

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA

Alexandria Division

TRANTAFYLLOS TAFAS,

Plaintiff,

- against -

JON W. DUDAS, et al.,

Defendants.

1:07cv846 JCC/TRJ

SMITHKLINE BEECHAM CORPORATION, et al.,

Plaintiff,

- against -

JON W. DUDAS, et al.,

Defendants.

1:07cv1008 (JCC/TRJ)
(consolidated)
Judge Cacheris

**BRIEF OF *AMICI CURIAE* POLESTAR CAPITAL AND NORSEMAN GROUP
IN SUPPORT OF PLAINTIFFS**

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I. Introduction

Polestar Capital Associates, LLC and The Norseman Group LLC, as *amici curiae*, submit this memorandum of law in support of the plaintiffs' motions for summary judgment, for a permanent injunction to enjoin the United States Patent and Trademark Office ("PTO") from enforcing the PTO's "Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications," 72 Fed. Reg. 161 at p. 46716 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1) (the "new Rules").

This Court has previously admonished the PTO to reexamine its "suspicious procedures."¹ But here, the PTO failed its procedural rulemaking obligations. First, material data, analysis, and computer models were not disclosed as required by the APA. Because of the lack of disclosure, the PTO's "10,000 page" record fails a number of APA requirements: the record lacks foundation, cannot be reliably understood, could not be fairly commented on during notice and comment, and could not receive proper executive branch review. Second, documents that were in the record have now been expunged from the "administrative record" given to this Court. Third, in replies to Freedom of Information Act (FOIA) requests in 2006 and 2007, the PTO asserted that certain documents did not exist; yet now they have suddenly appeared in the administrative record. The PTO's procedures are "suspicious" at best, and suggest that the "administrative record" is not an accurate or representative record of open-minded and reasoned decision making, but rather an *ex post* collection of documents cherry picked for this litigation.

There are at two legal consequences to the PTO's procedural failures.

First, the PTO's inadequate rulemaking procedures denied the public a meaningful opportunity for notice and comment. The PTO's selective disclosure of material information compromised review by the Office of Management and Budget ("OMB") and Small Business Administration ("SBA") during April-July 2007. Further, the Court cannot assess the reliability or validity of the PTO's conclusions because the PTO withheld its analyses. This renders the new Rules "arbitrary and capricious" and "without procedure required by law," 5 U.S.C. § 706(2)(A) and (D).

¹ The PTO "may be well-advised to examine its patent issuance process so that their normal operations are not compromised by such seemingly suspicious procedures." *Boudny v. U.S. Patent & Trademark Office*, 73 USPQ2d 1468, 1471 n.5 (E.D. Va. 2004) (Cacheris, J.).

Second, information that the PTO disseminated for public comment, and used as the foundation for its “Town Hall” presentations, did not adhere to the PTO’s own information quality rules. Agency failure to follow its own regulations, or to adhere to information quality principles, is symptomatic of decision-making that is incapable of reaching a reasoned outcome consistent with statutory confines.

The new Rules must be “held unlawful and set aside.” 5 U.S.C. § 706(2). The PTO should be instructed to conduct any future rulemaking proceedings with the transparency and the safeguards required by the Administrative Procedure Act and other procedural law applicable to rulemaking.

The issues raised in this brief relate to paragraphs 11, 69 and 70 of Dr. Tafas’ First Amended Complaint (Docket No. 14, September 7, 2007), and counts six (paragraphs 134-138) and eight (151-53) of GSK’s Amended Complaint (Docket No. 5, Oct. 11, 2007).

II. Background: Procedural History of the Rulemaking

On January 3, 2006, the agency published two Notices of Proposed Rulemaking. These two Notices did not disclose the PTO’s estimates of burden for complying with the requirements of the new Rules, and did not disclose any estimate by the PTO of the economic burden of the loss of patent value that would be caused by the new Rules. There was no disclosure of any of the PTO’s data, assumptions, computer models, analysis methodology, or measurement protocols. Many of the factual assertions in the Notices lacked any disclosed support whatsoever.

By February 1, 2007, the PTO had created a new page on its web site directed to the new Rules, and this page remained essentially unchanged through the end of the Notice and Comment period (Exhibit 3). Numerical data disclosed by the PTO was limited to a few top-level summary tables. In its public presentations (slides at A00043-00558), the PTO offered only qualitative graphs in PowerPoint presentations with no numerical data at all. None of the PTO’s underlying data, assumptions, computer models, measurement protocols, cost or efficiency estimates, or other factual foundations were disclosed.

During the Notice and Comment period, the full rulemaking file was requested. By telephone, the PTO stated that the file was empty. Robert Clarke, from the PTO’s Office of Patent Legal Administration, sent an email confirming that the public rulemaking file was empty, and that the PTO was withholding all supporting information from public review (Exhibit 4 at A01592-93):

We do not have a complete package of supporting information that is available for public inspection. The study for these packages was substantiated in a series of pre-decisional electronic communications that has not been made available to the public.

Several subsequent Freedom of Information Act (FOIA) requests were directed to the new rules. In May 2006, the PTO declined to make available any of the analytical methods, data or assumptions underlying the pendency projections in its non-numerical slides – it provided only conclusory numbers with no underlying support (Exhibit 5). In a FOIA reply of October 2006, the PTO stated that the full rulemaking file (leaving aside the public comment letters) included only 114 pages (Exhibit 6), none of which disclosed any analytically-useful data.

In April 2007, the PTO announced that the new Rules had been sent to OMB for review under Executive Order 12,866.² Another FOIA request for the PTO's supporting materials was filed, to permit preparation of comments to OMB. In its reply of June 12, 2007 (Exhibit 7, Exhibit 8), the PTO stated that "no records" existed for a number of categories of documents, including any analysis of underlying cause for the agency's backlog, any estimate or analysis of the costs to be saved by the new Rules, any estimate of new burdens that the new Rules would impose on the public, and any data, analysis or assumptions underlying the summary charts that the PTO presented.

In June and July 2007, several parties contacted OMB to assist OMB's review under E.O. 12,866. Because of the PTO's lack of disclosure, these presentations could only discuss generalities, with no direct comment on faults in the PTO's data, assumptions, or analysis. One public comment³ extensively discussed the PTO's lack of disclosure and failure to adhere to government-wide information quality criteria and standards, and the laws breached by that non-disclosure.

The PTO finally made some skeletal information available on its web site after the new Rules

² Executive Order 12,866, http://www.whitehouse.gov/omb/inforeg/eo12866/eo12866_amended_01-2007.pdf limits agencies to regulating only when they have identified a particular problem, and established that the proposed regulation is the best solution to that problem, and sets a number of other common-sense limits on agency regulation.

³ OMB's formal record, with all materials of all meetings, is at <http://www.whitehouse.gov/omb/oira/0651/meetings.html>, and letters are at <http://www.whitehouse.gov/omb/oira/0651/comments.html>. The discussion of lack of disclosure is at <http://www.whitehouse.gov/omb/oira/0651/meetings/619-3.pdf>, Attachment K (Exhibit 9, P000321-24).

were published on August 21, 2007. The vetting process then began. Several letters, including a peer-reviewed and sworn declaration provided to OMB, opined that the PTO's stated cost burden estimates were in error by large factors, and that the burdens that the PTO overlooked or otherwise failed to analyze dwarfed the small fraction that it actually analyzed.⁴

III. Standard of Review and Burden of Persuasion

All issues raised in this brief relate to breaches of procedure, including agency failure to follow its own rules. Doctrines of agency deference are irrelevant to those issues: an agency must follow the procedural rules of the road before it can attempt to claim deference, and the PTO did not do so.

An agency action must be set aside if it is contrary to law or without observance of procedure. 5 U.S.C. § 706(2)(A), (C) and (D). Review of procedural issues is non-deferential. *E.g.*, *Reuters v. FCC*, 781 F.2d 946, 950-51 (D.C. Cir. 1986) (“*Ad hoc* departures from [an agency’s] rules, even to achieve laudable aims, cannot be sanctioned.”); *Chocolate Mfrs’ Ass’n of the U.S. v. Block*, 755 F.2d 1098, 1103 (4th Cir. 1985) (review of “agency’s compliance with procedural rules” and “procedural integrity” is “strict” and on the court’s “own independent judgment”). “An initial burden of promulgating and explaining a non-arbitrary, non-capricious rule rests with the Agency.” *National Lime Ass’n v. EPA*, 627 F.2d 416, 433 (D.C. Cir. 1980).

An agency rule must also be set aside if it is “arbitrary [or] capricious.” 5 U.S.C. § 706(2)(A). *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) indicated several categories that are “normally” arbitrary and capricious (citations and quotations omitted):

[T]he 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. In reviewing that explanation, we must consider whether the decision was based on a consideration of the relevant factors... Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the

⁴ <http://www.whitehouse.gov/omb/oira/0651/meetings/663.pdf>, is directed to the IDS rule, a later rule in this family. A supporting affidavit accompanying this letter opines on the Continuations/5-25 RegFlex Certification, “I consider [the PTO’s Regulatory Flexibility Act Certification Analysis] quality as easily falling within the term ‘junk science’” [.../663.pdf](http://www.whitehouse.gov/omb/oira/0651/meetings/663.pdf), page 4 ¶ 27 *et seq.* The affiant is a patent attorney whose identity was withheld because of fear of retaliation by the PTO. See [.../663.pdf](http://www.whitehouse.gov/omb/oira/0651/meetings/663.pdf), page 1.

agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. The reviewing court should not attempt itself to make up for such deficiencies: We may not supply a reasoned basis for the agency's action that the agency itself has not given.

“Arbitrary and capricious” review is non-deferential when an agency has failed to “cogently explain why it has exercised its discretion in a given manner,” failed to address alternatives, or failed to address all relevant factors. *See Id.*, 463 U.S. at 47, 48, 57. Lower courts review these classes of issues on an essentially *per se* basis. *See Ohio River Valley Envt'l Coalition Inc. v. Kempthorne*, 473 F.3d 94, 103 (4th Cir. 2006); *Bratsk Aluminum Smelter v. U.S.*, 444 F.3d 1369, 1375-76 (Fed. Cir. 2006).

IV. The Rules Flunk Many *State Farm* Tests Designed to Identify “Arbitrary and Capricious” Agency Action

A. The PTO Declined to Make Essential Information Available

Agencies are required to disclose the factual bases for any rules they propose to adopt or adopt in final form.⁵ The agency must disclose statistics, computer models, and assumptions in a public rulemaking file. In *Hanover Potato Prods. v. Shalala*, 989 F.2d 123 (3rd Cir. 1993), the FDA failed to maintain a proper rulemaking record during a notice-and-comment rulemaking. Instead, it waited until it was sued, and then assembled the record on-the-fly. Because there was no integral record during the notice-and-comment period, the public had no opportunity to inspect it. The Third Circuit observed that the public has no duty to ferret out the documents missing from a less-than-complete record, because “one obviously cannot know the facts one does not know.” 989 F.2d at 129-30. The Third Circuit also held that

⁵ The PTO's brief asserts that no notice and comment was required. The PTO is wrong, for at least four reasons. First, the rules are “substantive,” as others have argued. Second, an agency is required to use notice and comment procedures for any rule to which the agency intends to give “force of law” or apply with “legally binding consequences” against the public. *Manufactured Housing Institute v. EPA*, 467 F.3d 391, 399 (4th Cir. 2006). The PTO repeatedly states in the Final Rule notice that it intends the new Rules to have binding effect, up to and including abandonment of an application. 37 C.F.R. § 1.75(b)(3), § 1.78(b)(5). The PTO also states that it intends to enforce the new rules against attorneys personally as a disciplinary matter. 72 Fed. Reg. 46779, col. 2. Third, “If a new agency policy represents a significant departure from long established and consistent practice that substantially affects the regulated industry, the new policy is a new substantive rule and the agency is obliged, under the APA, to submit the change for notice and comment.” *Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 630 (5th Cir. 2001). Reversal of previous policy is discussed in GSK's brief at pp. 24-25. Fourth, procedural rules that change “the very character” of a proceeding are substantive, and require notice and comment. *In re Fibreboard Corp.*, 893 F.2d 706, 711 (5th Cir. 1990). Under any of these four tests, full and fair notice and comment was required.

a challenger need not show prejudice from an omission. 989 F.2d at 128-29. The Court not only held the rule in question arbitrary and capricious, the Court awarded fees under the Equal Access to Justice Act, because the agency's position – without a timely record to support it – was unjustified. 989 F.2d at 130-131.

The Third Circuit explained the need for a timely, well-maintained, integral record:

In Texaco, Inc. v. Federal Power Commission, 412 F.2d 740, 744 (3d Cir.1969), we stated that one of the purposes of notice and comment rulemaking “was to give the public the opportunity to participate in the rulemaking process.” Other courts have agreed. For example, in *Connecticut Light & Power Co. v. Nuclear Regulatory Commission*, 673 F.2d 525, 530 (D.C. Cir. 1982), the court noted in *dictum* that

the purpose of the comment period is to allow interested members of the public to communicate information, concerns, and criticisms to the agency during the rule-making process.... In order to allow for useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules. To allow an agency to play hunt the peanut with technical information, hiding or disguising the information that it employs, is to condone a practice in which the agency treats what should be a genuine interchange as mere bureaucratic sport. An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary.

See also Home Box Office, Inc. v. FCC, 567 F.2d 9, 54 (D.C.Cir.1977) (“[e]ven the possibility that there is here one administrative record for the public and this court and another for the [agency] and those ‘in the know’ is intolerable”). We believe a regulated party automatically suffers prejudice when members of the public who may submit comments are denied access to the complete public record.

Hanover Potato, 989 F.2d at 130 n.9 (emphasis added); *see also Chocolate Mfrs.*, 755 F.2d at 1102-03;

National Crushed Stone Ass’n v. EPA, 601 F.2d 111, 117 (4th Cir. 1979), *reaff’d in relevant part* 643 F.2d 163 (4th Cir. 1981).

The PTO had a great deal of data before January 3, 2006. If there was to be meaningful public comment, the PTO was required to make its data available for scrutiny at the time of the Notice of Proposed Rulemaking. Though no showing of prejudice is required to find unsupported rules “arbitrary and capricious,” *Hanover Potato*, 989 F.2d at 130 n.9, the PTO's non-disclosure nonetheless caused clear prejudice to the entire public comment and executive branch review processes:

- A03554-3620 (Exhibit 10) is a 66-page report prepared in March 2005, to “answer [PTO General Counsel] Jim Toupin’s questions re the claim numbers to exceed a combined threshold.” A03661-78 (Exhibit 10) is a 17-page report prepared in June 2005 for the PTO’s Joe Rolla, with similar information. Had these data been available, the public would have been able to alert SBA that statements “certified” to it by PTO are simply false. For example, PTO says

“approximately 1,105 filings, or 1.0 percent, submitted by small entities and 3,742 filings, or 0.9 percent, submitted by all entities in FY 2006 would incur costs under the claims requirements,” (Exhibit 11 at A08284) – the actual number is far higher (*e.g.*, Exhibit 10 A03568: 5/25 affected 15.95% in 2004; A05028: 30% of retroactively-affected backfile).⁶

- Once the data of A03554-3620, A05042-52, A05729-07079 (Exhibit 10), were made available, the public was able to make enlightened comment. For example, one comment to the OMB under the Paperwork Reduction Act in October 2007 relied heavily on the quantitative data that the PTO belatedly made public in the production to Dr. Tafas (Exhibit 12).
- A07096 (Exhibit 10) identifies, without explanation or elaboration, what purports to be “key model assumptions” underlying the PTO’s computer generated data. Had the agency disclosed the information in this document, the PTO would have been unable to argue that it hoped for increased “productivity” from processing the same number of applications, because here the PTO admits much of its pendency reduction is to come from “reduced filings.” This would have shifted much of the debate, and is inconsistent with the “no substantial impact” statements to OMB, SBA, and in the Final Rule notice.
- A04524-25 (Exhibit 10) is a table of various classes of applications. Had this information been made available, public comments would have led to a correction of an error: this table omits Rule 62 “file wrapper continuations,” the pre-1997 equivalent to the “R129s” “CPA’s” and “RCE’s” that are reflected in the table. The PTO’s concerns for the growth of continuations may well be based largely on an erroneously-framed database query. Because the underlying data were not disclosed, the public had no opportunity to detect or correct any error.
- Exhibit 13 is a FOIA reply that provides material information as of December 22, 2005. The PTO states that extracting up-to-date data from its database (PALM) costs less than \$ 20.00. There is no cost reason that the PTO could not have made similar data available in the rulemaking file.

The PTO was required to disclose its data and assumptions during the rulemaking process.⁷ It did not do so. Just as a civil litigant cannot rely on evidence withheld during discovery, the PTO cannot now rely on information it kept hidden during the APA notice and comment processes to establish that its processes and final agency action were not arbitrary and capricious.

B. The PTO Has Still Not Disclosed Essential Information About the Computer Models by which the PTO Purported to Analyze Its Data

An agency may rely on computer models in rulemaking, but the agency must “explain the assumptions and methodology used in preparing the model” and “provide a complete analytic defense” if

⁶ This represents our best interpretation of these documents. The difference between 16% in 2004 and 30% in the entire backfile may well relate to misinterpretation (attributable to the PTO’s failures to explain the record material) or to simple error, see footnote 8, not any difference in the real numbers.

⁷ The E-Government Act of 2002, Pub.L. 107-347, Dec. 17, 2002, 116 Stat. 2899, § 206(d)(1) and (2), *codified in notes to* 44 U.S.C. § 3501, requires that rulemaking materials be made available by internet access, to the extent practicable. The PTO did not comply with this law, either.

the model is challenged. *Appalachian Power Co. v. EPA*, 251 F.3d 1026, 1035 (D.C. Cir. 2001). That information must be made available during the notice and comment period, so that the model can be vetted by the public. *Id.* While the Federal Rules of Evidence are not strictly applicable during agency rulemakings, “the spirit of *Daubert*... does apply to administrative proceedings... ‘Junk science’ has no more place in administrative proceedings than in judicial ones.” *Niam v. Ashcroft*, 354 F.3d 652, 660 (7th Cir. 2004) (Posner, J.). Computer output that is uninterpretable does not satisfy the APA.⁸

The PTO relies extensively on computer model output to show the effects of the new Rules: several hundred pages of the PTO’s administrative record are based on models to show effects of various cutoff numbers. For example, Exhibit 16 (A05641-721) is 81 pages of output from the PTO’s computer models, several pages of which bear dates before January 3, 2006. The projections (*e.g.*, Exhibit 16 at A05653, 05719) appear to increase or decrease according to variables such as “less 15% for discontinued continuation” and “efficiency gains,” but without any explanation of what these mean or could be based on. There is no analysis of how “efficiency gain” is obtained or measured. The budget submission tables state assumptions such as “5% reduction in filings from Continuation Limitation” and “FY 09 - 7.5% / FY 10/12 - 15% (Total) Efficiency Gain” that do not correlate to the numerical values on the same page, and that have no stated correlation to the new rules (*e.g.*, Exhibit 16 at A05685). There is no discussion of how the inputs affect the outputs of the model. There is no information about assumptions embedded in the software. The type of software used is not divulged. Numerous questions arise: Does the model use discrete queuing techniques, steady state differential equations, Monte Carlo techniques, or some other simulation method? Is it otherwise based on correct modeling principles? How large are the error bars on the results? What sensitivity analysis was performed on the inputs, so that the amount of error in the output can be evaluated? What portion of the input to the model comes from measured data, and what

⁸ *Engine Mfrs’ Ass’n v. EPA*, 20 F.3d 1177, 1181-82 (D.C. Cir. 1994) (R. B. Ginsburg, J.) (agency’s “page after page of impressive looking but utterly useless tables” that the public cannot understand without access to other unavailable information, and assumptions stated in “complete gibberish to anyone on less than intimate terms with the inner workings of the agency” are inadequate support for a rule). *Engine Manufacturers* answers the PTO’s mantra that its record consists of “10,000 pages.” Most of those pages are unintelligible because unexplained by other documents in the record. And it is too late for the agency to attempt to explain now, because *post hoc* rationalization is impermissible. See *State Farm*, 463 U.S. at 50.

comes from pure assumption? What validation techniques were used, and what is the history of software “bugs?” These are all questions that any knowledgeable person would ask of any model before relying on it. None of this was disclosed during notice and comment, and the PTO’s “administrative record” only wraps riddle in enigma in mystery.

Well-documented models exist. For example, a fully-documented computer model found that the PTO’s conclusions are probably wrong, as we discuss in § VII at page 18.

Several FOIA requests were made for documents that would encompass the underlying data, assumptions, and models. The request of May 2006 (Exhibit 5), specifically asked for “all documents that demonstrate (a) any data and assumptions on which the projections of [the PTO’s pendency projection PowerPoint] slide are based, and (b) the methodology or analysis used to generate the slide’s projections from the data and assumptions.” Note that this request is framed nearly word-for-word from the cases that identify the information that must be disclosed. A second, in October 2006, requested the full rulemaking file for the new Rules.

The PTO’s reply was surprising. In its June 2006 FOIA reply (Exhibit 5), the PTO provided only a handful of top-level conclusory numbers, but no information about the agency’s assumptions of future application populations, or any model used to generate its projections. In its October 2006 FOIA Reply (Exhibit 6), the PTO stated that the total contents of the rulemaking file was 114 pages of summary data, in PowerPoint graphs and high-level summary tables. Release of summary information is insufficient to meet an agency’s duty to disclose its models, data, and assumptions. *Washington Trollers Ass’n v. Kreps*, 645 F.2d 684 (9th Cir. 1981) (high level summary, without underlying model or data to “enable an interested or affected party to comment intelligently,” is arbitrary and capricious).

Five months after the close of Notice and Comment, on October 19, 2006, Commissioner Doll offered to make the PTO’s model available to hand-picked parties on an *ex parte* basis:⁹

The PTO invited the AIPLA board to take a look at the agency’s models and the assumptions they are based upon. Those models will reveal that the PTO’s

⁹ Exhibit 17, *PTO Commissioner Doll Says That Limiting Continuations Will Improve Patent Landscape*, 72 Patent Trademark and Copyright Journal (BNA) 704 (Oct 27, 2006), reporting a talk given by Commissioner Doll at the annual meeting of the American Intellectual Property Law Association.

proposed change to continuation practice will turn the backlog situation around, Doll said.

But October 2006 was well after the May cutoff for public comment. Commissioner Doll's offer was thus effectively a concession that the PTO "hid the peanut" during notice and comment, *Hanover Potato*, 989 F.2d at 130 n.9. Such a course of action was "arbitrary and capricious" and "without observance of procedure."

It is fundamentally unfair to permit the PTO to now rely on computer-generated documents after earlier denying their very existence, or at least denying that they were part of the record that supported the PTO's decision-making process (Exhibit 6, Exhibit 7).

The new Rules must be vacated until the computer models on which they are based can be knowledgably vetted. (Conversely, if the PTO did not rely on computer models, then the thresholds in the final rules were set arbitrarily and capriciously. One way or the other, the PTO erred.)

C. The PTO's Backlog Rationale Cannot be Affirmed Because the PTO "Failed to Consider Important Aspects of the Problem:" Revenue Losses to Itself, and Cost Burdens on the Public

In its June 2007 FOIA reply (Exhibit 7), the PTO asserted that there were no documents evaluating any cost savings from the new Rules, or estimating the cost shifts within the PTO that would occur as applicants shifted from traditional techniques to the new ones required or incentivized by the new Rules. Based on the skeletal information that the PTO disclosed, the PTO could not have had any idea whether the new Rules would or would not have any material affect on its problem. The PTO stated that there are "no documents" of the following categories (Exhibit 7):

(5) ... any analysis and estimate of costs that will be saved by the PTO if the proposed rules are adopted;

(31) ... any study, analysis, conclusion or assertion showing the effect of the proposed continuation rules on appeals to the Board of Patent Appeals and Interferences, including effects on the number, typical complexity or pendency of such appeals;

(33) ... any study, analysis, conclusion or assertion showing the effect of the proposed continuation rules on petitions submitted to the U.S. Patent and Trademark Office, including effects on the number, typical complexity or pendency of such petitions.

There are still no documents relating to most of these categories. Until the PTO can demonstrate some "rational connection between the facts found and the choice made," the rules are arbitrary and capricious.

State Farm, 463 U.S. at 43. The new Rules must at least be vacated for the required fact-finding.

Several public comment letters cited published data showing that the applications and claims that would not be filed under the Rules are the applications and claims that generate the largest fees for the least examining effort – continuation applications and “non-patentably distinct claims” raise issues similar to those the examiner is already familiar with, and can deal with efficiently. The rules shift the PTO from doing “profitable” work to “unprofitable” work, which will harm the PTO financially (*e.g.*, Exhibit 19 at page A03167; Exhibit 9 at P000301-317; Exhibit 18). These comments note that the Rules could well worsen backlog instead of improving it, if the PTO deprives itself of its most profitable work, and finds itself without financial resources to hire in a few years. The Final Rule notice makes no apparent response to these issues. The loss of its “easiest to examine” revenue renders the PTO’s “backlog” rationale “so implausible that it could not be ascribed to . . . the product of agency expertise.” Failure to consider an issue this fundamental, and to respond to comments, is “arbitrary and capricious.” *State Farm*, 463 U.S. at 43.

Conversely, 35 U.S.C. § 2(b)(2)(F), enacted to give the PTO the liberties of a “performance based organization,” imposed a counterbalancing obligation: the PTO’s processes must respect measurable “cost-effectiveness” and concerns for “principles of impartiality and competitiveness.” When an agency’s statute requires it to consider costs in its rulemaking, the agency errs in failing to do so.¹⁰ An agency cannot prevent an action from having a significant impact by mere *ipse dixit*; if the agency failed to provide support for its assertions in the Final Rule notice, the action must be vacated. *HLI Lordship Indus. Inc. v. Committee for Purchase from the Blind*, 791 F.2d 1136, 1141 (4th Cir. 1986).

The PTO repeatedly stated it had not considered costs to the public. There is no mention of costs to the public in the Notices of Proposed Rulemaking. As late as June 12, 2007, the PTO insisted that there

¹⁰ *Chamber of Commerce of the U.S. v. SEC*, 412 F.3d 133, 143-44 (D.C. Cir. 2005) (*Chamber I*) (even if costs are difficult to estimate, agency is not excused “from its statutory obligation to determine as best it can the economic implications of the rule it has proposed”); *Levine v. Apker*, 455 F.3d 71, 86 (2d Cir. 2006) (agency rule may not set numerical cutoff without considering all statutorily-specified effects on parties affected by the cutoff); *see also Michigan v. EPA*, 213 F.3d 663, 678 (D.C. Cir. 2000) (“It is only where there is ‘clear congressional intent to preclude consideration of cost’ that we find agencies barred from considering costs.”); *Sierra Club v. Costle*, 657 F.2d 298, 335 n.132 (D.C. Cir. 1981) (“fail[ure] to consider regulatory costs” is an example of an “artificial narrowing of options that (can be) arbitrary and capricious”).

were “no documents” on these two categories (Exhibit 7):

- (3) ... any analysis and estimate of costs that will be imposed by the Proposed Rules on applicants;
- (4) ... any analysis and estimate of costs that will be imposed by the Proposed Rules on business in the form of patent protection foregone;

The PTO eventually generated some cost estimates, but only exposed them to public comment after the rules were published in August. *E.g.*, RegFlex Certification Analysis, June 29, 2007 (Exhibit 11, A08270-306), first made public about a week after publication of the rules. Once the public had a chance to examine the PTO’s analysis, it became clear that the PTO had grossly understated the costs of the rules. Actual costs are likely to be in the **billions** of dollars, several times the PTO’s total budget.¹¹ The PTO has not yet made any public reply to those estimates, as required by 5 C.F.R. § 1320.5(a)(1)(iii)(F). Because the PTO failed to comply with its own information quality guidelines (see § VI and Exhibit 21), and the public comment estimates *prima facie* do comply with those guidelines¹², the comments’ estimates are the only cost estimates available. The PTO cannot be affirmed to have complied with § 2(b)(2)(F) based on its non-credible, non-IQA-compliant cost estimates.

The representations that the PTO made to this Court are inconsistent with the representations it made to OMB. Here, the PTO says that the “examination support document” (ESD of new Rule 265) is not a significant burden to any applicant that wishes to use it (PTO’s Memo in Support of SJ, docket no 127, at pp. 66-67). Yet, the PTO represented to OMB that ESD’s are *so profoundly burdensome* that only 2,900 will be filed, and that the other 140,000-some applications per year that currently exceed the 5-25 limit will simply drop claims (Exhibit 14 at A07341). The PTO made no analysis of the burden or social cost of those dropped claims, and apparently never informed OMB of its assumption of dropped claims; instead, it simply said the burden is “not significant.” Agency action that is either unexplained or inconsistently explained is “arbitrary and capricious.”

The PTO broke its own rules. Failure to consider or balance costs renders the rules “arbitrary and

¹¹ <http://www.whitehouse.gov/omb/oira/0651/meetings/663.pdf>, attached affidavit at page 4 ¶ 27, estimating burden of a related rule at \$ 7 billion per year, and Exhibit 12, estimating the burden of just some of the rules in this litigation at \$ 3.5 billion per year. The PTO’s total budget is about \$1.8 billion.

¹² <http://www.whitehouse.gov/omb/oira/0651/meetings/663.pdf>, pages 1-11.

capricious” for failure to consider relevant factors, and is “contrary to law.”

D. The PTO Relied on Factors Which Congress Did Not Intend

The Final Rule notice frequently reiterates the PTO’s substantive judgment that “new” applications are more important than “old” applications. *E.g.*, 72 Fed. Reg. at 46718 col. 3, 46719 col. 1 and 3. Congress did not intend such discrimination. § 120 provides that a continuation application “shall have the same effect” as a “new” application. The PTO cites no indication that Congress ever expressed any preference for “new” applications or antipathy toward “old” applications. The PTO has no authority to express its substantive judgment on the issue, let alone encode that judgment in binding rules.

Additionally, the rules attempt to undo Congress’ intent by causing substantial expropriation of property rights. Congress protected inventors from PTO delay by implementing “patent term adjustment” in 35 U.S.C. § 154(b): patent term is extended when PTO delays exceed certain limits. However, both the “streamlined examination procedure” set forth at 72 Fed. Reg. 46721, col. 1-2, and the closing of current “voluntary divisional” practice in favor of the “file all claims at once and let the PTO involuntarily divide” strategy required by § 1.78(d)(1) force an applicant to walk away from term adjustment. *E.g.*, one of Polestar’s applications (09/611,548) has 181 claims, and has been in prosecution for 7½ years, due overwhelmingly to examiner procedural failings (*see* § VII and Exhibit 27). Because of PTO delay, Polestar’s patent application is due about four years of term adjustment. Had Polestar prosecuted the application as the PTO prefers, 156 of its claims (over 80%) could not even have been filed yet, could not issue for several years after that (losing perhaps 10 years of the total 20 year term), and when they issue, they would be without the term adjustment they enjoy under statute.

Reliance on these “factors which Congress has not intended [the PTO] to consider” render the rules arbitrary and capricious. *State Farm*, 463 U.S. at 43.

V. Documents Are Missing from the Administrative Record, And Comments Raised are Left Unanswered in the Final Rule Notice

The following documents are missing from the administrative record:

- The PTO’s 2005 certification to the SBA that the Claims Rule “would not have a “significant economic impact on a substantial number of small entities.” USPTO, Notice of Proposed Rule Making, “Changes to Practice for the Examination of Claims in Patent Applications,” 71 Fed.

Reg. 61, 66 col. 2 (Jan. 3, 2006). This document likely contained statements that could have been challenged, and those challenges would have informed SBA's review of the rule.

- Communications to OMB.¹³ Some are in the record (e.g., A08433-42, A8503-04), and some are not. Exhibit 9, one of the omitted communications, is a presentation made to OMB and senior PTO officials on June 15, 2007. This presentation flagged a number of breaches of procedural rulemaking law, including the Information Quality Act and the Paperwork Reduction Act. The PTO's reply to the specific issues raised in Exhibit 9 is not apparent in the Final Rule notice.
- Notice and comment letters. Most are in the record, some are not. Heritage Woods, Inc. filed two copies of this letter (Exhibit 20) in the two different dockets. The PTO's web site has listed it twice for a year. Yet both copies are excluded from the record that the PTO provides this Court. This letter is one of the longest and most detailed. Its comments were not responded to by the PTO. It seems implausible that the PTO failed to include both copies of this letter in the administrative record as a matter of mere oversight. The PTO should be probed on this point when it appears before the Court again to make an oral presentation.

Both the Exhibit 9 and Exhibit 20 include points that should have been addressed in the Final Rule notice, but were not. For example, Exhibit 20, at P000591-92, notes that applicants must often present more than five legally-distinct but patentably-indistinct independent claims to the same conceptual invention, to adequately cover various situations involving imports, exports, repairs to a device, replaceable components, and the like. The proposal to limit the number of patentably-indistinct claims in an application makes it literally impossible to comply with various limits imposed by the courts. No reply to this comment is apparent in the Final Rule notice. "Unless an agency answers objections that on their face appear legitimate, its decision can hardly be said to be reasoned." *Mistick PBT v. Chao*, 440 F.3d 503, 512 (D.C. Cir. 2006).

Exhibit 9, at P000315-17 and Exhibit 20 at P000602-11, and dozens of other letters, present over two dozen alternatives to the new Rules. To the degree these alternatives are discussed in the Final Rule notice, the PTO dismisses them as "beyond the scope of this rulemaking." 72 Fed. Reg. at 46805 col. 2; 46818 col. 1; 46824 col. 1; 46826, col. 2. The only way that alternative solutions to the PTO's backlog problem could be "beyond the scope" is if the PTO had a predetermined and inflexible definition of the solution, such that no other solutions would be considered. An agency must approach its rulemaking, and conduct its notice and comment procedure, with a "flexible and open-minded attitude towards its own

¹³ The full list of meetings and comments, with links to the documents, are at <http://www.whitehouse.gov/omb/oir/0651/meetings.html> and <http://www.whitehouse.gov/omb/oir/0651/comments.html>.

rules.” *Chocolate Manufacturers*, 755 F.2d at 1103. An “agency must consider reasonably obvious alternatives and, if it rejects those alternatives, it must give reasons for the rejection...” *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 80 (2d Cir. 2006). The PTO did neither.

The record creates the appearance of being assembled after the promulgation of the final rules, specially for this court. The record also appears to be a whitewash for a pre-ordained result, rather than a record of “open-minded” deliberation. That is not a true administrative record and hence is “intolerable.” *Hanover Potato*, 989 F.2d at 130 n.9. The PTO has acted arbitrarily and capriciously.

VI. Because the PTO Violated Its Own Regulations Relating to Information Quality, the Administrative Record Cannot Be Relied On by the PTO

It is a “well-settled rule that an agency's failure to follow its own regulations is fatal to the deviant action.” *IMS, P.C. v Alvarez*, 129 F.3d 618, 621 (D.C. Cir. 1997). The PTO repeatedly chose not to follow its own regulations. The Office ignored respected analytic procedures that have been in place for more than 25 years; failed to abide by guidance the Office itself issued in 2002 and which it had committed itself to follow; and circumvented another law by reverse engineering a “determination” that small entities would not be significantly affected by its regulations

The Information Quality Act (IQA) (or Data Quality Act, codified in notes to 44 U.S.C. § 3616) requires agencies to “ensur[e] and maximiz[e] the “quality, objectivity, utility, and integrity of information (including statistical information) [they] disseminate...” The IQA required OMB to issue government-wide guidelines and for agencies to establish and follow their own implementing guidelines, taking account of their unique characteristics. PTO largely adopted OMB's language unchanged. “Objectivity” under OMB’s and PTO’s guidelines requires that information be “accurate, reliable, and unbiased,” and “presented in an accurate, clear, complete, and unbiased manner” (PTO IQG, Exhibit 15, § IV(A)(6)). Data and analyses must be transparent and “reproducible” by competent third parties. The PTO commits itself to full public disclosure (PTO IQG, Exhibit 15, § IV(A)(7), underline added):

“Reproducibility” of these analytic results does include “especially rigorous robustness checks” and when asked the USPTO does provide disclosure of the data sources that have been used and the specific quantitative methods and assumptions (if any) that have been employed

Data, analyses, statistics, and similar “representation[s] of knowledge” that the PTO disseminates in

rulemaking are covered by the IQA, and OMB's and the PTO's implementing guidelines (PTO IQG, Exhibit 15, "information that ... forms any part of the support of the policies of the agency" are covered).

However, none of the information PTO disseminated as foundation for the rules – its web site (Exhibit 3), the 18 slide presentations in the "record" (A00043-A00590), the 114 pages disseminated on its web site and as the full rulemaking file as of October 2006 (Exhibit 6), or the PTO's certification of "no significant impacts" on a substantial number of small entities – adhere to the objectivity standard. As one example, the analysis and data used to derive the "Pendency Projection" slides in the 18 slide shows and the 114-page October 2006 record have not been disclosed – the disseminated information has no "objective" support whatsoever (*e.g.*, A00091-96; copies at Exhibit 6, "Pendency" slides, PDF pages 6-10, slide footer numbers 50-53). Other examples of analytical omissions, discussed in §§ IV.A and IV.B, undercut "objectivity" under the IQA and the PTO's IQ Guidelines.

Exhibit 21 is a Declaration of Richard Belzer, a Harvard-educated economist with 20 years' experience in regulatory analysis, including 10 years as a professional economist in OMB's Office of Information and Regulatory Affairs. Dr. Belzer notes that the principles of regulatory review and impact analysis for major regulatory actions have been in place for 26 years, and must have been known to the PTO, yet the "PTO withheld from OMB information crucial for estimating, within even an order of magnitude, the likely costs" of the rules. ¶ 52. Dr. Belzer states "PTO knew or should have known that if it complied with the [its IQA guidelines], competent third parties were ... more likely than not to succeed in showing that the [PTO's] estimates ... were inaccurate and biased, and thus not substantively objective." ¶ 53. Dr. Belzer states with a "*very high level of confidence* [that] the PTO knew or should have known that its characterization of impacts on small entities ... were nonsensical." ¶ 54. The PTO's "certification" to no impacts to SBA relied on naked "belief" masquerading as data. ¶¶ 60-62. Dr. Belzer states, ¶ 55:

Because PTO has issued [IQA] Guidelines and committed to follow them, and it has had more than five years' experience doing so, it is inconceivable to me that PTO's decision not to adhere to its own reproducibility standard was inadvertent or accidental. In my professional judgment, it is certain that PTO knew that the information it had disseminated was not reproducible by competent third parties. Because affected parties asked for more extensive documentation, which PTO declined to disclose, it is all but certain that PTO intended that its information not be reproducible.

Dr. Belzer "*can state with certainty* that if all the analytic information I had been provided was the information [provided to the public], I would not have been able to perform a competent review." ¶ 51.

The PTO's breach of its own IQA regulations frustrated "procedure required by law."¹⁴ A remand would give the PTO opportunity to carry out its commitment to "objectivity," "reproducibility" and "disclosure [of] quantitative methods and assumptions." The PTO could attempt to justify its rules without withholding of information, and without disseminating non-objective information.

VII. The PTO Failed to Consider an "Important Aspect of the Problem," Its Cause – and Therefore Cannot Rationally Explain Its Rules

The PTO conceded that it had made no attempt to diagnose the cause of its backlog or "rework" problem. In its June 2007 FOIA reply, the PTO admitted (Exhibit 7) that "[t]here were no records" relating to any investigation of the cause of its backlog or "rework" applications:

(1) ... any factual investigation or analysis of underlying causes for "rework" applications used in developing the proposed "Continuations," "Examination of Claims," or "IDS" rules...;

At one of the public "Town Hall" meetings¹⁵, Commissioner Doll confirmed that the PTO did not analyze its data to ascertain the underlying cause of "rework" to evaluate the PTO's backlog:

Question: Commissioner Doll, did you do any studies to identify where these rework applications are coming from? Do you have any sense for whether they're caused by the examiner screwing up or the applicant screwing up? ...

Commissioner Doll: No, I didn't differentiate between whether it was an applicant error or an examiner error.

One paper, analyzing data the PTO's data, showed that the examining groups with highest backlog

¹⁴ The Fourth Circuit has held that "The IQA ... does not create any legal right to information or its correctness." *Salt Inst. v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006). But the plaintiff in *Salt Institute* was seeking judicial review of information disseminated by a non-regulatory agency in which no "final agency action" ever occurred, not judicial review of regulations. The APA plainly creates a private cause of action for the judicial review of agency rulemaking action. *Japan Whaling Ass'n v. American Cetacean Soc'y*, 478 U.S. 221, 231 n.4 (1986) ("the rule is that the cause of action for review of [agency] action is available absent some clear and convincing ... legislative intention to preclude review."). There is no reason that an agency's public embrace of the IQA's sensible regulation of quality for information it disseminates, combined with the same agency's complete disregard for those rules and procedures in practice, cannot be used by this Court as an indicator of arbitrary and capricious conduct. Similarly, the Court may require the PTO to observe its own statutorily founded and rationally issued self-regulatory rules – in particular, its own information quality guidelines (Exhibit 15).

¹⁵ Transcript of recording of afternoon session of AIPLA meeting in New York, April 7, 2006, obtained from AIPLA. Original on request. The PTO has indicated it wishes parties to submit transcripts rather than media recordings of materials such as these. See *Objection to Plaintiff Tafas Submitting Transcripts of Audio-Visual Clips*, filed by defendants as paper no. 85 (Nov. 26, 2007)

actually faced lower-than-average numbers of continuations.¹⁶ In contrast, the PTO has given no data-backed correlation between continuations and backlog. If the PTO cannot show how the data correlate some hypothesized-but-unmeasured cause to actual backlog, the PTO cannot “articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.” The new Rules are accordingly “arbitrary and capricious.” *State Farm*, 463 U.S. at 43.

However, several public comments did identify a likely source: the “suspicious procedures” for examination that this court has previously observed. 73 USPQ2d at 1471 n.5. For example, one comment letter assembled a number of the PTO’s own statistics to show that examiners are affirmed in less than 20% of appeals – a PTO error rate approaching **80%**.¹⁷ Another notice and comment letter showed examiner error rates of **90%**.¹⁸ A recent paper applies operations research techniques to study the source of the PTO’s backlog.¹⁹ This paper finds that continuations are not a material factor; the major factor in backlog is the large rate at which examiners must backtrack from an error and re-examine the application to correct that error.

The Court will recall that the PTO’s current policy is to give examiners “independent decision-making authority” up to and including authority to determine which of the PTO’s instructions to follow and which to ignore.²⁰ This leads to havoc. Several examples (including one of Polestar’s) of applications that have been delayed for years by examiners’ failure to follow PTO rules are shown in Exhibit 27. In its June 2007 FOIA reply, the PTO reiterated that it had no documented “mechanism[] by which the PTO

¹⁶ Schreiner and Doody, Patent Contaminations, American Bar Ass’n, Intellectual Property Law Section, Newsletter, vol. 24, no. 3, pp. 38 ff (Spring 2006) (Exhibit 23), endnote 78 and accompanying text.

¹⁷ Exhibit 20 at page 3. A more complete presentation with underlying data appears as Exhibit 22. A reversal rate of eighty percent suggests that the PTO’s examination procedures are unconstitutionally defective. *Mattern v. Weinberger*, 519 F.2d 150, 161 (3d Cir. 1975) (when an agency has a reversal rate of one third, its procedures “cannot be defended”), *vacated on other grounds*, 425 U.S. 987 (1976).

¹⁸ AIPLA’s letter on the Continuations Rule, http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/aipia.pdf at page 11.

¹⁹ Ayal Sharon and Yifan Liu, Improving Patent Examination Efficiency and Quality: an Operations Research Analysis of the USPTO, using Queuing Theory, Federal Circuit Bar J. Vol. 17, No. 2 (2007), available at <http://ssrn.com/abstract=1026320> and [.../abstract=1026372](http://ssrn.com/abstract=1026372) (Exhibit 24). “Operations research” is the branch of mathematics directed to decision-making analyses, especially process flows in a system.

²⁰ [Patent Office’s] Reply to Plaintiff’s Opposition to Defendant’s Cross-Motion for Summary Judgment, *Boundy v. Patent and Trademark Office*, Civ. 03-CV-557-A (E.D. Va. Apr. 23, 2004), Exhibit 25.

ensures that examiners, during examination . . . do not act outside the scope of authorization of [reasoning and criteria examiners are required or authorized to employ in rejecting claims]” (Exhibit 7 ¶ 17).²¹ A number of comment letters suggested that examination efficiency could be remarkably improved if examiners were held to predictable standards and procedures. The Final Rule notice dismisses that suggestion without comment or rebuttal.

All the evidence is that the PTO’s backlog problem arises largely from internal imprecision, carelessness, and failure to follow or enforce written procedures. A number of alternative solutions to the PTO’s backlog were suggested to the PTO; the PTO dismissed them out of hand. See § V.

Surprisingly, the new Rules are directed at taking away most of the options applicants have for dealing with the PTO’s haphazard procedures and high error rate. Comments 86 and 87 asked whether the PTO would grant continuations in cases where the examiner conceded substantive or procedural error or had failed to explain all positions “clearly” as required by 37 C.F.R. § 1.104(c), or where the examiner abandoned an old position and took a new position, or where the examiner’s position was “unusual and only recently understood by the applicant,” or when the applicant “discovers that the examiner is under a misunderstanding.” 72 Fed. Reg. at 46774. The PTO’s reply was that these examiner errors “more than likely would not be sufficient” grounds on which to continue examination. *Id.* At best, the PTO would decide on a case-by-case basis whether the applicant should have been able to read the examiner’s mind and “could have [] anticipated” the change in position. *Id.* The PTO does not explain its basis for punishing the applicant for the examiner’s failure to comply with the PTO’s formal and mandatory instructions to state all rejections completely and clearly.

Finally, the record reveals no attempt by the PTO to evaluate how applicants’ strategies will change, and how those changes will affect the PTO’s costs and efficiencies. Will alternative strategies reduce or increase the PTO’s costs and burdens? No one knows, because the PTO never asked.

It is grossly unfair for the PTO to impose billions of dollars of costs on the public before it

²¹ In the examining group formerly headed by John Love, now Deputy Assistant Commissioner for Patent Examination Policy, examiners believed and told applicants that they were instructed to delay all applications, rejecting without regard to the law. Exhibit 28.

establishes that the PTO itself is not substantially at fault, and before it establishes that these rules will actually accomplish any useful and statutorily-permissible result. (See § IV.C) Failures to “consider important aspects of the problem” are arbitrary and capricious.

VIII. Rule 104 Was Amended as a Non-Logical Outgrowth, Purporting to Create the Power for the PTO to Change Substantive Rules Without Notice And Comment

The Final Rule notice explains that the amendment to add the words “and other requirements” to 37 C.F.R. § 1.104 gives examiners authority to apply non-statutory, non-C.F.R. substantive provisions of the Manual of Patent Examining Procedure (MPEP) with full force of law against applicants. 72 Fed. Reg. 46737 at col. 1. This provision is invalid. First, this provision is not a “logical outgrowth” of the 2006 Notices of Proposed Rulemaking: there is nothing in the 2006 Notice to foreshadow this provision. Second, this is contrary to law: the PTO cannot sidestep the APA’s rulemaking requirements by popping new provisions into an informal document, without complying with rulemaking procedures of 5 U.S.C. § 553. 35 U.S.C. § 2(b)(2)(B). Third, this violates Executive Order 13,422: the President has directed that agency guidance documents promulgated without notice and comment may only bind the agency, not the public.²² The PTO cannot grant itself authority to sidestep rulemaking procedures in the future.

IX. Conclusion

In view of the foregoing, *amicus curiae* Polestar and Norseman urge the Court to grant Plaintiffs’ Motions for summary judgment. To the degree any aspect of the proposed rules survive “contrary to law” review, all should be remanded for a new rulemaking that starts over at the beginning, to give the PTO a chance to “observ[e] procedure required by law.”

²² Executive Order 13,422, 72 Fed. Reg. 3432 (Jan. 25, 2007), http://www.whitehouse.gov/omb/inforeg/eo12866/fr_notice_eo12866_012307.pdf; “Final Bulletin for Agency Good Guidance Practices” (OMB Memorandum M-07-07, January 18, 2007, <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf>); and “Implementation of Executive Order 13422 (amending Executive Order 12866) and the OMB Bulletin on Good Guidance Practices” (OMB Memorandum M-07-13, April 25, 2007, <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-13.pdf>). Executive Orders can be considered when deciding whether the PTO acted arbitrarily and capriciously. See *Coliseum Square Ass’n v. Jackson*, 465 F.3d 215, 232-33 (5th Cir. 2005).

Respectfully submitted,

/s/

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of December 2007, I electronically filed in the foregoing with the Clerk of the Court using the CM/ECF system, which will then send notification of such filing (NEF) to all counsel of record.

/s/

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