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Attorneys react to Teva's high court win in 'secret' patent sale case

By Patrick H.J. Hughes

The U.S. Supreme Court has sided with Teva Pharmaceuticals in finding that a sale, even if done in secret, can bar a patent application, and attorneys say this means patent applicants should file early and take certain precautions.

SUPREME COURT

Copyright registration debate filled with 'practical' concerns, attorneys say

By Patrick H.J. Hughes

Two media companies argued over practical matters and statutory construction before the U.S. Supreme Court, which is deciding whether the U.S. Copyright Office must issue a registration certificate before a copyright suit can be filed.



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An administrative law view of the PTAB’s ‘ordinary meaning’ rule

By David Boundy, Esq.
Cambridge Technology Law

The Patent and Trademark Office recently changed its claim construction rule from a “broadest reasonable interpretation” standard to an “ordinary meaning” standard.

The decision raises a number of issues under the Administrative Procedure Act and other authorities that govern rulemaking.

Just like any other federal agency rule, the ordinary-meaning rule is governed by various measures, including statutes, executive orders and implementing directives issued by various parts of the executive branch.

These measures are intended to guide and assist agencies toward genuine reasoned decision-making that is informed by various public interests.

When an agency neglects these laws public interest concerns get less consideration than Congress intended, public confidence in the agency’s commitment to the rule of law is eroded and the rule becomes vulnerable to being invalidated on judicial review.

The May 2018 ordinary-meaning notice of proposed rulemaking,¹ or NPRM, and the October final rule notice² contain many “anomalies” that suggest neglect and raise invalidity concerns.

‘SUBSTANTIVE’ (NOT ‘PROCEDURAL’), ‘LEGISLATIVE’ (NOT ‘INTERPRETATIVE’)

Basic taxonomy of rules under the APA

The APA sets out the key taxonomy of “rules”— legislative versus interpretative, substantive versus procedural and public-facing versus agency-facing.

These are three entirely separate, well-defined and mutually orthogonal concepts.

At the March 2018 Federal Circuit Judicial Conference, U.S. Circuit Judge S. Jay Plager recommended that the entire patent bar would do well to gain a better understanding of the administrative law, and that an earlier article of mine³ is a good place to begin.



David Boundy is a partner at **Cambridge Technology Law** in Boston. He practices at the intersection of patent and administrative law, has been responsible for quashing several Patent and Trademark Office rulemakings over the last decade, and now consults with other firms on court and administrative agency proceedings, including PTAB trials and appeals. In 2018 the U.S. Court of Appeals for the Federal Circuit asked him to lead a panel of eminent administrative law academics

and the president’s chief regulatory oversight officer in a program at the court’s judicial conference on administrative law issues. He can be reached at DBoundy@CambridgeTechLaw.com.

The centerpiece of my article is the following table, which shows the relationship of the “legislative versus interpretative” axis as four columns, and the “substantive versus procedural” axis in two rows:

		← greater procedure, greater binding effect		less procedure, less binding effect →	
		legislative rules and Chevron gap-fills	Chevron/Auer interpretations	interpretative rules	policy statements
substantive	public-facing substantive legislative or Chevron gap fill	A gap-filling regulation that sets the substantive claim interpretation standard to either “broadest reasonable interpretation” or to “ordinary meaning,” or any allocation of the burden of proof—if the statute is silent, such rules must be promulgated by “legislative” regulation if within the rule making grant of §§ 316(a)/326(a), and are invalid if under § 2(b)(2).	Most of the IRS’ “3 part tests” that, by regulation, give specific definitions for general terms in the Internal Revenue Code—for example, the IRS’ definition of the statutory term “student” that excludes medical residents	MPEP § 201.22(D)(B), which interprets 35 U.S.C.A. § 120 to permit filing of a continuation application on the day that the patent issues. The elaboration of the CREATE Act in MPEP § 706.02(I).	37 C.F.R. § 1.75(e), stating that patent claims “should” be in a format that eases the Patent Office’s examination. PTO’s policy to accept an attorney’s statement to establish common ownership to gain benefit of pre-AIA § 103(c) or post-AIA § 102(c), but leaving discretion for deeper inquiry
	procedural legislative or Chevron gap fill	Most of the familiar regulations by which agencies specify procedures before the agency, e.g., 37 C.F.R. Part 1 governing patent applications	37 C.F.R. § 1.7, defining the term “days” as used in the Patent Act as “calendar days”	Elaboration of agency procedural statutes and regulations in guidance—public-facing statements in agency staff manuals offering interpretations of agency procedural rules. E.g., MPEP § 607.02 interpreting refund provisions of 35 U.S.C.A. § 42.	MPEP § 503, concerning Patent Office policy after a paper was lost in the mail, explaining a sufficient condition for showing “lost in the mail” and asking the Patent Office to accept a substitute, but not implying that these are necessary conditions
procedural	procedural legislative or Chevron gap fill		Chevron/Auer interpretations of procedural law	procedural interpretative	procedural policy statement

The discussion in the Federal Register notices

Both the NPRM and the final rule state essentially the same analysis under the APA:

Administrative Procedure Act (APA): This final rule revises the rules relating to office trial practice for IPR, PGR and CBM proceedings. The changes set forth in this final rule will not change the substantive criteria of patentability. These rule changes involve rules of agency procedure and interpretation. See *Perez v. Mortg. Bankers Ass’n*, 135 S. Ct. 1199, 1204 (2015). (Interpretive rules “advise the public of the agency’s construction of the statutes and rules which it administers.”)

Accordingly, prior notice and opportunity for public comment are not required pursuant to 5 U.S.C.A. § 553(b) or (c) (or any other law). ...

The office, nevertheless, published the notice of proposed rulemaking for comment as it sought the benefit of the public’s views.⁴

The final rule notice accurately states that 5 U.S.C.A. § 553, the APA’s rulemaking statute, sets a default: In the absence of other law, “procedural” rules and “interpretative” rules are exempt from notice-and-comment rulemaking.

But the notice errs in three ways: (a) this rule is “substantive,” not “procedural,” (b) the rule is ineligible for the “interpretative” exemption,

and (c) notice and comment is required under “other law,” specifically the Patent Act and Paperwork Reduction Act.

Procedural vs. substantive

The NPRM and the final rule claim that the rule is “procedural,” and support that conclusion with the statement “this final rule will not change the substantive criteria of patentability.”

Elsewhere in the notice, the PTO acknowledges the obvious — that the whole point of the rule is exactly to change substantive criteria of patentability.

For example, the notice says “the office has determined that the same claim construction standard should apply to both a patentability determination at the PTAB and determinations in federal court on issues related to infringement or invalidity.”⁵

Interpretative vs. legislative

The NPRM and the final rule notice claim the “interpretative” exemption. This claim is odd in two respects.

First, to qualify for the “interpretative” exemption, a rule must “interpret.”

There must (a) be an underlying statute or regulation that itself has the force of law, (b) that law must have some tangible meaning, though with some “active” ambiguity (an ambiguous term, a general term, or a direct clash with another provision — not a passive silence, or empty or vague language like “fair and equitable” or “in the public interest”), and (c) the agency’s “interpretative rule” must only interpret that ambiguity, without adding new content beyond the “fair intendment” of the words of the underlying law.⁶

In the final rule notice, the PTO concedes that “there is no statute applicable to either the PTAB or federal courts that requires any different standards... for claim construction.”⁷

Therefore, by the PTO’s own admission, there’s no ambiguity to interpret. Thus, the “interpretative” exemption does not apply.

Second, the Supreme Court in *Perez*, in the two sentences immediately following the one quoted in the Federal Register, states that when an agency exercises the “interpretative” exemption from notice-and-comment, by that choice, the agency surrenders much of the power to enforce the rule:

The absence of a notice-and-comment obligation makes the process of issuing

interpretive rules comparatively easier for agencies than issuing legislative rules. But that convenience comes at a price: Interpretive rules do not have the force and effect of law and are not accorded that weight in the adjudicatory process.⁸

I am unaware of any upside for the PTO to assert that its “ordinary meaning” rule does not have force of law or is ineligible for *Chevron* deference. Nor can I see upside in citing Supreme Court authority for those two propositions.

Nonetheless, that’s what the PTO did.

PTO must act by ‘regulation’ and can’t dispense with notice and comment

Sections 316(a) and 326(a) of the Patent Act, 35 U.S.C.A. §§ 316(a) and 326(a), require that “[t]he Director shall prescribe regulations” to act in this area.

The PTO derives no benefit from underestimating the economic effect of its rules, other than the reduced staff time that any sound analysis takes.

As U.S. Circuit Judge Kimberly Ann Moore pointed out in her concurring opinion in *Aqua Products Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017), these statutes mean what they say — “regulations.” A “regulation” requires notice and comment.⁹

Likewise, the PRA requires agencies to follow certain procedures, including notice and comment, whenever they change the rules that govern papers to be submitted.¹⁰

But the PTO gathered notice and comment...

After playing fast and loose on whether it was required to seek notice and comment, the PTO went ahead and did so anyway. Didn’t that cure the problem? No harm no foul?

Well, not so fast.

The characterization as “procedural” versus “substantive” has consequences that ripple downstream through the rulemaking process.

The Regulatory Flexibility Act, the statute that requires agencies to analyze and minimize economic effect on small entities, applies differently to “substantive” rules than to “procedural” rules.

The Small Business Administration Office of Advocacy, or SBA Advocacy, enforces the RegFlex Act. It acts largely ex parte with only

minimal public participation, and it makes decisions without a written statement of reasons.

There will never be any way for the public to know whether the “ordinary meaning” rule was reviewed under the “substantive” standard that the “ordinary meaning” rule certainly deserved, or under the “procedural” standard that the PTO falsely represented to an ex parte tribunal.

***Aqua Products* redux?**

Strikingly, a false claim of “procedural” had been the undoing of another Patent Trial and Appeal Board rule only six months before.

In *Aqua Products* the U.S. Court of Appeals for the Federal Circuit invalidated a PTAB rule.

The court’s starting point was the PTAB’s claim that that the rule was “procedural” when it clearly wasn’t.

Though the court did not invalidate the rule specifically on that basis, the false characterization was the incongruity that drew the court’s skeptical attention and started it on its own sua sponte research through the record (there was essentially nothing in the party briefs).

The court unraveled the rule bit by bit, and at the end, the rule was deemed invalid because the PTO had “end-run around [the APA].”

It’s not clear why the PTO has been hesitant to implement the lessons of *Aqua Products* by firming up its rulemaking processes.

EXECUTIVE ORDER 12866

Executive Order 12866 requires agencies to allow the Office of Information and Regulatory Affairs, or OIRA (part of the president’s Office of Management and Budget), to review all rules, to ensure that rules advance the public interest.

Executive Order 12866 divides all rules into three tiers: “not significant” (rules that have essentially no economic effect), “economically significant” (“likely to result in ... an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy”), and “significant” (everything in between).

The classification determines the level of scrutiny that the OIRA gives the rule. Further, for an economically significant rule, an agency must conduct a “Regulatory Impact Analysis.”

This requirement is in place to ensure that the agency studies needs, effects and alternatives. It is further intended to ensure that the agency understands what it’s regulating, explores a range of alternatives so it can choose wisely, and understands its regulation to reduce the chance of unintended consequences.

The “ordinary meaning” rule almost certainly will “have an annual effect on the economy of \$100 million or more,” meeting the “economically significant” requirement.

It is intended to change the outcome for many dozens of patent litigations per year.

Large tech companies submitted comment letters showing that, at least from their perspectives, the rule will “adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs.”

Moreover, the distributive impacts between various private sector actors are almost certainly billions of dollars.

This is clearly an “economically significant” rule.

The NPRM “Costs and Benefits” section reads:

This rulemaking is not economically significant, and is not significant, under Executive Order 12866 (Sept. 30, 1993), as amended by Executive Order 13258 (Feb. 26, 2002) and Executive Order 13422 (Jan. 18, 2007).¹¹

This paragraph is remarkable in two respects:

- Executive Orders 13258 and 13422 were revoked in 2009. Citing them in 2018 is curious.
- The designation “not economically significant” is plainly false.

The PTO has a long history of lowballing. For example, in 2006, the reason that the “continuations” rule and the “claims” rule were separated into two separate NPRMs is that by splitting them, the PTO could claim that each half was below \$100 million in economic effect.¹²

With respect to the information disclosure statement rule, in which the PTO proposed the “examination support document,”

the PTO asserted that the rule was “not significant” — that is, that its economic effect would be essentially zero.¹³ In fact, public comments had estimated the costs to be in the billions.

The 2012 PTAB rule and 2013 first-to-file rules were classified as only “significant” (that is, the PTO represented to the OIRA that PTAB trials and first-to-file would have economic effect of less than \$100 million annually).¹⁴

The PTO derives no benefit from underestimating the economic effect of its rules, other than the reduced staff time that any sound analysis takes.

The OIRA does not penalize agencies for telling the truth — costs are what they are.

Deeper and more careful analysis allows agencies to gain more insight and avoid dumb mistakes.

To be sure, an “economically significant” rule requires an agency to expend time and resources to consider alternatives, make sound choices and explain that its regulatory choices are in the public interest.

The biggest risk for the PTO that I know of is that a proper analysis might show that a rule is a bad idea, and ought to be reconsidered in whole or in part.

THE PAPERWORK REDUCTION ACT

The PRA¹⁵ requires agencies to seek public input and analyze all new rules and rule changes to determine that the proposed rule is the least burdensome of available options.

The PTO exempted itself from the required analysis by explaining that “the overall cost burden on respondents is not expected to change.”¹⁶

That exemption is not in the statute, which requires the agency to follow procedure for any change.¹⁷

The statute requires an agency to submit a burden analysis to the OIRA for every new or changed rule.

The only carve-out is for emergencies; there is no carve-out for what the agency “believes” or “expects.”

How can the PTO know whether “ordinary meaning” briefing is no more burdensome than “broadest reasonable interpretation” if it declined to undertake the analysis required by statute?

On what basis does the PTO disagree with the lawyers who actually write both kinds of briefs and have explained why an “ordinary meaning” brief is much more intricate and time-consuming than a “broadest reasonable interpretation” brief?

The PTO did not respond to those questions.

The statute¹⁸ requires an agency to ask four questions in every NPRM to ensure that its rule is doing the right thing, in the right way, and at the lowest burden to the public.

Simplest thing in the world — just block copy language from the statute into the NPRM, and change a few pronouns and a little punctuation.

The PTO didn’t.

If the PTO didn’t ask the relevant questions, what confidence can anyone have in the PTO’s “expected” answers?

What does this omission communicate to the public about whether the PTO cares about doing the right thing, the right way, at the lowest burden to the public?

WHAT ARE THE CONSEQUENCES?

Virtuous ends don’t justify nonstatutory means, especially for a rule whose intended economic effect is in the multiple hundreds of millions of dollars per year.

In *Aqua Products*, after the court detected anomalous procedure, issues that agencies normally win started falling the other way, and the court ended up invalidating the rule at issue.

If the PTO wants the ordinary-meaning rule to have a longer life than the *Aqua Products* amendment rule, it’s not clear what goal is served by a rulemaking record of similar procedural shortcutting.

For parties before the PTAB, some of the procedural anomalies in the ordinary-meaning rule support easy judicial review and vacatur of adverse judgments by the PTAB, but some plainly don’t.

Some present opportunities that can be exploited by counsel with a sophisticated grasp of administrative law.

For example, some rulemaking laws facially limit judicial review. But when courts have been asked to consider an agency’s noncompliance with those laws, courts have invalidated or stayed rules when the agency failed to create even a pretense of compliance.

Sound process and precision are essential for the PTO to fulfill its mission — as essential as they are to running a major law firm or to engineering airplanes that stay in the air.

Reforming the PTO's commitment to process and precision, including the implementation of a sound rulemaking process, could be a transformative and permanent legacy.

How did the errors identified in this commentary evade detection during review of a final rule — a rule governing the multibillion-dollar proceedings of the PTAB, which I assume is one of the most formal, lawyer-intensive and multi-signoff activities in the office?

Are these isolated occurrences, or (if the solicitor made the same error at page 56 of the solicitor's June 2017 red brief in *Hyatt v. PTO*, appeal 17-1722, brief of PTO of June 12, 2017.) is it symptomatic of deeper problems, requiring systematic reform of the PTO's legal culture?

Fortunately, diagnoses, solutions and process reforms are ready to hand.

In 2011 the PTO requested comment on its compliance with rulemaking law and how it could improve its rulemaking processes to better align with the public interest.

Letters¹⁹ from Richard Belzer (an economist who had spent a decade in the OIRA assisting agencies to comply with their legal obligations) and from me give particularly helpful insight, a diagnosis and a treatment plan.

The PTO's inaction on these (and similar letters in response to similar calls for comment) leaves the suggestions in these letters ripe for action.

In addition, the PTO should establish a compliance department in the style of departments that perform compliance functions for private companies.

A compliance function requires two things: deep expertise in the relevant law and sufficient power to ensure that the client operates within that law.

A compliance officer should review public rulemaking notices and submissions to the regulatory review tribunal, such as the OIRA and SBA Advocacy (especially when their review is *ex parte*), under the administrative law and Professional Responsibility Rule 3.3, which is titled "Candor Toward the Tribunal."

The newly brewing "motion to amend" rule²⁰ could be a great opportunity to turn over a new leaf.

The PTO could demonstrate a new commitment to the rule of law and use the motion to amend rulemaking as a platform to cure many of the deficits in the ordinary-meaning rule. [WJ](#)

NOTES

¹ Patent and Trademark Office, *Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, Notice of Proposed Rulemaking, 83 Fed. Reg. 21221 (May 9, 2018).

² 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).

³ David Boundy, *The PTAB is Not an Article III Court, Part 1: A Primer on Federal Agency Rule Making*, ABA LANDSLIDE 10:2 (Nov.-Dec. 2017).

⁴ Final Rule, note 2 *supra*, 83 Fed. Reg. 51340.

⁵ *Id.*

⁶ *National Latino Media Coalition v. FCC*, 816 F.2d 785, 788–89 (D.C. Cir. 1987); Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, And The Like — Should Federal Agencies Use Them To Bind The Public?*, 41 DUKE L.J. 1311 (Jun. 1992). The 'interpretative' exemption is explained in deeper detail in David Boundy, *The PTAB is Not an Article III Court, Part 3: Precedential and Informative Decisions*, § II(D) at 13-15, forthcoming in AIPLA QUARTERLY JOURNAL, available at <https://bit.ly/2MoTrow>.

⁷ Final Rule, note 2 *supra*, Response to Question 5, 83 Fed. Reg. 51340.

⁸ *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199 (2015).

⁹ *Boundy*, Part 1, note 3 *supra* at 51-52; Part 3, note 6 *supra*, § II(B)(1).

¹⁰ 5 C.F.R. § 1320.3(c)(1), (c)(4)(i) (scope of coverage is any "rule or regulation," any "requirement contained in a rule of general applicability"); 44 U.S.C.A. § 3506(c)(2)(A) (60-day comment period for any change in information to be collected by the agency, not only those that increase burden).

¹¹ NPRM, 83 FED. REG. 21221.

¹² In other contemporaneous documents, the PTO acknowledged that the cost to the public would exceed \$1 billion per year. <https://bit.ly/2FikM4z>.

¹³ Patent and Trademark Office, *Changes To Information Disclosure Statement Requirements and Other Related Matters*, 71 Fed. Reg. 38808 (Jul 10, 2006). See analysis at <https://bit.ly/2CDN7oN>.

¹⁴ Patent and Trademark Office, *Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions, Notice of Proposed Rulemaking*, 77 Fed. Reg. 6879 (Feb 9, 2012); *Changes To Implement the First Inventor To File Provisions of the Leahy-Smith America Invents Act, Notice of Proposed Rulemaking*, 77 Fed. Reg. 43742 (July 26, 2012).

¹⁵ 44 U.S.C.A. § 3501 and implementing regulations at 5 C.F.R. Part 1320.

¹⁶ Final Rule, note 2 *supra*, 83 Fed. Reg. 51340.

¹⁷ 44 U.S.C.A. § 3506(c)(2); see also 5 C.F.R. § 1320.9.

¹⁸ 44 U.S.C.A. § 3506(c)(2)(A).

¹⁹ <https://bit.ly/2R7S3Y3>.

²⁰ Patent and Trademark Office, *Request for Comments on Motion To Amend Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 54319 (Oct. 29, 2018).