

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2008-1352

TRIANTAFYLLOS TAFAS,

Plaintiff-Appellee,

and

SMITHKLINE BEECHAM CORPORATION (doing business as GlaxoSmithKline),

SMITHKLINE BEECHAM PLC, and

GLAXO GROUP LIMITED (doing business as GlaxoSmithKline),

Plaintiffs-Appellees,

v.

JOHN J. DOLL, Acting Under Secretary of Commerce for Intellectual Property

and Acting Director of the United States Patent and Trademark Office,

and UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendants-Appellants.

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.

**COMBINED PETITION BY TRIANTAFYLLOS TAFAS
FOR PANEL REHEARING AND REHEARING *EN BANC***

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Date: June 3, 2009

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STATEMENT OF COUNSEL UNDER FED. CIR. R. 35(B)(2)

Based on my professional judgment, I believe the panel decision is contrary to the following decisions of the U.S. Supreme Court and precedents of this court:

<i>Gonzales v. Oregon</i> , 546 U.S. 243 (2006)	<i>Chrysler Corp. v. Brown</i> , 441 U.S. 281 (1979)	<i>Animal Legal Defense Fund v. Quigg</i> , 932 F.2d 920 (Fed. Cir. 1991)
<i>United States v. Mead Corp.</i> , 533 U.S. 218 (2001)	<i>Cooper Technologies, Co. v. Dudas</i> , 536 F.3d 1330 (Fed. Cir. 2008)	<i>In re Wakefield</i> , 422 F.2d 897 (CCPA 1970)
<i>Bowen v. Georgetown Univ. Hosp.</i> , 488 U.S. 204, 208 (1988)	<i>Eli Lilly & Co. v. Bd. Of Regents</i> , 334 F.3d 1264, (Fed. Cir. 2003)	<i>In re Warner</i> , 379 F.2d 1011, 1016 (CCPA 1967)
<i>Chevron U.S.A. Inc. v. NRDC, Inc.</i> , 467 U.S. 837 (1984)	<i>Merck & Co., Inc. v. Kessler</i> , 80 F.3d 1543 (Fed. Cir. 1996)	<i>In re Van Ornum</i> , 686 F.2d 937 (CCPA 1982)

Based on my professional judgment, I believe this appeal requires an answer to one or more precedent-setting questions of exceptional importance:

1. Does the standard “foreclose effective opportunity to present patent applications for examination” or “effectively foreclose[] [applicants] from obtaining patent rights to which they are entitled” comport with United States Supreme Court and Federal Circuit precedent classifying “substantive” rules as those which cause a change in existing law or policy affecting individual rights and obligations?
2. Are Final Rules 75, 114, and 265 impermissibly inconsistent with law so as to exceed the scope of the United States Patent and Trademark Office’s limited rule making authority under Section 2(b)(2) of the Patent Act?

Respectfully submitted,



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Attorney of Record for Plaintiff-Appellee Dr. Tafas

SUMMARY OF POINTS OF LAW AND FACT OVERLOOKED BY PANEL

On March 20, 2009, the Federal Circuit issued *Tafas v. Doll*, 559 F.3d 1345, wherein the majority found that the United States Patent and Trademark Office (“PTO”) was permitted to issue three of four rules limiting Request for Continued Examination filings (“RCE rule”) and requiring an applicant to provide a detailed patentability opinion to the PTO (“ESD rule”) if the applicant seeks more than 5 independent or 25 total claims in any application or among commonly owned applications wherein one or more claims of the same are found to be indistinct (“5/25 rule”). 72 Fed. Reg. 46,716-843 (Aug. 21, 2007) (collectively, the “Final Rules”).

Tafas respectfully submits this request for rehearing and rehearing *en banc* on the grounds that the majority: (1) misapplied significant binding Supreme Court and Federal Circuit precedent concerning the correct standard for classifying administrative rules as “substantive” versus “non-substantive”; (2) failed, contrary to Supreme Court and Federal Circuit precedent, to fully consider evidence that the Final Rules significantly and adversely affect individual rights and obligations under the law; (3) failed to correctly address, as required by Supreme Court precedent, the threshold question of whether the PTO has the jurisdictional authority under 35 U.S.C. § 2(b)(2) to enact the Final Rules; and (4) misapplied *Chevron* deference to its improper determination that Final Rules 75, 265 and 114 were not “inconsistent with existing law”.

ARGUMENT

I. The Test Used by the Panel to Determine Whether the Final Rules Are Substantive is Contrary to Existing Federal Circuit and United States Supreme Court Precedent.

Congress's delegation of rulemaking authority to the PTO is set forth at 35 U.S.C. § 2(b)(2). This Court has interpreted this statute to mean that the PTO does not have substantive rulemaking authority. *See, e.g., Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996); *Eli Lilly & Co. v. Bd. of Regents*, 334 F.3d 1264, 1269 n.1 (Fed. Cir. 2003); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336 (Fed. Cir. 2008); *Tafas*, 559 F.3d at 1352 (Fed. Cir. 2009).

Prior to the issuance of the majority opinion in this case, the test applied by the Federal Circuit to determine whether or not an administrative rule is substantive was clear. Under both Supreme Court and Federal Circuit precedent, a "substantive rule," as opposed to a "non-substantive rule" (*i.e.*, an "interpretative" or "procedural" rule), was defined as a rule that caused a change in existing law or policy and affected substantial individual rights and obligations. Therefore, if any or all of the Final Rules were found to cause such a change, they should have been classified as substantive and an impermissible extension of the PTO's authority under 35 U.S.C. § 2(b)(2). *See, e.g., Chrysler Corp. v. Brown*, 441 U.S. 281, 301-02 (1979) ("[A] substantive rule...[is] one affecting individual rights and obliga-

tions. This characteristic is an important touchstone for distinguishing those rules that may be binding or have the force of law”) (emphasis added)(quotation marks and internal citations omitted); *Morton v. Ruiz*, 415 U.S. 199, 231-232 (1974); *Cooper Techs.*, 536 F.3d at 1336 (“In this case, the Patent Office’s interpretation ... does not effect any change in existing law or policy[.] ... It is therefore ‘interpretive’ – rather than ‘substantive’”); *Animal Legal Def.*, 932 F.2d at 927 (“A rule is ‘substantive’ when it ‘effects a change in existing law or policy’ which ‘affect[s] individual rights and obligations’”)(citations omitted).

The majority seemingly found that the Federal Circuit’s own precedents were not dispositive because these cases examined the distinctions between substantive and interpretative rulemaking, as distinguished from the difference between substantive and procedural rulemaking. *Tafas*, 559 F.3d at 1355. This is a false distinction. As Judge Rader correctly noted in his dissent, here, the precise dividing line between interpretive and procedural rules is irrelevant – the proper issue is whether, applying the well-developed Federal Circuit standard, the Final Rules are substantive or not. *Tafas*, 559 F.3d at 1368-69.

Instead of conducting the required analysis of the Final Rules’ effect on existing patent law, policy and individual rights and obligations, the majority, relying on out-of-context statements from *JEM Broadcasting Co., v. Federal Communications Commission*, 22 F.3d 320 (D.C. Cir. 1994), and a misconstruction of

Lamoille Valley Railroad Co. v. Interstate Commerce Commission, 711 F.2d 295 (D.C. Cir. 1983), simply asserted that the RCE, ESD and 5/25 rules are “procedural” on the ground that while each may “alter the manner in which the parties present their viewpoints to the USPTO,” each “do[es] not, on [its] face, foreclose effective opportunity to present patent applications for examination” or “effectively foreclose[] [applicants] from obtaining the patent rights to which they are entitled.” *Tafas*, 559 F.3d at 1356. With these statements, the majority opinion created a new standard at odds with existing Federal Circuit precedents. This standard suggests that a PTO rule with any procedural aspect cannot be struck down as “substantive” unless it eviscerates applicants’ ability to successfully prosecute patent applications or utterly forecloses applicants’ ability to obtain the patent rights to which they are entitled.

Not only is this onerous standard inconsistent with governing precedent in this Circuit, it is a misapplication and misinterpretation of the D.C. Circuit’s holding in *JEM* as Judge Rader correctly noted in his dissenting opinion:

[A]s the D.C. Circuit stated in *JEM*, the “critical feature” of a procedural, non-substantive rule is that “it covers agency actions that do not themselves alter the rights or interests or parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency.” Although the court’s opinion today seizes upon this instructive language from *JEM*, it sadly overlooks *JEM*’s ensuing statement: “the issue, therefore, is *one of degree* ... our task is to identify which substantive effects are *sufficiently grave*. ... [A]s *JEM* illustrates, the test for substantive, ultra vires rules is a case-by-case inquiry, not a rigid application of a sentence out of context in *JEM*.”

Tafas, 559 F.3d at 1369-70 (citations omitted).

Likewise, the standard is inapposite to the holding of the D.C. Circuit in

Lamoille:

Thus, we put to one side cases like *Batterton* where a rule has definite substantive consequences but can arguably be called either “procedural” or “substantive,” and a court must decide which it is In such cases, courts inquire into how serious the substantive consequences are. *See Batterton*, 648 F.2d [694,] 708 [D.C. Cir. 1980] (agency’s choice of a methodology for calculating unemployment rates affects federal funding levels and thus ‘trenches on substantial private rights’) . . .

Lamoille, 711 F.2d at 328 & n.74.

Case law demonstrates that in the D.C. Circuit, just as in the Federal Circuit, the classification of an administrative rule as “substantive” turns on an analysis of its effects on individual rights and obligations. *See, e.g., Chamber of Commerce of the U.S. v. U.S. Dept. of Labor*, 174 F.3d 206, 212 (D.C. Cir. 1999) (“[T]he question whether a rule is substantive or procedural . . . is functional, not formal. That is why we examine how the rule affects not only the ‘rights’ of aggrieved parties, but their ‘interests’ as well”) (citations omitted); *Am. Hosp. Assoc. v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987) (“Determining whether a given agency action is . . . legislative [*i.e.*, substantive] is an extraordinarily case-specific endeavor”).

While “every change in rules will have some effect on those regulated,” *Neighborhood TV Co. v. FCC*, 742 F.2d 629, 637 (D.C. Cir. 1984), the relevant inquiry focuses on the magnitude of that effect and the nature of the rights impacted.

Morton, 415 U.S. at 232; *Animal Legal Def. Fund*, 932 F.2d at 929. As Judge Rader correctly noted, “the issue ... is one of degree [and] our task is to identify which substantive effects are sufficiently grave [.]” *Tafas*, 559 F.3d at 1369.

The majority erred in not conducting the required level of factual inquiry into the effect of the RCE, ESD and 5/25 rules on individual rights and obligations. In doing so, it ignored a plethora of evidence and argument submitted below by *Tafas* regarding the onerous prospective and retroactive burdens imposed by the Final Rules. (*See, e.g.*, Joint Appendix 3000-3839).

For example, in his appellate brief, *Tafas* noted that the 5/25-ESD requirement is “an insurmountable barrier for most applicants,” citing analysis by Dr. Belzer that if ESDs were filed as required in all relevant applications in a representative fiscal year, they would consume the full time efforts of between 8,000 and 23,000 patent attorneys, though there are only 15,000 patent attorneys registered in the United States. (*Tafas Appellate Brief*, pp. 36-37, citing JA. 3355 – 57). *Tafas* also presented evidence that he received an estimate of about \$25,000 to do a “bare bones” initial ESD for each of four applications, at a total cost of \$100,000. (JA. 3743). Of course, the real cost of an application may run much higher, since Final Rule 265(e) allows an Examiner to seek a supplemental ESD whenever amendment of any claim is made and the Examiner deems the initial ESD to “no longer

cover[] each of the claims.” The majority’s failure to consider this evidence as part of an inquiry into the effects of the Final Rules was an error.

II. The Panel Did Not Correctly Address the Fundamental Question of Whether the PTO Has the Jurisdictional Authority to Enact the Final Rules and Misapplied *Chevron*.

Under Article I, Section 8 of the United States Constitution, all patent rights flow from Congress. Consequently, a proper inquiry into the scope of the PTO’s rulemaking jurisdiction should have considered all of the limits on the scope of PTO’s rulemaking jurisdiction under 35 U.S.C. § 2(b)(2).

The majority’s analysis of the PTO’s rulemaking jurisdiction was almost exclusively concerned with the PTO’s authority to enact “procedural” rules. *See Tafas*, 559 F.3d at 1353-54. Rather than conducting the required analysis described above, the majority concluded the rules were procedural because “[i]n essence, they govern the timing of and materials that must be submitted with patent applications.” *Id.* at 1356. By incorrectly limiting its jurisdictional inquiry to whether or not the Final Rules were procedural, the majority opinion ignored the express limiting language to Section 2(b)(2), which clearly states that the PTO may only enact regulations “not inconsistent with law”.

It is, of course, axiomatic that any rule which conflicts with statute is void. *See, e.g., Caldera v. J.S. Alberci Constr. Co.*, 153 F.3d 1381, 1383 (Fed. Cir. 1998) (“Statutes trump conflicting regulations”). It is also axiomatic that courts are obli-

gated to try to give effect to every word and phrase of a statute so that no language is rendered superfluous, void or insignificant. *Alaska Dept. of Env'tl. Conservation v. EPA*, 540 U.S. 461, 489, n.13 (2004); *Pac Fung Feather Co. v. U.S.*, 111 F.3d 114, 117 (Fed. Cir. 1997). Under these two principles of statutory construction, the language “not inconsistent with law” cannot simply mean that the PTO may not pass rules that conflict with the statutory language of the Patent Act. Rather, as defined by the Court of Customs and Patent Appeals, the predecessor to this Court, such reference to “law,” which was also recited in former 35 U.S.C. §6(a), is directed not only to the face of all statutory law, but also to case law interpreting such statutes. *In re Van Ornum*, 686 F.2d 937, 945 (CCPA 1982) (“[t]he regulation clearly relates to application processing within the PTO in a manner consistent with statutory and case law [.]”).¹

Instead of comparing the Final Rules with the relevant statutes and case law to identify any possible inconsistencies, the majority treated the jurisdictional inquiry regarding “consistency with law” as part of its “*Chevron* Step One” inquiry. *Tafas*, 559 F.3d at 1359; *Chevron U.S.A. Inc. v. NRDC, Inc.*, 467 U.S. 837 (1984). Consequently, the majority inappropriately equated a “consistency with the law” analysis with an analysis of whether certain select patent statutes relied upon by the

¹ Such jurisdictional limit parallels, but is independent of, the requirement under 5 U.S.C. § 706.

District Court are ambiguous² so as to allow agency discretion in their interpretation.

Although the majority correctly noted the principle that an agency's determination of the scope of its own authority is not entitled to *Chevron* deference (*Tafas*, 559 F.3d at 1353), it nonetheless applied *Chevron* deference to the PTO's position that the Final Rules are not inconsistent with the Patent Act. *Id.* at 1359 ("Because each of the rules is procedural, we must, as discussed above, give *Chevron* deference to the USPTO's interpretation of the provisions of the Patent Act that relate to 'proceedings in the Office'")(citation omitted). This was fundamental error. The jurisdiction of the PTO is limited to enacting rules that are "not inconsistent with law". Thus, as part of its "*Chevron* Step Zero" analysis, the Court was required to consider whether or not the Final Rules were consistent with law and, therefore, within the PTO's jurisdiction. This analysis should have been done before granting *Chevron* deference to the PTO's interpretation of the Patent Act, not after, as in the majority opinion.

Chevron deference "is not accorded merely because the statute is ambiguous[.]" *Gonzales v. Oregon*, 546 U.S. 243, 258-59 (2006). Deference in accord

² Of course, ambiguity is often in the eye of the beholder. For example, Federal Circuit Judge Giles Rich, one of the drafting members of Section 120 of the Patent Act, stated that "Section[] 120 ... on careful reading ... [indicates] that the number of generations of the lineage is unlimited." *Tafas* Appellate Brief, p. 28. Judge Bryson in his concurrence finds ambiguity with respect to lineage matters in 35 U.S.C. § 120. *Tafas*, 559 F.3d at 1367.

with *Chevron* may be determined only after it is ascertained “that Congress delegated authority to the agency generally to make [the] rules[.]” *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001); *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649 (1990); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). This is because “[t]he legislative power of the United States is vested in the Congress, and the exercise of quasi-legislative authority by governmental departments and agencies must be rooted in a grant of such power by the Congress and subject to the limitations which that body imposes.” *Chrysler*, 441 U.S. at 302 (emphasis added). Section 2(b)(2) is clear that the PTO is prohibited from promulgating rules that are inconsistent with existing law.

III. The Majority Opinion Incorrectly Found That Final Rules 75, 265 and 114 Were Not Inconsistent with Applicable Law.

The deferential standard employed by the majority to determine inconsistency failed to properly consider whether or not each of the Final Rules were inconsistent with statute or existing case law. The majority incorrectly concluded that Final Rules 75, 265 and 114 were not inconsistent with applicable law.

A. The Majority Ignored Inconsistencies Between Final Rule 75 and 35 U.S.C. §§ 102, 103, 112, 131 and Case Law Interpreting Same.

The majority opinion’s conclusion that Final Rule 75 (the “5/25 rule”) does not conflict with existing law is erroneous. Final Rule 75(b)(1) requires that an applicant file an ESD “that covers each claim (whether in independent or depend-

ent form) before the issuance of a first Office action on the merits of the application if the application contains or is amended to contain more than five independent claims or more than twenty-five total claims.” (Emphasis added). Final Rule 75 (b)(4) permits the PTO, for purposes of determining whether an application has more than 5 independent or 25 total claims, to treat commonly owned applications determined to have one or more patentably indistinct claims as containing the totality of claims found in all of such applications. This is even if such finding is made after the first Office Action on the merits, or if no ESD was required to be filed before the first Office Acton on the merits.

35 U.S.C. § 131 mandates that “the Director shall issue a patent” if “it appears that the applicant is entitled to a patent under the law.” These conditions for patentability are expressed in non-ambiguous terms in 35 U.S.C. §102 (“A person shall be entitled to a patent unless...”) and further defined by 35 U.S.C. §103. However, Final Rule 75(b)(1) grants the PTO the right to withhold a patent on allowed claims in certain circumstances. Where no ESD was filed before the first Office Action on the merits, but six or more claims depending on a single independent claim are allowed by the Examiner if the applicant agrees to cancel the independent claim and rewrite each of the dependent claims in independent form, the applicant cannot receive patent protection on at least one of the allowed embodiments under Final Rule 75. This is contrary to 35 U.S.C. § 131. Furthermore, 35

U.S.C. § 131 requires that the PTO cause examination of an application filed by an applicant. No provision is made for the PTO to deny examination simply upon an examiner's finding that one or more claims among commonly owned patents are patentably indistinct, as Final Rule 75(b)(4) allows.

As noted by Judge Rader, 35 U.S.C. §112 allows an applicant "one or more claims" in which to "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." *Tafas*, 559 F.3d at 1372. Final Rule 75(b)(1) eliminates this right when an applicant does not provide an ESD before the first Office Action on the merits but it is later determined that additional claims are need to particularly point out and claim the subject matter. Final Rule 75 is also contrary to case law interpreting 35 U.S.C. §112. This Court has found that "an applicant should be allowed to determine the necessary number and scope of his claims." *In re Wakefield*, 422 F.2d 897, 900 (CCPA 1970).

B. The Majority Ignored Inconsistencies Between Final Rule 265 and 35 U.S.C. §102 and Case Law Interpreting Same.

Final Rule 265 (the "ESD rule") sets forth a number of requirements that are inconsistent with law. *Tafas*, 559 F.3d at 1373-74 (Rader J., dissenting). Contrary to the majority's finding that the ESD does "not require an applicant to make a prima facie case of patentability," (*Tafas*, 559 F.3d at 1364), the PTO's own comments to the Final Rule make it amply clear that Final Rule 265 does exactly that:

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.

(JA.78).

As clearly delineated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992), the patent statutes (in particular 35 U.S.C. § 102) place the initial burden, characterized as both the burden of production and persuasion, on the Examiner: “[T]he examiner bears the initial burden, on review of the prior art or any other ground, of presenting a prima facie case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.” (emphasis added). *See also In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984); *In re Warner*, 379 F.2d 1011, 1016 (CCPA 1967).

C. The Majority Ignored Inconsistencies Between Final Rule 114 and 35 U.S.C. §132

The majority ignored the specific reference in 35 U.S.C. §132 mandating the Director prescribe rules “to provide for the continued examination of applications[.]” Based upon case law finding a single reference to include the plural, it held that the plural use of the word “applications” did not mean that the provisions of Section 132 need to “be applied on a per application basis”. *Tafas*, 559

F.3d at 1366. Inexplicably, the majority failed to review the enactment section of the American Inventors Protection Act of 1999, Pub. L. No. 106-113, §4405(b)(1)(1999) (approvingly cited by Judge Rader in his dissent), which clearly indicates Congressional intent for the statutory rights to apply to all applications filed on or after June 9, 1995:

(b) AMENDMENTS MADE BY SECTION 4403...

(1) ... shall apply to all applications filed under section 111(a) of title 35, United States Code, on or after June 8, 1995, and all applications complying with section 371 of title 35, United States Code, that resulted from international applications filed on or after June 8, 1995[.]

CONCLUSION AND RELIEF SOUGHT

For the foregoing reasons, it is respectfully requested that Plaintiff-Appellee Triantafyllos Tafas's combined petition for rehearing and rehearing *en banc* be granted.

Dated: June 3, 2009

Respectfully submitted,

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