1992

The Effect of New Rule 56 on the Law of Inequitable Conduct

R. Carl Moy
Mitchell Hamline School of Law, carl.moy@mitchellhamline.edu

Publication Information

Repository Citation
http://open.mitchellhamline.edu/facsch/153

This Article is brought to you for free and open access by Mitchell Hamline Open Access. It has been accepted for inclusion in Faculty Scholarship by an authorized administrator of Mitchell Hamline Open Access. For more information, please contact sean.felhofer@mitchellhamline.edu.
The Effect of New Rule 56 on the Law of Inequitable Conduct

Abstract
This article discusses Rule 56 of the Patent and Trademark Office. Part II discusses changes from the old to the new Rule 56, and examines the former’s relationship to the law of inequitable conduct. Part III elaborates on the current status of the PTO’s rulemaking efforts, and Part IV is focused on the new Rule under the APA. Parts V and VI are about new Rule 56 as a hortatory statement and common-law jurisprudential limitations, respectively. The author ultimately concludes that the PTO could have chosen to approach the Federal Circuit as an amicus without a prior rulemaking proceeding. That choice might have allowed the PTO to act more quickly than the almost three years it has taken to reach this stage in the rulemaking process. If so, the PTO might have substantially changed the law of inequitable conduct already.

Keywords
Rulemaking, patents, new Rule 56, old Rule 56, PTO, law of inequitable conduct

Disciplines
Intellectual Property Law

This article is available at Mitchell Hamline Open Access: http://open.mitchellhamline.edu/facsch/153
I. INTRODUCTION

Patent owners and members of the patent bar generally agree that allegations of inequitable conduct are appearing too frequently in patent litigation. They have laid blame for this situation on the law that operates in this area. In their view, the law of inequitable conduct is either too vague, or requires too much from the patent applicant during prosecution. According to this view, the courts have been either unwilling or unable to produce a body of law capable of solving the problem.

---

*Assistant Professor, William Mitchell College of Law; Of Counsel, Merchant, Gould, Smith, Edell, Welner & Schmidt, P.A.

1. E.g., Lee, Introduction: The Special Ad Hoc AIPLA Committee on Rule 56 and the Evolution of Proposed Rule 57, 16 AIPLA Q.J. 1 (1988) ("Fraud and inequitable conduct charges in litigation have proliferated in recent years.""); [M]any practitioners and patent owners feel that indeed 'the sky is falling.'


3. E.g., PTO Notice of Proposed Rulemaking—Duty of Disclosure, 56 Fed. Reg. 37322 (Aug. 8, 1991) (hereinafter "Second PTO Rulemaking Notice") ("The current definition of information material to patentability has been criticized as vague and because it does not correlate with any concept applied in other areas of the patent law."); Lynch, 16 AIPLA Q.J. at 8 (asserting law to be unclear); Wegner, 16 AIPLA Q.J. at 60.
In response to this problem, the Patent and Trademark Office has promulgated a new Rule 56, which defines the duty patent applicants have to disclose information to the PTO. The new rule at-

---

4 Section 1.56, Title 37, C.F.R. The text of the new rule reads as follows:
§ 1.56 Duty to disclose information material to patentability.
(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability if any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and
(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
(2) It refutes, or is inconsistent with, a position the applicant takes in:
   (i) Opposing an argument of unpatentability relied on by the Office, or
   (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;
(2) Each attorney or agent who prepares or prosecutes the application; and
(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

tempts to define a lesser duty.\textsuperscript{5}

The substantive language of the new rule has generated significant comment and debate.\textsuperscript{6} To date, however, the PTO and others have focused little attention on the mechanism by which the new rule will affect litigation. Specifically, many participants appear to assume that simply changing Rule 56 will work a corresponding change in the law of inequitable conduct.\textsuperscript{7}

Under the relevant law, the PTO’s promulgation of new Rule 56 will likely not have this effect. Changing the standard in the rule will not compel the courts to adopt that standard as the law of inequitable conduct. In fact, new Rule 56 is outside both the PTO’s rulemaking authority and even the Administrative Procedure Act.\textsuperscript{8} As a result, the courts will be free to act on their own perceptions of whether the provisions of new Rule 56 are wise.

\section*{II. OLD RULE 56 AND ITS RELATIONSHIP TO THE LAW OF INEQUITABLE CONDUCT}

The first paragraph of old Rule 56 set out the patent applicant’s “duty of candor and good faith toward the Patent and Trademark
The duty included the obligation "to disclose to the office information . . . which is material to the examination of the application." Information was "material" where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue a patent.\(^9\) The term "inequitable conduct" refers to a set of legal rules that is different from, but related to, that of the duty-to-disclose. Inequitable conduct consists of unfair activities on the part of the patent owner that will result in a court refusing to enforce the subject patent, even though the patent may be valid and infringed.\(^10\) Perhaps the most common basis for inequitable conduct, and the one with which this article is concerned, involves allegations that the patent owner acted unfairly in the prosecution of the patent.\(^11\) The doctrine

---

\(^9\) Paragraphs (a) and (b) of old Rule 56 read as follows:
§1.56 Duty of disclosure; fraud, striking or rejection of applications.
(a) A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such 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. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application.
(b) Disclosures pursuant to this section must be accompanied by a copy of each foreign patent document, non-patent publication, or other non-patent item of information in written form which is being disclosed or by a statement that the copy is not in the possession of the person making the disclosure and may be made to the Office through an attorney or agent having responsibility for the preparation or prosecution of the application or through an inventor who is acting in his or her own behalf. Disclosure to such an attorney, agent or inventor shall satisfy the duty, with respect to the information disclosed, of any other individual. Such an attorney, agent or inventor has no duty to transmit information which is not material to the examination of the application.


\(^12\) The AIPLA has estimated that allegations of this type occur in 80% of patent-infringement litigations. E.g., Lee, AIPLA Bull. 88 (Oct.–Nov. 1991).
has developed entirely by common law;14 Title 35, U.S.C. refers nowhere to it.15

On its face, old Rule 56 addressed only the internal PTO standard for determining what information must be submitted to the PTO during prosecution. The rule is related to inequitable conduct, however, because the Federal Circuit has defined part of the legal standard in that area with references to Rule 56. Specifically, inequitable conduct cannot occur unless the patent applicant’s misrepresentations to the PTO are material. The Federal Circuit currently defines “material” in that sense according to the standard set out in old Rule 56.16

III. THE PRESENT STATUS OF THE PTO’S RULEMAKING EFFORTS

Because of the relationship between inequitable conduct and an applicant’s duty to disclose, both the PTO and the concerned interest groups hope that changing the rule governing the duty to disclose


15 The term “inequitable conduct” appears nowhere in Title 35, U.S.C. See PTO Policy Statement on Inequitable Conduct Determinations (Sept. 8, 1988), reprinted in 36 PTCI 616 (Oct. 6, 1988). The consequence of a finding of inequitable conduct, unenforceability, appears only in Section 282 as one of the defenses that must be affirmatively pled. Section 282 does not differentiate between inequitable conduct and other unfair activities, such as misuse and antitrust violations, that also give rise to unenforceability. See Digital Equipment Corp. v. Diamond, 653 F.2d 701, 708 (1st Cir. 1981) (observing, in the context of an examination of the Commissioner’s authority to promulgate old Rule 56, that the term “fraud” does not appear in Title 35, U.S.C.).

Congress has recently declined to provide a statutory definition of inequitable conduct. See the summary at 36 PTCI 63 (May 19, 1988) and 134 Cong. Rec. S14434-03, reprinted at 1988 W.L. 180647 at 10 (Cong. Rec.).

16 E.g., Am Hoist V. Sowa, 725 F. 2d at 1363.
will change the legal standard for inequitable conduct. As an initial step in this direction, the PTO on March 17, 1989, proposed dropping Rule 56 and redefining the duty to disclose in a new Rule 57. The proposed new Rule 57 would have required the applicant to disclose only information that the applicant knows or should have known would render unpatentable any pending claim.

The purpose of this new Rule was to limit inequitable conduct to situations of "but for" materiality; inequitable conduct would occur only when the PTO would not have allowed the particular patent to issue, but for the applicant's failure to disclose the subject information. After substantial proceedings, the PTO withdrew the proposed rule in August 1991.

---

17 E.g., PTO Notice of Final Rulemaking, 57 Fed. Reg. 2023 ("The rule as promulgated will provide greater clarity and hopefully minimize the burden of litigation on the question of inequitable conduct . . . "); Lee, AIPLA Bull. 90 (Oct.-Nov. 1991) (reporting position of PTO); Statement of Wamsley on behalf of the IPO, 42 PTCJ 575 (inequitable conduct implicit in PTO's rulemaking); accord, Statement of Jan Jancin on behalf of the ABA, id. See generally the papers collected as 16 AIPLA Nos. 1, 2 (1988).

This hope may rest on an unduly optimistic view of the relevant Federal Circuit decisions. The Federal Circuit has carefully avoided relying on the authority of Rule 56 when discussing inequitable conduct. Rather, the court has found the standard set out in Rule 56 persuasive on its merits. E.g., AmHoist v. Sowa, 725 F.2d at 1363. The standard for inequitable conduct need not be as lenient as the PTO's imposition of a duty to disclose information. Cf. Digital Equipment Corp. v. Diamond, 653 F.2d 701, 708 (1st Cir. 1981) (upholding the 1977 version of Rule 56; duty imposed by PTO no more stringent than the standard for inequitable conduct); Norton v. Curtiss, 433 F.2d 779 (CCPA 1970) (same). Simply changing the standard in Rule 56 therefore may not change the standard for inequitable conduct, even if the Federal Circuit holds new Rule 56 to control the PTO's handling of its own internal affairs.

This is significantly different from the mechanism Wamsley envisioned for Rule 56 in 1983. He asserted that a patentee's failure to comply with the PTO's duty to disclose regulations should affect infringement and validity determinations directly. Wamsley, Part II, 64 JPOS at 562.

It appears likely that the PTO will ask the Federal Circuit to equate the standard of inequitable conduct with the duty to disclose in new Rule 56. See supra note 7. In that event the court is likely to address the degree to which new Rule 56 is controlling, despite the prior decisions.


20 E.g., 54 Fed. Reg. at 11336 ("Section 1.57(b), as proposed, represents a significant departure from the standard defined under § 1.56. It adopts a "but for" standard of materiality . . . ").

21 The PTO formally withdrew its First Notice of Proposed Rulemaking at 56 Fed. Reg. 37322 (Aug. 6, 1991). It had indicated earlier, however, that it was abandoning the rulemaking effort. See the remarks of Commissioner Manbeck at the 1990 Chicago meeting of the ABA Section of Patent, Trademark, and Copyright Law, reprinted in 40 PTCJ 323 (Aug. 16, 1990). This change in the PTO's position roughly coincided with the Hon. Harry Manbeck replacing Donald Quigg as Commissioner of Patents and Trademarks. Lee, AIPLA Bull. 90 (Oct.-Nov. 1991).
Simultaneously, the PTO brought forward a proposal for a new and different Rule 56.\(^{22}\) Under this proposed new rule, information would be material if

(1) It creates, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It supports a position of unpatentability taken by the office which the applicant disputes, or it is inconsistent with a position in support of patentability on which the applicant relies.\(^{23}\)

Thus, the proposed new rule sought to impose an intermediate standard of disclosure, more lenient than the standard of present Rule 56, but more stringent than the "but for" standard of earlier-proposed Rule 57.\(^{24}\) The period for the public to submit comments on the new Rule 56 closed on October 8, 1991.\(^{25}\) The PTO held a public hearing on the matter that same day.\(^{26}\)

The PTO promulgated its new Rule 56 on January 17, 1992.\(^{27}\) In response to the public comments received, it made a number of changes from the proposed text.\(^{28}\) Among them, the rule now defines the term "material" somewhat differently. The new rule repeats the criterion set out in originally proposed subparagraph (1). The alternate criteria in subparagraph (2) of the new rule, however, are narrower than the originally proposed provision. That subparagraph now states that information is material if

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.\(^{29}\)

**IV. NEW RULE UNDER THE APA**

Generally speaking, the APA classifies agency rulemaking actions as either interpretive rules, or procedural and internal rules,
statements of policy, or substantive rules. Unfortunately, it does not define any of these terms. Instead, the courts have to do so. Interpretive rules, as the name suggests, "are statements as to what the administrative officer thinks the statute or regulation means." In general, the courts have defined rules of practice and procedure "as including agency rules that detail the procedures and methods to be used in executing any inquiry." A statement of policy is merely an announcement to the public of the policy which the agency hopes to implement in future rulemakings or adjudications. A general statement of policy, like a press release, presages an upcoming rulemaking or announces the course of action which the agency intends to follow in future adjudications.

Substantive rules are generally considered to be "any rule issued in accordance with law that is not an organizational, procedural, interpretive, or statement of policy announcement." While an agency must provide notice and comment before issuing a substantive rule, it need not undertake such procedures

---

31 See 5 U.S.C. § 553(b)(A). E.g., Brown Express, Inc. v. United States, 607 F.2d 695 (5th Cir. 1979) (noting failure to provide definition of interpretive rules); 3 Stein § 15.07[5] (discussing failure to define rules of procedure and practice); 3 Stein § 15.07[4] (discussing failure to define statements of policy).
32 Brown Express, 607 F.2d at 700 (quoting the cited passage from Gibson Wine Co. v. Snyder, 194 F.2d 329, 331 (D.C. Cir. 1952) as "[p]erhaps the most often cited definition of interpretive rules"). Interpretative rules are "rules or statements issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." Attorney General's Manual on the APA, at 30 n.3 (1947) (citing authorities).
33 3 Stein § 15.07[5] (citing authorities).
34 Pacific Gas & Electric Co. v. FPC, 506 F.2d 33, 39 (D.C. Cir. 1974). Stein has described statements of policy as "announc[ing] an agency's policy plan for enforcement of a particular statute. They impose no rights or obligations and have no substantial impact on affected members of the public.
3 Stein § 15.07[4] (citing authorities).

Substantive regulations—Many statutes contain provisions which become fully operative only after exercise of an agency's rule-making function. Sometimes the enjoyment of a privilege is made conditional upon regulations. Sometimes the extent of an affirmative duty is to be fixed by regulations. Sometimes a prohibition is made precise by regulations. In such instances the striking characteristic of the legislation is that it attaches sanctions to compel observance of the regulations by imposing penalties upon or withholding benefits from those who disregard their terms.


Professor Davis refers to substantive rules as "legislative," due to their relation to Congress' delegation of its legislative authority to the agency. See 2 Davis, Administrative Law §§ 7.8, 7.9 at 47 (2d ed. 1978) (hereinafter "Davis"); and the discussion infra at pp. 16–20.
before taking other forms of action. The procedures followed by the PTO with regard to new Rule 56 are consistent with the notice and comment required before issuing a substantive rule. The PTO, however, has not stated which type of action it considers new Rule 56 to be.

The assignment of new Rule 56 into these categories is a matter of some importance. Once promulgated, substantive rules are said to have the "force and effect of law," and bind the courts. Thus, if the PTO's new Rule 56 were considered a substantive rule, it would arguably bind the Federal Circuit to the PTO's viewpoint. Agency actions that fall into the other categories, in contrast, do not bind the courts. Still further, some decisions assert that the amount of deference that a non-substantive agency action will be given will vary depending on the category into which the action falls.

The relationship between new Rule 56 and the APA may be important for another reason. In a 1991 decision, Animal Legal Defense Fund v. Quigg, the Federal Circuit for the first time expressly referred to the APA at length in determining whether a PTO action

38 See the Second PTO Notice of Proposed Rulemaking, 56 Fed. Reg. 37321, 42 PTCJ 349. Wamsley asserted in 1983 that the PTO used noticed-and-comment procedures for all its rules. Wamsley, Part II, 64 JPOS at 543. That statement does not appear to describe the current PTO practice. See the procedures used in connection with the action at issue in Animal Rights Legal Defense Fund v. Quigg, 932 F.2d 920, discussed infra at pp. 15–16. The PTO now appears to engage in this type of summary action commonly. See, e.g., the Commissioner's recent notices regarding fraud and inequitable conduct in interference proceedings, infra pp. 32–33.
39 It is interesting to note that Wamsley asserts the PTO was unsure in 1977 whether old Rule 56 would have the "force and effect of law," by which he probably means to refer to whether the rule was substantive. Wamsley, Part I, 64 JPOS 519. Wamsley was Director of the PTO's Trademark Examining Operation at the time he made the statement.
40 Stein § 13.03[1]; 2 Davis § 7:13.
41 As to interpretive rules, see generally 3 Stein 15.07[3]. Interpretations . . . are not binding upon those affected for, if there is disagreement with the agency's view, the question may be presented for determination by a court.


See however, the discussion of Chevron, U.S.A. v. Natural Resources Defense Council, 467 U.S. 837 (1984), infra note 73. The uncertainty concerning deference to interpretive rulings is of little moment in any event, since it appears clear that new Rule 56 is not an interpretive rule. See the discussion infra pp. 27–30.

As to statements of policy, see generally 2 Davis § 7:5.
42 See 2 Davis § 7:5 at 24–25 and the discussion of Chevron, 467 U.S. 837, infra note 73.
43 932 F.2d 920.
was valid. The sophistication and rigorousness of the analysis in Animal Legal Defense Fund, penned by Chief Judge Nies for a five-judge panel, stands in sharp contrast to earlier treatments of similar administrative-law issues by the Court of Customs and Patent Appeals. It suggests that the Federal Circuit will scrutinize new Rule 56 carefully in light of accepted principles of administrative law.

A. Rule 56 as a Substantive Rule

Careful scrutiny is unlikely to result in new Rule 56 being characterized as a substantive rule. An agency's power to promulgate substantive rules derives from the Congress' delegation of its legislative authority. In other words, Congress must have delegated authority to an agency for the agency to adopt substantive rules. Substantive rules that extend beyond that authority are invalid.

Section 6 of Title 35, U.S.C., sets forth Congress' delegation of its legislative authority to the PTO. The language of that section appears to be too narrow to support new Rule 56 for several reasons. Section 6 limits the PTO's authority to rules that are "not inconsistent with law." The term "law" in Congress' delegation is broad enough to encompass the common law developed in the courts. It is abun-

---

44 Animal Legal Defense Fund dealt with an interest group's challenge to the PTO's decision to interpret 35 U.S.C. § 101 to include multi-celled organisms as patentable subject matter. The PTO had issued its decision in a notice without first providing interested persons with notice-and-comment. The interest group was therefore attempting to characterize the PTO action as a substantive rule, issued without proper procedure. The Federal Circuit held the action to be interpretive, and therefore exempt from the notice-and-comment provisions of the APA. Id. at 927-31.


46 See generally 1 Stein § 3.03.


49 He [the Commissioner] may, subject to the approval of the Secretary of Commerce, establish regulations, not inconsistent with law, for the conduct of proceedings in the Patent and Trademark Office.


50 See note 49. Ethicon v. Quigg, 849 F.2d at 1425 ("The ultimate question here is whether the Commissioner's exercise of authority to stay a reexamination purportedly pursuant to section 6(a) conflicts with laws governing reexaminations specifically. If it does, it cannot stand.").

51 Wamsley, Part II, 64 JPOS at 556 ("PTO rules must be consistent both with statutory law and with the established case law of the courts.").
dantly clear, however, that the primary purpose of new Rule 56 is not to describe the law of inequitable conduct as defined in the cases. Rather, the rule is plainly intended to set forth a standard that is significantly different from the current law. 52 Thus, new Rule 56 is expressly outside the Commissioner's legislative authority. 53

In addition, the Commissioner of Patents and Trademarks has been authorized only to "establish regulations . . . for the conduct of proceedings in the Patent and Trademark Office." 54 This is much narrower than the delegations that other agencies have received. 55 For example, Congress has phrased its delegation to the Food and Drug Administration in the following terms:

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary. 56

Congress' delegation appears to limit the Commissioner's authority to matters occurring within the PTO. In fact, however, it is entirely possibly that Congress has delegated to the Commissioner only the authority to promulgate the types of rules concerning procedure and internal management that are referred to in 5 U.S.C. §

52 See the discussion supra pp. 8-11. Other aspects of proposed Rule 56 in addition to the new standard of materiality are also different from the current law. For example, "[p]ushing misconduct would be much liberalized." Lee, AIPLA Bull. 90 (Oct.-Nov. 1991). In addition, the new rule would eliminate the adverse consequences of A.B. Dick Co. v. Burroughs Corp., 798 F.2d 1392 (Fed. Cir. 1986). Remarks of Lee on behalf of the AIPLA at the October 8, 1991 hearing, 42 PTCJ 574.

The now-abandoned Rule 57, of course, was also designed to present a standard different from the current law. See, e.g., supra pp. 8-10.

In contrast to the present rulemaking efforts, the 1977 version of Rule 56 was promulgated to codify the case law as it existed at the time.

The section codifies the existing Office policy on fraud and inequitable conduct, which is believed consistent with the prevailing case law in the Federal Courts. 42 Fed. Reg. 5589. See Wamsley, Part I, 64 JPOS at 518. This same relationship was apparently critical to the decision of the Court of Customs and Patent Appeals to uphold an earlier version of Rule 56 in Norton v. Curtiss, 433 F.2d at 792. See infra pp. 27-30.

53 According to the AIPLA, the PTO will argue to the courts that the standard of materiality in proposed Rule 56 is not inconsistent with the language of present Rule 56. Lee, AIPLA Bull. 92 (Oct.-Nov. 1991). Based on the foregoing discussion, however, this argument is likely to be held insufficient. The appropriate question is whether the standards of proposed Rule 56 are consistent with the existing caselaw, not with the PTO's prior rulemaking efforts.

54 See supra note 49.

55 A common formulation of delegation is to empower the agency to "make . . . such rules and regulations as may be necessary to carry out the provisions of this Act." See Mourning v. Family Publications Service, Inc., 411 U.S. 356, 369 (1973).

56 21 U.S.C. § 371(a). Even the broad language of this delegation did not forestall serious debate over the Secretary's ability to promulgate substantive, as opposed to merely interpretive, rules. See National Nutritional Foods Association v. Weinberger, 512 F.2d 688 (2d Cir. 1975).
If this view of Congress' delegation is correct, the PTO may have no power to promulgate substantive rules. If this view of Congress' delegation is correct, the PTO may have no power to promulgate substantive rules.

There appears to be a significant possibility that such an interpretation is the correct one. The legislative history of Section 6, 57 See generally Stein § 15.07[5].

58 The PTO has taken a curious series of positions regarding its power to revise Rule 56. Initially, in response to the AIPLA's resolution calling for the definition of "materiality" to be changed to a but-for standard, the PTO asserted that such a change "would require legislation." Tegtmeyer, The Patent and Trademark Office View of Inequitable Conduct or Attempted Fraud in the Patent and Trademark Office, 16 AIPLA Q.J. 88, 95 (1988). See also the PTO's view of the AIPLA's call to liberalize the standard for purging misconduct, id. at 94. Within a year, however, the PTO was proposing a but-for standard of materiality in now-abandoned Rule 57. See supra pp. 8–10. No intervening legislation had passed. See supra note 15.

Thereafter, when Mr. Manbeck became Commissioner, the PTO dropped the effort to promulgate Rule 57 in favor of retaining the materiality standard "in present Rule 56." One reason given was that present Rule 56 "is the standard followed by the Federal Circuit." "[T]he PTO must act in accordance with the Court decisions on inequitable conduct . . . ." 40 PTCJ 323 (Aug. 18, 1990) (reprinting text of Commissioner's statement to the ABA's Section of Patent, Trademark, and Copyright Law at its Chicago, 1990 meeting).

The standard in new Rule 56 is contrary to the standard followed by the Federal Circuit, see supra note 52, apparently reflecting yet another change in position. The PTO now asserts that "[t]he amendment to § 1.56 comes with the authority of the Commissioner for establishing regulations." PTO Notice of Final Rulemaking, 57 Fed. Reg. 2024. See infra p. 27.

59 See e.g., the following language in Animal Legal Defense Fund, 932 F.2d at 930: [T]he authority granted in section 6 is directed to the "conduct of proceedings" before the Office. A substantive declaration with regard to the Commissioner's interpretation of the patent statutes . . . does not fall within the usual interpretation of such statutory language.

Accord, McCrady, Patent Office Practice at 18 (2d ed. 1946). This same observation should apply to PTO actions interpreting common law. See Animal Legal Defense Fund, 932 F.2d at 928.

In connection with whether the PTO's delegation excludes substantive rulemaking power, it may be useful to compare that delegation to the Privacy Protection Study Commission's delegation in the Privacy Act, Pub. L. No. 93-579, 88 Stat. 1896 (1974). The Commission is authorized to adopt, amend, and repeal regulations governing the manner of its operations, organization, and personnel. Id. at § 5(e)(4).

This appears to be an example of Congress expressly excluding substantive rulemaking authority from its delegation to an agency. The legislative history of the Privacy Act reveals that the provision was specifically intended to "insure that the courts would not interpret these . . . rules which the Commission is authorized to issue as having the force of law with respect to any other Federal agency." S. Rep. No. 1183, 93rd Cong., 2d Sess., reprinted in 1982 U.S. Code Cong. & Admin. News 6916, 6954. See also id. at 6950.
although somewhat antiquated, also seems to support this view.\textsuperscript{60}

B. Rule 56 as a Procedural Rule

New Rule 56 is also unlikely to be characterized as a rule of procedure. In the past, courts refused to place agency rules in this category if they had a substantial impact on interested persons.\textsuperscript{61} More recently, the courts have tended to apply a functional analysis to the question.\textsuperscript{62} The law is not settled as to which test is correct.\textsuperscript{63}

New Rule 56 appears not to be a matter of procedure no matter which test is used. The new rule is intended to significantly curtail the obligations that patent applicants have to the PTO and, by extension, to the public with regard to the disclosure of information.\textsuperscript{64} In addition, the new rule is intended to create substantial new rights in the patent applicant.\textsuperscript{65}

These characteristics should cause new Rule 56 to fail the substantial-impact test. In this regard, \textit{Pharmaceutical Manufacturers Association v. Finch}\textsuperscript{66} is instructive. \textit{PMA} dealt with regulations promulgated by the Commissioner of Food and Drugs. The regulations set new standards of evidence necessary to demonstrate the effectiveness of drug products and applied those standards retroactively to drugs that had already been approved. Failure to establish that a drug was effective would have resulted in the marketing approval of the drug being either suspended or removed. Thus, the regulation called

\textsuperscript{60} Wamsley, Part II, 64 JPOS at 554. See the comments of Congressman Jenckes, \textit{reprinted in} Congressional Globe, 41st Cong., 2d Sess., 2855–56 (April 20, 1870) ("It is part of the recommendation of the committee . . . that the power which the Commission shall have and ought to have shall be that of regulating the manner in which the proceedings shall be conducted in his Office; the rules of court, so to speak, not the rules of decision but of government." (emphasis added)). The legislative history of the language in section 6 is discussed in some detail in Wamsley, Part I, 64 JPOS at 493-97.

Wamsley argues that, despite the legislative history, the Commissioner's delegation extends to substantive rules. \textit{Id.} at 554–56. He argues the CCPA held in \textit{Van Ornum}, 686 F.2d 937, that Congress' delegation to the PTO includes the power to promulgate substantive rules. \textit{Van Ornum}, however, can be best read as holding the particular rule to be interpretive, not substantive. \textit{See infra} pp. 25–27. Wamsley's expressed rationale for considering \textit{Van Ornum} to be otherwise is not compelling. \textit{Compare} Wamsley's statements at 64 JPOS at 542 with those at 554.

\textsuperscript{61} See \textit{e.g.}, \textit{First National Bank of Lexington, Tenn. v. Sanders}, 946 F.2d 1185 (6th Cir. 1991). For a discussion of the substantial impact test, see 3 Stein §§ 15.06, 15.07[5]; 1 Davis § 6:29.

\textsuperscript{62} \textit{E.g., First National Bank v. Sanders}, 946 F.2d 1185; \textit{Air Transport Association of America v. Department of Transportation}, 900 F.2d 369 (D.C. Cir. 1990).

\textsuperscript{63} \textit{E.g., First National Bank v. Sanders}, 946 F.2d 1188–89.

\textsuperscript{64} See \textit{supra} pp. 17–18.

\textsuperscript{65} \textit{See supra}, note 52.

into question the ability of drug manufacturers to continue marketing various products.

In an effort to persuade the court that the regulation was valid, the agency argued that it was procedural. The court, however, had little difficulty determining the impact of the regulation to be substantial. It therefore found the regulation to be substantive and not procedural.\(^{67}\)

The . . . regulations, which prescribe in specific detail, for the first time, the kinds of clinical investigations that will be deemed necessary to establish the effectiveness of existing and future drug products and which require that such evidence be submitted as a condition to avoiding summary removal from the market, are pervasive in their scope and have an immediate and substantial impact on the way PMA’s members subject to FDA’s regulation, conduct their everyday business. The regulations apply to more than 2000 drug products first marketed between 1938 and 1962 with FDA approval and place them all in jeopardy . . . .\(^{68}\)

There are interesting parallels between the regulation at issue in \textit{PMA} and the intended reach of the PTO’s new Rule 56. Both rules govern the information that an applicant must submit to an agency. Under both rules, the penalty for failing to provide the required information is the failure to obtain the applied-for right: in \textit{PMA}, the FDA would not authorize marketing of the drug, while in the case of Rule 56, the district courts will refuse to provide a remedy for patent infringement. Both rules, moreover, are concerned with balancing the private interests of the specific applicants with the interests of the public at large. Both seek to define how much information must be provided before the balance tips in favor of the applicant.

The same features of new Rule 56 should also cause it to fail the more modern, functional analysis of procedural rules. That analysis is based on the observation that the APA’s mention of procedural rules is essentially a “housekeeping” measure, “[t]he distinctive purpose of . . . [which] is to ensure ‘that agencies retain latitude in organizing their internal operations.’”\(^{69}\)

Thus,\(^{67}\) \(^{68}\) \(^{69}\)

---

\(^{67}\) Id. at 863–64.

\(^{68}\) Id. at 864.

\(^{69}\) \textit{Air Transport v. Dep’t. of Transportation}, 900 F.2d at 376 (citations omitted) (quoting \textit{American Hospital Association v. Bowen}, 834 F.2d 1037, 1041 (D.C. Cir. 1987)) (emphasis in original).
where nominally "procedural" rules "encode[] a substantive value judgment" or "substantially alter the rights or interests of regulated" parties," the rules will be considered substantive.\textsuperscript{70}

These comments apply directly to new Rule 56. It is beyond peradventure that new Rule 56 is intended to encode substantive value judgments regarding a patent applicant's duty to disclose information and, as a result, the fact required to hold a patent unenforceable. The Rule does not mean to address housekeeping details in the PTO only. Rather, it is intended to substantially alter the rights of both patent applicants before the PTO and patent owners before the courts in infringement litigation. The rule is therefore not procedural under the more modern test.

C. Rule 56 as an Interpretive Rule

Agencies have the power to promulgate rules that express the agency's opinion of how a legal rule should be applied.\textsuperscript{71} Interpretive rules such as these may address matters that are beyond the agency's statutory delegation.\textsuperscript{72} Thus, if new Rule 56 could be characterized as an interpretive rule, the problems discussed above in connection with Congress' delegation in Section 6 could be minimized. The recent trend in administrative law, in fact, is toward giving greater deference to an agency's interpretive decisions.\textsuperscript{73}

\textit{In re Van Omum}\textsuperscript{74} provides an example of the CCPA recognizing the PTO's interpretive powers. \textit{Van Omum} addressed the validity of Rule 1.321, 37 C.F.R., which pertained to terminal disclaimers. The appellant challenged the rule on two bases that are relevant to this discussion. First, the rule was said to be contrary to law.\textsuperscript{75} Second, it was argued that the rule did not relate to "the conduct of proceedings in the Patent and Trademark Office."\textsuperscript{76}

The appellant in \textit{Van Omum} thus essentially argued the regulation to be an invalid substantive rule. Both of the above grounds

\textsuperscript{70}Id. (quoting \textit{American Hospital Association}, 834 F.2d at 1041.
\textsuperscript{71} 3 Stein § 15.07[3].
\textsuperscript{72} See generally, 2 Davis § 7.11 at 55=57.
\textsuperscript{74} 688 F.2d 937 (CCPA 1982).
\textsuperscript{75} Id. at 949-50 (Judge Baldwin, dissenting).
\textsuperscript{76} Id. at 949 (emphasis in original).
went directly to the language of Section 6 limiting Congress' delegation to the Commissioner. As stated above, transgressing those limits is a primary basis for invalidating a substantive rule.

In response, the court determined the rule to be valid. It did not, however, find the rule to be substantive within the meaning of the APA. Rather, the court seemed to avoid that issue entirely. Instead, it was primarily interested in establishing that the substance of the rule was both wise and not contrary to prior decisional law.

The court therefore made the determinations necessary to uphold the regulation, not as a substantive rule, but as a valid interpretive rule. The court, in fact, went to some length to note that it agreed with the substance of the rule, a matter important to reviewing interpretive, but not substantive rules.

It is fundamentally clear, however, that new Rule 56 is not an interpretive rule. Interpretive rules are void to the extent that they conflict with the basic law that is being interpreted. As discussed above, conflict with the existing law is the basic purpose of new Rule 56.

There is evidence that the PTO either disagrees with or is not aware of this limitation on its authority to promulgate interpretive rules. The PTO has asserted that its power to promulgate new Rule 56 is demonstrated by the prior CCPA decision of Norton v. Curtiss.

---

77 Van Orhum does not analyze the validity of the regulation in terms of the APA. This may not, however, be uncommon. Professor Davis has observed that many decisions in the administrative-law field do not use precisely correct terminology, perhaps due to the failure of agencies and litigation counsel to provide clear guidance. E.g., 2 Davis § 7.13 at 61. There is reason to believe that this occurred in Van Orhum. See 686 F.2d at 945 ("Appellants say the regulation is 'invalid on its face' but they do not explain why beyond contending it is 'substantive and not procedural.'").

78 After noting the appellant's argument that the regulation was "substantive and not procedural," the court simply stated "[w]e can give no weight to that contention." It noted that many of the PTO's rules deal with conditions upon which patents will be granted. Immediately thereafter, the court presented a detailed history of the caselaw on the legal issue that the regulation addressed. 686 F.2d at 943-46.

79 Id. at 946-47.

80 See e.g., the following language:
Upon . . . extensive review of the situation, we consider it desirable to tie both the termination and the ownership of the two patents together, as is required by § 1.321(b), and seeing no substantial obstacle to doing so, hold it to be a valid regulation.
Id. at 948 (emphasis added).

81 E.g, 2 Davis § 7.8 at 42-43 ("When a rule purports to change the law, it cannot be merely interpretive.") See supra p. 12.

It appears settled that the PTO may promulgate interpretive rules that address common-law, rather than statutory, authority. See e.g., Animal Legal Defense Fund, 932 F.2d at 928.

The court in *Norton* did uphold the PTO’s authority to promulgate an earlier version of Rule 56.\(^{83}\) However, the court also found that version of Rule 56 to be coextensive with the common law of inequitable conduct.\(^{84}\) The opinion quotes the following passage from *In re Heany*,\(^ {85}\) which it describes as containing “unquestionable logic”:

[I]f the Commissioner should find . . . that an application or applications are so permeated with fraud as to justify the opinion that any patent or patents granted on those applications . . . would be annulled or set aside by a court of equity on petition of the United States through the Attorney-General, \(^ {86}\) on the ground that the patent was obtained through fraud, then it would be the duty of the Commissioner, under law, to refuse, upon that ground, to grant such a patent.\(^ {87}\)

“We take this to indicate,” the court continued in *Norton*,

that any conduct which will prevent the enforcement of a patent after it issues should, if discovered earlier, prevent the issuance of the patent. The only rational, practical interpretation of the term “fraud” in Rule 56 which could follow is that the term refers to the very same types of conduct which the courts, in patent infringement suits, would hold fraudulent.\(^ {88}\)

*Norton* therefore does not speak to whether the PTO has the power to promulgate new Rule 56. The court in *Norton* addressed whether the *PTO* could act in conformity with the common law. New

\(^{83}\) 433 F.2d at 791-92. The version of Rule 56 at issue in *Norton* read as follows:

56. Improper applications.

Any application sworn to in blank, or without inspection by the applicant, and any application altered or partly filled in after being signed or sworn to, and also any application fraudulently filed or in connection with which any fraud is practiced or attempted on the Patent Office, may be stricken from the files.


84 433 F.2d at 792.

85 1911 C.D. 139, 171 O.G. 983 (1911).

86 This reference to the Attorney General is apparently because private litigants could not raise the defense of fraudulent procurement in 1911. *See Norton*, 433 F.2d at 792 n.12.

87 *Id* at 792 (emphasis added).

88 *Id*. 
Rule 56, in contrast, seeks to force the courts to act in a particular manner by overturning the common law.\textsuperscript{89} The distinction should be critical to whether new Rule 56 is a valid interpretive rule.\textsuperscript{90} Simply put, new Rule 56 is not intended to interpret any existing authority. Rather, it is intended to lay out a new standard that is substantially different from the current law. It therefore cannot be an interpretive rule.

\textbf{D. Rule 56 as a policy statement}

It appears clear that new Rule 56 is also not a policy statement. The rule is plainly designed to impose a specific set of criteria for determining whether information in material. It provides for no discretion on the part of the decisionmaker.\textsuperscript{91} There is no indication that the PTO will reconsider the wisdom of the rule’s substance in any future proceeding where its application may be called for.\textsuperscript{92}

\textit{Pickus v. United States Board of Parole}\textsuperscript{93} provides an illustration of how these concerns relate to a particular agency action. Pickus

\textsuperscript{89} Digital Equipment Corp., 653 F.2d 701, appears to be to the same effect. There, the court fundamentally relied upon the fact that the version of Rule 56 at issue did nothing more than set forth the existing common-law rule of unenforceability due to inequitable conduct:

It is scarcely unreasonable that the Commissioner, in the exercise of his rule-making authority, should make provision for recognition of this equitable principle in the Patent and Trademark Office. Otherwise the PTO would be obliged to issue claims knowing that they were unenforceable as a matter of law. The question, then, is . . . whether . . . [the prohibition of fraud embodied in rule 56] is “inconsistent with law.” We cannot conclude that this is the case where the courts have determined “fraud” to be a basis of unenforceability of a patent.

\textit{Id.} at 710-11. See also the discussion at 653 F.2d at 712:

[Even if the PTO had reissued the claims in such circumstances [where fraud had occurred], it is likely that a court would have found them nonetheless unenforceable . . . . This being the case, there seems to be no good reason to prohibit the PTO from conducting its own examination of alleged fraudulent conduct, as part of its reissue proceedings . . . .] We conclude, therefore, that the PTO does not exceed its statutory authority when it refuses to reissue a patent on the ground that it was procured though fraud.

\textsuperscript{90} These observations are also relevant to whether cases such as Norton and Digital Equipment Corp. construe the PTO’s ability to promulgate rules “not inconsistent with law” according to the PTO’s Congressional delegation. See supra pp. 17-18.

91 “If it appears that a so-called policy statement is in purpose or effect one that narrowly limits administrative discretion, it will be taken for what it is — a binding rule of substantive law.” Guardian Federal Savings and Loan Assoc. v. FSLIC, 589 F.2d 658, 666 (D.C. Cir. 1978). See also Brown Express, 607 F.2d at 701 (“Nor does it [the agency notice] set a goal that future proceedings may achieve, for the change has been presented as a fait accompli.” (emphasis in original)).

92 See Pacific Gas & Electric Co. v. FPC, 506 F.2d 33, 39 (D.C. Cir. 1974) (“When the agency states that in subsequent proceedings it will thoroughly consider not only the policy’s applicability to the facts of a given case but also the underlying validity of the policy itself, then the agency intends to treat the order as a general statement of policy.”), and Brock v. Cathedral Bluffs Shale Oil Co., 796 F.2d 533, 537-38 (D.C. Cir. 1986).

93 507 F.2d 1107 (D.C. Cir. 1974).
involved a review of certain regulations setting out the factors that the Board would consider in determining whether to parole prisoners. The rules set out

a complex, detailed table which purport[ed] to state the range of months which the board will require an inmate to serve depending upon the severity of his offense . . . and his ‘salient factor score,’ a number computed according to factors also announced in the [rules].

According to the opinion,

[a] major Board contention is that, functionally viewed, its actions . . . are either general statements of policy, interpretive rules, or rules relating to agency organization . . . .

The court disagreed, and held the rule to be substantive. In doing so, the court specifically noted the effect of the disputed provisions on the Board’s future actions:

The guidelines which the board adopted prior to this action . . . were of a kind calculated to have a substantial effect on ultimate parole decisions. They consist of nine general categories of factors, broken down into a total of 32 sub-categories, often fairly specific. Although they provide no formula for parole determination, they cannot help but focus the decisionmaker’s attention on the Board-approved criteria . . . .

The November regulation is more formula like, and hence has an even greater impact on an inmates’ chances for parole . . . . Thus, the rules which define parole selection criteria . . . are substantive agency action, for they define a fairly tight framework to circumscribe the board’s statutorily broad criteria.

When judged according to these criteria, new Rule 56 is even less a policy statement than the agency action was in *Pickus*. New Rule 56 provides an all-inclusive formula for determining whether the patent applicant has disclosed information to the PTO sufficiently. Rather than simply tending to focus a decisionmaker’s attention on certain criteria, it requires that the decision be made according to its criteria exclusively. In fact, the court in *Pickus* observed that the rules there were “designed to, and almost surely will lead to, more nearly uniform decisions, and more restricted decisionmaking.” That same statement describes the purpose and intent behind new Rule 56 exactly.

94 *Id.* at 1110-11.
95 *Id.* at 1112.
96 *Id.* at 1112-13.
97 *Id.* at 1111.
Another obstacle may bar new Rule 56 from being a policy statement. Policy statements are promulgated to guide an agency’s own application of unclear or ambiguous legal standards.98 The PTO, however, does not apply Rule 56 to determine issues of inequitable conduct in the district courts. Until recently, it has refused to even comment on the issue when it appears in its own internal proceedings.99 It continues to avoid Rule 56 issues in the context of ex parte prosecution,100 which is by far the largest category of patent proceedings in the PTO.

Thus, the purpose of new Rule 56 is fundamentally different from that of a policy statement.101 It is not intended primarily to inform the public of how the PTO intends to decide future cases. Rather, it is plainly intended to create a legal standard via rulemaking procedures for the courts to follow.

V. NEW RULE 56 AS A HORTATORY STATEMENT

It therefore appears that new Rule 56, when viewed as an attempt to correct the law of inequitable conduct, is outside the APA. It is neither a substantive, interpretive, nor procedural rule, nor is it a statement of policy.102 What then is new Rule 56, and how should the courts treat it when the issue is raised by litigants and amici?

98 E.g., Pacific Gas & Electric, 506 F.2d at 38-39 (“A policy statement announces the agency’s tentative intentions for the future.” (emphasis added)); 3 Davis 15.07[4] (“General statements of policy announce an agency’s policy plan for enforcement of a particular statute.” (emphasis added)).

99 See PTO Policy Statement on Inequitable Conduct Determinations, (Comm’r. Pat. Sept. 8, 1988), reprinted at 36 PTCJ 616 (Oct. 6, 1988) and the clarification thereof at 1096 O.G. 19. The professed reason for this decision is that the PTO is not suited to deciding the questions of intent that are involved in inequitable conduct issues. Id.

The sole exception to this practice appears to have been the PTO’s continued practice of instituting disciplinary proceedings from time to time under 37 C.F.R., Part 10. These proceedings are typically initiated after a separate determination of inequitable conduct has been made in another proceeding, such as a district-court litigation.

The PTO has recently reversed itself as to interference proceedings. E.g., Consideration of Fraud and Inequitable Conduct in Patent Interference Cases, (Comm’r Pat. Oct. 24, 1991), reprinted at 42 PTCJ 611 (Oct. 31, 1991). It will now consider inequitable conduct issues when raised by motion in those proceedings.


101 See e.g., Industrial Safety Equipment Association v. E.P.A., 837 F.2d 1115 n.8 (D.C. Cir. 1988) (“[T]here is no evidence at all that the Guide [the agency’s rulemaking action] will alter the EPA or NIOSH’s regulatory behavior . . . , so the Guide would not even qualify as an agency statement of policy.”).

102 This result, although apparently unusual, is not unprecedented. E.g., Industrial Safety Equipment Association v. E.P.A., 837 F.2d 1115 (finding agency action to be outside the APA, and hence unreviewable).
A. Analogy to Skidmore v. Swift

In essence, the situation surrounding new Rule 56 is this: Because the PTO is not a party to patent infringement actions its opportunities to help shape the law of inequitable conduct are limited. At the same time, however, it apparently sees a need to participate in that process. New Rule 56 is the means the PTO has chosen to achieve that participation. Essentially, the PTO is using its new rule to exhort the Federal Circuit to adopt a particular legal definition of inequitable conduct.

It appears that agencies act as advocates in this manner infrequently. Nevertheless, the practice is not without precedent, and some useful analogies can be made. Skidmore v. Swift, for example, involved a federal agency's use of such a hortatory statement in connection with the Fair Labor Standards Act. Skidmore involved an action between an employer and employee. The employee had been hired to act as a firefighter at the employer's plant. The dispute centered on whether the time the employee was required to be on-call at the plant counted as time worked for purposes of calculating the employee's wages.

Under the Fair Labor Standards Act a federally appointed Administrator was to seek out and punish violations of the Act's provisions. His authority, however, was not exclusive, in that private persons could also file actions to enforce the Act. While the Administrator was not a party in Skidmore, his office had published an interpretive bulletin on the precise question at issue in Skidmore. In it, he substantially agreed with the position of the employee. His office participated in the Skidmore litigation as an amicus.

The Court in Skidmore discussed why the Administrator's position was relevant even though the Administrator was not a party.

103 E.g., Federal Labor Relations Authority v. Department of the Treasury, 884 F.2d 1446 (D.C. Cir. 1989).
104 323 U.S. 134 (1944). Skidmore was for a time a lead case on the extent to which courts should defer to the interpretive rulemaking of agencies.
105 The term "hortatory statement" is the author's own. Agencies have apparently advocated court adoption of similar non-APA rulemaking actions too rarely for a name to become generally accepted.
107 In this way, the Administrator's authority was coextensive with that of private plaintiffs much the same way that the Justice Department's authority to police antitrust violations is coextensive with that of complainants in civil actions.
In "[p]ursuit of his duties," the Court observed, the Administrator "has accumulated a considerable experience . . . ."\(^{108}\)

The Administrator's policies are made in pursuance of official duty, based upon more specialized experience and broader investigations and information than is likely to come to a judge in a particular case. . . . Good administration of the Act and good judicial administration alike require that the standards of public enforcement and those for determining private rights shall be at variance only where justified by very good reasons.\(^{109}\)

When new Rule 56 is offered as authority in a patent infringement suit, the situation will possess obvious factual parallels with *Skidmore*. The regulations at issue in each case purport to govern the legal issue before the court. Neither case, however, involves the agency's own application of the regulation. Thus, both cases concern whether an agency regulation should control matters beyond the context of agency action.

There are significant differences in the situations, however, some of which go directly to whether new Rule 56 is relevant. The Administrator in *Skidmore*, for instance, had a major responsibility for enforcing the law at issue. In contrast, the PTO has chosen largely not to involve itself in making duty-to-disclose determinations.\(^{110}\) The PTO, moreover, does not enforce the law of inequitable conduct via court action.\(^{111}\) As a result, the Commissioner's attempt to define inequitable conduct in new Rule 56 is therefore probably not "in pursuance of" any "official duty."\(^{112}\) As a further result, the Supreme Court's fear of a "variance" in the law does not apply.

**B. The persuasiveness of Rule 56 as a hortatory statement**

The Court in *Skidmore* recommended careful scrutiny of the particular hortatory statement under review:

The weight of [the Administrator's] judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.

---

\(^{108}\) 323 U.S. at 137-38.

\(^{109}\) Id. at 139-40.

\(^{110}\) See supra pp. 32-33.

\(^{111}\) Id. The sole exception appears to be the PTO's defense, on appeal to the courts, of interference determinations in which allegations of inequitable conduct have been raised by motion.

\(^{112}\) 323 U.S. at 139.

\(^{113}\) Id. at 140.
Applying this scrutiny to new Rule 56 yields mixed results. On the positive side, new Rule 56 is the result of extended notice-and-comment procedures.\textsuperscript{114} The major industry and professional groups have participated.\textsuperscript{115} The effort has spanned a considerable length of time. It presumably has involved considerable deliberation.

On the negative side, however, new Rule 56 is clearly not consistent with prior PTO pronouncements. Now-withdrawn proposed Rule 57 set forth a considerably different standard.\textsuperscript{116} The fact that successive Commissioners have taken such different positions is at least troubling, and possibly calls into question the validity of the reasoning behind the new standard.\textsuperscript{117}

A more important inconsistency arises out of the basic purpose of new Rule 56. The new rule is inconsistent with the current, common-law, judge-fashioned standard. Users of the patent system have failed to persuade the Federal Circuit directly, through advocacy as parties in individual cases, to adopt a more lenient standard. Stripped to its essentials, new Rule 56 is simply an effort to persuade on the same issue indirectly. The Federal Circuit's choice of a more stringent standard is presumably the product of careful, prolonged consideration at least rivalling that behind new Rule 56. The rulemaking origins of new Rule 56 therefore may not be a reason to choose it over the Federal Circuit's present standard.

\section*{VI. COMMON-LAW JURISPRUDENTIAL LIMITATIONS}

It is also clear that the standard principles of common-law development should limit the effect of new Rule 56. New Rule 56, as a hortatory statement, does not establish the law. Rather, it is merely

\textsuperscript{114} See \textit{supra} pp. 9-11.

\textsuperscript{115} The IPO, the AIPLA, and the Patent, Trademark, and Copyright Section of the ABA have all provided comments to the PTO. See the summary of the October 8, 1991 hearing, 42 PTCJ 573.

\textsuperscript{116} See \textit{supra} pp. 9-10.

\textsuperscript{117} The difference between the views of Commissioners Manbeck and Quigg appears to have been due at least in part to a fundamental lack of consensus among the PTO's various constituencies. See e.g., PTO Notice of Final Rulemaking, 57 Fed. Reg. 2023-33; summary of statements given at the PTO's October 8, 1991 hearing, 42 PTCJ 573. Roughly speaking, patent holders and their counsel appear to favor relaxation of the duty to disclose to the "but for" standard of now-withdrawn Rule 57. See the summary of statements by the IPO, ABA, and AIPLA, 42 PTCJ 575-74. \textit{Compare} the statement of the NYPTCLA, \textit{id.} at 575. Persons more concerned with the public interest appear less likely to favor change from the current standard. E.g., the statement of Professor M. Davis, Cleveland State University College of Law, \textit{id.} at 575. The general alignment of constituents in this manner raises the disturbing issue whether the PTO's rulemaking efforts are the result of a balanced presentation of the relevant public and private interests.
advice to the courts, who remain ultimately responsible for determining the correct standard. New Rule 56 therefore provides no reason for the courts to alter their traditional techniques of common-law decisionmaking, such as stare decisis and the distinction between holding and dicta.

This fact may be at significant odds with the plans of the relevant interest groups. According to the AIPLA, the PTO intends to appear as an amicus to ask the courts to adopt new Rule 56 as the law of inequitable conduct.118 The implication is that efforts will be made in one, or a small number of early cases.

New Rule 56, however, is very complex.119 It is virtually impossible for all of its substantive provisions to be present in a single case, or even in a reasonably small number of cases. Under accepted principles of common-law, therefore, the Federal Circuit will likely not address more than a small fraction of the rule at any given time. In fact, because dicta is not binding in subsequent cases the Federal Circuit may even lack the power to provide more expansive review.

Two prior decisions of the Federal Circuit show how these limitations have already operated specifically in the context of PTO regulatory action. In the first of these, Patlex Corp. v. Mossinghoff120 the Federal Circuit upheld M.P.E.P. § 2286 in the face of a challenge that the provision was in conflict with the statutory sections of Title 35, U.S.C., relating to reexamination proceedings.121 Some years later, the Federal Circuit struck down Section 2286 as inconsistent with that same group of sections in Ethicon v. Quigg.122 Ethicon is not inconsistent with Patlex. Rather, the result in Ethicon derives from the fact that each case reviewed different aspects of Section 2286. Section 2286 sets out the conditions under which the PTO would stay reexamination proceedings in light of ongoing district court litigation:

If reexamination is ordered the reexamination will continue until the Office becomes aware that a trial on the merits has begun at which time the reexamination will normally be stayed . . . .

118 See supra note 7.
119 See supra notes 4–5. New Rule 56 runs for over an entire column in the Federal Register. The text of all the regulatory changes, including changes proposed to the rules governing information disclosure statements and reexamination, runs for over two pages. PTO Notice of Final Rulemaking, 57 Fed. Reg. 2034-36.
120 758 F.2d 594 (Fed. Cir. 1985).
122 849 F.2d 1422 (Fed. Cir. 1988).
Patlex addressed whether the PTO could refuse to stay a reexamination proceeding. There, an infringement litigation concerning the same patent was pending in a district court. The district court had announced in advance that it would stay the district court proceeding if the reexamination went forward. The PTO refused to consider that factor in deciding whether to issue a stay, relying instead on the language in Section 2286. Ethicon, in contrast, addressed whether the PTO could stay a reexamination proceeding where trial of the patent in district court had concluded and a decision on the validity was expected. The seemingly opposite results in Ethicon and Patlex, therefore, are simply the result of judicial review being unable to address all aspects of a regulation in a single decision.

There is every reason to believe that these same limitations will apply to the Federal Circuit's review of new Rule 56. As a result, the PTO and interest groups will not change the standard of inequitable conduct quickly even if they are victorious as amici. Instead, only a series of decisions can entrench the standard of new Rule 56 as the law. A substantial period of time may elapse before this process is complete. The effort required to maintain a presence as amici over this period may be impractical. In any event, practitioners in the meantime will be left to guess whether the present standard or that of new Rule 56 is controlling.

VII. CONCLUSION

It appears that new Rule 56 may not solve the problems the patent bar perceives in the area of inequitable conduct. The provisions of the new rule may never replace the current law. Even if they do, they will not do so quickly. The existence of the new rule, moreover, with its ambiguous effect, will likely make the law of inequitable conduct more uncertain over the short term, not less so as was originally hoped.

123 Id. at 606-07.
124 Id. at 597-98.
125 849 F.2d 1424-25.
126 See also Animal Legal Defense Fund v. Quigg 932 F.2d 920, supra pp. 15-16. There, the Federal Circuit expressly avoided addressing whether a portion of the regulation in question was valid. 932 F.2d at 928 n.9 ("[T]he question whether section 553 requirements extend to that part of the Rule which precludes the patentability of humans is not in issue and we do not address it.").
127 See, e.g., Saxon, 42 PTCJ 575.
In addition, new Rule 56 may not alter the debate over inequitable conduct significantly. Whether the courts adopt new Rule 56 will turn largely on whether the standard in that rule is consistent with the aims of the patent system. These same policy arguments have always been available to patent litigants faced with inequitable-conduct issues; presumably they have been using them already.

Finally, there is reason to question whether rulemaking was the PTO's most effective means of obtaining the sought-after changes. An agency's position taken as an amicus can carry the same weight as an official rulemaking action. The PTO, therefore, could have chosen to approach the Federal Circuit as an amicus without a prior rulemaking proceeding. That choice might have allowed the PTO to act more quickly than the almost three years it has taken to reach this stage in the rulemaking process. If so, the PTO might have substantially changed the law of inequitable conduct already.

128 E.g., FLRA v. Treasury, 884 F.2d 1446.