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Agency Bad Guidance Practices at the Patent and Trademark Office: a Billion Dollar Problem¹

by David E. Boundy² December 4, 2018 (revised December 6, 2018)

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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

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executive branch agencies.³ 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, 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.⁴

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?⁵

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.⁶

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 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 billon. 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%.

³ Office of Management and Budget, Executive Office of the President, *Final Bulletin for Agency Good Guidance Practices*, https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy2007/m07-07.pdf (Jan. 18, 2007), reprinted in 72 Fed. Reg. 3432-40 https://www.federalregister.gov/documents/2007/01/25/E7-1066/final-bulletin-for-agency-good-guidance-practices (Jan. 25, 2007).

⁴ Dominic J. Mancini, Acting Administrator, Office of Info. & Regulatory Affairs, to Regulatory Policy Officers at Executive Departments and Agencies, *Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017*, Titled "Reducing Regulation and Controlling Regulatory Costs (Feb. 2, 2017), https://www.whitehouse.gov/the-press-office/2017/02/03/interim-guidance-implementing-section-2-executive-order-january-30-2017 ("Agencies should continue to adhere to OMB's 2007 Memorandum on Good Guidance Practices.").

⁵ Email questions and responses on file with the author.

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 full 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 1980s⁷ 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 make," and that exemptions from statutory rule making procedures are "limited."8

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

⁷ E.g., Natural Resources Defense Council, Inc. v. Thomas, 838 F.2d 1224 (D.C. Cir. 1988).

⁸ Batterton v. Marshall, 648 F.2d 694, 700-01 (D.C. Cir. 1980).

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 after all necessary procedure, has earned a place 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, 10

for conduct of IPR), § 321(a), § 322(a)(4), § 326 (same for PGR).

(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

⁹ 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 Bayh-Dole); § 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

 10 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."

- deadlines)¹¹ 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.¹²

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. Most importantly, rulemaking procedure requires an agency to look at its proposals from the point of view of regulated entities, not just from the agency's parochial or financial self-interest. 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

procedures for unintentionally delayed priority claim); § 122(b)(1)(A) (Director to determine procedures for publication of applications); § 384 (Director may establish

procedures for review of filing date for Hague design application).

¹¹ 5 U.S.C. § 553(d)(1) (a rule that "grants or recognizes an exemption or relieves a restriction" may be promulgated by mere publication in the Federal Register under § 552(a)); *American Farm Lines v. Black Ball Freight Service*, 397 U.S. 532, 539 (1970) ("It is always within the discretion of ... an administrative agency to relax or modify its procedural rules adopted for the orderly transaction of business before it when in a given case the ends of justice require it."). Delegations of rulemaking authority to relieve restrictions include 35 U.S.C. § 21(a) (Director may specify rules for lost mail); § 25 (Director may by rule provide for declaration in lieu of oath); § 27 (Director may establish procedures to revive an unintentionally abandoned application); §§ 119, 120, and § 365(b) (Director may establish

¹² In addition to the examples in notes 10 and 11, the following statutes grant to the Director rulemaking authority *without* regulation. 35 U.S.C. § 23 (Director may establish rules for affidavits and depositions); § 122(b)(1)(A) (Director to determine procedures for publication of applications); § 122(c) (Director shall establish procedures governing protest or pre-issuance opposition); § 122(d) (Director shall establish procedures governing secrecy orders); § 181 (Director may prescribe rules to appeal secrecy orders).

with the agency, like a blizzard of antiaircraft chaff. In addition to the statutory channels, PTO broadcasts rulemaking information through a *sui generis* Official Gazette (which is sometimes years out of date), agency staff manuals (that contain both information for agency staff, and in addition, have 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 (nominally directed to agency staff, but some of which have public-facing rule content), checkboxes on forms (that often create carve-outs from regulations that were adopted to protect the public), etc.. Because PTO does not even try to speak with a consistent voice, those nonstatutory pronouncements sometimes directly clash with statutory regulation and with each other.¹³ 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?

The default of 5 U.S.C. § 553 is that an agency must conduct all rulemaking activities via notice-and-comment rulemaking, subject to specific exemptions. The courts have repeatedly declared that the exceptions are to be narrowly construed and reluctantly recognized, so as not to defeat the salutary purposes behind the notice-and-comment provisions of § 553.14 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), 15 or
- that is covered by a notice-and-comment requirement of another administrative law statute (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. 16

¹³ PTO's uncoordinated rule statements, and some examples of direct clashes, are explained in Boundy, Part 3: *Precedential and Informative Decisions*, note 41 *infra*, at § II(B)(2), pages 8-

¹⁵ A nice picture showing how those exemptions interrelate is shown in Boundy, Part 1, note 39 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.

¹⁶ Tafas v. Dudas, 541 F.Supp.2d 805, 812, 86 USPQ2d 1623, 1628 (E.D. Va. 2008) held that 35 U.S.C. § 2(b)(2) "makes it clear that the PTO must engage in notice and comment rule making when promulgating rules it is otherwise empowered to make," criticized *Tafas v. Doll*, 559 F.3d 1345, 1352 n.3, 90 USPQ2d 1129, 1134 n.3 (Fed. Cir. 2009), panel opinion

¹⁴ See United States v. Picciotto, 875 F.2d 345, 347 (D.C. Cir. 1989); American Hosp. Ass'n v. Bowen, 834 F.2d 1037, 1044-45 (D.C. Cir. 1987) and cases cited therein.

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 agency¹⁷—a rule promulgated by less-than-regulation procedure has less-than-regulation binding effect against the public:

- To instruct the agency's own employees. These are carved out from the APA by § 553(a)(2) (exempting "matter[s] relating to agency management or personnel"). Instead, employee-facing rules are governed by the "Housekeeping Act," 5 U.S.C. § 301, and PTO's obligation to supervise its own employees, 35 U.S.C. § 3(b)(2)(B).
 - 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.¹⁸ This is the well-known "*Accardi* principle."¹⁹
- To *interpret* an "active" ambiguity, such as an ambiguous term, a general term, or a conflict. These are carved out from notice-and-comment (but not the rest of the APA) by § 553(b)(A). 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.²⁰

vacated, 328 Fed. Appx. 658, 91 USPQ2d 1153 (unpublished), on PTO's motion to dismiss as moot, district court reinstated sub nom. *Tafas v. Kappos*, 586 F.3d 1369, 1371, 92 USPQ2d 1693, 1694 (Fed. Cir. 2009). Apparently the Federal Circuit has not revisited the issue of notice-and-comment procedure for PTO's procedural rules since then. The continuing vitality of *Tafas* is discussed in Boundy Part 1, note 39 infra, at 51-52.

 $^{^{17}\,\}mbox{\it Perez}\,\mbox{\it v.}$ Mortgage Bankers Ass'n, 135 S.Ct. 1199, 1204 (2015).

¹⁸ 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).

¹⁹ Thomas W. Merrill, The *Accardi* Principle, 74 Geo. Wash. L. Rev. 569 (Jun. 2006).

²⁰ Anthony, note 42 *infra*, 41 DUKE L.J. at 1312-13; *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 761 (1969); *Mission Group Kan., Inc. v. Riley*, 146 F.3d 775, 781 (10th Cir. 1998) (quoting

- o 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.²¹
- o 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"²²—they are binding on the public with only *Skidmore* deference,²³ 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."²⁴ (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.)

Richard A. Posner, *The Rise and Fall of Administrative Law*, 72 CHI.-KENT L. REV. 953, 962 (1997)).

²³ 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.").

Skidmore deference, where an agency's interpretation is a "thumb on the scale" but not binding, stands in contrast to *Chevron* and *Auer* deference in which an agency's rule binds courts, the public, and the agency. But *Chevron* and *Auer* deference only apply where a rule is past the "procedurally defective" threshold, *Encino Motorcars, LLC v, Navarro,* 579 U.S. ___, ___, 136 S.Ct. 2117, 2125 (2016); *Gonzales v. Oregon,* 546 U.S. 243, 255–56 (2006). This article is about guidance rules that don't get across that first threshold.

²¹ Contrast Wyman-Gordon Co., note 20 supra, 394 U.S. at 761 (striking down a rule by which NLRB required employers to give employee lists to unions, because not promulgated by APA rulemaking procedure) against NLRB v. NLRB v. Bell Aerospace Co., 415 U.S. 267, 294 (1974) (approving a rule promulgated with exactly the same level of procedure as in Wyman-Gordon, because it had interpretative grounding in an ambiguous statutory term, "managerial employees"). A longer explanation of the contrast between Wyman-Gordon against Bell Aerospace is in Boundy, Part 3: Precedential and Informative Decisions, note 41 infra, at § II(D), pages 12-14.

²² Perez, note 17 supra, 135 S.Ct. at 1204.

²⁴ Good Guidance Practices, note 3 supra, § III(2)(b), .../m07-07.pdf at 21, 72 Fed. Reg. 3440 col. 2.

- 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).
 - "General statements of policy" require no procedure (other than publication), but have no binding effect whatsoever—that's the *quid* pro quo.²⁵
- 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)). An agency always has discretion to relax or waive a procedural regulation *in favor* of a member of the public, ²⁶ but none in favor of itself.
- 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)²⁷—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, PTO *could* offer non-binding suggestions 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 self-interest 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.²⁸ 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."²⁹

²⁷ See Boundy, Part 3: *Precedential and Informative Decisions*, note 41 infra.

²⁹ Christensen v. Harris County, 529 U.S. 576, 588 (2000).

²⁵ *Community Nutrition Institute v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987); Brock v. Cathedral Bluffs Shale Oil Co., 796 F.2d 533, 536–37 (D.C. Cir. 1986) (Scalia, J.).

²⁶ See note 11 *supra*.

²⁸ See note 20 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.³⁰

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. Asymmetry is not common in the law, but it's a defining feature of the law of guidance. 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 *Lopez v. Federal Aviation Administration*, 318 F.3d 242, 246–47 (D.C. Cir. 2003).³¹

³⁰ *Perez*, 135 S.Ct. at 1206 (to amend a rule, an agency must use the same procedure that was used in first instance); *Wyman-Gordon Co.*, note 20 *supra*, 394 U.S. at 763-66 (an agency may not bypass statutory rulemaking procedure).

31 While § 552(a) provides that an agency may not enforce a rule against any party other than the agency itself without publication in the Federal Register, many courts have noted that such publication is not required for enforcement against the agency itself. Service v. Dulles, 354 U.S. 363, 386-88 (1957) (unpublished 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," even though the agency has authority to change it without full § 553 procedures); Farrell v. Dep't of Interior, 314 F.3d 584, 590-91 (Fed. Cir. 2002) ("If an agency policy statement is intended to impose obligations or to limit the rights of members of the public, it is subject to the Administrative Procedure Act, and, with certain exceptions, must be published in the Federal Register as a regulation. 5 U.S.C. § 553(b)-(c) (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).

III. Consequences of short-cutting rulemaking procedure

A. Rules rendered unenforceable

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.³²
- 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. Very few agencies are so inept that they can't manage this simplest requirement in the entire administrative law, simple publication under § 552, but when they do, courts invalidate those rules.³³ 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.³⁴ Even more striking, PTO's trademark side has been running these notices for decades.³⁵

³² Wyman-Gordon Co., note 20 supra, 394 U.S. at 761, 763-66; McLouth Steel Products Corp. v. Thomas, 838 F.2d 1317, 1320 (D.C. Cir. 1988); Community Nutrition, note 25 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 Good Guidance Bulletin was issued in 2007 and implemented by other agencies, these cases evaporated to near zero. PTO is a remarkable outlier.

³³ 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).

³⁴ Patent and Trademark Office, Manual of Patent Examining Procedure, Ninth Edition, Revision of January 2018, Notice of Publication, 83 Fed. Reg. 4473 (Jan. 31, 2018).

³⁵ 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 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.³⁶

B. Statute of limitations

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.³⁷

The Paperwork Reduction Act provides a defense against enforcement of an invalidly-promulgated rule that may be asserted "at any time during the agency administrative process or judicial action," and "notwithstanding any other provision of law." 44 U.S.C. § 3512. Courts of Appeals have held that the defense is never waived, and may be first asserted in a Court of Appeals.³⁸ I know of no case directly on point vis-à-vis a statute of limitations, but it seems that the language of the statute is intended to leave agencies in no doubt that they put themselves at indefinite risk by noncompliance.

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.

³⁶ American Federation of Labor v. Chertoff, 552 F.Supp.2d 999 (N.D. Cal 2007); North Carolina Fisheries Ass'n, Inc. v. Daley, 27 F.Supp.2d 650 (E.D. Va. 1998).

³⁷ 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 33 *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...").

³⁸ United States v. Lee, 967 F.2d 594 (table), 1992 WL 144716 at *2 (9th Cir. 1992).

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 Federal Agency Rule Making.*³⁹ 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.⁴⁰
- David Boundy, The PTAB is Not an Article III Court, Part 3:Precedential and Informative Decisions,⁴¹ 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 Chairman of the Administrative Conference of the United States from 1974-79), *Interpretive Rules, Policy Statements, Guidances, Manuals, And The Like—Should Federal Agencies Use Them To Bind The Public?*⁴² (Interestingly, I think the law is a little "looser" in favor of agencies than Prof. Anthony does—I think that the range of "interpretative rules" that have *Skidmore* conditional binding effect is a little larger, and that the range of "policy statements" with no effect at all is a little smaller. But my view is conditioned on an agency honoring its obligation to entertain alternative interpretations.⁴³)

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

³⁹ 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.

⁴⁰ See note 15, *supra*.

⁴¹ David Boundy, *The PTAB is Not an Article III Court, Part 3:Precedential and Informative Decisions*, forthcoming in AIPLA Quarterly Journal, <u>here</u>. On the guidance issues of this article, pages 3-19 are particularly relevant.

⁴² 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)

⁴³ See note 24 supra.

different search classes, or give some other objective explanation for "serious burden."44

In April 2007, PTO issued a memorandum to examiners that removed the requirement for specific written showings; rather, an examiner could use one-sizefits-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:

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

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

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

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

PTO *kept this memo hidden from the public*; invisible for over 2½ years.⁴⁵ 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 2007 memo leaked out. Even then, there were no links to it anywhere on PTO's web site (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

https://www.uspto.gov/web/offices/pac/mpep/old/E8R6 800.pdf

45 http://wayback.archive.org/web/*/http://www.uspto.gov/web/ offices/pac/dapp/opla/documents/20070425 restriction.pdf

⁴⁴ E.g. MPEP § 803(II) and Form paragraphs 8.21.01 to .03 (2006),

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, and that's what the words in the Foreword say—but the attorney insisted that examiners using the 2007 language would not be reversed.⁴⁶

PTO eventually resolved the conflict between the MPEP Foreword and its non-obsolete 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:

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 difference process.

⁴⁶ 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. I've had multiple conversations with multiple attorneys (and nonattorney petition decision-makers) in the Office of Patent Examination Policy over the years, and these conversations consistently run on similar lines. The problem isn't any specific attorney. The problem is pervasive in the Office of Patent Examining Procedure: words don't mean what they say, procedural law isn't enforced, Supreme Court case law under the APA doesn't matter, and PTO promises to the public won't be kept. It would be unfair to pin that pervasive culture on one specific attorney.

- 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.⁴⁷ 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'

⁴⁷ Patent and Trademark Office, *Changes To Implement the Inventor's Oath or Declaration Provisions of the Leahy-Smith America Invents Act*, Final rule, 77 Fed. Reg. 48775 (Aug. 14, 2012).

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text—was explained by PTO in the 2012 Federal Register notice,⁴⁸ 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.⁴⁹

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 intraagency 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).⁵⁰ MPEP § 2144.03(C) is not correct.

⁴⁸ *Inventor's Oath* Final rule, note 47 *supra*, 77 Fed. Reg. 48775, 48785 col. 3, 48807, col. 3, 48786 col. 2 (Aug. 14, 2012).

⁴⁹ See, e.g., Carl Oppedahl's blog, https://blog.oppedahl.com/?p=1586.

PTO always bears the burden of proof to establish all facts to a preponderance of evidence, supported by substantial evidence.⁵¹ 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.⁵² But PTO has no relevant substantive rule making authority.⁵³ 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.
- 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

(PTAB Sep. 26, 2018) (quoting the incorrect language of MPEP § 2144.03(C) in italic, to shift the burdens of production and persuasion to the appellant).

⁵¹ 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).

⁵² Director, Office of Workers Compensation Programs, Dept. of Labor v. Greenwich Colliers, 512 U.S. 267, 271 (1994) ("assignment of the burden of proof is a rule of substantive law")

⁵³ 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.").

support the shift of burden of proof in MPEP § 2144.0(C). *Chevenard* and *Boon* are <u>court/agency</u> 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 <u>intra-PTO</u> 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 § 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 2012.⁵⁴ 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.

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

*Hyatt v. PTO*⁵⁵ concerns MPEP § 1207.04, a rule that PTO promulgated (unlawfully) through guidance, and that conflicts with a regulation (in the forbidden direction).⁵⁶

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.⁵⁷

⁵⁴ IEEE-USA explained the error in a comment letter under Paperwork Reduction Act, https://www.uspto.gov/sites/default/files/news/fedreg/comments/0651-0031_IEEE_Comment.pdf section 6.6 at pages 43-46 (May 29, 2012). PTO did nothing, not even a response to comments to explain its inaction (as required by statute).

⁵⁵ Hyatt v. U.S. Patent and Trademark Office, Appeal No. 17-1722, http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/17-1722.Opinion.9-24-2018.pdf (Sep. 24, 2018).

⁵⁶ I wrote an amicus brief on behalf of several inventor's organizations. *Hyatt v. U.S. Patent and Trademark Office*, Fed. Cir. appeal 17-1722, brief of amici U.S. Inventor et al (Nov. 21, 2018).

⁵⁷ E.g., Ex parte Peppel, https://e-foia.uspto.gov/Foia/RetrievePdf?system=BPAI&flNm=fd982848 at 9, 1998 WL 1766687 at *4 (Mar. 13, 2000) (after a "late hit" rejection, "there is nothing that can be done.")

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 new grounds are raised during appeal *only* if 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 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.

Normally a late hit gets a 15-yard penalty. Remarkably, MPEP § 1207.04 rewards the examiner with a first down instead.

I am aware of two cases where an examiner reopened *five times*, before allowing the appeal to proceed to the Board—which then reversed.⁵⁸

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 § 41.39(b) which itself was promulgated by notice and comment, and by, I believe, § $2(b)(2)(B)^{59}$), 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

⁵⁸ Several attorneys that gave me facts for this article asked me to me 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.

⁵⁹ See Boundy *Part 1*, note 39 *infra*, at 51-52. PTO stipulated to notice-and-comment in its moving papers in *Tafas v. Kappos* in 2009.

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." One of the key benefits of notice and comment is that it helps the agency avoid promulgating illegal rules!

- 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.⁶⁰

And PTO wouldn't be caught in an impossible *Chenery* or *State Farm* "arbitrary and capricious" squeeze, trying to defend a rule for which the agency had offered no timely explanation. ⁶¹ *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," and singling out failure to explain as a near *per se* ground for setting aside a rule. 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 acts⁶²—without that, all the

⁶⁰ 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").

⁶¹ 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").

⁶² 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 administrative action so that he can plan his course of action (including the seeking of judicial review)."), quoting Matlovich v.

other rights are nugatory.⁶³ 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.⁶⁴ 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*.⁶⁵

Chenery captures an important bit of wisdom: "When you're in a hole, stop digging." PTO's brief to the panel⁶⁶ argued a number of rationales for MPEP § 1207.04, which dug PTO even deeper into the hole of error:

- 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 validly-promulgated 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 argued that MPEP § 1207.04 is eligible for the "interpretive" or "procedural" exemptions from notice and comment. But even interpretive

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).

⁶³ 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.").

⁶⁴ Patent and Trademark Office, *Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals*, Final Rule, 76 Fed.Reg. 72269, 72287, Response 58 (Nov. 22, 2011) (MPEP § 1207.04 is "outside the scope" of issues under consideration).

⁶⁵ Pillai v. Civilian Aeronautics Board, 485 F.2d 1018, 1027 (D.C. Cir.1973).

⁶⁶ Hyatt v. PTO, Appeal No. 2017-1722, Brief of Appellees PTO (paper no 15) (Jun. 12, 2017).

- and procedural rules have preconditions and require some procedure. MPEP § 1207.04 didn'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 "general statements of policy" have no binding effect whatsoever.⁶⁷ By this argument, PTO concedes the case.
- PTO argues advantages of MPEP § 1207.04 that accrue to itself, but never explains public benefit. This argument concedes that MPEP § 1207.04 violates the Paperwork Reduction Act. "The agency shall also seek to minimize the cost to itself of collecting, processing, and using the information, but shall not do so by means of shifting disproportionate costs or burdens onto the public."68
- PTO's arguments ignore the fact that § 41.39(b) is not under challenge—if MPEP § 1207.04 is set aside, examiners will still have full power to raise new grounds *in an examiner's answer*. The only issue is whether the appellant maintains the choice to proceed to the Board over that new ground.

E. Example 5: the PTAB's Trial Practice Guide

The 2018 revision of the PTAB's *Trial Practice Guide*⁶⁹ 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.⁷⁰ That was a good move.

⁶⁷ See note 25 supra.

⁶⁸ 5 C.F.R. § 1320. 5(d)(1).

⁶⁹ Patent Trial and Appeal Board, *Trial Practice Guide*, https://www.uspto.gov/sites/default/files/documents/2018 Revised Trial Practice Guide. https://www.uspto.gov/sites/default/files/documents/2018 Revised Trial Practice Guide. https://www.uspto.gov/sites/default/files/documents/2018 Revised Trial Practice Guide. <a href="https://www.uspto.gov/sites/default/files/documents/2018 Revised Trial Practice Guide. https://www.uspto.gov/sites/default/files/documents/2018 Revised Trial Practice Guide. https://www.uspto.gov/sites/default/files/documents/2018 Revised Trial Practice Guide. https://www.uspto.gov/sites/default/files/documents/2018 Revised Trial Practice Guide. https://www.uspto.gov/sites/default/files/documents/2018. https://www.uspto.gov/sites/default/files/documents/2018. https://www.uspto.gov/sites/default/files/documents/2018. https://www.uspto.gov/sites/default/files/documents/2018. https://www.uspto.gov/sites/default/files/documents/gov/sites/default/files/documents/gov/sites/default/files/documents/gov/sites/default/files/documents/gov/sites/default/files/doc

 $^{^{70}}$ Patent and Trademark Office, *Office Patent Trial Practice Guide*, 77 Fed. Reg. 48755 (Aug. 14, 2018).

In contrast, the 2018 *TPG*, 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 and recommendations

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. PTO neglects to consider the rule from the public's point of view, as several statutes and executive orders require, and ends up regulating in self-interest. The public has no noticeand-comment opportunity. PTO does not prepare, and the Office of Management and Budget does not review, required cost-benefit analyses. The public gets 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 RCEs to correct its own errors. Do applicants or 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, and very large.

The problem, of course, is a classic of regulatory economics: 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?⁷¹ God bless Gil Hyatt.

PTO's brief in the *Hyatt* case does not reassure the public that PTO has capacity to comply with the law that governs 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.

⁷¹ Prof. Anthony notes that the cost of court relief is a problem that pervades nonregulatory rulemaking across many agencies. Anthony, *Interpretive Rules,*, note 42, 41 Duke L.J. at 1314 n.6, 1316-17.

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