

IN THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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TRIANAFYLLOS TAFAS, Plaintiff-Appellee

and

SMITHKLINE BEECHAM CORPORATION (doing business as GlaxoSmithKline),  
SMITHKLINE BEECHAM PLC, and GLAXO GROUP LIMITED (doing business as  
GlaxoSmithKline), Plaintiff-Appellees,

v.

JON DUDAS, Under Secretary of Commerce for Intellectual Property and Director of the United  
States Patent & Trademark Office, and UNITED STATES PATENT AND TRADEMARK  
OFFICE, Defendants-Appellants.

Serial No. 2008-1352

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Appeal from the United States District Court For the Eastern District of Virginia in Consolidated  
Case Nos. 1:07 – CV – 846 and 1:07 – CV – 1008, Senior Judge James C. Cacheris

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**BRIEF OF *AMICUS CURIAE* WILLIAM MITCHELL COLLEGE OF LAW  
INTELLECTUAL PROPERTY INSTITUTE IN SUPPORT OF APPELLEES**

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October 3, 2008

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

TAFAS and GLAXOSMITHKLINE v. DUDAS

No. 2008-1352

CERTIFICATE OF INTEREST

Counsel for the Amicus Curiae certifies the following (use "None" if applicable; use extra sheets if necessary):

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William Mitchell College of Law Intellectual Property Institute

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

(none)

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

(none)

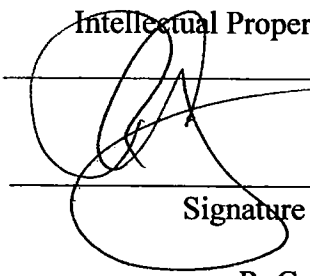
4.  There is no such corporation as listed in paragraph 3.

5. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

R. Carl Moy  
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Intellectual Property Law Institute

October 3, 2008

Date

  
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Signature of counsel

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Printed name of counsel

## STATEMENT OF INTEREST

The William Mitchell College of Law Intellectual Property Institute ('Institute') is an entity within William Mitchell College of Law. The mission of the Institute is to foster and protect innovation through education, research, and service initiatives. Among its activities, the Institute advocates for the responsible development and reform of intellectual property law, including patent laws and the patent system of the United States. A purpose of the Institute is to raise issues and arguments in light of the public interest and the best interests of the patent system as a whole. The Institute has no financial interest in any of the parties to the current action.

In accordance with Federal Rule of Appellate Procedure 29(a), the Institute has motioned leave of this court to file this amicus brief.

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## **I. SUMMARY OF ARGUMENT**

This case presents the question of whether a wide-ranging set of new rules promulgated by the United States Patent and Trademark Office (“USPTO”) should be allowed to go into effect.<sup>1</sup> The rules would change drastically aspects of application practice in United States patent law that previously have been considered both fundamental and settled.

Most segments of the patent community view the changes in these new rules as unwise. An even more basic point, however, is whether the rules are beyond the USPTO’s authority to make. This case therefore presents the very fundamental question whether the courts – and this Court in particular – are the primary shapers of patent law within Congress’s statutory framework, or whether that role instead belongs to the USPTO. Accordingly, the outcome of this case has the potential to impact the patent system profoundly. Virtually all the substantive laws of patentability may be affected. In the decision below, the District Court held that the contested rules were outside USPTO’s rule-making authority, and therefore

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<sup>1</sup>Patent and Trademark Office, Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Inventions, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46716 (Aug. 21, 2007) (“Final Rules”).

invalid.<sup>2</sup> Deciding whether this outcome was correct requires this Court first to categorize the contested rules according to the accepted principles of Administrative Law, and then determine whether the USPTO has the authority to make rules of that type.<sup>3</sup>

This process establishes that the contested rules are invalid, and that the District Court's decision was correct. Administrative Law recognizes rules that are either interpretive, legislative/substantive, or merely procedural.<sup>4</sup> Because the contested rules would have the effect of changing existing law, rather than simply elaborating on it, they are not interpretive.<sup>5</sup> The USPTO, moreover, has only a very limited role in the larger patent system,<sup>6</sup> and it has no authority to make rules of the legislative/substantive type.<sup>7</sup> Yet the non-procedural impacts of the

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<sup>2</sup>Tafas v. Dudas, 541 F.Supp.2d 805 (E.D. Va. Apr. 01, 2008).

<sup>3</sup>See generally, e.g., 1 Pierce, Jr., Administrative Law Treatise §§ 6.1 - 6.11 (2002); 3 Stein, et al., Administrative Law chs. 13 - 18 (2007).

<sup>4</sup>See generally, e.g., 1 Pierce, Jr., Administrative Law Treatise §§ 6.2 - 6.5 (2002); 3 Stein, et al., Administrative Law ch. 15 (2007).

<sup>5</sup>See generally, e.g., 1 Pierce, Jr., Administrative Law Treatise § 6.4 (2002); 3 Stein, et al., Administrative Law § 15.05[3] (2007).

<sup>6</sup>See, e.g., Moy, *Judicial Deference to the USPTO's Interpretations of the Patent Law*, 74 J. Pat. Tm. Off. Soc'y. 406 (1992).

<sup>7</sup>See, e.g., 35 U.S.C. § 2(b)(2). See also, e.g., Merck & Co., Inc. v. Kessler, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996)

contested rules are so prominent that the rules cannot be properly classified as simply rules of procedure.<sup>8</sup>

The end result of this is that the USPTO's contested rules cannot be valid under any of the accepted categorizations employed in Administrative Law.

Accordingly, the rules are invalid. The USPTO is simply not the proper entity in the patent system to be deciding the matters that the rules address.

## II. ARGUMENT

### A. The USPTO'S Rule-Making Authority Must Be Consistent With Administrative Law

Decisions of the Supreme Court repeatedly demonstrate that many rules of patent law are not *sui generis*. Instead, where they invoke larger, non-patent issues, the rules of patent law must conform to the broader rules of law that exist generally.<sup>9</sup>

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<sup>8</sup>*See generally, e.g.*, 1 Pierce, Jr., Administrative Law Treatise § 6.5 (2002)

<sup>9</sup>*See, e.g.*, Markman v. Westview Instruments, Inc., 517 U.S. 370 (1995) (law-fact categorization); Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank, 527 U.S. 627 (1999) (sovereign immunity of the States); Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc., 535 U.S. 826 (2002) (“arising under” subject-matter jurisdiction); eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006) (standard for grant of permanent injunction); MedImmune, Inc. v. Genentech, Inc., 548 U.S. 118 (2007) (jurisdictional threshold for declaratory judgment action).

This is specifically true regarding administrative law. *Dickinson v. Zurko*,<sup>10</sup> presented the question of whether patent law could employ rules contrary to the structure of the Administrative Procedure Act. The Supreme Court held that it cannot, asserting “[t]he APA was meant to bring uniformity to a field full of variation and diversity.”<sup>11</sup>

Under decisions such as *Zurko*, therefore, the question of whether the challenged rules of the USPTO are valid must be decided under the accepted principles that apply to rules and rule-making authority across Administrative Law generally.

#### **B. Administrative Law Separates Rule-Making Authority Into Discrete Categories**

By now, the portions of Administrative Law that deal with administrative rule making have evolved into a set of definite principles and structures.<sup>12</sup> Thus – despite the USPTO’s repeated invitations to do so – this case cannot be properly

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<sup>10</sup>*Dickinson v. Zurko*, 527 U.S. 150 (1999).

<sup>11</sup>*Dickinson v. Zurko*, 527 U.S. 150, 152 (1999). *See also id.* at 164 (“The Federal Circuit’s standard would require us to create § 559 precedent that itself could prove disruptive by too readily permitting other agencies to depart from uniform APA requirements.”).

<sup>12</sup>*See generally, e.g.*, Pierce, Jr., *Administrative Law Treatise* (2002); Stein, et al., *Administrative Law* (2007).

decided by simply reading specific provisions of the patent code, and then interpreting in a vacuum the words found there. Instead, a legally correct outcome requires first taking account of how Administrative Law divides both agency rules and rule-making power into classes, and then treating the specific rules of the USPTO accordingly.

While the Administrative Procedure Act refers to agency rules in terms of various categories,<sup>13</sup> it leaves those categories undefined.<sup>14</sup> Nevertheless, authorities in Administrative Law are fairly clear that agency rules are to be organized in the manner illustrated in Figure 1.<sup>15</sup> At the broadest level, the authorities distinguish between rules that simply control matters of “procedure or practice” and those that extend into matters that are non-procedural.<sup>16</sup> Stated

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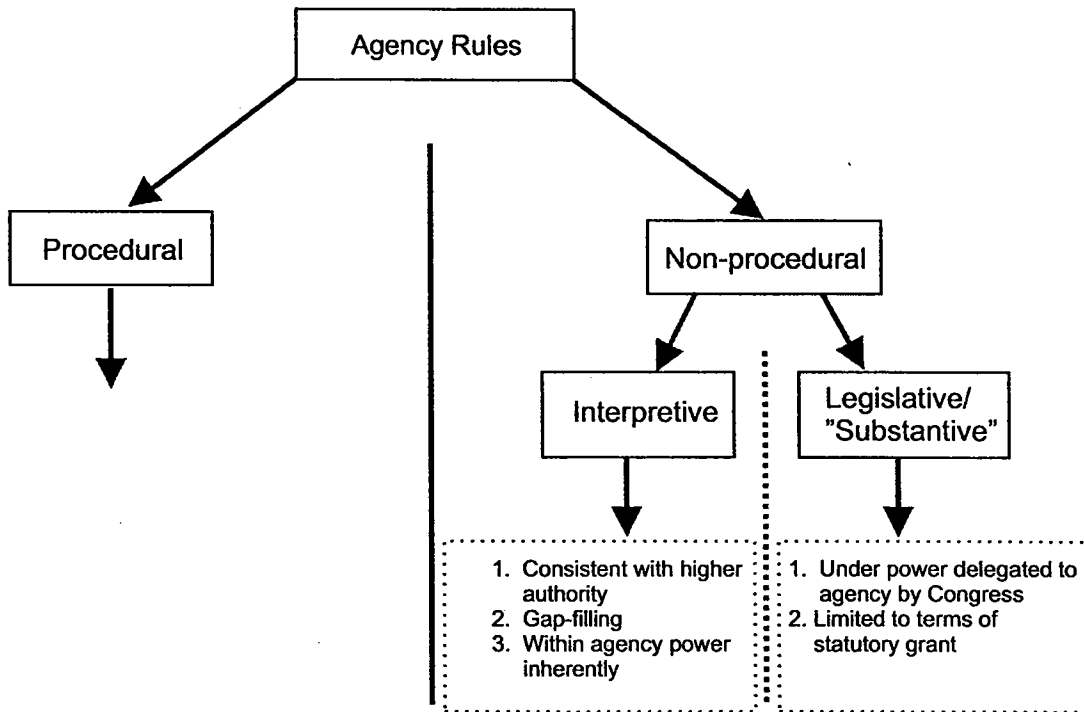
<sup>13</sup>*See, e.g.*, 5 U.S.C. § 553 (referring to “substantive rules,” “interpretative rules,” “general statements of policy,” and “rules of agency organization, procedure, or practice.”). *See also, e.g.*, 3 Stein, et al., *Administrative Law* §§ 13.02[1]-[2] (2007); 1 Pierce, Jr., *Administrative Law Treatise* § 6.1 (2002).

<sup>14</sup>*See, e.g.*, 3 Stein, et al., *Administrative Law* § 15.04 (2007) (“[T]he Act does not define the difference between the categories . . .”).

<sup>15</sup>*See generally, e.g.*, 1 Pierce, Jr., *Administrative Law Treatise* §§ 6.1 - 6.11 (2002); 3 Stein, et al., *Administrative Law* chs. 13 - 18 (2007).

<sup>16</sup>*See, e.g.*, 1 Pierce, Jr., *Administrative Law Treatise* § 6.5 (2002); 3 Stein, et al., *Administrative Law* § 15.05[5] (2007). *See also* 3 Stein, et al., *Administrative Law* § 13.03[2] (2007) (discussing whether procedural rules have binding effect).

RECOGNIZED RULE CATEGORIES





generally, procedural rules are those that control “the procedures and methods used in executing an[] inquiry.”<sup>17</sup> Non-procedural rules, in contrast, are those whose effects have a “substantial impact” or “significant effect” on the substantive rights of parties.<sup>18</sup>

Non-procedural rules are further divided into two categories. One of these categories consists of rules that are called “interpretive.”<sup>19</sup> As the name suggests, interpretive rules are those that interpret or construe other, higher authorities that already exist.<sup>20</sup> By definition, therefore, interpretive rules must be consistent with those higher authorities, and they are limited to the agency’s good-faith attempt to

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<sup>17</sup>1 Pierce, Jr., *Administrative Law Treatise* § 6.5 (2002); 3 Stein, et al., *Administrative Law* § 15.05[5] (2007).

*See also, e.g.*, *Pickus v. U.S. Parole Board*, 507 F.2d 1107 (D.C. Cir. 1974).

<sup>18</sup>*See, e.g.*, 3 Stein, et al., *Administrative Law* § 15.04 (2007) (“substantial impact”); 1 Pierce, Jr., *Administrative Law Treatise* § 6.5 (2002) (“significant effect”).

<sup>19</sup>*See generally, e.g.*, 1 Pierce, Jr., *Administrative Law Treatise* § 6.4 (2002); 3 Stein, et al., *Administrative Law* § 15.05[3] (2007).

<sup>20</sup>It has long been accepted that the USPTO’s interpretive rules must be consistent with at least the judicial decisions of the USPTO’s reviewing courts. *See, e.g.*, *In re Gibbs*, 437 F.2d 486, 491 (CCPA 1971); Eugene W. Geniesse, *The Examination System in the U.S. Patent Office*, Study no. 29 of the Subcommittee on Patents, Trademarks, and Copyright of the Committee of the Judiciary of the United States Senate, 85<sup>th</sup> Cong., 2nd Sess. (1961) (Study authored by USPTO employee) (“[D]ecisions of the Court of Customs and Patent Appeals . . . generally are controlling with respect to the Office.”).

explain what those higher authorities mean.<sup>21</sup> Because the act of interpretation is considered a necessary part of applying existing law to new cases, an agency's power to make interpretive rules is generally thought to be inherent.<sup>22</sup> That is, agencies are generally thought to have the power to make interpretive rules, even without express statutory permission to do so.<sup>23</sup>

The other category of non-procedural rule consists of those rules that make new law, independent any process of interpretation.<sup>24</sup> The making of non-procedural rules in this second category is a legislative function, and therefore, an agency power to do so extends only so far as Congress has delegated to the particular agency Congress's legislative power under Article I of the Constitution.<sup>25</sup> Although the relevant statutory provision uses the term

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<sup>21</sup>*See, e.g.*, 1 Pierce, Jr., Administrative Law Treatise § 6.4 (2002) (“[A]n interpretive rule cannot impose obligations on citizens that exceed those fairly attributable to Congress through the process of interpretation.”).

<sup>22</sup>*See, e.g.*, *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944); 1 Pierce, Jr., Administrative Law Treatise § 6.4 (2002) (“[A]ny agency has the inherent power to issue interpretive rules.”)

<sup>23</sup>*See, e.g.*, 1 Pierce, Jr., Administrative Law Treatise § 6.4 (2002).

<sup>24</sup>*See generally, e.g.*, 1 Pierce, Jr., Administrative Law Treatise § 6.4 (2002); 3 Stein, et al., Administrative Law § 15.05[2] (2007).

<sup>25</sup>*See, e.g.*, *Christensen v. Harris County*, 529 U.S. 576 (2000). *See also* 1 Pierce, Jr., Administrative Law Treatise § 6.4 (2002) (“[A]n agency has the power to issue binding legislative rules only if and to the extent Congress has authorized

“substantive” for this type of rule,<sup>26</sup> they are commonly referred to as “legislative,” to make clear their relation to the agency’s statutory grant of authority from Congress.<sup>27</sup> The APA sets out that, in the ordinary case, only substantive/legislative rules need to be promulgated to the process of notice-and-comment.<sup>28</sup>

The categorization of a contested rule can strongly affect the rule’s impact in a given case. Substantive/legislative rules, for example, are void if they exceed Congress’s delegation.<sup>29</sup> As another example, recent Supreme Court authority establishes that interpretive rules are not entitled to deference under *Chevron*

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it to do so.”). *See also id.* at § 2.6 (discussing operation of delegation doctrine).

<sup>26</sup>*See* 5 U.S.C. § 553(d).

<sup>27</sup>*See, e.g.,* 1 Pierce, Jr., *Administrative Law Treatise* § 6.1 (2002); 3 Stein, et al., *Administrative Law* § 15.05[2] n.22 (2007).

<sup>28</sup>5 U.S.C. § 553(d). *See also, e.g.,* 3 Stein, et al., *Administrative Law* § 15.05[1] (2007); 1 Pierce, Jr., *Administrative Law Treatise* § 6.4 (2002) (“[C]ourts universally understand this language [of section 553 regarding notice-and-comment procedures] to draw a distinction between legislative rules and interpretive rules.”).

It is possible that Congress has imposed onto the USPTO the unusual requirement that the agency must use notice-and-comment procedures for all types of rules. *See* 35 U.S.C. § 2(b)(2)(C).

<sup>29</sup>*See, e.g.,* 1 Pierce, Jr., *Administrative Law Treatise* § 6.4 (2002); 3 Stein, et al., *Administrative Law* § 15.05[2] (2007).

*U.S.A., Inc. v. Natural Resources Defense Council, Inc.*<sup>30</sup>

### C. The USPTO Cannot Make Legislative/Substantive Rules

The categorization scheme set out in the preceding section is particularly important to the present case. For example, the main statutory provision that addresses the USPTO's rule-making authority is section 2 of the patent statute.<sup>31</sup> The broadest grant there, paragraph 2(b)(2)(A), gives the agency only the power to "establish regulations, not inconsistent with law, which . . . shall govern the conduct of proceedings in the Office . . . ."<sup>32</sup>

This Court has already held, on repeated occasions, that this provision does not give the USPTO authority to grant rules of the legislative/substantive type. Cases extending over nearly two decades refuse to characterize the USPTO as having the authority to issue general legislative rules.<sup>33</sup> Instead, they view Con-

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<sup>30</sup>*Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

*See, e.g.*, *Christensen v. Harris County*, 529 U.S. 576 (2000). *See also* 1 *Pierce, Jr., Administrative Law Treatise* § 6.4 (2002) (discussing holding and significance of *Christensen*).

<sup>31</sup>35 U.S.C. § 2.

<sup>32</sup>35 U.S.C. § 2(b)(2)(A).

<sup>33</sup>*See, e.g.*, *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991); *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543 (Fed. Cir. 1996).

gress's relevant grant as simply procedural:

As we have previously held, the broadest of the PTO's rulemaking powers – 35 U.S.C. § 6(a)<sup>34</sup> – 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.<sup>35</sup>

As this court has stated succinctly, “Congress has not vested the Commissioner with any general substantive rulemaking power . . . .”<sup>36</sup>

These holdings are consistent with the statutory provision's legislative history. That history, which stems from the Patent Act of 1870, indicates that the provision was specifically intended to confer the power to regulate only procedural matters, and not matters of substance.<sup>37</sup>

In addition, the language of section 2(b)(2)(A) is much narrower than the formulation that Congress typically uses when it gives an agency the authority to

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<sup>34</sup>The relevant statutory language was repositioned, from section 6 of Title 35, U.S.C., to section 2, in 1999. *See*, Pub.L. No. 106-113, Div. B, § 1000(a)(9) [Title IV, § 4712], 113 Stat. 1536, 1501A-572 (1999).

<sup>35</sup>*Merck v. Kessler*, 80 F.3d at 1549-50 (quoting *Animal Legal*, 932 F.2d at 930, and collecting additional authorities).

<sup>36</sup>*Merck v. Kessler*, 80 F.3d at 1550 (Fed. Cir. 1996).

<sup>37</sup>*See* Congressional Globe, 41<sup>st</sup> Cong., 2<sup>nd</sup> Sess. 2855-56 (April 20, 1870) (“It is part of the recommendation of the committee . . . that the power that the Commissioner 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.”).

make legislative rules.<sup>38</sup>

The USPTO's contrary assertion is demonstrably incorrect. According to the agency, the statute gives it authority to make any rules, including those that are of a legislative/substantive nature, as long as the subject matter of the rules is somehow connected to "govern[ing] the conduct of proceedings in the Office."<sup>39</sup> This position proves too much. The USPTO has the statutory task of patent examination, during which it estimates whether a claimed invention is patentable.<sup>40</sup> Thus, any statement by the USPTO announcing its view of the substantive law of patentability would arguably "govern" the conduct of application proceedings. Accepting the USPTO's argument therefore would give the agency *carte blanche* authority to impose its own, independent, legislative views on, for example, the laws of statutory subject matter under section 101 of Title 35, U.S.C., anticipation under section 102, and non-obviousness under section 103. This would vastly expand the agency's rule making power beyond anything it has been understood to possess up to this point in history. That expansion of authority, moreover, would directly reduce the authority over

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<sup>38</sup>See, e.g., 21 U.S.C. § 371(a) (granting rule making authority to FDA).

<sup>39</sup>See, e.g., Appellant's brief, at 19.

<sup>40</sup>See, e.g., 35 U.S.C. § 131.

substantive patent law that this Court now wields.

The USPTO has essentially no response to this observation. According to it, the USPTO's views would take precedence only if the agency used notice-and-comment procedures, and additionally decided that its rules should have a dominating effect.<sup>41</sup> But those are no safeguards at all. Both could be overcome whenever the agency chose. In addition, the USPTO's proposed distinction between rule-making by notice-and-comment, versus adjudication, is inconsistent with accepted principles of Administrative Law.<sup>42</sup>

The cases offered by the USPTO are off-point. Several of the cases deal with the enrollment and discipline of agents and attorneys recognized to practice before the agency.<sup>43</sup> This type of activity is not governed by paragraph (b)(2)(A) of section 2, but by a completely different paragraph, specific to the registration of attorneys and agents, which employs language in that context that is much more

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<sup>41</sup>*See, e.g.*, Appellant's brief, at 22-23.

<sup>42</sup>*See, e.g.*, 1 Pierce, Jr., Administrative Law Treatise § 6.1 (2002) (noting general power of agencies to promulgate rules by either adjudication or notice-and-comment).

<sup>43</sup>*See, e.g.*, *Lacavera v. Dudas*, 441 F.3d 1380, 1383 (Fed. Cir. 2006); *Bender v. Dudas*, 490 F.3d 1361 (Fed. Cir. 2007).

extensive.<sup>44</sup> The USPTO is therefore taking the statements of these decisions grossly out of context.

Most of the other cases on which the USPTO has tried to rely dealt with matters that were clearly procedural, by any rational measure.<sup>45</sup> These cases thus could not present the question of whether the USPTO's rule-making authority extends to matters that are legislative/substantive. Thus, for example, the Federal Circuit's in statement *Stevens v. Tamai* that the USPTO has "plenary authority over PTO practice,"<sup>46</sup> is perfectly understandable, and in no way supports the agency's current position. In fact, the Federal Circuit in *Stevens* cited directly to *Merck v. Kessler*'s description of the USPTO's limited rule-making authority, with approval.<sup>47</sup>

Nor should this Court defer to the USPTO's view of its own rule-making

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<sup>44</sup>35 U.S.C. § 2(b)(2)(D).

<sup>45</sup>*See, e.g.*, *Stevens v. Tamai*, 366 F.3d 1325 (Fed. Cir. 2004) (timing of translation submission during interference); *In re Sullivan*, 362 F.3d 1324 (Fed. Cir. 2004) (hearing procedures during interference).

<sup>46</sup>*Stevens v. Tamai*, 366 F.3d 1325, 1333 (Fed. Cir. 2004).

<sup>47</sup>*Stevens v. Tamai*, 366 F.3d 1325, 1333-34 (Fed. Cir. 2004) ("In view of the reasonableness of the Office's rules governing the procedure in patent interferences, and the substantial deference we accord such rules, *see Merck & Co.*, 80 F.3d at 1549, we cannot agree with *Tamai* . . .").



authority. In fact, while the agency asserts that deference to it is “settled law,”<sup>48</sup> the truth is exactly the opposite. The USPTO quotes this assertion not from a majority opinion of the Supreme Court, but instead from the concurring opinion of a single Justice – to which three other justices of the Court dissented.<sup>49</sup> The date of the opinion, moreover, is 1988, not the 1998 date that the USPTO’s brief represents.<sup>50</sup> Numerous secondary authorities have since remarked that the Supreme Court has never accepted Justice Scalia’s position.<sup>51</sup> This means that the current state of the law is exactly the *opposite* of what the USPTO asserts. In fact, this Court has itself held that an agency’s interpretation of its own rule-making authority is *not* entitled to deference:<sup>52</sup> “[D]eference should not apply when the

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<sup>48</sup>See, e.g., Appellant’s brief, at 21.

<sup>49</sup>Mississippi Power & Light Co. v. Mississippi ex rel. Moore, 487 U.S. 354 (1988) (Scalia, J., concurring). Compare Mississippi Power & Light Co. v. Mississippi ex rel. Moore, 487 U.S. 354 (1988) (Brennan, J., dissenting). See also, e.g., Business Roundtable v. S.E.C., 905 F.2d 406 (D.C. Cir. 1990) (noting unresolved status of question).

<sup>50</sup>Appellant’s brief, at 21.

<sup>51</sup>See, e.g., Crawford, Comment, *Chevron Deference to Agency Interpretations That Delimit the Scope of the Agency's Jurisdiction*, 61 U. Chi. L. Rev. 957 (1994); Armstrong, *Chevron Deference and Agency Self-Interest*, 13 Cornell J.L. & Pub. Pol’y 203 (2004); Cope, *Judicial Deference to Agency Interpretations of Jurisdiction after Mead*, 78 So. Calif. L. Rev. 1327 (2005).

<sup>52</sup>See, e.g., Borlem S.A.-Empreeditmentos Industriais v. U.S., 913 F.2d 933, 937 (Fed. Cir. 1990); Forest v. Merit Systems Protection Bd., 47 F.3d 409, 410

issue is the legal scope of an agency's authority.”<sup>53</sup>

#### **D. The Contested Rules Are Not Interpretive**

Many aspects of the USPTO’s proposed new rules are plainly not interpretive. Instead, those rules would overturn legal rules that are both long standing and, more importantly, the result of judicial decisions that are directly on point. Final Rule 78 would place stringent limits on an applicant’s ability to file more than three continuation applications in sequence.<sup>54</sup> This is contrary to section 120 of the patent statute,<sup>55</sup> as specifically held by this Court’s predecessor, the Court of Customs and Patent Appeals, in *In re Henriksen*.<sup>56</sup>

Final Rule 75 would require an applicant, in some circumstances, to supply the USPTO with an Examination Support Document (“ESD”) as a condition of

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(Fed. Cir. 1995); *Roche v. U.S. Postal Serv.*, 80 F.3d 468, 470 (Fed. Cir. 1996); *King v. Briggs*, 83 F.3d 1384, 1387 (Fed. Cir. 1996); *Manley v. Dep’t. of Air Force*, 91 F.3d 117, 119-20 (Fed. Cir. 1996). *See also* *Armstrong, Chevron Deference and Agency Self-Interest*, 13 *Cornell J.L. & Pub. Pol’y* 203, 241 (2004)

<sup>53</sup>*Borlem S.A.-Empreedimentos Industriais v. U.S.*, 913 F.2d 933, 937 (Fed. Cir. 1990) (citing *Social Sec. Bd. v. Nierotko*, 327 U.S. 358, 369 (1946)).

<sup>54</sup>35 C.F.R. § 1.78

<sup>55</sup>35 U.S.C. § 120

<sup>56</sup>*In re Henriksen*, 399 F.2d 253 (CCPA 1968). *See also* *In re Hogan*, 559 F.2d 595 (CCPA 1977).

having her application examined on the merits.<sup>57</sup> The content that the applicant must supply in the ESD is extraordinarily burdensome. Not only must the ESD contain the results of a search that corresponds generally to what the USPTO would do during examination,<sup>58</sup> it must also set out, for each reference that the ESD cites, “an identification of all the limitations of each of the claims (whether in independent or dependent form) that are disclosed in the reference,”<sup>59</sup> and “[a] detailed explanation particularly pointing out how each of the independent claims is patentable over the cited references.”<sup>60</sup>

In fact, these aspects of the USPTO’s new rules are so onerous that they effectively require the patent applicant to bear the initial burden of proving that claimed invention is patentable. The USPTO’s Federal Register notice that accompanied the new rules makes clear that section 1.265(a)(4), in particular, involves the patent applicant essentially establishing, in advance, that the claims of the application avoid the art, under both the anticipation standard of section 102

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<sup>57</sup>37 C.F.R. § 1.75

<sup>58</sup>*Compare, e.g.,* 37 C.F.R. § 1.265(a)(1)-(2);

<sup>59</sup>37 C.F.R. § 1.265(a)(3).

<sup>60</sup>37 C.F.R. § 1.265(a)(4).

of the patent statute,<sup>61</sup> and the non-obviousness standard of section 103<sup>62</sup>:

A general statement that all of the claim limitations are not described in a single reference does not satisfy the requirements of § 1.265(a)(4). Section 1.265(a)(4) requires that the examination support document set out with particularity, by reference to one or more specific claim limitations, why the claimed subject matter is not described in the references, taken as a whole. The applicant must explain why a person of ordinary skill in the art would not have combined the features disclosed in one reference with the features disclosed in another reference to arrive at claimed subject matter. The applicant must also explain why the claim limitations referenced render the claimed subject matter novel and non-obvious over the cited prior art.<sup>63</sup>

Changing the patent system so that the patent applicants must prove they are entitled to a patent is a fundamental, sharp break with the previously accepted practice, in which the initial burden has been on the USPTO to prove that the applicants' inventions are unpatentable. Reference to this current practice is found in various recent decisions of both the Federal Circuit and the Court of Customs and Patent Appeals.<sup>64</sup>

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<sup>61</sup>35 U.S.C. § 102.

<sup>62</sup>35 U.S.C. § 103

<sup>63</sup>Final Rules, 72 Fed. Reg. at 46742.

<sup>64</sup>*See, e.g.*, In re Warner, 379 F.2d 1011, 1016 (CCPA 1967) (collecting and analyzing authorities); In re Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984); In re Oetiker, 977 F.2d 1443, 1444 (Fed. Cir. 1992) (“[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward

The cases have noted that this burden can be discerned from the preamble of section 102 of the patent statute, which lists various scenarios as exceptions to the default conclusion, that a patent should issue.<sup>65</sup>

This reading of the statute is consistent with basic principles of pleading and the allocation of proof: the contrary position, of placing the initial burden on the patent applicant, essentially requires the patent applicant to establish an exhaustive series of negatives. Such a contrary position is both illogical and impractical, and one can assume that Congress did not intend it when the statute was enacted.

The USPTO's proposed rules requiring the submission of ESDs are therefore contrary to sections 102 and 103 of the patent statute. As a result, they cannot qualify as rules of interpretation. Even more fundamentally, they are *ultra vires*.<sup>66</sup>

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with evidence or argument shifts to the applicant.”).

<sup>65</sup>*See, e.g.*, In re Warner, 1011, 1016 (CCPA 1967) (“We think the precise language of 35 U.S.C. § 102 that ‘(a) person shall be entitled to a patent unless,’ concerning novelty and unobviousness, clearly places a 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 . . .”).

<sup>66</sup>*See, e.g.*, 35 U.S.C. § 2(b) (limiting USPTO rule-making authority to rules “not inconsistent with law”).

In fact, the conclusion that the patent statutes assign the initial burden of proof to the Patent Office, finds support not only in modern case law, but also in decisions that date back to the Patent Office's earliest years. Explicit reference to it can be found in a reported decision from 1857,<sup>67</sup> and there are suggestions there that the practice was already old at that time.<sup>68</sup> Stated bluntly, the practice that the USPTO seeks to overturn is essentially as old as the Patent Office itself, and the basic function of patent examination.<sup>69</sup>

These early decisions held that the burden of proof was allocated to the Patent Office through the statutory requirement that the patent applicants supply an oath, asserting that their inventions were believed to be patentable.<sup>70</sup> The

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<sup>67</sup>In re Wagner, 1 MacArthur's Patent Cases 510, 517 (C.C.D.C. 1857).

<sup>68</sup>See In re Wagner, 28 F.Cas. 1327, 1329-30 (C.C.D.C. 1857) (referencing Patent Office behavior after Heath v. Hildreth, 11 F. Cas. 1003, No. 6309 (C.C.D.C. 1841)).

<sup>69</sup>Compare Patent Act of 1836, 5 Stat. 117 (1836) (reforming patent system to create Patent Office, and instituting system of patent examination).

<sup>70</sup>See, e.g., In re Wagner, 28 F.Cas. at 1329-30 (“[T]he oath of the party [i.e., the patent applicant] is to be considered in the character of *prima facie* evidence of the novelty of the invention. [Citation omitted] According to this admitted construction, it may be properly insisted that it is the Commissioner's duty and power to resort to any circumstances legitimately in his possession for the purpose of repelling the presumption . . .”).

analysis proved stable and persistent for many years.<sup>71</sup>

The requirement that inventors supply an oath with the patent application has been carried forward in the patent statute to this day.<sup>72</sup> As in previous versions of the statute, the provision relating to the oath continues to insist that inventors swear that they believe they are the first and true inventor of the subject matter for which patent rights are being sought. Accordingly, the text of section 115 of the patent statute, as interpreted by the judiciary, supplies another ground on which to conclude that the USPTO's proposed rules requiring the submission of ESDs are contrary to law, and thus not interpretive.

#### **E. The Contested Rules Are Not Procedural**

The USPTO's contested rules also do not fall within the narrow definition of rules that are procedural. According to one classic formulation, procedural rules "should not be deemed to include any action which goes beyond formality and substantially affects the rights of those over whom the agency exercises

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<sup>71</sup>*See, e.g.*, 2 William C. Robinson, *The Law of Patents for Useful Inventions* § 559 (1890) (describing the process of rejecting an application after examination: "If the ground of the rejection be that the applicant is not the first and true inventor of the art or instrument described, the examiner must cite references establishing his assertion, or himself make oath to it, to overcome the presumption arising from the oath of the alleged inventor.").

<sup>72</sup>35 U.S.C. § 115.

authority.”<sup>73</sup> It is true that categorizing particular rules as either procedural or non-procedural can be difficult.<sup>74</sup> In particular, every rule of procedure has the possibility to affect substantive outcomes in some circumstances.<sup>75</sup>

This does not mean, however, that the substantive effects of a rule are to be ignored in determining whether the rule is procedural or not.<sup>76</sup> Instead, the best-reasoned modern authorities categorize a rule as procedural or not by applying a determined by a balancing test, which weighs the agency’s need to regulate its internal affairs against the other interests that are at stake.<sup>77</sup>

In present case, this balancing test weighs significantly against the

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<sup>73</sup>Pickus v. U.S. Parole Board, 507 F.2d 1107 (D.C. Cir. 1974). *See also*, e.g., 1 Pierce, Jr., Administrative Law Treatise § 6.5 (2002); 3 Stein, et al., Administrative Law § 15.05[5] (2007).

<sup>74</sup>*See, e.g.*, 1 Pierce, Jr., Administrative Law Treatise § 6.5 (2002).

<sup>75</sup>*See, e.g.*, Chamber of Commerce of U.S. v. U.S. Dept. of Labor, 174 F.3d 206 (D.C. Cir. 1999). *See also* 1 Pierce, Jr., Administrative Law Treatise § 6.5 (2002).

<sup>76</sup>*See, e.g.*, 3 Stein, et al., Administrative Law § 15.04 (2007) (“substantial impact”).

<sup>77</sup>*See, e.g.*, Pickus v. U.S. Parole Board, 507 F.2d 1107 (D.C. Cir. 1974); JEM Broadcasting Co., Inc. v. F.C.C., 22 F.3d 320 (Fed. Cir. 1994); Chamber of Commerce v. Dept. of Labor, 174 F.3d 206 (D.C. Cir. 1999) (interest of public in participation via notice-and-comment proceedings); James V. Hurson Associates, Inc. v. Glickman, 229 F.3d 277 (D.C. Cir. 2000) (same); National Whistleblower Center v. Nuclear Regulatory Com’n., 208 F.3d 256 (D.C. Cir. 2000). *See also*, e.g., 1 Pierce, Jr., Administrative Law Treatise § 6.5 (2002).



