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From: Hamilton, Melissa - Cantor Fitzgerald **On Behalf Of** Alderucci, Dean - Cantor Fitzgerald

Sent: Friday, September 08, 2006 4:58 PM

To: AB95 Comments

Cc: Alderucci, Dean - Cantor Fitzgerald

Subject: Re: Comments to the July 10, 2006, Changes to Information Disclosure Statement Requirements and Other Related Matters, 71 Fed. Reg. 38808 (July 10, 2006)

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8 September 2006

VIA EMAIL AND FIRST CLASS MAIL

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RE: Comments to the July 10, 2006, Changes To Information Disclosure Statement Requirements and Other Related Matters, 71 Fed. Reg. 38808 (July 10, 2006)

Dear Sir:

A. Summary of Issues.

The proposed rules violate several tenets of Administrative Law and, if promulgated, would be clearly in violation of Supreme Court jurisprudence and in excess of statutory authority.

First, there is no evidentiary basis and no reasoned justification articulated in the proposed rule for adopting any requirements that would shift burdens of examination from U.S. Patent and Trademark Office (PTO) to applicants. Even if authority existed to promulgate such rules, the PTO would need to issue a new notice of proposed rulemaking with an adequate record to support its proposal.

Second, there is no evidentiary basis and no reasoned justification articulated for imposing on applicants the specific explanation, non-cumulative description, and patentability justification requirements of proposed Section 1.98(a)(3), in order for applicants to have the PTO consider information that applicants are required or permitted to submit in satisfying their duty of disclosure under 37 CFR § 1.56.

Third, the proposed rules would shift burdens of examination to applicants, impermissible altering burdens of proof and production regarding applicants' compliance with the duty of candor. The proposed rules cannot be justified as implementing or interpreting the duty of disclosure, as that duty addresses only the withholding of material information.

Fourth, the proposed rules would impose serious, adverse potential liabilities on applicants if they choose to comply with the proposed requirements, as well as if they refuse to comply. The proposed rules thus will increase the likelihood of lowering the quality of examination and increasing the likelihood of inequitable conduct allegations and litigation, both which the PTO should seek to discourage rather than foment.

Fifth, the PTO lacks statutory authority to issue the proposed rules, which are substantive rules, and not procedural rules as suggested in the proposal nor interpretive rules. Even if the PTO were to possess adequate authority, the proposed rules are a bad idea and should not be issued.

Please note that if a reasoned response is not provided to every comment, then the proposed rules, if passed, would be subject to invalidation as arbitrary and capricious.

Please also note that a promulgated rule which is not a “logical outgrowth” of a proposed rule would likewise be subject to invalidation for not having been subjected to notice and comment.

B. Administrative Law Principles Applicable to This Rulemaking.

The U.S. Patent and Trademark Office (PTO) must follow administrative law requirements, including the Administrative Procedure Act (APA) reasoned decisionmaking requirements, under the APA's judicial review standards of 5 USC § 706. See *Dickinson v. Zurko*, 527 U.S. 150, 164 (1999) (“Moreover, if the Circuit means to suggest that a change of standard could somehow immunize the PTO's fact-related 'reasoning' from review, 142 F.3d, at 1449-1450, we disagree. A reviewing court reviews an agency's reasoning to determine whether it is 'arbitrary' or 'capricious,' or, if bound up with a record-based factual conclusion, to determine whether it is supported by 'substantial evidence.' E.g., *SEC v. Chenery Corp.*, 318 U.S. 80, 89-93, 63 S.Ct. 454, 87 L.Ed. 626 (1943).”).

Relevant APA requirements in regard to rulemaking by the PTO are that for substantive (or “legislative”) rules, the PTO must follow notice and comment procedures under 5 USC 553(b) and (c), including providing a reference to the legal authority under which the rule is proposed to be promulgated and a concise statement of basis and purpose for the rule. In response to public participation, the PTO must provide a reasoned response to any comments received (“reasoned decisionmaking” under the APA judicial review standards discussed below). See, e.g., *Air Transport Ass'n of Canada v. F.A.A.*, 254 F.3d 251, 278 (D.C. Cir. 2001) (“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.” *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168, 83 S.Ct. 239, 9 L.Ed.2d 207 (1962). In reviewing that explanation, we must “consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.” *Bowman Transp., Inc. v. Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 285, 95 S.Ct. 438, 42 L.Ed.2d 447 (1974); *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971).”).

Any changes to a proposed rule must be a “logical outgrowth” of the proposal (if the final rule is responsive only to comments and not to the proposal, the PTO may need to “renotify” the changes to the proposal for additional comment). See, e.g., *Environmental Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005) (“[The APA's n]otice requirements are designed (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review.” *International Union, United Mine Workers of America v. Mine Safety & Health Administration*, 407 F.3d 1250, 1259 (D.C.Cir.2005)] (citing *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 547 (D.C.Cir.1983)). Given the strictures of notice-and-comment rulemaking, an agency's proposed rule and its final rule may differ only insofar as the latter is a “logical outgrowth” of the former. See *Shell Oil Co. v. EPA*, 950 F.2d 741, 750-51 (D.C.Cir.1991); *Northeast Maryland Waste Disposal Auth.*, 358 F.3d at 952 (stating a final rule is a “logical outgrowth” of a proposed rule only if interested parties “ 'should have anticipated' that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period”) (quoting *City of Waukesha v. EPA*, 320 F.3d 228, 245 (D.C.Cir.2003)). The “logical outgrowth” doctrine does not extend to a final rule that finds no roots in the agency's proposal because “[s]omething is not a logical outgrowth of nothing,” *Kooritzky*, 17 F.3d at 1513, nor does it apply where interested parties would have had to “divine [the agency's] unspoken thoughts,” *Arizona Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1299 (D.C.Cir.2000) (quoting *Shell Oil*, 950 F.2d at 751), because the final rule was “surprisingly distant” from the Agency's proposal. *International Union*, 407 F.3d at 1260.”).

Thus, the agency must provide sufficient facts in the record for its proposal to allow for meaningful comment. See, e.g., *Chamber of Commerce of the U.S. v. S.E.C.*, 2006 WL 890669, at *8 (D.C. Cir. 2006) (“In essence, the question is whether “at least the most critical factual material that is used to support the agency's position on

review ... [has] been made public in the proceeding and exposed to refutation.” Ass'n of Data Processing, 745 F.2d at 684; see Air Transp. Ass'n, 169 F.3d at 7. By requiring the “most critical factual material” used by the agency be subjected to informed comment, the APA provides a procedural device to ensure that agency regulations are tested through exposure to public comment, to afford affected parties an opportunity to present comment and evidence to support their positions, and thereby to enhance the quality of judicial review. See Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin., 407 F.3d 1250, 1259 (D.C.Cir.2005).”

The requirement to provide in the docket for the proposed rule sufficient facts to support informed comments for evaluating the final rule on judicial review is critically important given the potential for preclusion of judicial review under the theory of “administrative exhaustion.” See, e.g., *Advocates for Highway and Auto Safety v. Federal Motor Carrier Safety Administration*, 429 F.3d 1136, 1148-50 (D.C. Cir. 2005) (“It is black-letter administrative law that '[a]bsent special circumstances, a party must initially present its comments to the agency during the rulemaking in order for the court to consider the issue.’”) (quoting *Appalachian Power Co. v. EPA*, 251 F.3d 1026 (D.C.Cir.2001) (quoting *Tex Tin Corp. v. EPA*, 935 F.2d 1321, 1323 (D.C.Cir.1991))). Although litigants are not precluded from challenging rules in regard to clear points that an agency must consider *sua sponte* (like its statutory authority) or issues actually considered by an agency - see, e.g., *id.* at 1150 (citing *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 51 (1983)); *Engine Mfrs. Ass'n v. U.S. Environmental Protection Agency*, 88 F.3d 1075, 1084 (D.C. Cir. 1996) - the administrative rulemaking process of notice and comment and subsequent deference to reasoned agency determinations depend on agencies providing a clear factual basis and adequately articulated reasoning for proposed rules. See, e.g., *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (“The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency. Nevertheless, 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.’”) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)); *In re Lee*, 277 F.3d 1338, 1342 (Fed. Cir. 2002) (“Judicial review ... is thus founded on the obligation of the agency to make the necessary findings and to provide an administrative record showing the evidence on which the findings are based, accompanied by the agency's reasoning in reaching its conclusions.”). Thus, even without comments on an issue in the docket, an agency “retains a duty to examine key assumptions as part of its affirmative burden of promulgating and explaining a nonarbitrary, non-capricious rule,” and therefore must justify its basic “assumption[s] even if no one objects during the comment period.” *Appalachian Power Co. v. EPA*, 135 F.3d 791, 818 (D.C.Cir.1998) (quoting *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 534-35 (D.C.Cir.1983)) (internal quotation marks omitted).

Rules promulgated by the PTO are generally subject to judicial review under the “arbitrary, capricious, an abuse of discretion, or not in accordance with law” standard of the APA, 5 USC 706(A). Although the standard is deferential, the agency must meet the requirements of reasoned decisionmaking. See, e.g., *In re Gartside*, 203 F.3d 1305, 1312 (Fed. Cir. 2000) (under the “arbitrary and capricious” standard, “a reviewing court 'must consider whether the decision was based on a consideration of relevant factors and whether there has been a clear error of judgment.’”) (quoting *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971)). See generally *Air Transport Ass'n of Canada v. F.A.A.*, 254 F.3d 251, 278 (D.C. Cir. 2001) (“The scope of review under the “arbitrary and capricious” standard is narrow and a court is not to substitute its judgment for that of the agency. Nevertheless, 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.” *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168, 83 S.Ct. 239, 9 L.Ed.2d 207 (1962). In reviewing that explanation, we must “consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.” *Bowman Transp., Inc. v. Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 285, 95 S.Ct. 438, 42 L.Ed.2d 447 (1974); *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971). 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 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. SEC v. Chenery Corp., 332 U.S. 194, 196, 67 S.Ct. 1575, 91 L.Ed. 1995 (1947).”); Tripoli Rocketry Ass'n, Inc. v. Bureau of Alcohol, Tobacco, Firearms, and Explosives, 437 F.3d 75, 76 (D.C. Cir. 2006) (“This court routinely defers to administrative agencies on matters relating to their areas of technical expertise. We do not, however, simply accept whatever conclusion an agency proffers merely because the conclusion reflects the agency's judgment. In order to survive judicial review in a case arising under § 7006(2)(A), an agency action must be supported by 'reasoned decisionmaking.' Allentown Mack Sales & Serv., Inc. v. NLRB, 522 U.S. 359, 374, 118 S.Ct. 818, 139 L.Ed.2d 797 (1998) (quoting Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 52, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983)). 'Not only must an agency's decreed result be within the scope of its lawful authority, but the process by which it reaches that result must be logical and rational. Courts enforce this principle with regularity when they set aside agency regulations which, though well within the agencies' scope of authority, are not supported by the reasons that the agencies adduce.' Id. The problem in this case is that ATFE's explanation for its determination that APCP deflagrates lacks any coherence. We therefore owe no deference to ATFE's purported expertise because we cannot discern it.”). Similarly, agency action constitutes an “abuse of discretion” “when a decision is based on an erroneous interpretation of law or ... factfinding [lacking substantial evidence], or if that “decision represents an unreasonable judgment in weighing relevant factors.” In re Gartside, 203 F.3d at 1315-16 (quoting A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020, 1039, 22 USPQ2d 1321, 1333 (Fed.Cir.1992) (en banc)).

The Administrative Law standards which the PTO must adhere to in all rulemaking are different than those standards (perhaps more familiar to most patent attorneys) which are applicable to “adjudications” (e.g., examination of patent applications). In contrast to rules, PTO decisions adopted in the context of and reviewed on a complete record are “adjudications” subject to review under the “substantial evidence” standard of 5 USC 706(E), i.e., “unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute.” See In re Gartside, 203 F.3d at 1315 (holding that the closed-record nature of judicial review of appeals from the Board of Appeals and Interferences dictates application of the “substantial evidence” standard) (citing Association of Data Processing Serv. Orgs., Inc. v. Board of Governors of Fed. Reserve Sys., 745 F.2d 677, 683-84 (D.C.Cir.1984)). The “substantial evidence” standard asks whether a reasonable fact finder could have arrived at the agency's decision.... 'substantial evidence' review involves examination of the record as a whole, taking into account evidence that both justifies and detracts from an agency's decision.” Id. at 1313 (citing Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229, 59 S.Ct. 206, 83 L.Ed. 126 (1938), and Universal Camera Corp. v. NLRB, 340 U.S. 474, 487-88, 71 S.Ct. 456, 95 L.Ed. 456 (1951)) Adjudications are defined in 5 USC 551(7) as “agency process for the formulation of an order, which is defined in 5 USC 551(6) as “the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing.” See Gartside, 203 F.3d at 1313 (referring to “Board adjudication” reviewed under 35 USC § 145 for appeals and 35 USC § 146 for interferences).

C. The Proposed Rules Lack any Evidentiary Basis and are Otherwise Arbitrary and Capricious.

1. Proposed § 1.98(a)(3)(i)(C) to require an explanation for references when greater than twenty references are submitted during the first time period.

The proposal lacks any relevant evidentiary basis in the record and any appropriate explanatory justification for imposing the additional explanatory requirements of proposed Section 1.97(b) and 1.98(a)(3)(i)(C) & 1.98(a)(3)(iv), for prior art references when greater than twenty are submitted during the first time period (*i.e.*, three months from the filing date or national stage entry or before the mailing of a first Office action on the merits). The proposal purports to justify this new requirement based on a study of applications that determined average numbers of prior art references submitted in information disclosure statements (IDSs) filed prior to first office actions under the current rules. However, nothing in the proposal explains why an average number of submissions would constitute a relevant criterion for imposing the new obligation on applicants, other than an

articulated belief by the Agency that relatively few applicants (by percentage, and not by total number) will thereby be adversely affected. Simply put, minimizing the adversity of the proposal does not provide a justification for imposing the proposed requirements in the first instance. “The Office has surveyed, across all technologies, 3,084 small entity applications and 9,469 non-small entity applications, covering a six week period of allowed applications to determine the appropriate threshold number of cited information.... Approximately eighty-five percent of the sample included twenty or fewer submitted documents, while eighty-one percent of applications included fifteen or fewer submitted documents. Thus, the Office has determined that for IDSs submitted prior to a first Office action on the merits, a threshold of twenty documents would not require a change in practice for most applications. *It should be noted that a threshold of twenty documents for IDSs submitted prior to a first Office action on the merits would not require a change in practice for most applications....* The threshold of twenty cited pieces of information is deemed adequate, particularly in view of the fact that documents resulting from a foreign search or examination report when accompanied by a copy of the foreign search or examination report, would be excepted (not counted towards the threshold number).... *These required explanations are intended to provide meaningful information to the examiner when a large IDS, considering all IDSs cumulatively which are filed within this window of time, is presented before a first Office action on the merits has been given.*” 71 Fed. Reg. 38809/3 to 38810/1-2 (emphasis added).

It is not apparent that the limited test that the PTO conducted to determine this average number was accurate and was representative of different times for submitting information. The PTO has not placed in the docket the information regarding the specific IDSs reviewed, nor information confirming that all IDSs filed prior to a first office action were in fact surveyed during the relevant time frame, nor information or any analysis to demonstrate the representativeness of the sampling methodology and period. Apparently, the PTO simply conducted a one-time numerical calculation over a six-week period in the Winter of 2005, assessing the total number of references that had been filed in applications that issued during that period. *See* 71 Fed. Reg. at 38809/3 to 38810/1; docket information supplied by Robert Bahr. The data does not differentiate how many of the references were filed prior to the first office action (to which period the proposed rules would apply the average from its calculation), but does separate small entities from large entities. The data demonstrate no precipitous reduction in the numbers of applications containing references above twenty (e.g., for small entities 21 applications contained 20 references which decreased slowly to single digit numbers of applications – with one exception -- only at 35 references cited; for large entities 76 applications contained 20 references, 70 applications contained 25 references, 32 applications contained 35 references, and decreased to single digit numbers of applications – with one exception – only at 56 references). The average is heavily weighted towards lower numbers by the large number of cases in which *no* references were filed (1255 applications of small entities and 2196 applications of large entities), which reflects the lack of any requirement on applicants to perform the PTO’s job of searching for material information (which once discovered must then be disclosed).

Of perhaps greater significance, the sampling data were not analyzed to differentiate numbers of references submitted in IDSs among different art units, types of inventions, or types of claims (e.g., apparatus v. method). Thus, the overall average may fail to recognize important patterns for particular inventions, technologies, or claiming strategies where the average number of prior art documents submitted is greater than twenty. Even if the average number of documents were somehow relevant to the justification for the proposed requirements (which it is not), the PTO’s decision to collect only the average of the overall data collected would be irrational and arbitrary if the purpose for doing so was to draw lines that would identify appropriate cutoff points that would generally minimize the burdens to applicants. The proposed rules have nothing to do with minimizing those burdens, but rather with transferring the PTO’s burdens of examination to applicants, as discussed below.

Further, many of these applications may not yet be public (and in any event they were not identified in the record). There is thus no way to determine if the Agency’s factual analysis is correct or to supply alternative evidence to contest the agency’s factual findings regarding what the average number sampled was, much less whether that number is representative of any other time period. There is thus no basis in the record for the public to challenge these facts or for them to be evaluated on judicial review. This is clearly an insufficient record to support *any* action, as agency rules can only be based on assumptions or beliefs that are supported by

evidence in the record that is capable of being assessed and for which contradictory evidence may be considered. See, e.g., *Northeast Maryland Waste Disposal Authority v. EPA*, 358 F.3d 936, 953-54 (D.C. Cir. 2004) (“In *Sierra Club v. EPA*, 167 F.3d 658 (D.C.Cir.1999), the court rejected EPA’s similar use of state permit limits to set the MACT floor for medical waste incinerators (MWIs). The court recognized that CAA § 129 may permissibly be construed “to permit the use of regulatory data” but only “if they allow EPA to make a reasonable estimate of the performance of the top 12 percent of units.” 167 F.3d at 662. The court rejected the use of such data in that case because “[a]lthough EPA said that it believed the combination of regulatory and uncontrolled data gave an accurate picture of the relevant MWIs’ performance, it never adequately said why it believed this.” *Id.* at 663. EPA fares no better here. ... As in *Sierra Club*, EPA here stated only that it “believes” state permit limits reasonably reflect the actual performance of the best performing units without explaining why this is so. There is also evidence here that the MWCs, like the MWIs in *Sierra Club*, “might be substantially overachieving the permit limits,” that is, “the regulatory limits are in fact much higher than the emissions that units achieve in practice,” 167 F.3d at 663. See *Sierra Club’s Br.* at 22 (asserting, with record evidence, that EPA’s testing data show MWCs in general (and small MWCs in particular) “routinely overachieve their permit limits”). Given the absence of evidence that the permit levels reflect the emission levels of the best-performing 12 percent of existing MWCs and the affirmative evidence that they do not, we cannot uphold the MACT floors for existing units under the CAA.”). *Mistick PBT v. Chao*, 440 F.3d 503, 512 (D.C. Cir. 2006) (“An agency’s “failure to respond meaningfully to the evidence renders its decisions arbitrary and capricious. Unless an agency answers objections that on their face appear legitimate, its decision can hardly be said to be reasoned.” *Tesoro Alaska Petro. Co. v. FERC*, 234 F.3d 1286, 1294 (D.C.Cir.2000) (citing *Int’l Harvester Co. v. Ruckelshaus*, 478 F.2d 615, 648 (D.C.Cir.1973); *City of Vernon v. FERC*, 845 F.2d 1042, 1048 (D.C.Cir.1988)).”).

In any event, the Agency must articulate a valid policy rationale for imposing on applicants the proposed additional burden of explanation (on grounds for which the Agency possesses legal authority). The proposal does not state any rationale, but one can surmise from various statements that the unstated justifications for the proposal are an assertion (without any evidentiary support in the record) that applicants routinely file immaterial information in IDSs (in violation of their ethical obligations) and that the proposed rules will therefore reduce the burdens of examining information that is submitted in IDSs (by shifting to applicants the examining corps’ existing obligations to review the information in the examination record). See, e.g., 71 Fed. Reg. at 38808/2 (the PTO is proposing changes “to improve the quality and efficiency of the examination process”); *id.* at 38809/1 (“Although § 1.56 clearly imposes a duty to disclose material information, that rule neither authorizes nor requires anyone to file unreviewed or irrelevant documents with the Office.... One goal of the changes proposed in this notice is to enable an examiner to identify the most relevant prior art in an efficient and expeditious manner, even when an IDS containing a large number of documents is submitted.”); *id.* at 38809/1-2 (“Applicants and their representatives are reminded that the presentation of an IDS, like any other paper filed in the Office, is subject to the provisions of § 10.18 ... [which] requires that information in an IDS be reviewed to assure its submission does not cause unnecessary delay or needlessly increase the cost of examination.... Likewise, when an IDS includes several documents of marginal relevance, combined with other evidence suggesting that the marginally relevant information was submitted with the intent to obscure material information, this may run afoul of the duty of candor and good faith set forth in § 1.56(a).”); *id.* at 38809/2 (“Current §§ 1.97 and 1.98 do not encourage applicants to bring the most relevant information to the attention of the examiner ... because applicants and practitioners mistakenly believe that people associated with a patent application must submit questionably or marginally relevant documents in order to ensure compliance with the § 1.56 duty of disclosure.”); *id.* (“It appears that applicants sometimes file large collections of information for the examiner’s review without first having reviewed the information themselves for relevance in the mistaken belief that such action is permitted under the current rules.”); *id.* at 38809/3 (“Under the proposed rules, when an applicant submits an unusually large amount of information before a first Office action, the applicant must help to ease the burden on the Office associated with the examiner’s consideration of the information.”). There is simply no evidence in the record to substantiate these assumptions. Significantly, the PTO’s six-week study did not even attempt to determine how many or what percentages of the prior art references submitted prior to first office actions were not material to patentability. Obviously, the average number of prior art references has

no relationship to whether applicants are required by the duty of disclosure to supply more than twenty prior art references in any particular application. Nor does the average number have any relation to whether applicants have failed to review the documents when they submit significantly more than twenty prior art references.

Nor does the PTO cite to any other data demonstrating that applicants routinely file in IDSs prior art references that are not material as defined by Section 1.56. The PTO has not conducted a study of the materiality (or not) of prior art references submitted in IDSs, much less placed any such information in the record for its judgments regarding materiality (or not). Thus, the PTO has not demonstrated the existence of any problem that warrants correcting. Rather, the PTO apparently has sought to shift the burden to applicants of sifting through material (or even immaterial) references to determine which references are most relevant to making a case of unpatentability. *See* 71 Fed. Reg. at 38809/2 (“If irrelevant information is filtered out before an IDS is filed, the examiner will be able to focus upon the more relevant information, and perform a more efficient, effective examination.”). Although this purpose is impermissible, as discussed below, it is clearly arbitrary and capricious to do so based on unsupported statements and assumptions that applicants routinely submit “unreviewed or irrelevant” documents that are not material information. 71 Fed. Reg. at 38809/1. As the PTO itself acknowledges, failure to review documents can “implicate obligations of registered practitioners under §§ 10.23(b) and (c), and § 10.77(b)” and that submission of marginally relevant information “with the intent to obscure material information” may lead to a finding of bad faith relevant to determinations of inequitable conduct that will prevent the patent from being enforced. *Id.* Thus, the PTO’s assumptions run counter to the inferences from its own acknowledgement that incentives exist to assure adequate review and to avoid knowingly submitting immaterial information. Yet the PTO has not done any analysis of the number of applications for which it has found a violation of the review duties of registered practitioners or findings of inequitable conduct, perhaps because they would reflect an insignificant percentage of total applications filed and thus would demonstrate the lack of any substantial problem other than the burdens of examining material prior art for the large numbers of applications that currently are filed. Nor would any such review necessarily demonstrate any correlation to the total number of references submitted in IDSs prior to a first office action, much less a correlation to the particular figure of twenty references.

It is important to note, moreover, that the current rules already define cumulative information as *not* material to patentability, and require a high threshold (establishing a *prima facie* case of unpatentability or refuting a position of an applicant opposing a PTO argument regarding unpatentability or asserting patentability). *See* 37 CFR § 1.56(b) (“information is material to patentability when it is not cumulative to information already of record *or being made* of record ... A *prima facie* case of unpatentability is established when the information *compels* a conclusion that a claim is unpatentable ...”) (emphasis added). Thus, absent any evidence on which to presume that applicants are not following the rules, the PTO logically should presume that applicants in fact file only material information that is directly relevant to examiners and is not cumulative of other information. Although it is possible to speculate that the PTO believes that judicial standards for inequitable conduct may differ from its own rules and thus induce applicants to file cumulative or immaterial information in IDSs, such speculation cannot ground the proposed rulemaking.

Even if (contrary to any evidence of record) there were a problem of applicants filing IDSs containing immaterial information that imposed unnecessary burdens on examiners, it is not clear from the PTO’s proposal why stricter enforcement of the PTO’s own rules regarding the duty of diligence would not take care of the problem (although one can surmise that the PTO would again seek to avoid expending the additional resources required to enforce these rules through disciplinary action). Further, if the PTO were to believe that the problem does not result from a failure of diligence but uncertainty regarding whether information is in fact material, it can clarify its definition of material information. Without an articulated analysis of why such alternatives are not more appropriate (to solve a problem that the PTO has not demonstrated to exist), the proposal does not reflect reasoned decisionmaking.

2. Proposed § 1.98(a)(3)(i)(B) to require an explanation for references greater than twenty-five pages submitted during the first time period.

The proposed rule similarly lacks any relevant evidentiary basis in the record and any appropriate explanatory justification for imposing the additional explanatory requirements of proposed Section 1.97(b) and 1.98(a)(3)(i)(B) & 1.98(a)(3)(iv), for prior art references greater than twenty-five pages submitted during the first time period. The only relevant discussions do not contain evidence regarding improper filing or any other articulated rationale except to reduce PTO examiners' burdens of reviewing material information in the adjudicatory record. *See* 71 Fed. Reg. at 38810/2 ("If an applicant presents unusually long documents, foreign-language documents, or a large number of documents, more than a brief review by the examiner is likely to be needed to reveal the most pertinent portions of the documents. In such situations, the applicant's help is needed so that the examiner may provide the best and most efficient examination possible."); *id.* at 38813/2-3 ("The threshold for document size is over twenty-five pages. In calculating documents over twenty-five pages, sequence listings, or computer program listings, pursuant to § 1.52(e)(1) would be excluded (§ 1.98(a)(3)(i)(B)).... Applicant is permitted to submit only a portion of a document and is encouraged to do so where that portion can be considered without further context and is the only portion that is relevant to the claimed invention."). Unlike for the twenty document provision, however, the proposal provides no factual basis (however irrelevant) for choosing the figure of twenty-five pages, much less provide any factual basis for any inference that more than twenty-five pages represent "unusually long documents" submitted in IDSs (or otherwise). This is the epitome of arbitrary agency action. *See Merriam-Webster Online Dictionary* (defining "arbitrary" as "**3 a** : based on or determined by individual preference or convenience rather than by necessity or the intrinsic nature of something <an *arbitrary* standard> <take any *arbitrary* positive number> <*arbitrary* division of historical studies into watertight compartments -- A. J. Toynbee> **b** : existing or coming about seemingly at random or by chance or as a capricious and unreasonable act of will <when a task is not seen in a meaningful context it is experienced as being *arbitrary* -- Nehemiah Jordan>").

3. Proposed § 1.98(a)(3)(i)(A) to require an explanation for foreign language references submitted during the first time period.

The proposed rule similarly lacks any relevant evidentiary basis in the record and any appropriate explanatory justification for imposing the additional explanatory requirements of proposed Section 1.97(b) and 1.98(a)(3)(i)(A) & 1.98(a)(3)(iv), for prior art references in foreign languages (and for subjecting any submitted translations to the twenty-five page explanation requirement under proposed Section 1.98(a)(3)(xi)). Although existing 37 CFR § 1.98(a)(3)(i) requires a concise statement of the relevance of any document in a foreign language, the proposed requirements for explanation (discussed below) far exceed that minimal requirement. No justification for requiring applicants to supply such information is provided, other than the general one of shifting examination burdens to applicants. *See* 71 Fed. Reg. at 38810/2. *Cf. id.* at 38813/2 ("Foreign language documents of any length would trigger the explanation ... requirements."). In contrast, the PTO has not in the past or in the proposed rules required applicants to undertake the examination burden of obtaining translations that they do not already possess or that can readily be obtained without cost. *See* 37 CFR § 1.98(a)(3)(ii) (requiring the filing of a translation of a reference cited in an IDS only if it is readily available to individuals subject to the duty of disclosure); proposed Section 1.98(a)(3)(xi). Lacking any articulated rationale for imposing these requirements, or for choosing to reduce only particular burdens to examiners without regard to relative costs or benefits, the proposed foreign language document requirements also are arbitrary and capricious.

4. Proposed § 1.98(a)(3)(iv) explanation, (v) non-cumulative description, and (vi) patentability justification.

The proposed rule lacks any relevant evidentiary basis in the record and any appropriate explanatory justification for imposing the additional explanatory requirements of proposed Section 1.98(a)(3)(iv), non-cumulative description requirements of proposed Section 1.98(a)(3)(v), and patentability justifications of proposed Section 1.98(a)(3)(vi). As noted above, the proposed rule would impose the additional explanatory requirements without an evidentiary basis or demonstration of any problem regarding submission of cumulative

or irrelevant information, in order to shift the burdens of examination to applicants. Even if such a justification were permissible (which it is not, as discussed below), the proposed rule lacks any justification for adopting the particular burden-shifting measures proposed here. The rulemaking record is wholly devoid of any analysis of the benefits to the PTO and costs to applicants of the specific proposal, much less any evaluation of less (or even more) burdensome alternative requirements that might be imposed and how they relate to some purpose to be accomplished by the rule. Nor are alternatives to shifting burdens of examination to applicants considered, such as requesting additional funds from Congress for the Patent Office or better training examiners to identify relevant information in submitted references. Rather, the proposal simply articulates procedures that the PTO would like to adopt to reduce its examination burdens, presumably in the hope of reducing an ever-increasing backlog of applications and of blunting widespread criticism that its procedures result in routine issuance of invalid patents.

Explanations. Specifically, proposed Section 1.98(a)(3)(iv) would require “an identification of at least one portion causing the document to be cited, including a specific feature, showing, or teaching, and correlation to specific claim language, or where correlation to claim language is not possible, correlation may be made to a specific portion of the supporting specification” (subject to certain limited exceptions where such explanations may already be supplied by foreign search or examination reports or for documents submitted pursuant to a request for information under 37 CFR § 1.105). 71 Fed. Reg. at 38813/2. *See also id.* at 38814/2-3 (the explanation consists of two identifications and one correlation: identification of the “specific feature(s), showing(s), or teaching(s) that caused a document to be cited” and of “a portion(s) of a document where the specific feature(s), showing(s), or teaching(s) may be found”; and correlation “to specific corresponding claim language, or to a specific portion(s) of the specification that provides support for the claimed invention, where the document is cited for that purpose”). These requirements are wholly unclear, as the proposal does not explain what is meant by the “specific feature, showing, or teaching” (which presumably relates somehow to demonstrating elements of claim language or motivations to combine such elements in the prior art) and the “cited for that purpose” language (which presumably relates to the same things or to statements of unclaimed elements or statements of utility in the specification). The requirements are not related by the proposal to the existing duty of disclosure, which requires only submission of information that non-cumulatively establishes a prima facie case of unpatentability, or that refutes an applicants’ argument regarding patentability. Accordingly, applicants cannot readily determine whether the reasons they are submitting information under the duty of disclosure provide a basis for providing the required identifications or correlations. And if the documents do not provide a basis for the required identification (because the applicant is “unaware of any specific relevant portion(s) of the document” to correlate), the proposal instructs that the document “should not be submitted to the Office,” notwithstanding the potential application of 37 CFR § 1.56.

Of greater importance, this explanation imposes substantial costs of analysis on applicants and registered practitioners and requires them to make statements against interest that are wholly inappropriate. The proposed rule seeks to downplay the burdens that it will impose, stating that the PTO “does not contemplate that complying with the identification and correlation of additional requirements (sic) will require an extensive submission. The Office believes that, in most cases, a compliant submission would include several sentences that: identify a specific feature, showing, or teaching causing submission of a document ... identify the portion of the document where the feature, showing, or teaching may be found ... and correlate ... to specific claim language. Applicant’s attempted correlation of a specific feature, showing, or teaching in a document may not, for example, be readily recognizable as actually correlating to identified claim language, particularly where such claim language may be a more generic or alternative way of reciting the feature, showing, or teaching. In such instances, applicant would need to add some explanatory material, particularly to avoid a possible finding of noncompliance by the examiner with the correlation requirement.” Thus, applicants and registered practitioners will now have to draft carefully worded statements that seek to avoid the Scylla of making statements that may be construed as admissions of materiality and (worse yet) of admissions of the existence of relevant elements or motivations in the prior art with the Charybdis of avoiding ambiguous statements or omissions that will lead the PTO to find noncompliance or litigants to allege inequitable conduct. For precisely this reason, the current rules do not require explanations of the relevance of prior art submitted in IDSs, and

expressly provide that “filing of an information disclosure statement shall not be construed as an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b).” 37 CFR § 1.97(h). *See* 57 Fed. Reg. 2021, 2024/3 to 2025/1 (Reply adopting Comment 11: justifying § 1.97(h) given that the 1992 change to the standard of materiality in § 1.56 – tied to a prima facie case of unpatentability – “would make a submission of information to the Office an implied admission of the prima facie unpatentability of a claim”); 42 Fed. Reg. 5587, 5590/1 (discussing -- in the context of adopting the duty of disclosure and information disclosure statement rules in 1977 and the standard of materiality required for submission of information to the Securities and Exchange Commission under *TSC Industries v. Northway*, 426 U.S. 438 (1970), on which the rules were based – that the standard “should not be so low that persons would be ‘subjected to liability for insignificant omissions or misstatements,’ or so low that the fear of liability would cause management ‘simply to bury the shareholder in an avalanche of trivial information’”); *id.* at 5590/3 (noting that the adopted prior art statements rules “are *not* mandatory”) (emphasis added); *id.* at 5594/2 (adopting 37 CFR § 1.98(a)(2) requiring any statement under § 1.97 to include “a concise explanation of the relevance of each listed item.”). *Cf. id.* at 5590/3 (such statements “will be construed as a representation that the prior art listed includes what the submitter considers to be the closest art of which he is aware”). This potential for admissions against interest is not solved by § 1.97(h), as the explanations require statements of relevance made by applicants or their representatives, and not just the submission of information which is not characterized by the applicant. Requiring such explanations thus will breed inequitable conduct disputes both in the PTO and in the courts, which the PTO should seek to avoid. As discussed below, the proposed “safe harbor” rule implicitly recognizes that the rules will generate these problems, but provides a wholly inadequate prophylactic and admits that it is not binding on the courts, *see* 71 Fed. Reg. at 38812/1, much less on the litigants who will make inequitable conduct allegations.

Significantly, the proposed “explanation” requirements impose much more substantial and much more troubling requirements than the “patentability statements” that the PTO had proposed in 1976 and, after receiving adverse public comments, rejected in 1977 in favor of “prior art statements.” *See* 41 Fed. Reg. 43729, 43733/2 (proposed 37 CFR §§ 1.97 and 1.98); 42 Fed. Reg. at 5954/2 (adopting 37 CFR §§ 1.97 and 1.98, as modified from the proposal). These patentability statements would have required applicants and their representatives to provide scaled-down equivalents of a “patentability ‘brief’” that would “explain why the invention is patentable over prior art which the applicant considered most ‘relevant’ during preparation of the application.... As to the ‘most relevant’ references, the requirement is for an explanation of those references which meet this qualification in the opinion of the applicant, which will not necessarily be the same as the opinion of the examiner. The requirement that only the most relevant references need be explained is an attempt to minimize extra burden on the applicant and the Office.... Reasons for patentability need not be stated if no relevant information was considered in preparing the application.” 41 Fed. Reg. at 43730/1-2. Thus, unlike the “explanation” proposed here, which requires that applicants or their representatives explain why the reference is material, potentially requiring admissions against interest, the proposed 1976 “patentability statements” only required applicants to make statements regarding why they believed their inventions were patentable in light of what they believed to be the references of which they were aware that were (in their opinion) the most relevant to patentability. Further, recognizing the significant burdens involved, the PTO did not propose in 1976 (at a time when applications typically referenced many fewer prior art references than in the present) that patentability statements would require applicants to address all references, but only the most relevant.

After receiving numerous adverse comments on the 1976 proposal, the PTO rejected even the requirement for a *distinguishing* explanation as inappropriate. *See* 42 Fed. Reg. at 5590/3 (“The sections have been substantially changed from the proposal, in response to comments received.”). Instead, the PTO continued to rely on the basic requirement (previously codified as a basis for striking applications, and reflecting case law on inequitable conduct) that applicants and their representative should not withhold material information. *See* 37 CFR § 1.56 (1976) (“Any application signed or sworn to in blank, or without actual inspection by the applicant, and ... any application fraudulently filed or in connection with which any fraud is practiced or attempted on the Patent and Trademark Office may be stricken from the files.”). Applicants continued to be required, to avoid committing fraud, from withholding known material information that they possessed, and the PTO adopted revisions to the

language of § 1.56 to assist applicants in understanding what information would be material. *See* 37 CFR § 1.56(a) (1977); 42 Fed. Reg. at 5589/3 (“In response to the comments, language is substituted in § 1.56 and related sections which is believed to establish a clearer standard for determining whether information need be disclosed to the Office. ‘Relevant’ is replaced by ‘material’ because the latter term connotes something more than a trivial relationship. It appears to be more commonly used in court opinions. In addition, the third sentence of §1.56, which defines materiality is rewritten. The sentence now states that information is material ‘where there is a *substantial* likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.”). Nothing more was required, as the prior art statements that were adopted were “not mandatory.” 42 Fed. Reg. at 5590/3.

Further, applicants remained free to distinguish the references they submitted to avoid the potential for fraud, where they believed it was in the interest of their clients to do so (and could do so without making admissions against interest). *See id.* at 5590/2 (“The submission of information under § 1.56 does not preclude the submission of arguments that such information does not render the subject matter of the application unpatentable.”). This freedom of advocacy – not a requirement of explanation – was important and necessary given the inevitable overbreadth that resulted from the definition of materiality – information a reasonable examiner would consider important, but not information that demonstrated unpatentability (or the application itself would be a fraud). In recognition of the fact that materiality might not be self evident and that applicants would be required to provide information that the PTO ultimately might find unimportant, the PTO in 1983 changed the title of the voluntary statement rules in §§ 1.97 and 1.98 from “prior art statement” to “information disclosure statement.” 48 Fed. Reg. 2712/1. In doing so, the PTO did not adopt the 1982 proposed change to “material information disclosure statement.” 47 Fed. Reg. 47753/2. As the PTO noted, “[i]nformation which is required to be submitted pursuant to § 1.56 may ultimately be determined not to be ‘prior art,’ but nevertheless may be ‘material’ pursuant to § 1.56. Section 1.97 has also been modified from that proposed by eliminating the word ‘material’ since information submitted pursuant to § 1.97 may be considered to be of questionable materiality or may be determined, upon examination, not to be ‘material.’” 48 Fed. Reg. at 2700/2. Nor did this fact change when the PTO amended the substantive standard of materiality in 1992 to essentially its current form so as to make the standard of materiality more objective and to better conform to patentability criteria, and simultaneously modified the information disclosure statement rules to require additional identifying information regarding any listed documents and a “concise explanation of the relevance” only of non-English language documents. *See* 57 Fed. Reg. 2021, 2034/1-2 (amending 37 CFR § 1.56(b)); *id.* at 2034/3 to 2034/2 (amending 37 CFR §§ 1.97 and 1.98); 56 Fed. Reg. 37321, 37322//3 (“Proposed § 1.56(b) presents a clearer and more objective definition of information material to patentability. The current definition ... has been criticized as vague and because it does not correlate with any concept applied in other areas of patent law.”). Rather, the PTO expressly recognized that IDSs would contain, and encouraged applicants to file IDSs that contained, some cumulative information, and thus sought to *relieve* applicants from the burdens of providing copies of listed documents if they were cumulative. *See id.* at 2023/1 (Reply to Comment 3: “If information is not material, there is no duty to disclose the information to the Office. *The Office believes that most applicants will wish to submit the information, however, even though they may not be required to do so, to strengthen the patent and avoid the risks of an incorrect judgment on their part on materiality or that it may be held that there was an intent to deceive the Office.*”) (emphasis added); *id.* at 2024/1 (Reply to Comment 4: “Presumably, applicants will continue to submit information for consideration by the Office in applications *rather than making and relying on their own determinations of materiality....* In addition, the new rules will actually facilitate the filing of information since the burden of submitting information to the Office has been reduced [from the proposal] by eliminating, in most cases, the requirement for a concise statement of the relevance of each item of information listed in an information disclosure statement.”) (emphasis added); 2031/2 (Reply to Comment 73: “The concept that cumulative information is not material is set forth in § 1.56(b)). Section 1.98 *does not deal with what information must be submitted*, but provides for an exception for cumulative information *to the requirement for a copy to be submitted* of each item of information listed in an information disclosure statement.”) (emphasis added). Further, the PTO recognized that restricting the information to be submitted (by adopting a narrower standard of materiality) -- like the inevitable result of requiring applicants to determine materiality on their own, as rejected before, or to make explanatory statements of relevance as proposed here – “would not cause the

Office to obtain the information it needs to evaluate patentability so that its decisions may be presumed correct by the courts.” *Id.* at 2024/1 (Reply to Comment 5).

In adopting the prior art statement rules instead of proposed 1976 patentability statements, moreover, the PTO reiterated not only that such explanations were voluntary but also that they were extremely limited. The entire premise of the prior art statements was to provide a mechanism by which applicants *could* (but were not required to use to) satisfy the duty of disclosure under § 1.56, nothing more. *See* 42 Fed. Reg. at 5590/3 (“New §§ 1.97, 1.98, and 1.99 deal with prior art statements and provide a mechanism by which patent applicants may comply with the duty of disclosure provided in § 1.56.... It is nevertheless believed that applicants will find that the use of prior art statements complying fully with the requirements of §§ 1.97 through 1.99 will be the best way to satisfy the duty of disclosure.”). The prior art statement rules “[d[id] not prescribe the content of what materials should be submitted,” and the statements would be construed only “as a representation that the prior art listed *includes* what the submitter considers to be the closest art of which he is aware. The submitter need not decide which particular items of prior art are the closest or identify any items as such; *the representation is simply that he is not withholding known prior art which he considers closer than that which is submitted.*” *Id.* (emphasis added). When providing the *voluntary* “concise explanation of the relevance of each listed item,” the PTO made clear that all that “[t]his may be nothing more than identification of the particular figure or paragraph of the patent or publication which has some relation to the claimed invention.” Although the PTO also suggested that applicants *could* provide “a simple statement pointing to the similarities between the item and the claimed invention,” which would be “essentially as useful to the examiner as the formerly proposed explanation of patentability,” it did not in any way require such explanations. Thus, unlike the 1977 rules, the proposal for § 1.98(a)(3)(iv) explanations here would require applicants to go far beyond simply identifying by page and line or figure number the most relevant portion of the most relevant references. The proposal would require an *explanation* of why *all* the submitted references are relevant to patentability.

In 1977, the PTO refused to shift this burden of examination to applicants, even though it would clearly have assisted the PTO’s operations. Similarly, in response to comments on the 1991 proposal to require applicants and their representatives to provide a “concise explanation of the relevance” of all items of information submitted in an IDS, the PTO again abandoned the proposal in 1992 (requiring such explanations only for foreign language documents) while again noting that voluntary explanations “would be helpful to the Office.” 57 Fed. Reg., at 2030/3 to 2031/1 (Reply to Comment 67). In 2000, the PTO yet again did not proceed with earlier proposals (called for in the PTO’s Advance Notice of Proposed Rulemaking) to require “a statements of personal review or for a unique description ... and the number of citations that may be submitted is not presently limited.” 65 Fed. Reg. 54604, 54631/2. No justification is provided for the agency’s current change in position, or its decision at this time to propose reinstating and substantially expanding the explanations that would have been required of applicants under the rejected proposed 1976 rules (other than the irrelevant and possibly inaccurate statement that applications on average file IDSs containing twenty references). Further, and more significantly, in rejecting this approach in 1977, the PTO made clear that applicants would *not* engage in inequitable conduct or violate their duty of disclosure by *not* performing the job of the examiner. That applicants and their representatives have not chosen to shoulder the PTO’s burden since does not in any way suggest that there has been fraud, violations of the duty of disclosure, violations of PTO rules requiring reasonable inquiry, or submissions causing unnecessary delay or needless increases in the costs of examination (as implicitly suggested by the current proposal and as explicitly suggested by the PTO’s Office of Enrollment and Discipline). *See* 71 Fed. Reg. at 38809/2 (“remind[ing]” applicants and their representatives of the duty to review information and stating that “when an IDS includes several documents of marginal relevance, *combined with other evidence suggesting* that the marginally relevant information was submitted with the intent to obscure material information, this may run afoul of the duty of candor and good faith set forth in § 1.56(a). In such circumstances, an inference that the applicant or their representative attempted to cover up or conceal a material reference could be drawn.”) (emphasis added); Office of Enrollment and Discipline, Monitoring Practitioner Compliance with Disciplinary Rules, April 2006, at 18 (“Examples of conduct that may be perceived as failure to make reasonable inquiry: – A reference material to patentability is buried among a large

number of cumulative references.”); *id.* at 22 (“Examples of situations potentially involving improper purpose or delay. – A reference material to patentability is buried among a large number of cumulative references.”).

This change of legal requirements and of policy positions clearly demonstrates (as discussed below for additional reasons) that the proposed rule is a substantive, not a procedural or interpretive, rule. An agency may not make a binding interpretation of a statutory or regulatory provision and then reverse that position without it being a legislative rule subject to notice and comment rulemaking. See, e.g., *Environmental Integrity Project v. EPA*, 425 F.3d 992, 997 (D.C. Cir. 2005) (“However, EPA's final rule in this case did more—after taking its first bite at the interpretive apple in its *Pacificorp* and *Fort James* orders, EPA adopted a “reinterpretation” of Part 70's unrevised text. This flip-flop complies with the APA only if preceded by adequate notice and opportunity for public comment. Compare *Alaska Prof'l Hunters Ass'n, Inc. v. FAA*, 177 F.3d 1030, 1034 (D.C.Cir.1999) (“When an agency has given its regulation a definitive interpretation, and later significantly revises that interpretation, the agency has in effect amended its rule, something it may not accomplish without notice and comment.”), and *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 586 (D.C.Cir.1997) (“Once an agency gives its regulation an interpretation, it can only change that interpretation as it would formally modify the regulation itself: through the process of notice and comment rulemaking.”), with *Hudson v. FAA*, 192 F.3d 1031, 1036 (D.C.Cir.1999) (stating agency may change its longstanding policies without notice and comment, so long as “there is no dispute as to the regulation's meaning”), and *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 94 (D.C.Cir.1997) (“[I]nterpretative rules and policy statements are quite different agency instruments. An agency policy statement does not seek to impose or elaborate or interpret a legal norm. It merely represents an agency position with respect to how it will treat—typically enforce—the governing legal norm.”)... In 2004, EPA's final rule carried similarly forceful effect (albeit in the diametrically opposite direction): EPA has determined that the correct interpretation of [the 'umbrella' rules] is that these provisions do not establish a separate regulatory standard... EPA has determined that where the periodic monitoring rules do not apply, [the 'umbrella' rules] do not require or authorize a new and independent type of monitoring in permits in order for the permits to contain monitoring to assure compliance as required by the Act. 69 Fed.Reg. at 3204 (emphases added). Given the mandatory language in both of EPA's interpretations, there can be little doubt that both purported to “bind[] private parties or the agency itself with the 'force of law.' ” *Gen. Elec. Corp. v. EPA*, 290 F.3d 377, 382 (D.C.Cir.2002). As such, EPA's revised interpretation of its Part 70 rules required adequate prior notice and an opportunity to comment. See *Alaska Prof'l Hunters Ass'n, Inc. v. FAA*, 177 F.3d 1030, 1034 (D.C.Cir.1999); *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 586 (D.C.Cir.1997).”).

Further, the change of legal requirements (because such requirements were considered and rejected earlier) requires for reasoned decisionmaking that the agency explain why it now views matters differently. Of legal relevance to this rulemaking procedure, the entire prior rulemaking records on these issues (including comments in public hearings and adverse comments received in response to proposals) from the 1977 rulemaking, the 1992 rulemaking, the 2000 rulemaking, and any other relevant rulemakings should be placed in the docket for this rule. Those comments remain potentially relevant to the current proposals, and the PTO has an obligation to respond to those comments to the extent they continue to be relevant to the decisions that the PTO is planning to make. Given that these comments from public hearings were not part of the rulemaking docket for this rule, the PTO also will need to re-notice the proposal for comments once a complete docket has been compiled. In any event, the failure to respond to relevant comments from the prior rulemaking efforts on the same set of issues would constitute a failure of reasoned decisionmaking, as the PTO has a duty to consider relevant information already in its possession without regard to whether a particular commenter brings that information to the agency's attention (and particularly when it was previously brought to the agency's attention). See *Appalachian Power Co. v. EPA*, 135 F.3d 791, 818 (D.C.Cir.1998).

Non-cumulative descriptions. Proposed Section 1.98(a)(3)(v) would require a non-cumulative “description of how each document is not merely cumulative of any other information disclosure statement cited document ... as citation of merely cumulative information must be avoided pursuant to paragraph (c) of this section,” which in turn would provide that citing “documents that are merely cumulative of other documents cited must be avoided.” The only purported justification for the new requirement to explain why the cited documents are not

cumulative is that if “an applicant presents cumulative information, review of such information would waste examiner resources.... To aid in compliance with this prohibition, applicants are required to submit a non-cumulative description for IDSs submitted after a first Office action and after allowance. A non-cumulative description is one that describes a disclosure in the cited document that is not present in any other document of record. *Thus, while there may be substantial overlap between a currently cited document and a document previously of record, the currently cited document must include a teaching, showing, or feature not provided in other documents of record* and the non-cumulative description must point this out.” 71 Fed. Reg. at 38810/2-3 (emphasis added). However, cumulative information by definition is not material information required to be submitted to the PTO. *See* 37 CFR § 1.56(b). Nor is there any evidence in the record to suggest that there is any problem with IDSs containing cumulative, non-material information. Failure to review submissions can be sanctioned under a practitioners’ duty of diligence, as noted by the proposal. *See* 71 Fed. Reg. at 38809/1.

Thus, the proposal fails to articulate why the PTO is choosing to adopt this particular remedy of adding to applicants burdens to solve a problem of submitting cumulative information that has not been demonstrated to exist. As noted above, the PTO previously recognized the practical necessity for applicants to submit references that might be deemed to be cumulative by examiners to avoid the potential for inequitable conduct and to assure that the PTO received all prior art known to the applicant that might be relevant to examination. No reason is given for the change in position of the PTO. Further, the required description regarding the non-cumulative nature of the documents cited in the IDS will be certain to be qualify as admissions, and will be even more closely scrutinized by litigants for inequitable conduct allegations than the explanations of what parts of a document are relevant to claim language or specification language. Where doubt exists, applicants may choose to avoid submitting documents that are debatably cumulative rather than make affirmative statements (against their interests) as to why they are not cumulative. Excluding such documents from IDS will even more certainly lead to inequitable conduct allegations.

Further, the new description requirement does not clearly state what constitutes cumulative information in an IDS, but may suggest a different standard for cumulative information than under 37 CFR § 1.56 (i.e., a teaching, showing, or feature not provided in other documents). Thus, applicants who submit only documents that are deemed non-cumulative under § 1.98(a)(3)(v) may fail to submit documents that are material under 37 CFR § 1.56, and even surer invitation to an inequitable conduct violation. The lack of clarity in the proposed rule strongly suggests that *if* there is a problem with submission of cumulative information (which has not been demonstrated), it would derive from ambiguity in the definition of material, non-cumulative information in 37 CFR § 1.56. The obvious solution to any such problem would be to clarify the definition for both applicants and examiners. Instead, the proposal will make matters much worse, by suggesting ambiguities in the definition that do not exist and by imposing vague standards that may conflict with the definition.

Patentability justifications. The proposed rule would require in Section 1.98(a)(3)(vi) a “patentability justification” containing “reasons why the independent claims are patentable over the information in the information disclosure statement being submitted, considered together, and in view of any information already of record; or ... reasons why an amendment causes claims, admitted to be unpatentable over the information in the submitted information disclosure statement, either alone or in combination with any information already of record, to now be patentable over such information ...” 71 Fed. Reg. at 38821/3. The patentability justification would be required for any information disclosure statement filed “after a mailing date of a notice of allowability ... [and to contain] reasons why the claims are patentable over the cited document(s).” 71 Fed. Reg. at 38810/2. Further, pursuant to proposed Section 1.98(a)(3)(vii)(B), patentability justifications “must address specific claim language relative to the specific feature(s), showing(s), or teaching(s) of the cited documents, or those already of record.” 71 Fed. Reg. at 38815/3. This proposal is extremely opaque, to the point of unintelligibility. In particular, it is unclear what is meant by “must address specific claim language” (and whether this imposes limitations on the discretion of applicants or their representatives to determine how best to argue patentability consistent with their duty of zealous advocacy) and by “admitted to be unpatentable” (which would appear to require admissions that might then be impossible to overcome). *Cf.* 57 Fed. Reg. at 2026/1 (Reply to Comment 23: “The rule does not require an applicant to combine references against its own claims.”);

id. at 2026/3 (Reply to Comment 31: “The final rule language avoids the perceived problems of requiring an applicant to submit information supporting a position taken by the examiner.”). The PTO should clarify what is meant and provide another opportunity for comment.

In any event, no justification of any sort is provided for requiring applicants to supply these additional patentability justifications. No explanation is given for why the justification is limited (during the third period proposed under Section 1.97(d)(1)) to independent claims, and none is given for requiring an admission (that somehow is to be overcome by applicant arguments) in the fourth period proposed under Section 1.97(d)(2). In contrast, the PTO previously rejected any requirement for applicants to submit patentability statements, and no justification is provided for why the PTO has changed its mind and now is requiring justifications similar to patentability statements. Unlike those patentability statements, moreover, the proposed patentability justifications require “address[ing]” the specific features, showings, or teachings (similar to the correlation requirements of the proposed explanations under Section 1.98(a)(3)(iv)) rather than simply permitting the applicant to explain why the claim remains patentable without making admissions or addressing unnecessary issues (creating potentially adverse admissions for inequitable conduct allegations and substantive problems for future litigation in the prosecution history).

5. Proposed § 1.98(a)(3)(ii) to require explanations and non-cumulative descriptions for references submitted during the second time period and § 1.98(a)(3)(iii) to require patentability justifications during the third and fourth time periods.

The proposed rule lacks any relevant evidentiary basis in the record and any appropriate explanatory justification for imposing the additional explanatory requirements and non-cumulative descriptions of proposed Section 1.98(a)(3)(ii) for references submitted during the second time period of proposed Section 1.97(c) and for imposing the patentability justifications of proposed Section 1.98(a)(3)(iii) for the time periods of proposed Section 1.97(d). The only articulated rationale for these proposals is that “[m]ore extensive disclosure requirements would apply to IDS submissions after a first Office action on the merits. Thus, applicant would be required to provide a non-cumulative description as well as an explanation, or a copy of a recently issued foreign search or examination report, for each document submitted after a first Office action on the merits. Where an IDS is filed after the mailing date of a notice of allowability or a notice of allowance under § 1.311, applicant would be required to provide an appropriate patentability justification, which includes the explanation and non-cumulative description required after a first Office action, and reasons why the claims are patentable over the cited documents.” 71 Fed. Reg. at 38810/2. If the PTO were to document a problem with late submissions of known material information, that problem is conceptually distinct from and can be addressed separately from any proposal to impose explanatory burdens on applicants regarding materiality and patentability. At a minimum, the PTO would have to explain why it is proposing to address that problem in this fashion. Similarly, if the PTO were to document a problem regarding the acquisition of newly acquired material information during the period following notices of allowance, that problem also is conceptually distinct and can also be addressed separately and requires explanatory justification in the rulemaking record.

6. Proposed § 1.56(f) “safe harbor”.

Proposed Section 1.56(f) would create a “safe harbor” from PTO disciplinary rules by deeming the disclosure requirements of proposed Section 1.98(a)(3) “deemed satisfied where a § 1.56(c) individual has made reasonable inquiry of the relationship of the documents cited in an information disclosure statement ... and the individual has acted in good faith to comply with the disclosure requirements by having a reasonable basis for the statements made in such a disclosure.” *See also* 71 Fed. Reg. at 38811/3 to 38812/1. As the proposed rule recognizes, however, “the proposed amendment to § 1.56 may not act as a complete defense in all situations, particularly as the court is not bound by any duty of disclosure standard established by the Office.” Not only are the standards for the safe harbor – “reasonable inquiry of the relationship” and “good faith” – insufficient to provide any clear guidance for applicants and registered practitioners on how to address ambiguities of application of the proposed Section 1.98(a)(3) requirements, but they also are insufficient to create any binding

obligation on the PTO because of the wide interpretive discretion encompassed by the language and the lack of explanatory background or standards articulated in the proposal. Thus, even if a court would seek to apply the PTO's safe harbor, it may have no guidance for determining when to do so. If the PTO is to adopt a safe harbor, its application should and must be made clear.

Of greater importance, the safe harbor proposed here is at best an inadequate, second-best solution to a problem created by the proposal itself, which otherwise would not exist. Any lack of clarity in regard to the application of the materiality standard adopted in 37 CFR § 1.56, when combined with the proposed new explanatory requirements of Section 1.98(a)(3), will be certain to lead to even greater problems, to significantly increased costs of prosecution (for applicants and their representatives to determine what to say and how to say it), and to inequitable conduct allegations. The PTO should not as a matter of policy subject applicants to such legal uncertainty caused by adopting vague rules that could readily be clarified. And if the PTO were to document a problem that results from uncertainty regarding the application of the materiality standard itself, the PTO can further clarify the standard rather than adding explanatory requirements that could not and would not solve the problem of a vague materiality standard.

D. The proposed requirements improperly shift to applicants the burdens of examination.

As noted above, under “the proposed rules, when an applicant submits an unusually large amount of information before a first Office action, the applicant *must* help to ease the burden on the Office associated with the examiner’s consideration of the information.” 71 Fed. Reg. at 38809/3 (emphasis added). The proposed rules cite to no authority for imposing this mandatory obligation on applicants to assist examiners perform their statutorily required duties to “cause an examination to be made of the application” and to “notify the applicant [of a rejection or any objection or requirement,] together with such information and references as may be useful in judging of the propriety of continuing the prosecution....” 35 U.S.C. §§ 131, 132. On the face of the statute, the burdens of providing information and explanations regarding the reasons for any unpatentability determinations fall squarely on the PTO, and not on the applicant. In contrast to these burdens of explanation on the PTO, the rules regarding the duty of disclosure of material information have an entirely different source, which does not provide any authority for the PTO to impose explanatory burdens on the applicant.

As the PTO noted when codifying the duty of disclosure of 37 CFR § 1.56 in 1977, applicants were required to submit known material information regarding patentability *by courts*, so as to avoid judicial findings of inequitable conduct. The failure to supply for agency decisionmaking known material information relevant to patentability was treated by courts as a form of fraud, similar to such failures in the context of securities regulation. The PTO thus issued what were (at the time) *interpretive* rules. In 1992, over objections in comments noting that the previously existing 37 CFR § 1.56 was “presently in conformance to the materiality standard being applied” by courts, the PTO sought “greater clarity” and adopted its own requirements in the hope of “minimiz[ing] the burden of litigation on the question of inequitable conduct” that would “present a clearer and more objective definition of what information the Office considers to be material to patentability.” 57 Fed. Reg. at 2023/2-3 (Comment 1 and Reply); *id.* at 2024/3 (Reply to Comment 10).

Significantly, the premise of the duty of disclosure rules before and after the change was to assure that applicants did not withhold relevant information in their possession from the PTO’s consideration during examination. Nothing in those rules (or in the judicial precedents on which the rules were based) required applicants to submit explanations of the relevance of the material information submitted in order to avoid an inference of fraudulent withholding (originally relevant and subsequently prima-facie-case supporting) material information. Rather, as noted in the 1977 rules, the *standard* for materiality adopted by the PTO (based on that adopted by the Supreme Court) was intended to avoid applicants facing potential inequitable conduct liability, and only in regard to “insignificant omissions or misstatements.” 42 Fed. Reg. 5990/1. In contrast, the fear of over-inclusion by setting the standard too low was a problem only for the PTO (and not for the applicant). Submission of “trivial information” would achieve “a result that is hardly conducive to informed decisionmaking.” *Id.*

Following the 1977 rules, the PTO repeatedly reaffirmed that the duty of disclosure was precisely what its title suggested – a duty to disclose material information known to the applicant to avoid committing fraud by withholding material information. Nothing in that duty has anything to do with providing excessive information that may burden the Office for any reason. The proposed rules to shift the burdens of examination simply cannot be justified based on the duty of disclosure. This is true even if the agency were somehow to provide evidence to show that practitioners routinely improperly evaluate what is relevant or routinely err on the side of over-inclusion of submitted information to avoid any possibility of fraud. Consequently, any duty to avoid submitting too much information to the Office, or to explain what the relevance is of the information submitted, must be found in the duty of candor and good faith in § 1.56(a) or in the ethical rules of § 10.18, or in interpretive or inherent authority of the PTO to prevent fraud.

The proposal appears to justify the additional requirements by referring to the duty of candor and good faith, citing to the decision in *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995). 71 Fed. Reg. at 38809/2. The proposal states that where “marginally relevant information was submitted *with an intent to obscure material information*, this may run afoul of the *duty of candor and good faith set forth in § 1.56(a)*. *In this circumstance, an inference that the applicant or their representative attempted to cover up or conceal a material reference could be drawn.*” 71 Fed. Reg. at 38809/1-2 (emphasis added). But the language from *Molins* quoted by the proposal states only that “burying a particularly material reference ... *can be probative of bad faith,*” not that providing excessive information necessarily constitutes bad faith. 71 Fed. Reg. at 38809/2 (quoting 48 F.3d at 1184) (emphasis added). Absolutely nothing in *Molins* implies that an IDS which contains a large number of references, *even when some of the references are cumulative*, is *sufficient* to draw an inference of a bad faith intent to deceive. Nevertheless, the proposal would require additional burdens of explanation based on such an inference, for IDSs containing more than twenty references or for references containing more than 25 pages.

In imposing these burdens based on the duty of candor, the PTO has shifted the presumptions of producing evidence and of proving bad faith, without placing *any* evidence of bad faith in the record (much less any evidence of routine bad faith that would warrant such a stringent prophylactic measure). The record does not contain *any* evidence that information actually being submitted in IDSs is immaterial, much less that any cumulative or otherwise immaterial information was submitted by persons knowing it to be immaterial *with an improper intent to conceal more relevant information*. The proposal thus assumes bad faith without any basis for doing so and thereby shifts the burden to applicants to prove they have not engaged in bad faith, by making costly and time-consuming statements of relevance that may be admissions against interest and that certainly risk inequitable conduct allegations.

The burden-shifting approach of the proposed rules, based on a rulemaking record devoid of any relevant facts, is clearly impermissible. The APA prohibits an agency from shifting by rulemaking the burden of proof or persuasion in adjudications. In such cases, the rule is invalid under 5 USC. § 556(d) (“Except where otherwise provided by statute, the proponent of a rule or order has the burden of proof.”). See, e.g., *Director, Office of Workers Compensation Programs, Dept. of Labor v. Greenwich Colliers*, 512 U.S. 267, 275-81 (1994) (unless superseded by statute, Section 556(d) prohibits an agency from shifting the burden of persuasion regarding issues the agency is required to prove in order to grant or deny an order). *St. Mary's Honor Center v. Hicks*, 509 U.S. 502, 510-11 (1993) (a rebuttable presumption, “having fulfilled its role of forcing the [other party] to come forward with some response, simply drops out of the picture”).

In contrast, where the rule is intended to shift only a burden of production, it remains subject to challenge as being contrary to law and arbitrary and capricious, as failing to accord procedural due process (e.g., if it adopts procedures that do not afford a meaningful opportunity to be heard or are subject to substantial risks of error), or as denying equal protection or other constitutional rights. See, e.g., *Heckler v. Campbell*, 461 U.S. 458, 465-70 (1983) (discussing arbitrary and capricious review under the APA of agency “guidelines” adopted by rule that shifted the burden of production, where the underlying statute provided authority to “adopt reasonable and

proper rules and regulations to regulate and provide for the nature and extent of the proofs and evidence”); *Patlex Corp. v. Mossinghoff*, 771 F.2d 480, 484 (Fed. Cir. 1985) (due process requires courts to consider “[f]irst, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail. (citing *Matthews v. Eldridge*, 424 U.S. 319, 335 (1976)); *Lacavera v. Dudas*, 441 F.3d 1380, 1383-84 (Fed. Cir. 2006) (equal protection challenge) (citing *See Matthews v. Diaz*, 426 U.S. 67, 78, 96 S.Ct. 1883, 48 L.Ed.2d 478 (1976), and *City of Cleburne, Tex. v. Cleburne Living Center, Inc.*, 473 U.S. 432, 439, 105 S.Ct. 3249, 87 L.Ed.2d 313 (1985)). Significantly, the shifting of a burden of production requires both that the agency address legislative (not adjudicative) facts and similarly that the facts presumed “may be resolved as fairly through rulemaking” as through evidence in adjudication. *Heckler*, 461 U.S. at 468. See *id.* at 467 (agencies may rely on rulemaking authority to determine “issues that do not require case-by-case consideration”) (citing *FPC v. Texaco, Inc.*, 377 U.S. 33, 41-44, 84 S.Ct. 1105, 1110-1112, 12 L.Ed.2d 112 (1964); *United States v. Storer Broadcasting Co.*, 351 U.S. 192, 205, 76 S.Ct. 763, 771, 100 L.Ed. 1081 (1956)). And even then, the rule determining the issues (even presumptively) is subject to APA review for lack of statutory authority and also to APA review for arbitrary and capricious action based on whether the record reflects sufficient factual support and a reasoned decision for adopting the production-burden-shifting presumption. *Id.* at 465, 470 n.14 (citing *Herweg v. Ray*, 455 U.S. 265, 275, 102 S.Ct. 1059, 1066, 71 L.Ed.2d 137 (1982); *Schweiker v. Gray Panthers*, 453 U.S., 34, 44, 101 S.Ct., 2633, 2640 (1981)).

Historically, as the PTO has recognized – in the extensive procedures for attorney discipline in 37 CFR § 10 – that the PTO bears the burden of proving violations of the duty of candor and good faith. This burden on the PTO was also implicit in the now-rescinded rules under 37 CFR § 1.56(c) (1977) (with the power retained as inherent authority) that authorized the PTO to strike or to reject applications for fraud or for violations of the duty of disclosure through bad faith or gross negligence. See 47 Fed. Reg. 21746, 21751/2-3 (revising 37 CFR § 1.56(d); *id.* at 21747/1 (noting that applications can be rejected for fraud or bad faith upon determinations that would be made by “examiners with legal training assigned to the Office of the Assistant Commissioner for Patents . . . if it is established by clear and convincing evidence”); 57 Fed. Reg. at 2024/2 (Reply to Comment 6: “The Office has reserved its inherent authority to reject an application under appropriate circumstances where fraud or other inequitable conduct has occurred). The proposed rules effectively shift this burden of proving fraud, bad faith, or violations of the duty of candor, because the PTO can now refuse to consider an information disclosure statement that fails to conform to the new requirements. It appears that the proposed rules would shift the burden not only of production but also of proof, and thus would be per se impermissible. The rule requires the applicant to conform to the additional requirements to disprove the presumption of bad faith on which the requirements are justified, but having disproved the presumption has already incurred the burdens to be avoided.

But even if the proposal were to shift only the burden of production, it cannot be sustained on this record. The proposed IDS rules will shift at least the burden of production regarding lack of materiality and cumulateness (thereby imposing potentially draconian consequences) based on a rulemaking record that presumes fraud, bad faith, or lack of candor merely from submitting more than twenty documents in an IDS or any documents containing more than 25 pages. The proposed rule thus is factually insufficient. A rule that seeks to shift the burden of production on an adjudicatory issue will violate the APA if it allows an agency to meet its burden of proof without ever providing *any* evidence to support a prima facie case. See, e.g., *Greenwich Colliers*, 512 U.S. at 278-79 (“That the proponent of a rule or order has the burden of proof means not only that the party initiating the proceeding has the general burden of coming forward with a prima facie case but that other parties, who are proponents of some different result, also for that purpose have a burden to maintain. Similarly the requirement that no sanction be imposed or rule or order be issued except upon evidence of the kind specified means that the proponents of a denial of relief must sustain such denial by that kind of evidence.”) (quoting S. Rep. No. 752, 79th Cong., 1st Sess. 22 (1945) (emphasis added)); *id.* at 279 (““In other words, this section means that every proponent of a rule or order or the denial thereof has the burden of coming forward

with sufficient evidence therefor; and in determining applications for licenses or other relief any fact, conduct, or status so shown by credible and credited evidence must be accepted as true except as the contrary has been shown or such evidence has been rebutted or impeached by duly credited evidence or by facts officially noticed and stated.”) (quoting H.R.Rep. No. 1980, 79th Cong., 2d Sess., 36 (1946) (emphasis added)). Without such evidence, the burden-of-production-shifting rule is arbitrary and capricious, as it would provide a presumption of adjudicatory facts that would allow the agency to “make” a prima facie case without any (or without an adequate) evidentiary basis for the issue on which the agency must produce such evidence and bear the burden of persuasion where the prima facie case is rebutted. *See National Mining Assn v. Babbitt*, 172 F.3d 906, 910 (D.C. Cir. 1999) (“Although we recognize that at a certain point along an evidentiary continuum a shift in the burden of production can become de facto a shift in the burden of persuasion, we do not think it is necessary in this case to draw the line. For a factual presumption that causes a shift in the burden of production must be reasonable (as we explain below, this means essentially that the circumstances giving rise to the presumption must make it more likely than not that the presumed fact exists, see *Secretary of Labor v. Keystone Coal Mining Corp.*, 151 F.3d 1096, 1100-01 (D.C.Cir.1998)). For two reasons, the agency's presumption fails that test. The first is that the nature of subsidence evidence that triggers the presumption has become hopelessly confused in this litigation, and the second is that the geographical boundary in which the presumption obtains—the angle of the draw—is irrationally broad.”).

The evidentiary failures of the proposed rules detailed above also demonstrate why the proposed rules improperly seek to shift the burden of production to applicants regarding adjudicatory and not legislative facts. *See, e.g., Committee for Effective Cellular Rules v. F.C.C.*, 53 F.3d 1309, 1319 (D.C. Cir. 1995) (citing *Telocator Network v. FCC*, 691 F.2d 525, 551 (D.C.Cir.1982) (rulemaking powers are appropriately employed when issues “involve legislative rather than adjudicative facts, and have prospective effect and classwide applicability.” (footnotes omitted)). The facts regarding whether any documents submitted with information disclosure statements are material, what portions are relevant and how they are relevant, whether they are cumulative of other documents, and whether they reflect fraud, bad faith, or a lack of candor are invariably particular to the application and do not have class-wide applicability. They are thus not the kind of facts that are susceptible to a burden-of-production-shifting presumption under *Heckler*, as discussed above. *See American Airlines, Inc. v. Civil Aeronautics Board*, 359 F.2d 624, 633 n. 25 (D.C. Cir. 1996) (“Adjudicative facts usually answer the questions of who did what, where, when, how, why, with what motive or intent; adjudicative facts are roughly the kind of facts that go to a jury in a jury case. Legislative facts do not usually concern the immediate parties but are general facts which help the tribunal decide questions of law and policy and discretion.”) (quoting 1 Davis, *Administrative Law* § 7.02, p. 413 (1958)); *Broz v. Schweiker*, 667 F.2d 1351, 1357 (D.C. Cir. 1982) (substantive rulemaking powers may be exercised in regard to statutory rights to an adjudicative hearing in regard to legislative, but not adjudicative, facts: “adjudicative facts, however, must be determined at a hearing”).

Moreover, the proposed burden shifting rules would have serious consequences. Applicants may not meet their duty of disclosure under 37 CFR § 1.56(b) and may be subject to sanctions by the PTO for failure to comply with the additional explanation, non-cumulative description, and patentability justification requirements (including discipline for representatives). Similarly, the failure to comply may be found in litigation to constitute inequitable conduct (by failing to follow the rules in a manner that would lead to PTO consideration of material documents actually submitted) or may lose the presumption of validity (or the strength accorded thereto) of the patent, given that the relevant evidence in the record would not have been evaluated by the PTO. *See* 71 Fed. Reg. at 38820/2 (proposed Section 1.97(a) (“In order for an applicant to have an information disclosure statement considered by the Office ... the information disclosure statement must satisfy the requirements of § 1.98”); *id.* at 38815/3 to 38816/1 (“Section 1.98(a)(3)(vii)(C) would provide that where the explanations or non-cumulative descriptions do not comply with § 1.98(a)(3)(vii)(A), or the reasons for patentability justifications do not comply with § 1.98(a)(3)(vii)(B), the Office may decline to consider the information disclosure statement. *See also* § 1.97(i)(1).”); *id.* at 38816/2 (the proposed rules would now allow the PTO to “decline to consider an information disclosure statement citing documents that are merely cumulative”). In contrast, complying with the proposed explanation, non-cumulative description, and

patentability justification rules may impose equally severe consequences, by documenting admissions against interest that adversely affect applicants' rights and that may potentially foment inequitable conduct allegations and litigation.

The proposal does not, however, highlight these draconian legal consequences of either a refusal to file an IDS meeting the proposed Section 1.98(a)(3) requirements or of filing such an IDS. Instead, the proposal seeks to minimize the costs and burdens actually associated with compliance and to focus attention only on the PTO's ability to refuse to consider a non-compliant IDS (which will permit the applicants to then come into compliance but will not result in an abandonment of the application). Further, applicants will face a Hobson's choice when they believe the information already submitted is not cumulative, but the examiners disagree and refuse to process the IDSs in part or in whole without non-cumulative descriptions. To get the documents reviewed (and thus to meet the duty of disclosure), applicants will be required either to file non-cumulative descriptions that contain admissions against interest and that applicants may believe are inaccurate – and thus may constitute false statements risking not only inequitable conduct allegations but also potential criminal liability – or to withdraw the references from consideration relying on the examiners' decisions – again risking inequitable conduct allegations (particularly when the applicant did not agree with the examiners' conclusions). Given that the proposed rule does not consider or evaluate these obvious adverse consequences, it must fail the reasoned decisionmaking standard.

E. Lack of Statutory Authority

Nothing in 35 U.S.C. §§ 2(b), 131, and 132(a) provides the PTO with substantive rulemaking authority to issue rules that require applicants to perform an examiners' work, *i.e.*, “to enable an examiner to identify the most relevant prior art in an efficient and expeditious manner, even when an IDS containing a large number of documents is submitted.” 71 Fed. Reg. at 38809/1. Not only does the 13th Amendment to the U.S. Constitution prevent involuntary servitude or forced labor for the government, Section 2(b)(2)(A) governs the conduct of proceedings, not the manner of presentation of claims to the government. Nor does Section 2(b)(2)(D) authority to regulate the conduct of representatives provide grounds for regulating the arguments presented by applicants or their representatives, much less to require them to make statements and admissions against interest. Rather, the PTO in the past was careful to require only the submission of factual information already within the applicants' constructive possession and that was considered objectively reasonable for the government to request (in the conduct of its statutory duty of examination and as relating to grounds for rejection that the government might properly assert).

Even when the PTO in 2000 adopted a rule authorizing examiner to request information from applicants during examinations, and expanded that rule in 2004, the PTO authorized only requests for submission of factual information. *See* 65 Fed. Reg. 54604, 54671/3 to 54672/1 (adopting 37 CFR § 1.105); 69 Fed. Reg. 56482, 56542/3 (amending 37 CFR § 1.105). It did not compel characterizations of the documents to be submitted, which would result in forced statements and admissions against interest. Nor did it require generation of information not in the applicant's possession or not otherwise “readily available,” nor even an explanation of what efforts had been made to determine that the information was unknown or not “readily available.” 65 Fed. Reg. at 54634/1. Similarly, even when expressly authorizing examiners to request facts by stipulation, the PTO was careful to state that “requirements under § 1.105(a)(3) are not requesting opinions that may be held or would be required to be formulated by applicant.” 69 Fed. Reg. 56512/2. Further, the PTO took pains to note that the requests for information “are not routinely made. They are to be used only where there is an absence of necessary information within the record. Any such requirement should be tailored to treat specific issues on a case-by-case basis.” *Id.* at 56513/1.

In contrast to § 1.105, the requests for explanation, non-cumulative descriptions, and patentability justifications of proposed Section 1.98(a)(3) will routinely be triggered in countless applications (given the presence of material information exceeding the thresholds or discovered after the first office action). The proposed requirements will not be carefully tailored to treat specific issues, but will require extensive, costly, and time

consuming efforts by applicants and their representatives. And the explanations will not be limited to facts, but rather will compel adverse opinions that constitute admissions against interest. Even if statutory authority existed to adopt such a rule under §§ 2(b), 131, and 132, the PTO would act irrationally by invoking it in this manner.

Such authority, however, simply does not exist. As discussed above and further below, the proposal for explanations, non-cumulative descriptions, and patentability justifications are not mere rules of agency procedure. Nor are these requests within the inherent authority of the PTO that could be authorized by 35 U.S.C. § 2(b). Nor are the proposed Section 1.98(a)(3) requirements interpretive rules, as it is clear that there is no law under the duty of disclosure or the duty of candor that would allow the PTO to impose these new requirements by applying, rather than creating, the law. Section 2(b), moreover, is not a grant to the Patent Office of substantive rulemaking power. See, e.g., *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) (“As we have previously held, the broadest of the PTO’s rulemaking powers--35 U.S.C. § 6(a)--authorizes the Commissioner to promulgate regulations directed only to “the conduct of proceedings in the [PTO]”; it does NOT grant the Commissioner the authority to issue substantive rules. *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 930, 18 USPQ2d 1677, 1686 (Fed.Cir.1991).”). Nor can Sections 131 or 132 be used to suggest substantive rulemaking power that is not conveyed by Section 2(b).

In short, no authority was granted by Congress to the PTO to issue rules that compel applicants to make statements against interest and to undertake burdensome and inappropriate actions simply to relieve examiners from performing their jobs. Nothing in the majority decision in *Star Fruits S.N.C. v. United States*, 393 F.3d 1277 (Fed. Cir. 2005), moreover, would suggest that the PTO possesses such authority. *Star Fruits* did not address a challenge to the substantive power of the PTO to issue the information request rule, but rather addressed only the application of that rule and whether that application constituted an abuse of discretion under the APA. See *id.* at 1280, 1282. The Federal Circuit recited the purpose of the rule to require information that is “reasonably necessary to properly examine or treat the matter,” and construed the rule to authorize requests for information beyond that already required to be submitted under the duty of disclosure (as it would “make no sense ... to promulgate [such] a rule”). *Id.* at 1282. On this basis, the Federal Circuit held there was no abuse of discretion in requiring compliance with the information request and imposing the penalty of abandonment for failure to comply, as the validity of requesting information that might be based on an erroneous understanding of the applicable law could only be challenged by appealing an improper rejection once the information was supplied, and not by withholding information that might not be reasonably necessary if a proper understanding of the law were applied. See *id.* at 1284-85. In dissent, Judge Newman argued that the PTO lacks authority to change the law, and if the information was not reasonably necessary to reaching a determination under a proper understanding of the applicable law, the PTO could not require it at all, much less under a rule purporting to authorize information requests only when “reasonably necessary to properly examine or treat the matter.” See *id.* at 1285-88. Like the majority, Judge Newman did not address the legality of the rule itself, but rather whether its application was not “in ‘accordance with law.’” *Id.* at 1288.

Further, there are good reasons to doubt that Congress has granted the PTO the power to issue 37 CFR § 1.105 if it is to be construed as the majority did in *Star Fruits*, *i.e.*, as authorizing examiners to require information that applicants are not required to supply to avoid fraud. But if such authority exists, it would clearly be limited to requiring factual information already in the applicant’s possession, as to require more is to inappropriately shift the burden of examination to applicants that Congress has placed on the PTO. *StarFruits* thus can provide no precedent for the dramatically greater requirements to be imposed on applicants and their representatives that the PTO has proposed here in Section 1.98(a)(3).

Further, unlike requests for factual information under 37 CFR § 1.105, there will be no separate basis for examiner invocations of requests for explanations under proposed Section 1.98(a)(3), as the requirements for explanation, non-cumulative descriptions, and patentability justifications will operate as a matter of law upon adoption of the proposed rule. Consequently, there will be no record of an adjudicative decision for requiring the submission of explanations, non-cumulative descriptions, and patentability justifications other than the

record for the present rulemaking. As the PTO noted in adopting § 1.105, however, the new “authority [wa]s not intended to be used by examiners without a reasonable basis, but to address legitimate concerns that may arise during the examination of an application or consideration of some matter.” 65 Fed. Reg. at 54633/3.

Under § 1.98(a)(3), moreover, there will be no opportunity to obtain timely judicial review of the requirements that apply. Once an applicant files the application, and assuming that the application is accompanied by an IDS containing more than twenty material references or a single material reference containing greater than twenty-five relevant pages, the rules automatically impose the requirements for additional explanation. Applicants may have no means to avoid the problem of incurring the costs involved in responding to the rule’s requirements, as a petition to the Director (which would add to those costs and to delays in processing) would likely be futile given adoption of the rule. *Cf.* 65 Fed. Reg. at 54634/1 (“a requirement for information that is not in fact reasonably necessary to properly examine the application, may be addressed by way of petition under § 1.181.”). Even if a petition were not futile, the premise of the challenge would have to be a *de facto* challenge to the rule, seeking its withdrawal (at least as applied in the particular matter, and without any additional decision-making, factual record, or exercise of judgment by an examiner). This would likely convert the petition into a petition for rulemaking, and it is not evident that the PTO would act on that petition in a timely fashion, much less do so favorably whenever it ultimately addressed the issue. Thus, applicants will not be able to reach a timely final determination of whether to comply with the additional explanatory requirements. As a practical matter, they either would have to file mandamus actions in court challenging the validity of the rule or risk the consequences of failure to comply with the rule if they seek to proceed to issue without first seeking judicial review. *Cf. Star Fruits*, 393 F.3d at 1280 (appealing to court after unsuccessfully petitioning a notice of abandonment to the Director and subsequently receiving a second notice of abandonment after refusing to comply with the § 1.105 information request). A mandamus action also might result in substantial delays in processing the application, resulting in significant commercial harm to the applicant. Further, unintentional or intentional non-compliance with the rules, as well as intentional compliance with the rules, may lead to significant potential new liabilities.

To avoid such a situation, and because no additional factual developments will affect the rulemaking record on which judicial review of an application subject to the rules would occur, the PTO should not seek to oppose any challenge to the validity of proposed Section 1.98(a)(3) if and when it were to be issued on the grounds that such a challenge is unripe for judicial review. The problem will be recurrent and predictable, so judicial review following any such adoption but before application in a particular adjudication will be critically important to prevent harm if the rules are invalid, as demonstrated above.

F. The Proposed IDS Rules Are Substantive Not Procedural or Interpretive Rules

Historically, the PTO has treated examination rules as rules of agency procedure, not subject to notice and comment requirements and authorized by Section 2 of the Patent Act. See, e.g., 70 Fed. Reg. 30360, 30362, 30364 (May 26, 2005) (“The change does not ‘encode a substantive value judgment,’ but simply discontinues a purely procedural practice ... The changes in the final rule relate solely to the procedures to be followed in prosecuting a patent application.... Therefore, these rule changes involve interpretive rules, or rules of agency practice and procedure under 5 U.S.C. 553(b)(A).”) (quoting *Public Citizen v. U.S. Dept. of State*, 276 F.3d 634, 640 (D.C. Cir. 2002)). See also *American Hospital Ass’n v. Bowen*, 834 F.2d 1037, 1047 (D.C. Cir. 1987) (“[o]ver time, our circuit in applying the § 553 exemption for procedural rules has gradually shifted focus from asking whether a given procedure has a ‘substantial impact’ on parties to ... inquiring more broadly whether the agency action ... encodes a substantive value judgment.”); 35 USC § 2(b)(2) (the Office “may establish regulations, not inconsistent with law, which- (A) shall govern the conduct of proceedings in the Office; (B) shall be made in accordance with section 553 of title 5; (C) shall facilitate and expedite the processing of patent applications, particularly those which can be filed, stored, processed, searched, and retrieved electronically, subject to the provisions of section 122 relating to the confidential status of applications;”).

This proposal is no different, as the PTO has suggested that it is only a rule of agency procedure, having no substantive effect other than to have the IDS placed in the application file “with the noncomplying information not being considered” and the application not going abandoned. 71 Fed. Reg. 38818/3. But proposed Section 1.98(a)(3) goes much further and adopts additional substantive (but not clearly identified) value judgments regarding what conduct is required of applicants either to satisfy their ethical obligations or to meet the PTO’s desires for adequate worksharing, or for some other reason nowhere expressed but on which the PTO would determine adequacy of a submission. As discussed above, proposed Section 1.98(a)(3) would require applicants and their representatives to undertake significant and costly actions that are currently required to be undertaken by the PTO if they are to obtain the statutory examination required. They do so based on a premise that applications containing too many references or too many pages for cited references or references filed when discovered after an office action reflect fraud, bad faith, or lack of candor. Nothing in the existing judicial interpretations of the law of inequitable conduct would support such rules, and nothing in the existing duty of candor and other ethical obligations of registered practitioners would either. (Nor could the PTO bootstrap its authority by promulgating ethical rules and then arguing that the failure to share the PTO’s work burdens would violate those rules.) Further, although the proposed rules would apply to the conduct of adjudicative proceedings, that does not make them procedural rules. A procedural rule cannot modify or add to a legal norm and should not affect the outcome of agency adjudications. See, e.g., *Batterton v. Marshall*, 648 F.2d 694, 707 & n.70 (D.C. Cir. 1980) (“A useful articulation of the exemption's critical feature is that it covers agency actions that do not themselves alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency.... [T]he exemption relating to agency practice or procedure 'should not be deemed to include any action which goes beyond formality and substantially affects the rights of those over whom the agency exercises authority. Certainly, it does not include formalized criteria adopted by an agency to determine whether claims for relief are meritorious.' *Pickus v. United States Board of Parole*, 507 F.2d 1107, 1113 (D.C.Cir.1974).”).

It is abundantly clear that the proposed rules - which would dramatically affect rights and liabilities and would codify substantial discretion for the PTO according to standards nowhere recited in the statute - do not purport to be interpretive rules. Substantive rules thus are distinguished from interpretive rules and procedural rules by their having the force of law and establishing new requirements that affect individuals' rights or obligation. See, e.g., *Tunik v. Merit Systems Protection Board*, 407 F.3d 1326, 1344 (Fed. Cir. 2005) (“In *Chrysler Corp. v. Brown*, the Supreme Court described a substantive, or legislative, rule-as opposed to an interpretive rule-as 'one “affecting individual rights and obligations.”’ 441 U.S. 281, 302, 99 S.Ct. 1705, 60 L.Ed.2d 208 (1979) (quoting *Morton v. Ruiz*, 415 U.S. 199, 232, 94 S.Ct. 1055, 39 L.Ed.2d 270 (1974)). The Supreme Court went on to say that '[t]his characteristic is an important touchstone for distinguishing those rules that may be “binding” or have the “force of law.”’ *Id.*”). As discussed above, the proposed Section 1.98(a)(3) rules will adversely affect individual rights in the absence of applicants coming forward with the newly required explanations, non-cumulative descriptions, and patentability justifications, by potentially altering liability for inequitable conduct and presumptions of validity that may attach to the issued patent. It will thus create new substantive obligations for applicants, even if the applications continue to be processed and do not go abandoned by failure or refusal to comply with Section 1.98(a)(3) requirements. Further, intentional failure or refusal to comply may lead to potential disciplinary sanctions, and compliance with the rule (which surely must be considered in promulgating it) will lead to other forms of potential liability for inequitable conduct as well as potential admissions against interest that may affect patentability determinations in the PTO and validity and infringement determinations in litigation. In short, there is far too much substantive consequence to this rule, and very little that is simply procedure without creating new legal standards.

As the U.S. Court of Appeals for the Federal Circuit has repeatedly noted, the Commissioner's rulemaking authority under 35 USC § 2(a) to promulgate rules governing the “conduct of proceedings” does not provide for substantive lawmaking authority. Section 2(a) (formerly Section 6) authority “is directed to the 'conduct of proceedings' before the Office. A substantive declaration with regard to the Commissioner's interpretation of the patent statutes, whether it be section 101, 102, 103, 112 or other section, does not fall within the usual interpretation of such statutory language. See, e.g., *General Elec. Co., Inc. v. Gilbert*, 429 U.S. 125, 141 & n.

20, 97 S.Ct. 401, 410 & n. 20, 50 L.Ed.2d 343 (1976) (EEOC guideline interpreting Title VII of the Civil Rights Act not within the statutory authority to 'issue ... suitable procedural regulations to carry out the provisions of the subchapter,' 42 U.S.C. § 2000e-12(a)). That is not to say that the Commissioner does not have authority to issue such a Notice but, if not issued under the statutory grant, the Notice cannot possibly have the force and effect of law." *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991). Similarly, "it does not grant the Commissioner the authority to issue substantive rules.... Because Congress has not vested the Commissioner with any general substantive rulemaking power, the [action] at issue in this case cannot possibly have the "force and effect of law." *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996) (citing *Animal Legal Defense Fund*, 932 F.2d at 930 and *Chrysler Corp. v. Brown*, 441 U.S. 281, 302, 99 S.Ct. 1705, 1718, 60 L.Ed.2d 208 (1979)). Unlike procedural rules (such as requirements on paper for filing applications and briefs, or even for particular forms for declarations or documents), the proposed Section 1.98(a)(3) rules will impose significant costs and additional hurdles that cannot be overcome by formal compliance measures. Rather, they require substantive value judgments to force applicants to make statements reflecting legal positions, and substantive value judgments (according to vague and discretionary criteria) by the PTO regarding the adequacy of those positions. *See* proposed Section 1.98(a)(3)(vii) ("*Meaningful compliance...* [with explanations] must include a level of specificity commensurate with specifics [and] must not be *pro forma* types of explanation.... [and] the reasons for patentability justification ... must discuss specific[s]...." Failure to meet these discretionary criteria will be costly, but applicants and their representatives will not know in advance the discretionary criteria that the PTO will employ.

Thus, in addition to proposing to adopt an impermissible substantive rule, the PTO is proposing to adopt a rule calculated to breed litigation by its unprincipled and arbitrary exercise. Even if authority existed to adopt the proposal, the PTO should not do so.

Sincerely,

Dean Alderucci