In 2007, the Office of Management and Budget in the Executive Office of the President issued the Bulletin on Agency Good Guidance Practices addressed to all executive branch agencies. The Bulletin does two things. First, it reminds agencies of a number
of basic statutory principles of administrative law. Second, the Bulletin constitutes OMB's implementing guidance for several statutes and Executive Orders (including the Information Quality Act), and itself carries the authority of an Executive Order, to assist agencies in improving the "quality, utility, objectivity, and integrity of information" disseminated by agencies (including their guidance documents), and to help agencies improve their rulemaking processes. The Bulletin is no dusty old historical relic—within 10 days of his inauguration, President Trump put the Bulletin front and center in his deregulatory agenda, and reminded agencies of their obligations to adhere to it.  

PTO has been, well, a bit behind the times on implementing this Bulletin. In fact, PTO is now coming up on twelve years delinquent in implementing the statutory requirements noted in the Bulletin, let alone the directives issued on the authority of the President. Not only is PTO now over a decade late, it's several billion dollars short. In early November, I asked the following question of one of the patent attorney email lists:

As a percentage of your post-filing prosecution (after initial filing, before allowance), what percentage of your time do you spend dealing with PTO error due to misuse of guidance?

The median (half above, half below) response was “a little under 50%,” and mode (most common response) was 50%. This translates into over $1.5 billion per year in direct costs—attorney fees, excess fees paid to PTO, and the like. The cost to the public for the waste arising from PTO’s delay in implementing the Good Guidance Bulletin is about equal to (and perhaps greater than) PTO’s budget for its entire patent operation.

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5 Email questions and responses on file with the author.

6 PTO’s most recent estimate of direct costs of prosecution, after filing and before allowance, not including appeals, in 2012, was $3.9 billion per year. 77 Fed. Reg. 16813-17. (Public comments noted that PTO’s estimate was too low, skewed by incorrect choices of statistical
Several survey respondents gave narrative elaborations of their numerical answers. Many noted that inventors often can’t afford to fight PTO errors, and instead sacrifice patent coverage to which they are entitled by law. One respondent wrote:

[T]hings like this don’t just waste our time as practitioners; they are seriously harmful to the US economy. Big businesses get slowed down and waste resources …, and small businesses often just do not have the expertise or money to deal with it at all, and so they abandon research that could have resulted in valuable products. I know this is true—I’ve seen it. I’m sure you’ve all seen it.

When the value of attorney fees, lost patent protection, companies not formed, companies that fold because of delays and unpredictability of their patent applications, business opportunities not pursued, and similar economic effects are factored in, the economic damage caused by PTO’s bad guidance practices is well into the billions each year.

Maybe it’s time for PTO to follow the law. This article is a primer on one of the key issues in the law of guidance: when may PTO act by less-formal-than-regulation guidance, vs. when must the agency use regulation promulgated under statutory procedure? What are the legal consequences when PTO uses less procedure than required by law? Among PTO’s non-regulatory guidance, are there especially-costly rules that were invalidly promulgated, that should be removed from guidance? Which could be re-promulgated by proper regulation? Which are simply illegal and should be dropped entirely?

I. “Guidance?” “Rule?” “Regulation?” What do those words mean?

“Guidance” is an informal term that doesn’t appear in any statute. The term started showing up in D.C. Circuit decisions in the late 1980s to refer to any “rule” that isn’t a “regulation.”

What’s a “rule?” The Administrative Procedure Act, 5 U.S.C. § 551(4), defines “rule” as “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...” One of the key administrative law cases from the D.C. Circuit notes that the definition of “rule” in § 551(4) “include[s] nearly every statement an agency may

methods, under-inclusions, and obsolete data.) 50% of $3.9 billion is $1.95 billion (in 2012). In contrast, for FY2012, the budget for PTO’s entire patent business unit was about $1.5 billion. PTO Performance and Accountability Report FY2012
https://www.uspto.gov/sites/default/files/about/stratplan/ar/USPTOFY2012PAR.pdf at 74. FY2018 numbers are up over FY2012 by about 28%.

make,” and that exemptions from statutory rule making procedures are “limited.”

What’s a “regulation?” To my knowledge, the term isn’t defined. However, in recent years, idiomatic use has coalesced around the Code of Federal Regulations—a “regulation” is a “rule” that has been run through the procedures required by various statutes (the APA’s rulemaking provisions of 5 U.S.C. § 553, the APA’s publication requirements of § 552, the notice-and-comment and other vetting requirements of the Paperwork Reduction Act and its implementing regulations, 44 U.S.C. §§ 3506 and 3507, and 5 C.F.R. Part 1320, the Regulatory Flexibility Act, etc.) and Executive Orders (E.O. 12,866, 13,771, etc.), and has come to rest in the Code of Federal Regulations.

In the Patent Act, Congress is remarkably consistent and precise in its use of terms: Congress uses “regulation” when delegating rulemaking authority that (under one or another of the administrative law statutes) requires notice-and-comment rulemaking procedure, and Congress uses another less-specific term such as “rule” or “procedure” where no administrative law statute requires a “regulation” (in the sense of the previous paragraph). The Patent Act consistently uses “regulation” to delegate rulemaking authority where PTO is to bind the public with respect to issues that are foreseeable and determine substantial rights. In contrast, authority to act by non-regulation “rule” or to set “procedures” is delegated only for rules that fall within a recognized exception to the “regulation” requirements of the administrative law:

(a) supervision of acts of agency employees,

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8 The following statutes grant the Director the authority to promulgate regulations. 35 U.S.C. § 2(b)(2)(D) (Director may promulgate general procedural regulations), § 2(b)(2)(D) (Director may promulgate regulations to govern recognition of attorneys and agents); §§ 41 (Director may, by regulation, set fees and conditions for refund), § 115(d) and (h) (Director may specify regulations for substitute statements), § 119(a) and (e) (Director may promulgate regulations for priority claims to foreign applications and provisional applications), § 123(a) (Director may issue regulations to define “micro entity”); § 132(b) (Director shall prescribe regulations for RCEs); § 135 (Director shall prescribe regulations for derivation proceedings); § 154(b)(2) and (3) (Director shall prescribe regulations for term adjustment); §§ 206, 208 (Secretary of Commerce shall issue regulations for BayhDole); § 257(d) (Director shall issue regulations to govern supplemental examination), 311(a) (Director shall, by regulation, establish fees for IPR), § 312(a)(4) (Director may govern IPR petitions by regulation); § 316(a) and (d)(2) (Director shall prescribe regulations for conduct of IPR); § 321(a), § 322(a)(4), § 326 (same for PGR).

9 Housekeeping rules, by which an agency binds its employees, are governed by the “Housekeeping Act,” 5 U.S.C. § 301, and carved out from the rulemaking provisions of § 553 (§ 553(a)(2) (exempting “matter[s] relating to agency management or personnel!”)). 5 U.S.C. § 3(b)(2)(A) charges that the Commissioners of Patents and Trademarks “shall be responsible for the management and direction of all aspects of the activities of the Office that affect the administration of patent and trademark operations, respectively.”
(b) issues where equitable discretion is needed to adjudicate forgiveness for one-off errors (for example, to waive a rule to cure lost mail or missed deadlines) but foresight of all possible future situations is nigh impossible, and (c) ministerial acts, and acts of PTO that are tangential to adjudicating substantial rights.  

35 U.S.C. § 257(d)(2) is particularly instructive on Congress’ exacting care: the Director shall issue regulations for the public to follow in requests for supplemental examination, and procedures for PTO employees to follow in reviewing those requests.

Administrative law rulemaking statutes and executive orders obligate agencies to consult with the public, introspect, analyze, and provide an explanation of rationale for any rule. Statutory rulemaking procedure is designed to ensure that an agency does not raise costs on the public by $2 to reduce agency costs by $1, does not create costs on the public that can be reduced through better internal agency controls, does not impose undue burden on small entities, etc. Statutory rulemaking procedure ensures predictability and, ultimately, “reasoned decisionmaking.” When an agency bypasses any of these obligations, there’s a high risk that the agency will fail to act in the public interest. And of course the incentives and risks are even higher when an agency is funded by user fees.

Rulemaking procedure, the Code of Federal Regulations, and the Federal Register as the publication venue for official interpretations of the Code, are important to agency predictability, so that the public has a single, consolidated, internally consistent place to look, and thereby know how to interact with the agency. The alternative to orderly and predictable “regulations” and rulemaking procedure is a
cacophony of other “stuff” that looks, to a member of the public trying to interact with the agency, like a blizzard of antiaircraft chaff: a sui generis Official Gazette, agency staff manuals that contain rules purporting to bind the public, internal memoranda (some visible to the public, some not), Q&A and FAQ web pages, PowerPoint slides, webinars (many of which are presented once, with no stored copy on the agency’s web site), precedential decisions spread over several lists on PTO’s web site, “informative” decisions that the agency treats as precedential, Standard Operating Procedures (some of which have rule content), checkboxes on forms (that often create carve-outs from regulations that were adopted to protect the public), etc., that sometimes directly clash with regulation and with each other.\textsuperscript{10}\textsuperscript{11} The Administrative Procedure Act, Paperwork Reduction Act, Information Quality Act, and Good Guidance Bulletin are supposed to prevent this kind of bedlam.

II. When may an agency act by non-regulation guidance?
An agency must act by “regulation” for any “rule” that does not fit one of the exemptions of 5 U.S.C. § 553(a), (b)(A), (b)(B), or (d),\textsuperscript{12} or that is covered by a notice-and-comment of other administrative law statutes (for example, the Paperwork Reduction Act requires notice-and-comment for almost all of PTO’s procedural rules, e.g., 44 U.S.C. § 3506(c)(2)(A); 5 C.F.R. § 1320.3(c)(4)(i)), or if the agency's own organic statute requires.\textsuperscript{13}

When may an agency act by less-than-regulation guidance? Simple question, simple answer: when a rule doesn’t fall into a category that requires “regulation” rulemaking. But these exemptions have a “price” for the agency—\textsuperscript{14}—a rule promulgated by less-than-regulation procedure has less-than-regulation binding effect:

\textsuperscript{10} PTO’s uncoordinated rule statements, and some examples of direct clashes, are explained in Boundy, Part 3: Precedential and Informative Decisions, note 39 infra, at § II(B)(2), pages 8-

\textsuperscript{11} A nice picture showing how those exemptions interrelate is shown in Boundy, Part 1, note 37 infra. Wouldn’t you know. About two weeks after the Part 1 article went to press, I realized an even better way to visualize the taxonomy of all rules, and I started writing the next article. If you ask nicely, I would likely send you this work-in-progress article.


\textsuperscript{13} Perez v. Mortgage Bankers Ass’n, 135 S.Ct. 1199, 1204 (2015).

- Once an agency issues guidance that uses mandatory language to state obligations of agency employees with respect to “important procedural benefits” to the public, or publishes an “interpretative” rule interpreting the agency’s statute or regulation, agency employees (including ALJs) are bound, the public is entitled to rely on employees’ observing the guidance, and the agency is obligated to enforce the procedural commitments it makes to the public. This is the well-known “Accardi principle.”

- To interpret an “active” ambiguity, such as an ambiguous term, a general term, or a conflict. A passive silence in the underlying statute or regulation, or a new rule that is merely “consistent with” or “not negated” by the underlying statute or regulation, or that fleshes out empty or vague language like “fair and equitable” or “in the public interest” are almost never eligible for the “interpretative” exemption of § 553(b)(A).

For example, the Supreme Court blessed the NLRB when it used guidance to interpret the statutory term “managerial employee,” but shot down an NLRB procedural rule that, while entirely consistent with the statute, and within the NLRB’s power to order as a one-off adjudication order, was invalid as a rule, because promulgated without APA procedure.

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15. *In re Kaghan*, 387 F.2d 398, 401, 156 USPQ 130, 132 (CCPA 1967) (“we feel that an applicant should be entitled to rely not only on the statutes and Rules of Practice but also on the provisions of the MPEP in the prosecution of his patent application.”); *Vitarelli v. Seaton*, 359 U.S. 535, 545 (1959) (holding that an agency action was “illegal and of no effect” because the agency's dismissal “fell substantially short of the requirements of the applicable department regulations”); *Service v. Dulles*, 354 U.S. 363, 386–88 (1957) (finding that an unpublished manual was binding, and violation of that manual was a ground for setting aside agency action); *Accardi v. Shaughnessy*, 347 U.S. 260 (1954); *Gulf States Mfrs, Inc. v. NLRB*, 579 F.2d 1298, 1308-09 (5th Cir. 1978) (an agency manual (whether procedural or substantive) is binding on agency staff, up to and including ALJs, even if not published in the Federal Register).


18. Contrast *Wyman-Gordon Co.*, note 19 supra, 394 U.S. at 761 (striking down a rule by which
Interpretations that rely on the “interpretative” exemption to bypass “regulation” procedure “do not have the force and effect of law and are not accorded that weight in the adjudicatory process”\(^\text{21}\)—they are binding on the public with only Skidmore deference,\(^\text{22}\) until an interpretation is confirmed by an Article III court. In the meantime, the agency may not rely on an interpretative rule to “foreclose consideration by the agency of positions advanced by private parties.”\(^\text{23}\)

(An interpretation within the non-regulatory Skidmore framework is like Schrödinger’s cat—it’s impossible to know whether the agency’s interpretation is live or dead, until an Article III court peeks into the box.)

- To offer an agency’s advisory thoughts, that the agency does not intend to enforce (typically using the word “should”) as a “general statement of policy” under § 553(b)(A). o “General statements of policy” require no procedure (other than publication), but have no binding effect whatsoever—that’s the *quid pro quo*.\(^\text{24}\)

- To relax or waive a procedural regulation *in favor* of a member of the public.\(^\text{25}\) An agency has great discretion to grant waivers in favor of the public, but none in favor of itself.


\(^{21}\) Perez, note 16 supra, 135 S.Ct. at 1204.

\(^{22}\) Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944) (“We consider that the rulings, interpretations and opinions of the [agency], while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance. The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.”).

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NLRB required employers to give employee lists to unions, because not promulgated by APA


25 See note 11 supra.

Amendments to “recognize[] an exemption or relieve[] a restriction” can be promulgated on simple notice (§ 553(d)(1)); rules to raise burdens on the public must go through statutory rulemaking procedure (e.g., 5 U.S.C. §§ 553(b) and (c), 603, 604; 44 U.S.C. § 3507(a)).

• There are a few cases where an agency can issue guidance when it can’t act by regulation. For example, PTO has no substantive rulemaking authority, and so cannot bind the public on substantive patent law by regulation (nor by any other mechanism, such as precedential opinion)20—but has not only the power but the duty to instruct examiners on substantive law. 35 U.S.C. § 3(b)(2)(B). Similarly, PTO could offer non-binding “interpretative” or “policy statement” guidance on issues where it has no rulemaking authority at all—for example, on state assignment law in the context of PTO’s patent or trademark activities.

Note that these exceptions are all targeted at areas where the effect of a rule is too small to warrant full rulemaking procedure (e.g., interpretation of ambiguity, or non-binding advisory policy statements), or the agency’s incentives to act in selfinterest instead of the public interest are small enough that Congress can trust the agency to be self-policing.

When may an agency **not** use guidance? In other words, when **must** an agency act by “regulation?”

• An agency may **not** use non-regulation guidance to bind the public under a rule that goes beyond interpreting an “active” ambiguity.21 To bind the public, an agency must use statutory rulemaking procedure. If a law itself has force of law, then an agency may “interpret” ambiguities in that law, § 553(b)(A), but may not, “under the guise of interpreting a regulation, … create de facto a new regulation.”22

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21 See note 19 supra.


• If an agency regulation speaks to an issue, the agency can interpret ambiguity in that regulation using guidance, but may not add additional provisions or carve-outs that add burden to the public or attenuate the agency’s responsibilities.\(^{23}\)

The astute reader will note the asymmetry: an agency may bind itself and its employees easily. An agency may waive a rule that operates against the public. But the opposite doesn’t apply: agencies can’t renege on deals they make with the public during notice-and-comment, or grant themselves waivers from promises they make to the public in their guidance, or add burdens or obligations to the public. The asymmetry is stated on the face of the APA, 5 U.S.C. § 552(a), and the way § 553(a)(2) exempts “matter[s] relating to agency management or personnel” from the high procedure of § 553(b), and remits them to the low-procedure mechanisms of § 301. The D.C. Circuit explained the asymmetry in \(\textit{Lopez v. Federal Aviation Administration}, 318\ F.3d 242, 246–47 (D.C. Cir. 2003).^{30}\)

\section*{III. Consequences of short-cutting rulemaking procedure}

Almost all of the laws that govern rulemaking provide that an agency may not enforce a rule promulgated with less than statutory procedure, and that agency adjudications under invalid rules may likewise be set aside:

• The cases are legion where an agency shortcuts rulemaking procedure by acting through guidance, tries to attach binding effect to its guidance, and gets caught, and a court orders the agency to stand down on the rule.\(^{24}\)

\(^{23}\)\(\textit{Perez}, 135\ S.Ct. at 1206 (to amend a rule, an agency must use the same procedure that was used in first instance); \(\textit{Wyman-Gordon Co.}, note 19 supra, 394\ U.S. at 763-66 (an agency may not bypass statutory rulemaking procedure).\)

\(^{24}\)\(\textit{Wyman-Gordon Co.}, note 19 supra, 394 U.S. at 761, 763-66; \(\textit{McLouth Steel Products Corp. v. Thomas}, 838\ F.2d 1317, 1320 (D.C. Cir. 1988); \(\textit{Community Nutrition}, note 24 supra, 818\ F.2d at 947-49. It’s striking how few cases there are on this point after the mid-1990s—most agencies figured out how to comply with the law, most of the time. After the \textit{Good Guidance}\)
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(2000). If it is not, it is invalid. ... Here, however, we have a different situation. The issue is not whether the agency statement is binding on the public, but whether it is binding on the agency itself. ... The general consensus is that an agency statement, not issued as a formal regulation, binds the agency only if the agency intended the statement to be binding. The primary consideration in determining the agency's intent is whether the text of the agency statement indicates that it was designed to be binding on the agency.”); Warder v. Shalala, 149 F.3d 73, 82 (1st Cir. 1998) (“Of course, a rule with the force and effect of law—binding not only the agency and regulated parties, but also the courts—is by definition a substantive rule. However, a rule may lack this force and still bind agency personnel.”); Zhang v. Slattery, 55 F.3d 732,748 (2d Cir. 1995) (“We have ruled, however, that a regulation need not necessarily be published [in the Federal Register] in order to be enforced against the government.”); New England Tank Industries of New Hampshire v. United States, 861 F.2d 685, 688, 694 (Fed. Cir. 1988). Asymmetry is not common in the law, but it pervades the law of guidance.

5 U.S.C. § 552(a) requires publication in the Federal Register, and guarantees to the public that it can watch one, and only one, channel to be fully informed of breaking news relating to agency rulemaking. Courts regularly invalidate agency rules that were not published as required by § 552. Remarkably, even though this statute has been in effect for seventy years, and the MPEP has been around for sixty, the Office of Patent Examination Policy only got around to complying with § 552 ten months ago. Even more striking, PTO’s trademark side has been running these notices for decades.

25 Even if a rule might be eligible for both the “interpretative” and “procedural” exemptions from notice-and-comment, if not published in the Federal Register, the rule may not be enforced. W.C. v. Heckler, 629 F.Supp.2d 791, 801 n.19 (W.D. Wash. 1985).


27 The difference between the two sides of PTO in levels of compliance with the administrative law, and ability to learn from failures, is jarring. Contrast Aqua Products, Inc. v. Matal, 872 F.3d 1290 (Fed. Cir. 2017) (setting aside a rule promulgated by the PTAB, because of “an end-run around [the APA] by conducting rulemaking” without statutory rulemaking procedure—PTAB’s misstatement that the rule was “procedural” was the error that started the court’s unraveling of PTO’s position); David Boundy and Andrew B. Freistein, The PTAB Is Not an Article III Court, Part 2: Aqua Products v. Matal as a Case Study in Administrative Law, ABA LANDSLIDE 10:5, pp. 44-51, 64 (May-Jun. 2018) (available here, explaining the violations of law in PTAB’s attempted rulemaking); Patent and Trademark Office, Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, Final Rule, 83 Fed. Reg. 51340, 51357 col. 2 (Oct. 11, 2018) (the PTAB’s claim construction rule is “procedural” because it “will not change the substantive criteria of patentability”—if this very same misstatement got the PTAB in hot water in Aqua, what’s it doing again here?).
• The Paperwork Reduction Act is explicit in barring agencies from shortcutting, 44 U.S.C. § 3507(a) and § 3512—if an agency rule falls within the Act (most PTO procedural rules do, see the definitions in the implementing regulations, 5 C.F.R. § 1320.3), and PTO shortcuts necessary procedure (e.g., MPEP rules by guidance), then the agency may not penalize a member of the public for failure to comply with that rule.

• The Regulatory Flexibility Act is interesting. The Act nominally restricts judicial review. However, a number of courts have invalidated agency rules when agency paperwork gave the facial appearance of compliance, and gave the facial appearance of triggering the preclusion of review statute. When a

bulletin was issued in 2007 and implemented by other agencies, these cases evaporated to near zero. PTO is a remarkable outlier.

court looks below the surface and finds that agency compliance was illusory, that the agency’s analysis was implausibly thin, or that the agency had improperly avoided inquiry into the practical consequences on small entities, courts set aside rules.28

In addition, if an agency’s shortcutting is so extensive that a rule never went into enforceable effect, or the public never had appropriate notice of an effective date, the statute of limitations never begins, and the agency may be divested of any opportunity to assert any statute of limitations defense to challenges to the rule.29

IV. Good additional sources on guidance
Four good introductions to the law of guidance may be found in:

• The Bulletin for Agency Good Guidance Practices. The Bulletin itself creates no legal rights, but it usefully restates conventional APA law.

• David Boundy, The PTAB is Not an Article III Court, Part 1: A Primer on

There are several structural differences between the patent and trademark sides of the agency that might steer the patent operation to shortcut laws that the trademark operation follows. Perhaps a subject for a future article.


29 National Resources Defense Council v. Nat’l Highway Traffic Safety Admin, 894 F.3d 95, 106 (2d Cir. 2018) (a rule does not go effective until published in the Federal Register, and that’s the event that commences the limitations period); W.C. v. Heckler, note 32 supra, 629 F.Supp.2d at 806; State of New York v. Heckler, 105 F.R.D. 118, 124 (S.D.N.Y. 1985) ("the absence of formal publication of [an agency rule]... had the same effect ... for purposes of the limitations period... ").
• Federal Agency Rule Making. At the March 2018 Federal Circuit Judicial Conference, Judge Plager recommended this article to the entire patent bar. The article presents a helpful taxonomy of the entire landscape of “rules” that clarifies a great deal.

• David Boundy, The PTAB is Not an Article III Court, Part 3: Precedential and Informative Decisions, including a more-elaborated explanation of “do’s” and “don’ts” for non-regulation guidance, is forthcoming in AIPLA Quarterly Journal.

• Robert Anthony (who was, at the time, the Chairman of the Administrative Conference of the United States), Interpretive Rules, Policy Statements,

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30 David Boundy, The PTAB is Not an Article III Court, Part 1: A Primer on Federal Agency Rule Making, ABA LANDSLIDE 10:2, pp. 9-13, 51-57 (Nov-Dec. 2017), at [here](#) or [here](#).

31 See note 14, supra.

32 David Boundy, The PTAB is Not an Article III Court, Part 3: Precedential and Informative Decisions, forthcoming in AIPLA Quarterly Journal, [here](#). On the guidance issues of this article, pages 3-19 are particularly relevant.
Guidances, Manuals, And The Like—Should Federal Agencies Use Them To Bind The Public?33

V. Examples of rules improperly promulgated by guidance

A. Example 1: The secret 2007 restriction memo

35 U.S.C. § 121 allows PTO to divide an application when it claims “independent and distinct” inventions. For decades, the MPEP required a showing of “serious burden” as part of a restriction requirement. The pre-2007 MPEP required an examiner to support a restriction by showing that the two inventions are to be searched in different search classes, or give some other objective explanation for “serious burden.”34

In April 2007, PTO issued a memorandum to examiners that removed the requirement for specific written showings; rather, an examiner could use one-size-fits-all boilerplate, with no showings, no identification of facts specific to the case. The 2007 form language is a list of five reasons, two of which have nothing to do with “independent and distinct,” with no blanks that need to be filled in. The 2007 memo invites applicants to guess at the examiner’s reasoning—the examiner doesn’t even have to identify which of five reasons applies:

PTO kept this memo hidden from the public; invisible for over 2½ years.35 All that applicants could see was that applications were being divided for no explained reason. Eventually, even though PTO made no effort to publish it, the URL for the

33 Robert Anthony, Interpretive Rules, Policy Statements, Guidances, Manuals, And The Like—Should Federal Agencies Use Them To Bind The Public?, 41 Duke L.J. 1311 (June 1992)

34 E.g. MPEP § 803(II) and Form paragraphs 8.21.01 to .03 (2006), https://www.uspto.gov/web/offices/pac/mpep/old/E8R6_800.pdf

2007 memo leaked out. Even then, there were no links to it anywhere on PTO’s website (at least none that Google or the Internet Wayback Machine could find). One had to know the URL.

Once the leaked URL reached me, I petitioned to have this memo withdrawn. A more-detailed explanation of 20-some violations of law embodied in the 2007 memo may be found in 10/446,572, Petitions of April 2012 and May 2011 (summarized in pages 21-25). Even more remarkable are PTO’s reasons for refusing to correct the violations of statute or to withdraw the 2007 memo, which will make nice topics for future articles.

In the meantime, PTO had issued two revisions to the MPEP, both reiterating the decades-old language requiring specific showings. At the time, the MPEP Foreword stated “Orders and Notices, or portions thereof … which have been omitted or not incorporated in the text may be considered obsolete.” In 2009, I phoned the MPEP Office to ask that the 2007 memo, which had not been incorporated into two revised editions of the MPEP, be obsoleted, as the MPEP promised. The attorney in the MPEP office conceded all relevant facts, but insisted that the 2007 memo survived the “considered obsolete” promise of the MPEP, because the specific part of the MPEP involved had not been revised. I pointed out that that’s not what the MPEP Foreword says—if guidance is to survive into a new edition, then it’s PTO’s job to “incorporate” it, that’s the whole point of new editions—but the attorney insisted that examiners using the 2007 language would not be reversed.36

PTO eventually resolved the conflict between the MPEP Foreword and its nonobsolete secret memoranda by removing the “considered obsolete” sentence from the MPEP Foreword, in 2013. Applicants are now left to guess what guidance is in effect, and what is obsolete. Even though the Good Guidance Bulletin, and PTO’s own self-regulations under the Information Quality Act, require the agency to accurately inform the public of what guidance is in effect, what isn’t, and when each was issued or withdrawn, PTO proceeds outside the bounds of the law.

A decade later, although today’s MPEP nominally requires examiners to make specific showings (though less-specific than before 2007), the no-fact-showing practice fostered by the 2007 memo remains the practical day-to-day norm. In the restriction papers that I receive, the overwhelming majority short-cut required fact showings. Many make bald assertions that a material difference between inventions exists, and serious burden, with no identification of what that difference or burden might be. One recent example reads:

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36 I have the name of the specific attorney in my notes, and it’s available on request, but it’s not that relevant. This specific attorney isn’t the problem. The problem is the consistent behavior by the Office of Patent Examining Procedure: specific words, procedural laws, and PTO promises to the public don’t matter. It would be unfair to pin that pervasive culture on one specific attorney.
2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the golf training apparatus as claimed can be used in a materially different process.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because at least the following reason(s) apply:
   - the inventions have acquired a separate status in the art in view of their different classification
   - the inventions have acquired a separate status in the art due to their recognized divergent subject matter
   - the inventions require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search strategies or search queries).

Not a single word of analysis of the two claims that are purportedly divided. I wish I could tell you that this one is an outlier. It isn't.

Due to PTO's unilateral rewriting of examiner restriction guidance, in evasion of all the laws that govern agency rulemaking, thousands of applications per year are divided unnecessarily. Since 2007, I've had applications divided into 20-way restrictions, when the application would have been undividable under "classical" pre-2007 restriction standards. Assuming other attorneys experience the same kinds of excess restrictions as I do, and all divisionals were filed, the cost to the inventing public is in the hundreds of millions of dollars per year. But of course, at that cost, all divisionals are not filed, so the loss to the economy of valuable patent rights is probably of the same magnitude. Competitors, who used to be able to look at one patent to understand their infringement posture, now have to look at multiple divisionals. PTO unilaterally increases its fee income, and reduces the quantum of work it does on each application. But PTO has never explained any benefit to applicants, to the public, or to the patent system that they receive in return for PTO's improved finances.

B. Example 2: Unpublished rules for ADS submission of bibliographic data

The 2012 Final Rule for AIA regulations gave applicants a range of options for providing bibliographic data (inventor name, priority claims, applicant name, and the
like). A full Application Data Sheet could be filed either with the “day one” application filing package, or as the first ADS filed thereafter. More-complex rules for any amended ADS only came into play for the second ADS. This interpretation of the regulations—the only interpretation that’s consistent with the regulations’ text—was explained by PTO in the 2012 Federal Register notice, and in the August 2012 MPEP.

Nonetheless, PTO began bouncing papers that complied with its regulations and published interpretation. PTO’s confusing behavior was the single most-discussed question on some of the attorney discussion email lists for several years.

Finally, in October 2015, PTO revealed a unilateral and heretofore-unwritten change in the rules. A rewrite of MPEP § 601.05(a) mandated that only one of the range of options negotiated during notice-and-comment would be acceptable. A straightforward ADS would be accepted only if it was filed with the initial filing package. Under this 2015 rewrite of the MPEP, that very same ADS, if filed after initial filing, had to comply with the rules for amended ADS, even if it was the first filed ADS and was making no amendments.

PTO never told anyone that it had unilaterally changed the rules (at least not through the channels set by statute, 5 U.S.C. § 552(a)), and never asked anyone for input (for example, using the notice and comment required by the Paperwork Reduction Act and Good Guidance Bulletin)—the rules just changed unilaterally and, for some years, in secret.

I’m sure that the new rule saves costs for PTO. But it’s not the rule that PTO negotiated during notice-and-comment. The public had no § 552 notice of PTO’s change of mind. This violation of guidance law, and unilateral abrogation of a fair-and-square deal negotiated with the public, for the PTO’s unilateral benefit, created costs for the public in the millions of dollars for several years, and continues to surprise attorneys that rely on PTO’s properly-published regulations.

C. Example 3: MPEP § 2144.03(C) misstatement of the law of intra-agency Official Notice

MPEP § 2144.0(C) misstates the law of Official notice. The law is simple: PTO always has the burden of proof to show each element of unpatentability, and to support each element with substantial evidence. 37 C.F.R. § 1.104(d)(2) is clear that all an applicant has to do to traverse an issue of fact supported by no more than examiner explanation is to “call for” substantial evidence.


In contrast, MPEP § 2144.03(C) purports to require that an applicant must make an affirmative showing to rebut an assertion of Official notice. At least, that’s how many examiners and the PTAB read MPEP § 2144.03(C). MPEP § 2144.03(C) is not correct.

PTO always bears the burden of proof to establish all facts to a preponderance of evidence, supported by substantial evidence. MPEP § 2144.03(C) violates this simple principle of law, and rulemaking law, in at least three respects:

- First, when PTO shifts of a burden of proof, that’s a “substantive” rule. But PTO has no relevant substantive rule making authority. It is beyond PTO’s authority to require an applicant to show “why the noticed fact is not considered to be common knowledge or well-known in the art.” If the evidence is in equipoise at 0-to-0, the appellant wins.

- Second, MPEP § 2144.03(C) is unlawful because it conflicts with 37 C.F.R. § 1.104(d)(2), which permits an applicant to traverse official notice by simply “calling for” substantial evidence. Agencies do not have authority to attenuate a regulation that runs in favor of the public by stating opposite provisions in guidance documents.

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41 In re Oetiker, 977 F.2d 1443, 1445-46, 24 USPQ2d 1443, 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).

42 Director, Office of Workers Compensation Programs, Dept. of Labor v. Greenwich Colliers, U.S. 267, 271 (1994) (“assignment of the burden of proof is a rule of substantive law”)

43 Koninklijke Philips Electronics N.V. v. Cardiac Science Operating Co., 590 F.3d 1326, 1337, 93 USPQ2d 1227, 1235 (Fed. Cir. 2010) (“We remind ... the Board that they must follow judicial precedent instead of [PTO-formulated substantive rules] because the PTO lacks the substantive rulemaking authority to administratively set aside judicial precedent.”); Merck & Co. v. Kessler, 80 F.3d 1543, 1549–50, 38 USPQ2d 1347, 1351 (Fed. Cir. 1996) (statute “does NOT grant the Commissioner the authority to issue substantive rules.”).
• Third, PTO neglected rule making requirements when it promulgated MPEP § 2144.03(C). If PTO wants to impose a mandatory requirement on applicants relating to burdens of proof or substantive patentability, it must do so through the rulemaking procedures of 5 U.S.C. §§ 552 and 553, which—at a minimum—require publication in the Federal Register under § 552(a), notice and comment under the Paperwork Reduction Act, and, I believe, notice and comment under § 553. PTO has never run MPEP § 2144.03 through the procedural requirements of the APA or Paperwork Reduction Act—therefore the imposed burden is unapproved and subject to the law’s public protection provisions.

The error in MPEP § 2144.03(C) is demonstrated by PTO’s reliance (in different editions of the MPEP) on In re Chevenard, 139 F.2d 711, 713, 60 USPQ 239, 241 (CCPA 1943) and In re Boon, 439 F.2d 724, 727, 169 USPQ 231, 234 (CCPA 1971) to support the shift of burden of proof in MPEP § 2144.0(C). Chevenard and Boon are court/agency review cases. They’re simply irrelevant to intra-PTO proceedings. Further, they’re both abrogated. Before 1997, the CCPA’s standard of review favored PTO, and required an appellant to show “clear error.” That was abrogated by Dickinson v. Zurko in 1998. In contrast, during intra-PTO proceedings, the presumption of the standard of proof is and always has been in favor of the applicant, and the burden is on PTO to support any adverse finding by substantial evidence.

By evading the law that governs rulemaking and guidance, PTO lost opportunities for second-set-of-eyes review that helps avoid error. PTO now instructs examiners to act in error. The requirements for public vetting in the Good Guidance Bulletin to seek notice and comment, and in 35 U.S.C. § 2(b)(2)(B) to act by “regulation,” would have prevented that agency error. Had PTO taken its obligations under the Paperwork Reduction Act seriously, the error would have been caught and fixed in response to notice and comment letters no later than 2012. But PTO didn’t act on those letters.

The costs of dealing with this particular rulemaking error and examination error are substantial, probably over $100 million per year in attorney fees and lost patent asset value.

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D. Example 4: MPEP § 1207.04 and an examiner’s power to abort an appeal

Hyatt v. PTO\textsuperscript{47} concerns MPEP § 1207.04, a rule that PTO promulgated (unlawfully) through guidance, and that conflicts with a regulation (in the forbidden direction).\textsuperscript{48}

From 1997 to 2004, the rules for ex parte appeals stated that “An examiner’s answer must not include a new ground of rejection” 37 C.F.R. § 1.193(a)(2) (2003). That didn’t work. When examiners raised new grounds anyway, the Board was put in an untenable squeeze between its obligations under the substantive law and obligations under procedural law.\textsuperscript{49}

In 2004, PTO corrected by adopting 37 C.F.R. § 41.39(b): an examiner may raise a new ground in an examiner’s answer, and the appellant has the choice to either reopen prosecution before the examiner or maintain the appeal for decision by the Board. Rule 39(b) fairly recognizes that examiners aren’t perfect, and should be allowed to raise new grounds—but simultaneously recognizes that the whole reason for appeal is that the applicant believes the examiner isn’t “getting it” and higher-level review is needed. When an examiner raises a new ground, a choice has to be made, between going back to the examiner or forward to the Board. PTO explained, twice, that the proper “chooser” is the appellant. 69 Fed.Reg. 49980, Answer 69; 76 Fed.Reg. 72286, Response 31. This, of course, makes perfect sense—remember, that appeals only get to this point because the examiner erred in putting forth less than the best rejections during “regulation time” prosecution, and fell below the “compact prosecution” obligations of 37 C.F.R. § 1.104(c).

But PTO, through MPEP § 1207.04, allows the examiner, “with approval from the supervisory patent examiner, [to] reopen prosecution to enter a new ground of rejection.” PTO has never offered any explanation of public benefit for giving a conflicting choice to examiners. The choice allows examiners to short-circuit the appellants’ access to the PTAB, effectively allowing the examiner to put the costs onto the appellant for the examiner’s oversight during ordinary prosecution. Nonetheless, that’s exactly what MPEP § 1207.04 provides. MPEP § 1207.04 removes a burden from the examiner and imposes the burden on the applicant. Imposing such a burden


\textsuperscript{49} E.g., Ex parte Peppel, https://e-foia.uspto.gov/Foia/RetrievePdf?system=BPAL&INm=fd982848 at 9, 1998 WL 1766687 at *4 (Mar. 13, 2000) (after a “late hit” rejection, “there is nothing that can be done.”)
on the public is a clear-cut trigger for several rule-making procedural statutes (e.g., the Paperwork Reduction Act, 44 U.S.C. § 3507(a)), none of which PTO followed.

I am aware of two cases where an examiner reopened five times, before allowing the appeal to proceed to the Board—which then reversed.50

Had PTO put MPEP § 1207.04 through notice-and-comment (as required by three things: the Paperwork Reduction Act, the fact that PTO is trying to amend 37 C.F.R. § 41.39(b) which itself was promulgated by notice and comment, and by, I believe, § 2(b)(2)(B)51), the public comments would have pointed out:

• The conflict with statute, which requires that the PTAB “shall review,” and the conflict with United States ex rel. Steinmetz v. Allen, 192 U.S. 543, 565 (1904), in which the Supreme Court held that “It was the duty of the Commissioner to compel the appeal. [Inventors have certain rights at PTO.] The first of those rights is a hearing [on an applicant’s appeal]. If that be denied other rights cannot accrue.” Since PTO never asked the question, the agency proceeded at its own risk.

• The practical costs of MPEP § 1207.04. Appeal starts when costs are already high. One side or the other (or perhaps both) has stopped engaging with anything the other has to say. Putting the application back into prosecution before the same examiner is utterly absurd on its face, even if PTO had such legal authority.

• The inconsistency between MPEP § 1207.04 and PTO’s obligations to “proceed to conclude a matter presented to it,” 5 U.S.C. § 555(b), and the obligation to avoid bouncing a matter between various levels of intra-agency review.52

50 Several attorneys that gave me facts for this article asked me to to keep their names and serial numbers confidential—for the sin of asking PTO to follow the law, the fear of retaliation by PTO is pervasive and palpable. I will confirm that that fear is well-founded; I’ve experienced it.
And PTO wouldn’t be caught in an impossible *Chenery* or *State Farm* “arbitrary and capricious” problem trying to defend a rule that had not gone through rulemaking.53 *Chenery* is the classic case holding that agencies may only defend themselves in court based on the explanations they gave when they took the action in the first place, and courts are not supposed to entertain *post hoc* rationalizations that weren’t given at the proper time. *State Farm* is the classic case defining “arbitrary and capricious.” Together, *Chenery* and *State Farm* establish that the most fundamental right in administrative law is the right to a written explanation for agency action, at the time the agency acts59—without that, all the other rights are nugatory.60 Lack of a cogent explanation at the time the agency promulgates a rule is probably the single most common reason for a court to set aside agency action.

PTO gave no such explanation—in fact, the PTO’s most recent statement in the Federal Register is a refusal to reconsider, and refusal to explain.61 That’s illegal. Once an agency identifies the problem to be solved (in 2011, retailoring the appeal rules), it must address all suggested solutions to that problem. Artificially narrowing options under consideration is arbitrary and capricious *per se*.62

PTO’s brief to the panel63 argued a number of rationales for MPEP § 1207.04. The Solicitor might have been wise to honor *Chenery* and avoid raising new outside-therecord, *post hoc* arguments. One of my old bosses used to say “When you’re in a hole, stop digging.” The arguments in PTO’s brief simply dug PTO even deeper into the hole of error that it started in 2004:

59 *Amerijet Int’l Inc. v. Pistole*, 753 F.3d 1343, 1350 (D.C. Cir. 2014) (“We have explained that a ‘fundamental requirement of administrative law is that an agency set forth its reasons for decision; an agency’s failure to do so constitutes arbitrary and capricious agency action.”); *McHenry v. Bond*, 668 F.2d 1185, 1192 (11th Cir. 1982) (“The fundamental principle of reasoned explanation embodied in ... (agency) decisions serves at least three interrelated purposes: enabling the court to give proper review to the administrative determination; helping to keep the administrative agency within proper authority and discretion, as well as helping to avoid and prevent arbitrary, discriminatory, and irrational action by the agency; and informing the aggrieved person of the grounds of the

53 *Motor Vehicle Mfrs. Ass’n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43, 48, 50 (1983) (“the agency must examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made,’” and agency action is “arbitrary and capricious” on essentially a *per se* basis if the agency failed that obligation to explain); *Burlington Truck Lines v. United States*, 371 U.S. 156, 168–69 (1962) (an agency decision can only be affirmed “on the same basis articulated in the order by the agency itself”); *SEC v. Chenery Corp.*, 318 U.S. 80, 93–95 (1943) (“an administrative order cannot be upheld unless the grounds upon which the agency acted in exercising its powers were those upon which its action can be sustained”).

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administrative action so that he can plan his course of action (including the seeking of judicial review.), quoting Matlovich v. Sec’y of the Air Force, 591 F.2d 852, 857 (D.C. Cir. 1978); People of the State of Illinois v. U.S., 666 F.2d 1066, 1073 (7th Cir. 1981) (“The primary requirement of the ‘arbitrary and capricious’ standard of review is the ‘simple but fundamental rule of law’ that an ‘agency must set forth clearly the grounds on which it acted.’”), quoting Atchison, Topeka & Santa Fe Ry. Co. v. Wichita Bd. of Trade, 412 U.S. 800, 807 (1972).

60 Roelofs v. Secretary of Air Force, 628 F.2d 594, 599–600 (D.C. Cir. 1980) (the APA embodies a “simple but fundamental’ requirement that an agency or official set forth its reasons, a requirement that is essential to ‘the integrity of the Administrative process,’ for it tends to require ‘the agency to focus on the values served by its decision, . . . hence releasing the clutch of unconscious preference and irrelevant prejudice.’).


• PTO argued that MPEP § 1207.04 stems from an examiner’s “inherent authority” to reconsider an earlier decision. But this inherent authority is a power of an agency, not of its individual employees. Individual agency employees have only the authority delegated by the agency’s validlypromulgated rules. The only validly-promulgated rule in the area is § 41.39(b)—the examiner may raise a new ground in an examiner’s answer, but not in an Office Action reopening prosecution.

• PTO argued that MPEP § 1207.04 is “consistent with the Patent Act.” Even if that were true (which it isn’t), it’s irrelevant—an agency can only issue rules “consistent with” its organic statute if the rule also “conform[s] with any procedural requirements imposed by Congress. . . . [to] ‘assure fairness and mature consideration of rules of general application’.” Chrysler Corp. v. Brown, 441 U.S. 281, 303 (1979). PTO didn’t.

• PTO’s briefs argue that MPEP § 1207.04 is eligible for the “interpretive” or “procedural” exemptions from notice and comment. But even interpretive and procedural rules require preconditions and some procedure. MPEP § 1207.04 doesn’t.

• PTO argues that MPEP § 1207.04 is a “general statement of policy”—and in the next breath argues that it should be enforceable. But even an
administrative law novice knows that “general statements of policy” have no binding effect whatsoever.54

E. Example 5: the PTAB’s Trial Practice Guide
The 2018 revision of the PTAB’s Trial Practice Guide55 is an example of appropriate use of non-regulatory guidance. It contains two kinds of statements:
• direct quotations of regulatory text, and court interpretations of the Federal Rules of Evidence. An agency is permitted to (and indeed, encouraged to) consolidate this kind of information in a form most useful to the public, so long as the agency does not try to inject additional legal obligations (or grant itself carveouts) that are not reflected in underlying statutory or regulatory text.

• various non-binding, purely advisory lists of non-exclusive discretionary factors, non-binding expressions of “Board’s experience,” practical guidance, and the like. These are perfectly good “general statements of policy” exempted from rulemaking procedure by § 553(b)(A), but (as part of the quid pro quo) entirely unenforceable.

The original 2012 Trial Practice Guide was published in the Federal Register.56 That was a good move. The 2018 TPG, in contrast, presents a quibble: the August 2018 Federal Register notice is only a notice of publication, not an incorporation by reference as required by 5 U.S.C. § 552(a). But the 2018 TPG sets no binding standards, and so long as the PTAB doesn’t rely on the TPG as if it were binding, no harm done.

VI. Conclusion
The law is as it is to provide predictability and fairness for everyone—the agency and the public. By promulgating rules by guidance when statute requires rulemaking by regulation, PTO evades the introspection, analysis, and cost-benefit balancing at the core of Congress’ laws and the President’s direction. The public has no notice-and-comment opportunity. PTO does not prepare, and the Office of Management and Budget does not review, required cost-benefit analyses. The public is sandbagged with rules that pop out of nowhere with no meaningful notice, and sometimes no notice at all. Examiners benefit because they are permitted to do less work per compensation count. The agency benefits because it can exact more user fees for less time spent, and still more user fees for excess RCEs and similar user fees required to

54 See note 24 supra.
induce PTO to correct its own errors. Does the public benefit? When PTO enacts rules by guidance, it provides no explanation of benefit to offset the costs of its rules, as would be required by the APA, Paperwork Reduction Act, and executive orders. In the case of the rules examined in this article, such public benefit probably doesn’t exist. But the costs are very real.

The problem, of course, is one of concentrated benefit (for PTO) and distributed harm (500,000 applicants). I’ve raised these issues with several senior PTO officials over the years—uniformly, the response has been “So sue me.” Who can afford six figures to sue over these kinds of issues for an individual patent application? God bless Gil Hyatt.

PTO’s brief in the *Hyatt* case does not reassure the public that PTO has capacity to comply with the laws that govern it. Rather than taking action against the very applicants that PTO is tasked with supporting, PTO should establish a compliance department, analogous to the compliance function in any private sector company. A compliance function requires two things: deep expertise in the relevant law, and sufficient power to ensure that the client operates within that law.

When an agency sidesteps these statutory obligations, the costs on the public can be immense. For an agency whose fundamental purpose is the economic health of the nation, that sidestepping and the concomitant costs are unconscionable. It’s time for PTO’s bad guidance practices to stop.

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David Boundy is a partner at Cambridge Technology Law. Mr. Boundy practices at the intersection of patent and administrative law, and consults with other firms on court and administrative agency proceedings, including PTAB trials and appeals. In 2007–09, Mr. Boundy led teams that successfully urged the Office of Management and Budget to withhold approval of the USPTO’s continuations, 5/25 claims, information disclosure statements, and appeal regulations under the Paperwork Reduction Act. In 2018, the Court of Appeals for the Federal Circuit asked Mr. Boundy to lead a panel of eminent academics and the President’s chief regulatory oversight officer in a program at the court’s Judicial Conference on administrative law issues. Judge Plager recommended Mr. Boundy’s papers published in ABA LANDSLIDE, *The PTAB is Not an Article III Court, Part I*, to the patent bar. He may be reached at DBoundy@CambridgeTechLaw.com.