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**To:** AB94Comments; AB93Comments

**Subject:** Proposed Rules - Via e-mail and facsimile - 571-273-7735

These comments are submitted in response to the Proposed Rules of the U.S. Patent and Trademark Office at 71 Fed. Reg. 48 (January 3, 2006) and 71 Fed. Reg. 62 (January 3, 2006).

## 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.

Those rules which would either shift the burden of proof or the burden of production is in direct violation of Supreme Court jurisprudence. See, e.g., Director, Office of Workers Compensation Programs, Dept. of Labor v. Greenwich Colliers, 512 U.S. 267, 275-81 (1994)

Critical factual evidence on which the U.S. Patent and Trademark Office would have had to have relied upon in formulating the new rules either does not exist or has not been subjected to informed comment by the public.

The U.S. Patent and Trademark Office lacks the required statutory authority to pass the proposed rules limiting continuation applications.

### 1. Requirements for reasoned agency decisionmaking and standard of review.

The 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 its 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 U.S. Patent and Trademark Office 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).

2. APA and other limits on shifting burdens of production and persuasion by rulemaking. Significantly for the present proposal, the burden of proof or persuasion for an agency rule is conceptually distinct from whether the rule adopted is arbitrary and capricious or not authorized by the statute. See, e.g., *Allegheny Power v. Federal Energy Regulatory Commn.*, 437 F.3d 1215, 1219 (D.C. Cir. 2006) ("The arbitrary and capricious standard speaks, of course, to the degree of deference that we owe the agency, not to burden of proof or persuasion."). The APA prohibits an agency from shifting by rulemaking the burden of proof or persuasion of issues for 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 *Mathews 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 Mathews 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 a legislative (not an adjudicative) fact 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 *See 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 review for lack of statutory authority and arbitrary and capricious review to determine if 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)).

In ex parte prosecution (which is an adjudication), the U.S. Patent and Trademark Office has the burden of persuasion to demonstrate, with evidence, that a claim is unpatentable. See, e.g., *In re Warner*, 379 F.2d 1011, 1016, 154 USPQ 173, 177 (CCPA 1967) (*Graham [v. John Deere Co.]*, 383 U.S. 1, 86 S.Ct. 684, 15 L.Ed.2d 545, 148 USPQ 459 (1966),) is interpreted as continuing to place the "burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under sections 102 and 103"). When an agency bears the burden of persuasion in an adjudication, it will thus also bear the burden of producing evidence to create a prima facie case (unless the burden of production also is shifted by statute). In such a situation, a rule that seeks to shift the burden of production on an issue will also be a violation of the APA if it allows an agency to meet its burden of proof of an issue without ever providing evidence to support proof of 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)). For an agency to shift its burden of production, it must adopt an evidentiary presumption that provides a prima facie case of the required issue to be proved, and the administrative record for an evidentiary presumption adopted by rule must contain a sufficient evidentiary basis for its application to adjudications in which the presumption will be applied. Without such evidence, the burden-of-production-shifting rule is arbitrary and capricious as it would provide a presumption 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 proposed continuation rules thus would improperly shift the burden of production to applicants, in regard both to: (1) demonstrating some new criteria regarding why the claims could not have been or were not presented earlier in the prosecution (which criteria, as discussed below, even if clarified would be contrary to law as Section 120 of the Patent Act defines the relevant criteria); and (2) demonstrating that claims presented in a continuation application having overlapping disclosures are not invalid for double patenting (according to criteria that the Patent Office has not identified and thus may also be contrary to existing law regarding double patenting). The illegality of the additional restrictions on continuation practice and the potentially illegal and ambiguous standards for shifting the burden of production on double patenting are discussed in detail in Sections \_\_ below.

Note that the proposed continuation rules are, both legally and logically, very different from the authorization in 37 CFR Section 1.105 under which the examiner may shift to the applicant the burden of producing prior art and other information already in applicant's possession that the examiner believes is relevant to determining patentability. Requests under Section 1.105 not only must have reasonable grounds to believe the information is relevant to patentability determinations, but also are premised on the examiner meeting her burden of production in adjudication. See *Star Fruits N.C. v. United States*, 393 F.3d 1277, 1284 (Fed. Cir. 2005) (“So long as the request from the examiner for information is not arbitrary or capricious, the applicant cannot impede the examiner's performance of his duty by refusing to comply with an information requirement which proceeds from the examiner's view of the scope of the law to be applied to the application at hand. To allow such interference would have the effect of forcing the Office to make patentability determinations on insufficient facts and information. Such conduct inefficiently shifts the burden of obtaining information that the applicant is in the best position to most cheaply provide onto the shoulders of the Office and risks the systemic inefficiencies that attend the issue of invalid patents. Examination under such circumstances is neither fair and equitable to the public nor efficient.”). Cf. *id.* at 1285-88 (Newman, J., dissenting) (noting that Section 1.105 requests are also subject to the “contrary to law” standard of 5 U.S.C. § 706(2)(A) and that the Patent Office cannot demand information that cannot lead to a rejection on the merits). In contrast, the proposed continuation rules shift the burden of production from the examiner without regard to any particularized determination of the need for or relevance of the information, and without a factual record to support this production shifting by rule.

### 3. Lack of Evidentiary Support for the Proposed Rules

In regard to the evidentiary basis in the record for the agency's proposed continuation rules, the rules can only be based on assumptions or beliefs that are supported by evidence in the record, and the agency must take into account and appropriately consider any contradictory evidence. 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)).”)

The extent of the “evidence” recited in the proposed rule regarding the reasons for shifting the burden of production in regard to “[u]nrestricted continued examination filings and multiple applications containing patentably indistinct claims,” moreover, either is facially insufficient or wholly irrelevant to the decision to shift the burden of production, given the lack of agency authority to impose additional restrictions on continuation practice or to alter the standards for double patenting rejections. 71 Fed. Reg. at 49. The principle evidence cited is a law review

article analyzing continuations, a Presidential Commission report, unsupported discussions of burdens on agency examiners and excessive backlogs allegedly caused or exacerbated by continuation applications, and unsupported discussions of failures by applicants (or their attorneys) to particularly point out and distinctly claim their inventions or of “a small minority of applicants [who] have misused continuing examination practice with continued examination filings in order to simply delay the conclusion of examination.” *Id.* at 49. See *id.* at 49-51. The law review article cites empirical evidence for the large numbers of continuation applications and the burdens such applications place on examiners (who lack sufficient time to adequately review all pending applications), and explains some good reasons (such as adding late-drafted claims to track changes in the marketplace) and some less “good” (but legally permitted) reasons why such applications may be filed. See Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuation*, 84 B.U. L. Rev. 63, 69-81 (2004) (citing, *inter alia*, *Kingsdown Medical Consultants v. Hollister*, 863 F.2d 867, 874 (Fed. Cir. 1988); *id.* at 95-97 (discussing four “good” reasons why patentees’ private interests are served by pursuing continuations, although society as a whole may be worse off – to extend effective life of patents, to avoid having to disclose technology too early, to change claims to cover competitors’ products, and to continue to seek protection for which applicants believe they are entitled); 71 Fed. Reg. at 49 (citing *PIN/NIP, Inc., v. Platt Chemical Co.*, 304 F.3d 1235, 1247, 64 USPQ2d 1344, 1352 (Fed. Cir. 2002), for authority to file continuations to be able to add claims to cover “developments in similar or parallel technology”). Similarly, the proposed rule cites to data regarding the total numbers of continuations and their additional burdens for examiners, but provides no analysis whatsoever of the grounds for filing any of these applications and whether those grounds constitute “abuse.” See 71 Fed. Reg. at 50. But the proposed rule and the cited article are devoid of any evidence regarding whether any, many, or most applications are filed for improper reasons, much less for reasons (if any exist) in regard to which the agency may refuse to process an application. As the proposed rules themselves concede, the proposal is not an attempt to codify *In re Bogese*, 303 F.3d 1362, 64 USPQ2d 1448 (Fed. Cir. 2002) (*Bogese II*) “or to simply combat such extreme cases of prosecution laches.” 71 Fed. Reg. at 50. See Lemley & Moore, 84 B.U. L. Rev. at 111-12 (noting that the equitable defense of “continuing prosecution laches” has been applied only once by a district court and is “not, at present, well defined,” and “courts lack clear standards and hard evidence upon which to base a decision on reasonableness.”). Rather, Lemley & Moore themselves dispute the evidentiary basis for determining that any significant abuse of continuations has occurred or will occur that would warrant adopting an evidentiary presumption that shifts the burden of production that a continuation is not abusive (under a standard that is nowhere specified).

Similarly, Lemley and Moore note that numerous means have already been adopted to limit what they characterize as “abuse” of continuation rules, 84 B.U. L. Rev. at 84-93, but conclude without data that the remaining continuations continue to pose “the problem of continuation abuse.” *Id.* at 93. This analysis (and that of the proposed continuation rules) reflects an unjustified terminological bias, as the remaining “problems” that they refer to of social costs are imposed by legitimate and statutorily justified filings that have private benefit and thus do not constitute “abuse.” Rather, in many cases they constitute legitimate conduct of which the courts have expressly approved (as recognized in the proposed rules), such as filing continuations to cover competitors’ products (when the continuations have adequate support in the earlier applications for the new claims). See, e.g., *id.* at 108 (“One of the most egregious abuses of continuation applications described above is the use of the process to change patent claims to track inventions first made by one of the applicant’s competitors.”). The proposed continuation rules similarly refer to “abuse” without defining what constitutes abuse or providing any evidence that abuse actually occurs. Thus, the proposed continuation rules attempt to address an undefined “problem” of unspecified proportions in regard to conduct that the agency itself has not identified (and lacks authority to identify) as abusive or otherwise illegal, in a transparent effort to reduce the agency’s workload. Again, as Lemley and Moore note, the principal reasons for such a rule is to assure that applicants do not “wear down” examiners into making improper allowances of claims, see, e.g., 84 B.U. L. Rev. at 97, notwithstanding that the Patent Office already charges fees for filing continuation applications and requests for continued examination. In short, the Patent Office is proposing these rules simply to find some way to improve the performance of its own examiners

in examining applications by reducing their workload. Such lack of an evidentiary basis or reasoned analysis of the grounds for adopting the presumptions that a continuation application is unjustified must be arbitrary and capricious; it has no rational relation to the reasons why applicants file and prosecute continuing applications.

The proposed continuation rules similarly lack any evidentiary justification for shifting the burden of production in regard to demonstrating a double patenting grounds for rejection. The proposed rules simply state the conclusion – without tying it to any supporting evidence – that “current continued examination practice and the filing of multiple applications containing patentably indistinct claims are impairing the Office’s ability to examine new applications without real certainty that these practices effectively advance prosecution, improve patent quality, or serve the typical applicant or the public.” 71 Fed. Reg. at 50 (emphasis added). What is missing is any evidence and reasoned analysis that such filings often, much less typically, contain patentably indistinct claims that would warrant shifting the evidentiary burden. Instead, the proposed rules substitute a policy preference to avoid receiving such applications for evidence.

Significantly, these evidentiary failures of the proposed rules also demonstrate why the proposed rules improperly seek to shift the burden of production 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 continuing application is justified or might be prohibited under applicable law or regarding whether it contains patentably indistinct claims are invariably particular to the application and do not have classwide applicability. They are thus not the kind of facts that are susceptible to shifting a burden of production under *Heckler*, as discussed above. *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”).

The U.S. Patent and Trademark Office did not otherwise make publicly available any evidentiary support for the proposed rules in the “rules docket”. See attached Exhibit A, in which Deputy Director Clarke acknowledges that there is no publicly available information in, e.g., the rules docket. because there is information potentially supporting the PTO’s decisionmaking that has not been made available to the public for review it cannot form part of the rulemaking record, cannot be relied upon to justify the rule, and should not be placed in the docket or used to justify the rule without providing another opportunity to comment on the information.

4. The Patent Office lacks statutory authority to promulgate the continuation rule.

Courts have repeatedly referred to the ability of applicants to file a series of continuation applications that meet the statutory requirements of Section 120 as a “right,” “statutory right,” or “entitlement.” “In our view, § 120 gives to any applicant for a patent complying with its terms the right to have the benefit of the filing date of an earlier application. The language is mandatory.” *Racing Strollers, Inc. v. TRI Industries, Inc.*, 878 F.2d 1418, 1421 (Fed. Cir. 1989) (emphasis in original). See also, e.g., *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 557 (Fed. Cir. 1994) (citing *Weil v. Fritz*, 572 F.2d 856, 865 n. 16, 196 USPQ 600, 608 n. 16 (CCPA 1978); *Wagoner v. Barger*, 463 F.2d 1377, 1380, 175 USPQ 85, 86 (CCPA 1972); *In re Van Langehoven*, 458 F.2d 132, 136, 173 USPQ 426, 429 (CCPA 1972); *In re Lukach*, 442 F.2d 967, 968, 169 USPQ 795, 797 (CCPA 1971); *In re Shaw*, 202 USPQ 285, 293 (Comm.Pat.1978)); *In re Bauman*, 683 F.2d 405, 409 & n.10, 410 (C.C.P.A. 1982) (citing *United States v. American Bell Telephone Co.*, 167 U.S. 224, 247, 17 S.Ct. 809, 813, 42 L.Ed. 144 (1897), and *Ex parte Solomons*, 201 U.S.P.Q. 42 (PTO Bd. App. 1978)). Accordingly, the Patent Office cannot without statutory authority issue legislative rules that would impair or condition this right, and it is obvious from the case law that there is no existing statutory authority

that would allow it to do so. Nor is there any intervening development in the statutory or case law on which the Patent Office could purport to ground continuation rules that would impair or condition this right as interpretive rules.

the 1952 Patent Act codified Section 120 in order to legislatively ratify the practice of the Patent Office in response to the decision in *Godfrey v. Eames*, 68 U.S. 317, 325-26 (1864), which treated continuing applications as an amendment to an existing application. See *Transco Products, Inc.*, 38 F.3d at 557 (Fed. Cir. 1994) (“The Supreme Court’s explanation illuminates the meaning of “shall have the same effect” and clearly requires that we view appellants’ applications as “parts of the same transaction” and “as constituting one continuous application” for the continuing subject matter recited therein.) (citing *In re Hogan*, 559 F.2d 595, 603 (C.C.P.A. 1977) (emphasis in *Transco*)); *In re Henriksen*, 399 F.2d 253, 258-60 (C.C.P.A. 1968). As noted in the comments of Harold Wegner filed on March 14, 2006, Congress in the 1952 Patent Act rejected a preliminary draft of Section 120 that would have treated continuing applications like a real amendment to a pending application (by limiting the term of any patent issuing on the continuation application to that of any patent issuing on the earlier application). Instead, Congress expressed an intention to permit continuations under Section 120 even when to do so would permit multiple patents having terms extending a full 17 years from issue of the continuation (subject to judicially created double patenting restrictions).

Significantly, *Godfrey* addressed the situation where the public had the benefit of an invention for more than the statutory grace period prior to the filing of a renewed (but not an original) application claiming priority to a pending application that had not been abandoned (by withdrawing the original application – which had been rejected “for want of novelty” – and submitting the new application in regard to which “the claims of novelty, and the models, were in some respects different” but which could have been patented if “engrafted as an amendment to the first application”). 68 U.S. at 317-18. *Godfrey* thus recognized the potential to file new claims (even a new disclosure) after the original application and to claim priority to the original, even though the subject matter would have been irrevocably dedicated to the public domain if such priority were lacking. The Court specifically held that the Patent Act of 1839 had “relieved the applicant from this consequence” and “gave him the right to apply for a patent at any time within two years after the use and sale of his invention.” *Id.* at 325. The Court also was told that significant time might pass before the filing of the continuing application. See *id.* at 320 (“and although he should afterwards withdraw that application and some time should elapse before he renewed it”) (emphasis in original).

Specifically, the Court in *Godfrey* held that if an applicant withdraws an application intending to file a new petition drawn to the same inventive subject matter so that there was no abandonment of the invention to the public (although potentially with different descriptions or claims), “the two petitions are to be considered as part of the same transaction, and both as constituting one continuous application, within the meaning of the law.” *Id.* at 326. As a result of this decision, continuation application arose. As later noted in *In re Henriksen*, the lack of abandonment of the disclosed subject matter to the public was the critical aspect of the requirement adopted in 1952 for the prior application to be “co-pending,” and why the continuation right applied to a chain of pending applications. See 399 F.2d at 257 (discussing the copendency requirement and Committee Print preliminary draft Section 35, which was later amended to become Section 120); *id.* (the copendency requirement “is found in the requirement that ‘the later application’ must be filed before the ‘prior application’ is patented or abandoned or proceedings thereon terminated.”). Further, *Henriksen* made clear that the statute imposes “no restriction on the number of applications which may be so involved” and specifically rejected the arguments of the Patent Office that although continuations might extend to four applications in a chain, it did not create an “inference[] of unlimitedness” regarding how many continuations could be filed. *Id.* at 257, 259. See *id.* at 261 (“We agree with appellant’s analysis to the effect that the statute provides no limit to the number of applications that may be copending.”). The Court also noted the policy concern “that a patent should be granted on an application depending upon another application filed over 20 years ago” but held that that was an issue that only Congress could address. *Id.* at 262. Other cases have affirmed the right to file continuations, even when they broaden claims in issued patents. See *In re Vogel*, 422 F.2d 438 (C.C.P.A. 1970) (finding “‘obvious variation’ type”

double patenting subject to a terminal disclaimer in regard to a copending application in light of applicants issued patent).

The legislative history of the 1952 Act also makes clear that applicants were given a statutory right to file an unlimited series of continuing applications. As the relevant House and Senate reports noted, "Sections 120 and 121 express in the statute certain matters which exist in the law today but which had not been before written into the statute, and in so doing make some minor changes in the concepts involved." H.R. Rep. No. 1923, 82d Cong., 2d Sess. (1952), at 7; S. Rep. No. 1979 (1952), at 6. Section 120 enacted a right to the priority filing date in any continuation that met these new statutory requirements. "When these three conditions obtain the second application is entitled to have the same effect as though filed on the same date that the first application was filed, with respect to an invention disclosed in both applications. The first two requirements specified are substantially the same as existed under the prior case law... The third requirement of the statute is that the second application must contain a specific reference to the first application."

Since 1952, Congress has repeatedly confirmed the right to file and receive priority to earlier applications for a continuation application filed at any time and meeting the specific statutory requirements (typically to make the relevant identification and priority claim, and to provide written description support in the earlier application). In fact, Congress has expanded it to include continuations claiming priority to the (no longer new) provisional applications, to various foreign applications (including "subsequent regularly filed applications[s] ... instead of the first filed foreign application"), and where not all the inventors are the same. See, e.g., 35 U.S.C. §§ 119(a)-(e), 120; Act "To carry into effect certain provision of the Patent Cooperation Treaty, and for other purposes", P.L. 94-131; Patent Law Amendments Act of 1984, P.L. 94-131; Consolidated FY2000 Appropriations Act, P.L. 106-113 (enacting S.1948 The Intellectual Property and Communications Omnibus Reform Act of 1999, Title IV American Inventors Protection Act of 1999). Similarly, Congress has effectively extended continuation practice without the need to file a new application, recodifying the "right" to file continuation applications by permitting requests for continued examinations in which new claims may be added to a pending application (and which obviously will continue to maintain any priority claim they may possess). See 35 U.S.C. § 132(a) & (b); P.L. 106-113. Congress was certainly aware of and thus expressly extended its coverage, in the process impliedly ratifying the long-standing interpretation given to Section 120 by the courts. See, e.g., *Central Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. 164, 185 (1994) (ratification is implied when Congress "reenact[s] statutory language that has been given a consistent judicial construction"). Thus, there can be no doubt that Section 120 (and 132(b)) do not admit of any limitations on the right to file a continuing application seeking priority, and the right of an applicant to a patent based on such a continuing application even if claims are presented "late."

As noted earlier, 35 U.S.C. § 2 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)."). And if Congress were to delegate any substantive lawmaking authority in regard to continuation applications (which it has not), it would likely do so to the courts (as it has historically done with patent law, unlike other laws administered by federal agencies) and not to the Patent Office. Thus the proposed continuation rules would arrogate to the Patent Office and administrative branch powers confined to the legislative or judicial branches. Such arrogation would raise constitutional concerns regarding separation of powers, and thus a construction of the statute that would authorize substantive rulemaking powers under the guise of Section 2 procedural rulemaking authority should be avoided. See, e.g., *I.N.S. v. St. Cyr*, 533 U.S. 289, 299-300 (2001) ("if an otherwise acceptable construction of a statute would raise serious constitutional problems, and where an alternative interpretation of the statute is "fairly possible," ... we are obligated to construe the statute to avoid such problems.") (citing *Ashwander v. TVA*, 297 U.S. 288, 341, 345-348, 56 S.Ct. 466, 80 L.Ed. 688 (1936) (Brandeis, J., concurring)). Much though the Patent Office still may wish that Congress would delegate rulemaking authority to limit

continuation applications, Congress has not done so and only Congress may address any “problem” that may exist (as Henriksen recognized).

Nor was substantive rulemaking authority to limit the number of continuations filed or create new requirements to limit continuing applications provided to the Patent Office in the 1999 American Inventors Protection Act, which granted authority to the Patent Office to establish “such time during the pendency of the application as required by the Director” for submitting priority claims and to “establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.” 35 USC § 120. This authority was carefully circumscribed, and does not provide any suggestion that the Patent Office could restrict continuing applications that make a timely claim for priority. Rather, Congress was aware of the requirement for publication of applications simultaneously adopted, and expressed a discretionary authorization to remedy failures to timely make priority claims. Similarly, *Stevens v. Tamai*, 366 F.3d 1325, 1333 (Fed. Cir. 2004), does not support such a broad reading of the Patent Office’s Section 2(b) rulemaking authority, when authorizing procedures for applicants claiming foreign priority to provide translations of non-English applications to prove priority in interferences. This is particularly true given that the movant, and not the Patent Office, has the burden of proof in interferences. Rather, such requirements for submitted information are similar to the Section 1.105 information request upheld in *Star Fruits N.C. v. United States*, and limited to acquiring information for the examiner (for interferences, the Board) to make its adjudicatory determinations. See 393 F.3d 1277, 1284 (Fed. Cir. 2005).

In summary, Congress in 1952 was (and has been since) fully aware of the potential for late claiming in regard to filing of continuing applications, but has consciously retained the right of applicants to file a series of continuing applications containing new (even broader) claims so long as copendency has been maintained (and the other identified requirements have been met). At most, Section 120 is limited only with regard to the late-claiming case law of prosecution laches (and arguably Section 120 superceded that case law, so that recent cases on prosecution laches are wrongly decided). Simply put, neither Section 120 nor any other rulemaking authority granted to the Patent Office provides authority to issue rules that would restrict the filing of continuation applications (even if equity would preclude their enforcement by prosecution laches), particularly where no intervening rights were at issue. See, e.g., *Symbol Technologies v. Lemelson Medical*, 277 F.3d 1361, 1355-56 (Fed. Cir. 2002) (holding that the 1952 Act preserved the equitable defense of prosecution laches originating in *Woodbridge v. United States*, 263 U.S. 50, 44 S.Ct. 45, 68 L.Ed. 159 (1923) and *Webster Electric Co. v. Splitdorf Electrical Co.*, 264 U.S. 463, 44 S.Ct. 342, 68 L.Ed. 792 (1924), and made subject in its application to the existence of “intervening rights” in *Crown Cork & Seal Co. v. Ferdinand Gutmann Co.*, 304 U.S. 159, 58 S.Ct. 842, 82 L.Ed. 1265, 37 USPQ 351 (1938) and *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 304 U.S. 175, 58 S.Ct. 849, 82 L.Ed. 1273, 37 USPQ 357 (1938)); cf. *id.* at 1369 (Newman, J., dissenting) (“The long-standing rule, until today, is that when the statutory requirements for continuing applications are met, patents are not subject to attack on non-statutory grounds.”). And even if the equitable judicial doctrine of prosecution laches provided a basis for the Patent Office to impose interpretive rules restricting filing of continuation applications, it has not purported to do so here. Further, the limited, existing precedent regarding the equitable judicial doctrine of prosecution laches departs dramatically from the standards for limiting continuations proposed by the rules, and the principle concern for prosecution laches (gaming the patent system by extending the issue date and thus patent term until a market develops for the patented invention) is wholly inapplicable to continuing applications that claim priority but are subject to the post-Uruguay Round Amendments Act term of 20 years from the earliest claimed priority date. See *id.* at 1371 n.3 (noting that the holding in *Symbol Technologies* accomplishes the retroactive effect of limiting continuations and term for pending applications that Congress refused to provide in those amendments).

Significantly, in *In re Bogese*, 303 F.3d 1362 (Fed. Cir. 2002), the Patent Office’s rejection of a particular application based on prosecution laches was upheld. In particular, the Court held that “we think the PTO’s authority to sanction undue delay is even broader than the authority of a district court to hold a patent unenforceable,” and citing the Patent Office’s Section 2 authority stated that the “PTO may impose reasonable deadlines and requirements on parties that appear before it.” *Id.* at 1367-68. As noted by the dissent, however, “equitable determinations are

generally reserved to the courts.” *Id.* at 1370 (Newman, J., dissenting). Not only does the decision in *Bogese* conflate equitable constraints (unenforceability) with legal limitations (invalidation of a patent or rejection of a patent application), but it provides no warrant to extend the Patent Office’s authority to restrict Section 120 rights beyond what equity allows. Because Congress has not granted substantive rulemaking authority to the Patent Office to specify equitable limitations on Section 120 rights, and because there is no case law on which the Patent Office could interpret rules to guide the application of its equitable discretion, it cannot possibly issue interpretive rules that define the contours of such limits. For this reason, the proposed rules lack any intelligible standard (and thus when applied will run afoul of the concern in *Henricksen* of retroactively and unfairly penalizing applicant). In any event, the Patent Office has disclaimed that it is seeking to interpret *Bogese* in promulgating these rules and the concerns underlying *Bogese* have no application to the proposed rules for continuations for patents that will have a term extending 20 years from the priority date. (Similarly, the double patenting doctrine also has little continuing importance – except in regard to term extensions – for claims issuing on priority-claiming continuations. See *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, (Fed. Cir. 2005) (“The double patenting doctrine ... polices the proper application of the patent term for each invention.”).) The proposed rules lack authority for their issuance and should be withdrawn. If there is a “problem” to address, the Patent Office needs to make its case to Congress and obtain a change to the law or substantive rulemaking powers to itself make such a change. Finally, as noted in the comments of Samson Helfgott filed on April 6, 2006, the proposed rules by limiting continuations also would violate the Paris Convention (citing Article 4(G)(2)) and the Patent Cooperation Treaty (citing PCT Rule 51bis). Similarly, Paris Convention Article 4(H) prohibits denial of priority when protection is sought in a domestic application for claims that were not included in an original foreign application, so long as disclosure support exists therefore. Under the “Charming Betsy” principle, reviewing courts (and the Patent Office) should read existing statutes consistent with U.S. treaty obligations. See *Murray v. The Schooner Charming Betsy*, 6 U.S. 64, 111 (1804) (“[A]n act of Congress ought never to be construed to violate the law of nations if any other possible construction remains, and, consequently can never be construed to violate neutral rights, or to affect neutral commerce, further than is warranted by the law of nations as understood in this country.”). Accordingly, if there were any ambiguity (which there is not), the PTO should not interpret Section 120 to provide authority to restrict continuations, so as to assure consistency with international law.

5. Because these are substantive rules promulgated without statutory authority, Chevron deference is not appropriate.

When evaluating legislative rules, the Court will normally accord the agency “Chevron” deference in regard to statutory interpretations that underlie any of the rules – i.e., the reviewing court “must first exhaust the ‘traditional tools of statutory construction’ to determine whether Congress has spoken to the precise question at issue.” *Natural Resources Defense Council, Inc. v. Browner*, 57 F.3d 1122, 1125 (D.C.Cir.1995) (quoting *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 n.9 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984)). If, however, “the statute is silent or ambiguous with respect to the specific issue,” Congress has not spoken clearly, and a permissible agency interpretation of the statute merits judicial deference. *Id.* at 1046-47 (quoting *Chevron*, 467 U.S. at 843, 104 S.Ct. at 2782). Courts will defer to agency interpretations if they are reasonable and consistent with the statutory purpose. See *Troy Corp. v. Browner*, 120 F.3d 277, 285 (D.C.Cir.1997) (noting that an agency’s interpretation must be “reasonable and consistent with the statutory purpose”); *City of Cleveland v. U.S. Nuclear Regulatory Comm’n*, 68 F.3d 1361, 1367 (D.C.Cir.1995) (providing that an agency’s interpretation must be “reasonable and consistent with the statutory scheme and legislative history”). However, a court will not uphold an interpretation “that diverges from any realistic meaning of the statute.” *Massachusetts v. Department of Transp.*, 93 F.3d 890, 893 (D.C.Cir.1996).

Courts will not review agency rules for Chevron deference, however, when the rules fail to accord reasoned decisionmaking by failing to explain the basis for any change from a proposed rule. See, e.g., *General Electric Co. v. U.S. Dept. of Commerce*, 128 F.3d 767, 774 (D.C. Cir. 1997) (“We would ordinarily analyze NOAA’s interpretation of OPA under Chevron, asking first whether Congress spoke clearly to the issue or, if not, whether NOAA’s interpretation of the statute is permissible and thus entitled to deference. *Chevron*, 467 U.S. at 842-43, 104 S.Ct. at 2781-82. The parties disagree about whether NOAA is even entitled to Chevron deference given the primary role that EPA and the Coast Guard play in oil removal. See, e.g., *Rapaport v. United States Dep’t of Treasury*, 59 F.3d 212, 216-17 (D.C.Cir.1995) (holding that the Office of Thrift Supervision receives no deference for its interpretation of the Federal Deposit Insurance Act because it shares the administration of the statute with other agencies). We need not resolve this dispute, however, or even the underlying question of statutory authority because, by not explaining the difference between the residual removal authority of section 990.53(b)(3) and the language of the proposed rule, NOAA failed to exercise reasoned decisionmaking.”) Chevron deference also does not apply to interpretive rules for which Congress has not delegated legislative rulemaking authority, but rather only “Skidmore” deference based on the “thoroughness” of the agency’s consideration and the “soundness” of the agency’s reasoning. *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996) (citing *E.E.O.C. v. Arabian American Oil Co.*, 499 U.S. 244, 257, 111 S.Ct. 1227, 1235, 113 L.Ed.2d 274 (1991); *General Elec. Co. v. Gilbert*, 429 U.S. 125, 140-46, 97 S.Ct. 401, 410-13, 50 L.Ed.2d 343 (1976); *Skidmore v. Swift & Co.*, 323 U.S. 134, 140, 65 S.Ct. 161, 164, 89 L.Ed. 124 (1944)). See also *Arnold Partnership v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004) (“This court reviews statutory interpretation, the central issue in this case, without deference. *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed.Cir.1996).”).

Thus, if the agency lacks authority to promulgate substantive rules, it cannot seek Chevron deference and claim that the rules themselves are only interpretive or procedural. Interpretive rules, procedural rules, and statements of agency policy, however, do not need to undergo notice and comment rulemaking (which also is not required when good cause exists to dispense with such procedures), unless otherwise required by statute. 5 USC 553(b). The line between interpretive or procedural rules and substantive rules is not easy to distinguish, but the Agency cannot itself change or create the legal standard absent a substantive delegation of rulemaking authority to establish the legal standard. See, e.g., *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 927 (Fed. Cir. 1991) (“A rule is ‘substantive’ when it ‘effects a change in existing law or policy’ which ‘affect[s] individual rights and obligations.’ *Cubanski v. Heckler*, 781 F.2d 1421, 1426 (9th Cir.1986) vacated as moot, sub nom. *Bowen v. Kizer*, 485 U.S. 386, 108 S.Ct. 1200, 99 L.Ed.2d 402 (1988); see also *Chrysler Corp. v. Brown*, 441 U.S. 281, 302, 99 S.Ct. 1705, 1717, 60 L.Ed.2d 208 (1979) (‘affecting individuals’ existing rights and obligations’); *Gosman*, 573 F.2d at 39 (change existing law or policy). To be ‘substantive’, a rule must also be promulgated pursuant “to statutory authority ... and implement the statute.” *Cubanski v. Heckler*, 781 F.2d at 1426 [citation omitted]; see also *Chrysler Corp.*, 441 U.S. at 302-03, 99 S.Ct. at 1717-18. In contrast, a rule which merely clarifies or explains existing law or regulations is ‘interpretative.’ See *American Hosp. Ass’n*, 834 F.2d at 1045; *Powderly v. Schweiker*, 704 F.2d 1092, 1098 (9th Cir.1983); *Gosman*, 573 F.2d at 39”); *Syncor Int’l Corp. v. Shalala*, 127 F.3d 90, 94-95 (D.C.Cir.1997) (“An interpretative rule, on the other hand, typically reflects an agency’s construction of a statute that has been entrusted to the agency to administer. The legal norm is one that Congress has devised; the agency does not purport to modify that norm, in other words, to engage in lawmaking. To be sure, since an agency’s interpretation of an ambiguous statute is entitled to judicial deference under *Chevron*, it might be thought that the interpretative rule—particularly if it changes a prior statutory interpretation as an agency may do without notice and comment—is, in reality, a change in the legal norm. Still, in such a situation the agency does not claim to be exercising authority to itself make positive law. Instead, it is construing the product of congressional lawmaking ‘based on specific statutory provisions.’ See *United Technologies Corp. v. U.S. EPA*, 821 F.2d 714, 719 (D.C.Cir.1987); see also *Connecticut Dep’t of Children and Youth Servs. v. HHS*, 9 F.3d 981, 984 (D.C.Cir.1993) (interpretative rule ‘purport[s] to define statutory terms’); *National Latino Media Coalition v. FCC*, 816 F.2d 785 (D.C.Cir.1987). That is why we have said that ‘[t]he distinction between an interpretative rule and substantive rule ...

likely turns on how tightly the agency's interpretation is drawn linguistically from the actual language of the statute.' [See *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 588 (D.C.Cir.1997)]. ... A substantive rule has characteristics of both the policy statement and the interpretative rule; it is certainly in part an exercise of policy, and it is a rule. But the crucial distinction between it and the other two techniques is that a substantive rule modifies or adds to a legal norm based on the agency's own authority. That authority flows from a congressional delegation to promulgate substantive rules, to engage in supplementary lawmaking. And, it is because the agency is engaged in lawmaking that the APA requires it to comply with notice and comment."); *Batterton v. Marshall*, 648 F.2d 694, 705 (D.C. Cir. 1980) ("An interpretative rule is one which does not have the full force and effect of a substantive rule but which is in the form of an explanation of particular terms in an Act.") (emphasis added). Similarly, a procedural rule cannot modify or add to a legal norm and should not affect the outcome of agency adjudications. See, e.g., *Batterton*, 648 F.2d at 707 & n.70 ("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).").

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.*"). It is abundantly clear that the proposed rules – which would codify substantial discretion according to standards nowhere recited in the statute – do not purport to be interpretive rules regarding the language and limits of Section 120 (and as discussed in Section \_\_\_ below, they could not validly do so). As the proposal notes, the proposed rules would require applicants: (1) to "show that the third and following applications ... are necessary to advance prosecution"; (2) for "any second or subsequent continuing application [to] show to the satisfaction of the Director that the amendment, argument, or evidence could not have been submitted" earlier; and (3) to "show that later filed applications ... are necessary to claim the invention – and do not contain unnecessarily delayed evidence, arguments, or amendments that could have been presented earlier." 71 Fed. Reg. at 50 (emphasis added). Similarly, the proposed rules would impose a presumption of double patenting whenever there is "substantially overlapping disclosure," which can be rebutted "by explaining to the satisfaction of the Director how the application contains only claims that are patentably distinct" or "submit a terminal disclaimer." 71 Fed. Reg. at 55 (emphasis added). These conflicting standards clearly are the product of (unauthorized) substantive lawmaking, not interpretation. Nor are they merely procedural rules, as the rules not only shift the burden of production and thus result in rejections when applicants do not come forward with evidence but also would require determinations in regard to any evidence put forward under a highly discretionary, new legal standard for continuations and for double patenting that "encodes a substantive value judgment" and that is so poorly articulated in the proposal ("to the satisfaction of the Director") as to be inherently arbitrary in its prospective application. *Public Citizen*, 276 F.3d at 640; *In re Henricksen*, 399 F.2d 253, 261-62 (C.C.P.A. 1968) ("The action of the board is akin to a retroactive rule change which may have the effect of divesting applicants of valuable rights to which, but for the change in Patent Office position brought about by the board's decision, they were entitled. Nothing appears in the Patent Office Rules of Practice or the Manual of Patent Examining Procedure which sanctions such a result.").

Although the line between legislative rules, interpretive rules, procedural rules, and statements of agency policy are not clear, an agency also 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).”) Prior to the proposed continuation rules, the Patent Office has interpreted Section 120 as not containing any restrictions remotely resembling these proposed requirements, and does not purport to justify them based on interpretation of intervening case law. See, e.g., 71 Fed. Reg. 50; 50 Fed. Reg. 9368, 9369 (Mar. 7, 1985) (noting the change to Section 120 to permit divisionals to claim priority when not all inventors in the joint application are the same as those in an earlier application, without suggesting any limitation on the right to file a continuation other than written description support; “in order for a claim to be entitled to the benefit of an earlier pending application, the subject matter of the claim of the later application would have to be disclosed in the earlier application”); 62 Fed. Reg. 53132, 53143, 53145 (Oct. 10, 1997) (revising continuation rules without suggesting that any legal restrictions might apply to filing “a chain of applications” so long as the applications properly referenced the earlier applications for purposes of priority; taking “under advisement” a comment suggesting that the Office address the “cause of the filing of a continuing application” in regard to the need for second action final practice); 65 Fed. Reg. 50092, 50101 (Aug. 16, 2000) (noting in regard to requests for continued examination that first office actions may be made final under certain conditions if the applicant does not advance prosecution, but recognizing that continued examination may be requested under Section 132(a) and (b) “with or without amendment”); 65 Fed. Reg. 57024, 57047 (Sept. 20, 2000) (also revising continuation rules without suggesting any such legal restrictions; noting that continued prosecution applications filed after November 29, 2000 should include amended claims for publication so as to assure that applicants “can take full advantage of provisional rights under 35 U.S.C. 154(d).”); 66 Fed. Reg. 67087, 67090 (Dec. 28, 2001) (noting that Section 119(e) eliminated the requirement for copendency in order to claim the benefit of priority to a provisional application); 68 Fed. Reg. 70996, 70998 (Dec. 22, 2003) (discussing in regard to a “bypass’ continuation application” that the applicant may file a petition in the abandoned international application to claim an earlier priority date). Accordingly, the proposed rules cannot be treated as interpretive rules and are subject to notice and comment rulemaking because they clearly change any prior interpretations without relevant intervening legal authority. Cf. *Animal*

Legal Defense Fund v. Quigg, 932 F.2d at 928 (treating Commissioner's rule as interpretive of Board decisions and thus as not "a 'change' in the law by the Commissioner.") (emphasis in original).

Historically, the PTO has treated examination and continuation 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;"). But the continuation rules proposed by the agency go much further and adopt additional substantive (but not clearly identified) value judgments regarding when an application will not be entitled to be filed and provided with priority under Section 120, and when such an application will be considered invalid for double patenting. See, e.g., 71 Fed. Reg. at 50, 55. The fact that the proposed rules would adopt presumptions that shift the burden of production does not deprive them of their substantive character, as they will adversely affect individual rights in the absence of applicants coming forward with evidence and thus create new obligations for applicants to produce evidence. Further, they do so according to standards that are clearly contrary to law and beyond statutory authority in regard to filing and receiving priority for continuations and may be contrary to law and beyond agency authority in regard to double patenting. The fact that the agency is shifting the burden without clearly identifying the standard for such determinations itself demonstrates the arbitrary and capricious nature of the rulemaking, given that the failure to provide prior notice of the standards for rejecting continuation applications has already been found to violate Section 120. See *In re Henriksen*, 399 F.2d at 261-62; 71 Fed. Reg. at 50 ("In addition, in those earlier cases the Office had not promulgated any rules, let alone given the public adequate notice of, or an opportunity to respond to, the ad hoc limits imposed) (citing *Henriksen*, at 399 F.2d at 261-62).

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)).

EXHIBIT A

From: Clarke, Robert [Robert.Clarke@USPTO.GOV]

Sent: Wednesday, May 03, 2006 12:54 PM

To: Alderucci, Dean - Cantor Fitzgerald

Subject: RE:

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

Robert A. Clarke

Deputy Director

Office of Patent Legal Administration

571 272 7735

-----Original Message-----

From: Alderucci, Dean - Cantor Fitzgerald [mailto:DAlderucci@cantor.com]

Sent: Wednesday, May 03, 2006 12:49 PM

To: Clarke, Robert

Subject:

May 3, 2006

Robert Clarke

Deputy Director

Office of Patent Legal Administration

Office of the Deputy Commissioner for Patent Examination Policy

U.S. Patent and Trademark Office

Dear Bob,

Thanks very much for returning my call this morning.

I was looking for anything else that might be in the "rules docket" (Docket No. 2005-P-066 and -067) for the PTO's proposed rules. You mentioned that there was no actual docket.

From this I understand that there is no other supporting documents, studies, etc. for the proposed rules – just the notices themselves in the Federal Register.

If this is true, please confirm my understanding. If I have misunderstood, please contact me.

Best regards,

Dean Alderucci

(212) 829-7009 (office)

(212) 308-7505 (direct fax)

(646) 523-7584 (mobile)