevolent grant of permission, reflects a complete upending of the very foundations of American administrative law.

The Notice states “Therefore, if appellant does not wish to contest one of the rejected claims, appellant must file an amendment canceling that claim. The amendment must be filed separately for the notice of appeal and appeal brief.” The Notice cites no authority having force of law for this “must.” The PTO cannot create “musts” by just saying so; if the PTO wants to make a rule, it must do so in the manner prescribed by law.

The mention of 37 C.F.R. § 1.113 reflects further confusion. § 1.113 governs “replies to final rejection” before the examiner, as an implementing regulation for 35 U.S.C. § 132(a). An appeal brief is filed under 37 C.F.R. Part 41, the implementing regulations for 35 U.S.C. § 134. If § 1.113 has *any* relevance to appeals, the basis for that relevance is not explained in the Notice.

The Notice states that “it has long been USPTO practice that an appellant must either appeal from the rejection of all rejected claims or cancel those claims not being appealed. *Ex parte Benjamin*, 1903 C.D. 132 (1903).” This is false. A more truthful statement would be “Over a century ago, before the enactment of the Administrative Procedure Act, before the 1952 Patent Act, before the Paperwork Reduction Act, and under appeal rules quite different from today’s, it **was** PTO procedure to...” However, since at least 1961, old 37 C.F.R. § 1.191 *et seq.* and Part 41 have required applicants

to separately identify the claims that are appealed, and have permitted appeal of less than all claims rejected. The Notice's representation that *Benjamin* "has long been USPTO practice" at best reflects a careless choice of verb tense and careless reasoning, and is certainly misleading. The Notice reflects ***no consideration whatsoever*** of the text of today's § 41.37—a case arising under a totally different rule is totally irrelevant. Overt carelessness, verging on misrepresentation, is harmful to the trust between the bar and the PTO that will be required to improve operations.

The discussion of *Benjamin*, over a century old, neglects to account for intervening changes in facts. First, before the 1960's, final rejection and post-appeal practice—to the degree they existed at all—were quite different from today's, and the rationale underlying the decision in *Benjamin* is simply irrelevant now. Second, *Benjamin* turns on a concern that the Office had no means of knowing an applicant's intent—but that concern is fully resolved by today's § 41.37(c)(1)(iii), which provides exactly the information that the PTO sought in *Benjamin*.

The Notice several times mentions § 41.31 and the lack of any requirement in a Notice of Appeal to identify particular claims²²—but the Notice identifies no problem that is not fully ameliorated by the "identification of claims to be appealed" in the Appeal Brief (§ 41.37(c)(1)(iii)). First, as noted above, the lack of any stated requirement is effectively a grant of permission to applicants to do that which is not forbidden, and the Notice identifies no provision of law that would create an exception to that general provision of administrative law. Consider Forms 1 and 3 to the Federal Rules of Appellate Procedure: both require an appellant only to identify the final judgment, not the individual issues in that final judgment that will eventually be appealed. FRAP 28, much like § 41.37, makes clear that issues presented for appeal need not be identified until the opening brief.

²² See also the definition of "agency action" in 5 U.S.C. § 551(13) ("agency action" includes the whole or a part of an agency ... order, ... or the equivalent or denial thereof"). It is commonplace to subdivide agency actions for different legal treatment.

IV. The PTO should implement internal procedures to ensure compliance with the Paperwork Reduction Act, Executive Order 12,866, and the *Good Guidance Bulletin*

Six times in the last two years, the PTO has been forced to withdraw major rules or guidance publications because of failures to observe the Paperwork Reduction Act, Executive Order 12,866, the *Good Guidance Bulletin*, and similar laws governing rule making procedure. Why are the same failures repeated here? What is the PTO's view of its obligations under the Paperwork Reduction Act, Executive Order 12,866, and the *Final Bulletin on Agency Good Guidance Practices*—does the PTO have any intent or schedule to implement compliance with the law? What problem with “withdrawn from the appeal” or MPEP § 1205.02 is the PTO trying to solve via the Notice? When the Notice describes additional costs and burdens the PTO plans to impose on appellants, but can identify no practical utility and no problem to be solved, how does the PTO explain itself under Executive Order 12,866 and the Paperwork Reduction Act? The Notice's failure to even pretend to follow these laws speaks volumes.

The President's *Good Guidance Bulletin* (see footnote 3) will be three years old in two weeks. I (and several others) have brought the *Bulletin* to the attention of the Office of Patent Legal Administration and the Board in several notice and comment letters, Petitions, and emails, yet there is no indication that the PTO has implemented the *Bulletin*. At what point does OPLA's and the Board's failure to follow Presidential instruction tip from carelessness to deliberate mutiny against the President and the rule of law? Is three years a good dividing line?

The PTO should implement the following provisions of the *Good Guidance Bulletin*:

- Predictability of PTO procedures (particularly Board appeals) would be significantly improved if the Board and OPLA staff received the training in basic principles of administrative law that the President urges in the *Bulletin*.²³

²³ *Good Guidance Bulletin*, footnote 3, preamble § C(I), .../m07-07.pdf at 11, 72 Fed.Reg. 3436, col. 2 (“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)”).

- “Agency employees should not depart from significant guidance documents without appropriate justification and supervisory concurrence.”²⁴
- “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).”²⁵
- “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...; (c) Invite public comment on the draft document; and (d) Prepare and post on the agency’s website a response-to-comments document.”²⁶

V. Conclusion

The Notice offers no rational basis for departing from “withdrawn from the appeal,” the procedural course used by every other tribunal. Rather, the Notice confirms that pre-2008 “withdrawn from the appeal” procedure is the PTO’s best vehicle for complying with its obligations under the law. PTO statements that are inconsistent with “withdrawn from the appeal” procedure, including *Ghuman* (and footnote 8 of *Bilski*) should be expunged. The PTO should implement the President’s directives in the *Final Bulletin for Agency Good Guidance Practices*.

Sincerely,

/s/ David E. Boundy

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²⁴ *Good Guidance Bulletin*, footnote 3, § II(1)(b).

²⁵ *Good Guidance Bulletin*, footnote 3, § III(2)(b).

²⁶ *Good Guidance Bulletin*, footnote 3, § IV(1).



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 GGPs 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.

Attachment B

Draft “Restatement of the Law of Appeals Jurisdiction” for MPEP § 1201

Attachment B

Draft “Restatement of the Law of Intra-PTO Jurisdiction” for inclusion in MPEP § 1201

The United States Patent and Trademark Office (Office) in administering the Patent Laws makes many decisions of a substantive nature which the applicant may feel deny him or her the patent protection to which he or she is entitled. The differences of opinion on such matters can be justly resolved only by prescribing and following judicial procedures. Where the differences of opinion concern the denial of patent claims because of prior art or other patentability issues, the questions thereby raised are said to relate to the merits, and appeal procedure within the Office and to the courts has long been provided by statute (35 U.S.C. § 134). Where the differences opinion lie between the examiner and mandatory instructions issued pursuant to supervisory obligations of the Director of the U.S. Patent and Trademark Office (Director) and Commissioner for Patents (Commissioner), or the procedural rulemaking authority of the Office, relief by petition is provided by rule (37 C.F.R. § 1.181).⁹⁶

The line of demarcation between appealable matters for the Board of Patent Appeals and Interferences (Board) and petitionable matters for the Director of the U.S. Patent and Trademark Office (Director) should be carefully observed. The Board will not ordinarily hear a question that should be decided by the Director on petition, and the Director will not ordinarily entertain a petition where the question presented is a matter appealable to the Board. On appeal, the Board reviews only “adverse decisions of examiners upon applications for patents.” 35 U.S.C. § 6(b), § 134(a). This has two important implications, first that appealable issues relate to “rejections,” second, that only “decisions” are appealable. Both of these are explained further below.

~~However, since~~ Since 37 C.F.R. § 1.181(f) states that any petition not filed within 2 months from the action complained of may be dismissed as untimely and since 37 C.F.R. § 1.144 states that petitions from restriction requirements must be filed no later than appeal, petitionable matters will rarely be present in a case by the time it is before the Board for a decision. *In re Watkinson*, 900 F.2d 230, 14 USPQ2d 1407 (Fed. Cir. 1990).

This chapter is primarily directed to *ex parte* appeals. For appeals in *inter partes* reexamination proceedings, see 37 C.F.R. §§ 41.60 to 41.81 and MPEP §§ 2674 to 2683.

A. “Rejection” is a Necessary But Not Sufficient Condition For Appealability

The Board cannot have jurisdiction over issues where there is no rejection of claims. For example, in *In re Volk*, 634 F.2d 607, 609-10, 207 USPQ 1086, 1087-88 (CCPA 1980), the appellant objected to the claim construction that had been applied to the claims in determining that the claims were patentable. The court held that because there was no rejection, there was no jurisdiction.

⁹⁶ If the Office ever had authority to decline to enforce its internal guidance, that authority was revoked by the President in January 2007.

The mere label “rejection” vs. something else is not determinative of the Board’s jurisdiction, in either direction. For example, an apparently-procedural limit may be so restrictive that no claim of a given scope could ever be examined, let alone issued, even though not denominated a “rejection.” Such *de facto* rejections are appealable. *In re Haas*, 486 F.2d 1053, 1056, 179 USPQ 623, 625 (CCPA 1973) (labeling a requirement “rejection” or not cannot be determinative of jurisdiction; when prosecution of claims is closed such that “[the claims] were never to be considered on the bases of § 102, § 103 and § 112” then a requirement not phrased as a rejection may nonetheless be appealable).

Similarly, the mere label “reject” does not create jurisdiction in the Board, as discussed in sections (B), (C) and (D).

B. The Board Only Has Jurisdiction to Review “Decisions” of Ultimate Statutory Patentability, not Underlying Reasons or Issues of Examination Procedure

Appeal to the Board is from a “decision” of the examiner, not from the reasons upon which such decision is based. 35 U.S.C. § 6(b), § 134(a); 37 C.F.R. § 41.31(a); *Ex parte Maas*, 14 USPQ2d 1762, 1764 (BPAI 1987); *see also* 37 C.F.R. § 41.50(a)(1) (“The Board, in its decision, may affirm or reverse the decision of the examiner in whole or in part on the grounds and the claims specified by the examiner.”); *In re Priest*, 582 F.2d 33, 37, 199 USPQ 11, 14 (CCPA 1978) (rejecting the PTO’s argument that “opinions” merge with “decisions” for review, holding that an “opinion” is almost always distinct from a “decision,” and only the single sentence “decision” is reviewable by the Board, with only “narrowly defined” exceptions).⁹⁷

C. The Board has Supplemental Jurisdiction over Many but Not All Issues Underlying Ultimate Decisions of Non-Patentability

Decisions of patentability involve underlying issues, most of which are reviewable by the Board as part of the review of the ultimate decision.

The Board reviews examiners’ assertions of fact with no deference. All elements of all *prima facie* elements of all grounds of rejection by either the Board or the examiner must be supported by “substantial evidence.” 5 U.S.C. § 706(2)(E); *Universal Camera Corp. v. Nat’ Labor Relations Bd.*, 340 U.S. 474, 487-88 (1951); *In re Gartside*, 203 F.3d 1305, 1312, 53 USPQ2d 1769, 1773 (Fed. Cir. 2000). “Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” The substantiality of evidence must take into account whatever in the record fairly detracts from its weight. Agencies such as the PTO may not rely on “irresponsible admission and weighing of hearsay, opinion, and emotional speculation in place of factual evidence” or “suspicion, surmise, implications, or plainly incredible evidence.” *Universal Camera*, 340 U.S. at 478, 484, 488. Only if this evidentiary burden is met for all *prima facie* elements does the burden of coming forward with rebuttal argument or evidence shift to the applicant. The Board must review the factual sufficiency of the examiner’s decision (either based solely on the *prima facie* case or on the evidence in the record as a whole, if the applicant has rebutted) on a preponderance of evidence. On further judicial review, the Board’s decisions on issues of fact will be reviewed on a “substantial evidence” standard, so appellants are well advised to come forward with rebuttal evidence before appeal.

⁹⁷ *Ex parte Miller*, 1995 WL 1768479 (BPAI 1995) (“We review the decision, not the reasoning...”).

Issues of law are reviewed *de novo*. Decisions of the Court of Appeals for the Federal Circuit or its predecessor, the Court of Customs and Patent Appeals, are normally considered as binding precedent on the Board. *Ex parte McGrew*, 41 USPQ2d 2004, 2007 (BPAI 1995), *aff'd sub nom. In re McGrew*, 43 USPQ2d 1632 (Fed. Cir. 1997), *Ex parte Holt*, 19 USPQ2d 1211, 1214 (BPAI 1991); Standard Operating Procedure No. 2 (revision 6, Aug. 10, 2005) § VI, <http://www.uspto.gov/web/offices/dcom/bpai/sop2.pdf>.

When primary jurisdiction for an issue lies either with the Board or with the Director by Petition, in a few cases the other may have concurrent or supplemental jurisdiction to review the identical issue. These are primarily issues that are ordinarily reviewable by petition, but that may be reviewed on appeal when bound up in a rejection and that “require the exercise of legal judgment:”

- a) “New interpretations of law” in an Examiner’s Answer are subject to concurrent petitions jurisdiction, MPEP § 1003 ¶ 10 (reviewable by T.C. Director), or an applicant may obtain the Board’s adjudication of such questions of law.
- b) Whether a final decision of the Board introduces a “new ground of rejection” that triggers the procedural protections of 37 C.F.R. § 1.196(b). *In re Oku*, 25 USPQ2d 1155, 1157 (Comm’r Pats. & TM 1992)(stating the issue is primarily appealable, but within supplemental petitions jurisdiction when 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).
- c) Obtaining an earlier filing date to antedate prior art. MPEP § 1002.02(b) (petitionable); *In re Makari*, 708 F.2d 709, 711, 218 USPQ 193, 194 (Fed. Cir. 1983) (appealable).
- d) The correctness of a restriction requirement between species of a Markush group. *In re Weber*, 580 F.2d 455, 458, 198 USPQ 328, 332 (CCPA 1978) (appealable); 37 C.F.R. § 1.113(a) (petitionable).
- e) Consideration of an affidavit to overcome a rejection. MPEP § 1002.02(c)(3)(d) (petitionable); *In re Searles*, 422 F.2d 431, 435, 164 USPQ 623, 626 (CCPA 1970) (primary jurisdiction over the examiner’s decision was exclusively by petition, but the Board had supplemental jurisdiction when the issue was “determinative of a rejection” and review “required the exercise of technical skill and legal judgment”).

This concurrent jurisdiction may persist in one tribunal even after adjudication by the other. *E.g.*, *Searles*, 422 F.2d at 435, 164 USPQ at 626; *Oku*, 25 USPQ2d at 1157.

The Board does not have jurisdiction over the following issues:

- f) Premature final rejection, MPEP § 706.07(c).
- g) Issues arising under sources of law other than the substantive patent law, 35 U.S.C. §§ 101, 102, 103, 112, and 135(b) and similar statutes. The Board only has jurisdiction to determine whether a patent may lawfully be granted on the claims presented.⁹⁸ Issues of proper examination procedure arising under other law, such as 35 U.S.C. §§ 131 and 132 (a renewed rejection must state “reasons”), 37 C.F.R.

⁹⁸ *Ex parte Vander Wal*, 109 USPQ 119, 123 (1955).

§§ 1.104 and 1.113, the Manual of Patent Examining Procedure⁹⁹ (including requirements that the examiner address all elements of *prima facie* unpatentability), the Administrative Procedure Act¹⁰⁰, constitutional procedural guarantees¹⁰¹, and similar procedural law are generally not within the Board's jurisdiction.

- h) Questions regarding the conduct of an examiner in abusive rejections of claims are petitionable rather than appealable.¹⁰² Supervision of examiners – including examiners' rejection of claims – is committed by statute to the Director and Commissioner of Patents, 35 U.S.C. § 131 (“the Director shall cause an examination to be made...”); 35 U.S.C. § 3(b)(2)(A) (Commissioner for Patents is responsible “for the management and direction of all aspects of the activities of the Office that affect the administration of patent . . . operations.”), not the Board.

D. Available Relief and Supervisory Authority of the Board

An issue is not appealable when the Board lacks power to grant the relief requested.¹⁰³

The relief available in an appeal to the Board is a reversal of rejections. A reversal is not a declaration of patentability; it is only a reversal on the issues then pending. The

⁹⁹ *Sehgal v. Revel*, 81 USPQ2d 1181, 1186-87 (BPAI 2005) (MPEP is “directed to patent examiners conducting normal examination,” not to the Board); *Ex parte Haas*, 175 USPQ 217, 220 (Bd. Pat. App. 1972) (*Haas I*) (“If the examiner fails to follow the Commissioner’s directions in the M.P.E.P., appellant’s remedy is by way of petition to the Commissioner since this Board has no jurisdiction over the examiner’s action.”) (Lidoff, EIC, concurring), *rev’d on other grounds*, 486 F.2d 1053, 179 USPQ 623 (CCPA 1973) (*Haas II*). The Board’s Standard Operating Procedure No. 2 (revision 6, Aug. 10, 2005) § VI, lists the authority by which the Board considers itself bound. The MPEP is not even on the list. Similarly, in *Ex parte Holt*, 19 USPQ2d 1211, 1214 (Bd. Pat. App. & Interf. 1991), the MPEP is absent from the list of precedent by which the Board considers itself bound.

¹⁰⁰ *See In re Wiechert*, 370 F.2d 927, 938, 152 USPQ 247, 255 (CCPA 1967) (jurisdiction for APA review lies with district court, not the Board).

¹⁰¹ *See Ex parte Kimbell*, 226 USPQ 688, 690 (BPAI 1985) (Board does not have jurisdiction to evaluate constitutionality of statutes, breaches of due process, or alleged harassment by examiner).

¹⁰² *Ex parte Global Patent Holdings LLC, U.S. Pat. No. 5,235,341*, Appeal No. 2006-0698, <http://des.uspto.gov/Foia/RetrievePdf?system=BPAI&fINm=fd2006069812-26-2006>, at p. 9 (BPAI Dec. 26, 2006).

¹⁰³ A particular set of facts may give rise to rights to different kinds of relief, and different claims for relief on the same facts may have different jurisdictional paths. *E.g., Federal Communications Comm’n v. NextWave Personal Communications Inc.*, 537 U.S. 293, 302-03 (2001) (same facts gave rise to New York bankruptcy action and D.C. Administrative Procedure Act action, and decision in favor of agency in one court did not preclude discharge of debt in the other). An agency may not require that an issue be presented to a tribunal that has no power to grant the type of relief requested. *McCarthy v. Madigan*, 503 U.S. 140, 148 (1992); *Maggitt v. West*, 202 F.3d 1370, 1377 (Fed. Cir. 2000). Thus, issues of examiner non-compliance with PTO procedural rules are not appealable as stand-alone issues (and only rarely within the Board’s supplemental jurisdiction), only the ultimate rejection.

examiner has authority to re-open prosecution on different issues, though under narrow limits prescribed by the Director. *See, e.g.*, MPEP § 1214.04; *see also Blacklight Power Inc. v. Rogan*, 295 F.3d 1269, 1273-74, 63 USPQ2d 1534, 1537 (Fed. Cir. 2002) (PTO may withdraw a patent from issue, but only after it fully presents a *prima facie* case of unpatentability).

The Board may also remand an application to the examiner, 37 C.F.R. § 41.50(a)(1), but only when the parties have not provided the Board with sufficient information to make a final adjudication. 5 U.S.C. § 555 (agency appellate tribunals are required “within a reasonable time, ... to conclude a matter presented to it,” and may not “bounce” matters to lower-level adjudicators when the information necessary to reach a final decision is available).¹⁰⁴ The Board does not have authority to issue mandatory supervisory instructions in a remand order.¹⁰⁵ For a non-exhaustive list of bases for remand, see MPEP § 1211.

The Board's jurisdictional statutes (35 U.S.C. §§ 6 and 134) do not charge the Board with supervision of the patent examining operation. The Board does not exercise supervisory authority over examiners,¹⁰⁵ and has no management power over the examining corps. In examining claims under §§ 131 and 132, an examiner acts as an agent of the Director, not of the Board. Statements framed in mandatory language in the MPEP or Code of Federal Regulations are binding on examiners and enforceable by the examiner's supervisory chain. Executive Order 13,422; Executive Office of the President, Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432 (Jan. 25, 2007).¹⁰⁶ Thus, actions of an examiner that violate written mandatory language in the MPEP or 37 C.F.R. § 1.104 are outside of the delegation of authority from the Director principal to the

¹⁰⁴ *British Airways Board v. Port Authority of New York and New Jersey*, 564 F.2d 1002, 1012 (2d Cir. 1977) (an agency must pursue some path that will “resolve those issues in the reasonably foreseeable future.”); *Deering-Milliken Inc. v. Johnston*, 295 F.2d 856, 865 (4th Cir. 1961); *McDonnell Douglas Corp. v. National Aeronautics and Space Admin.*, 895 F.Supp. 316, 319 (D.D.C. 1995) (condemning “second bites” and an agency's “never ending loops”)

¹⁰⁵ Even on remand, “The board does not exercise supervisory authority over examiners.” Board of Patent Appeals, Frequently Asked Questions page, <http://www.uspto.gov/web/offices/dcom/bpai/bpaifaq.htm>, “Answer to Question 8, Part One.” This attorney has searched diligently, and in the history of the Board, there appears to be only one instance in which the Board has ever issued a mandatory order to an examiner. Note that the remand cases listed in footnote 109 consistently remand with no mandatory order. The Board's acknowledges that it lacks power to compel an examiner's compliance with any rule on further examination. *E.g.*, *Gambogi*, 62 USPQ2d at 1212 (“We decline to tell an examiner precisely how to set out a rejection”). The Board at most offers non-binding “suggestions,” with nothing like the detail set out in the MPEP.

¹⁰⁶ *See also Ethicon Inc. v. Quigg*, 849 F.2d 1422, 1425, 7 USPQ2d 1152, 1154 (Fed. Cir. 1988) (“The MPEP states that it is a reference work on patent practices and procedures and does not have the force of law, but it ‘has been held to describe procedures on which the public can rely.’”); *PerSeptive Biosystems Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1321, 56 USPQ2d 1001, 1005 (Fed. Cir. 2000) (MPEP sets out “required” actions, and “details the ‘rules’ ... to be used by examiners”).

examiner agent.¹⁰⁷ These relate to examination procedure rather than ultimate issues of patentability, and the appropriate relief is supervisory oversight, which should be obtained by telephone calls to the examiner's supervisory chain, or by Petition under 37 C.F.R. § 1.181.¹⁰⁸ Supervisory oversight is not within the Board's powers of relief.

Several other forms of relief are solely within the authority of the Commissioner and Director: reopening of prosecution, *In re Oku*, 25 USPQ2d 1155, 1157 (Comm'r Pats. & TM 1992), and withdrawal of premature final rejection, MPEP § 706.07(c). Thus, issues seeking these forms of relief are not appealable.

Appeals are “manifestly not ready for a decision” and “not ripe”¹⁰⁹ – that is, the Board lacks jurisdiction to render a final decision – where the examiner has omitted findings on an element of the relevant *prima facie* case. The Board cannot efficiently perform its

¹⁰⁷ Restatement 2d (Agency), § 33 (“An agent is authorized to do, and to do only, what it is reasonable for him to infer that the principal desires him to do in the light of the principal's manifestations...”); Restatement 2d (Agency) § 214 (“A ... principal who is under a duty to ... to have care used to protect others or their property and who confides the performance of such duty to a servant or other person is subject to liability to such others for harm caused to them by the failure of such agent to perform the duty.”)

¹⁰⁸ The Federal Circuit recently clarified the distinction between merits issues and procedural issues, in a way that clarifies that procedural issues underlying rejections of claims are within the scope of the Director's supervisory obligations: “The scope of APA review is not, as the district court feared, to test the examiner's theory of the case or the examiner's findings of fact. The district court, on APA review, does not enmesh itself in the decision-making process of the examiner. Its function, instead, is simply to guard against the possibility of arbitrary or capricious behavior by examiners in seeking information.” *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1285, 73 USPQ2d 1409, 1415 (Fed. Cir. 2005)

¹⁰⁹ The Board has persistent inability to decide cases because of omissions in the examiner's half of the record. *E.g.*, *Ex parte Daleiden*, Appeal 2007-1003, fd2007100303-14-2007.pdf (Mar. 14, 2007) (remanding because examiner failed to respond to arguments in the Appeal Brief); *Ex parte Rozzi*, 63 USPQ2d 1196, 1200-03 (BPAI 2002) (McKelvey, J.) (remanding without decision because of a host of examiner omissions and procedural errors); *Ex parte Gambogi*, 62 USPQ2d 1209, 1212 (BPAI 2001) (“We decline to tell an examiner precisely how to set out a rejection.”); *Ex parte Jones*, 62 USPQ2d 1206, 1208 (BPAI 2001) (refusing to adjudicate an issue that the examiner has not developed); *Ex parte Schricker*, 56 USPQ2d 1723, 1725 (BPAI 2000) (“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 1999) (noting that the appeal is “not ripe” because of omissions and procedural defects in the examiner's analysis). Other appellate tribunals frequently state that they are unable to review decisions when inferior tribunals have not stated the necessary findings, or otherwise present an undeveloped record. *E.g.*, *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 811, 229 USPQ2d 478, 479 (1986) (obviousness has separate “procedural” and “substantive” aspects, and the Supreme Court cannot review the substantive issue when the underlying decision is procedurally incomplete); *Warner-Lambert Co. v. Teva Pharmaceuticals USA, Inc.*, 418 F.3d 1326, 1337-38, 75 USPQ2d 1865, 1872-73 (Fed. Cir. 2005) (remanding because of district court's failure to make findings, rendering appellate review impossible); *Nazomi Communications Inc v. ARM Holdings Inc.*, 403 F.3d 1364, 1371-73, 74 USPQ2d 1458, 1463-64 (Fed. Cir. 2005) (same)

adjudicatory functions unless applicants and examiners, possibly with the assistance of the supervisory authority of the Director and Commissioner, ensure that prosecution and examination are complete before an appeal commences. To ensure appeals are fully ripe, and that a “clear issue for appeal” is developed before appeal, MPEP § 706.07, final rejection and issues of examination procedure should be addressed by telephone conference with the examiner, or the examiner’s supervisor, by request for correction pursuant to MPEP § 710.06, or by petition under 37 C.F.R. § 1.181, to clarify the following types of omissions from examiners’ actions:

- i) complete omission of comparison of one or more claim elements to any reference;
- j) mere designation of a “portion” of a reference, without “clear explanation” when required by 37 C.F.R. § 1.104(c)(2);
- k) reliance on facts within the personal knowledge of an employee of the Office after timely applicant action as specified in 37 C.F.R. § 1.104(d)(2);
- l) omission of discussion of one or more *prima facie* elements as defined in the relevant portions of MPEP Chapters 700 or 2100, or substitution of an unauthorized legal test for a test stated in mandatory terms in the MPEP;
- m) failure to answer all material traversed, MPEP § 707.07(f).

Generally, an applicant is entitled to receive some written notice of the examiner’s position on each *prima facie* element of non-patentability, and each claim element. It is the responsibility of the Director and Commissioner to ensure that the examiner does not “sit mum, leaving the applicant to shoot arrows into the dark.” *In re Oetiker*, 977 F.2d 1443, 1449, 24 USPQ2d 1443, 1447 (Fed. Cir. 1992) (Plager, J., concurring)¹¹⁰ However, once those positions are articulated to at least some minimal degree, appeal to the Board is the appropriate resolution of disagreements.

E. Jurisdiction to Determine the Board’s Jurisdiction Lies with the Board

Like almost all other statutorily-constituted tribunals, the Board of Patent Appeals and Interferences has jurisdiction to determine its own jurisdiction. *Ex parte Lemoine*, 46 USPQ2d 1432, 1434 (BPAI 1995) and cases cited therein. Decisions regarding the Board’s jurisdiction by other portions of the PTO, while worthy of serious consideration, are not, and can not be, binding on the Board. *Lemoine*, 46 USPQ2d at 1434. The Board’s jurisdiction does not attach until the examining corps has finished its job and transfers the application file to the Board. The examining operation can not create jurisdiction where none exists. *Lemoine*, 46 USPQ2d at 1434.

¹¹⁰ *In re Deuel*, 51 F.3d 1552, 1557, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995) (“The examiner bears the burden of establishing a *prima facie* case of obviousness,” emphasis added); *In re Oetiker*, 977 F.2d 1443, 1445-46, 24 USPQ2d 13443, 1444 (Fed. Cir. 1992) (“the examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. ... If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent ... We think that the PTO is correct in treating the concept of the *prima facie* case as of broad applicability, for it places the initial burden on the examiner, the appropriate procedure whatever the technological class of invention” emphasis added).