

No. 2008-1352

United States Court of Appeals
for the Federal Circuit

TRIANTAFYLLOS TAFAS,

Plaintiff-Appellant,

and

**SMITHKLINE BEECHAM CORPORATION (D/B/A GLAXOSMITHKLINE), SMITHKLINE
BEECHAM PLC, and GLAXO GROUP LIMITED (D/B/A GLAXOSMITHKLINE),**

Plaintiffs-Appellants,

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-Appellees.

**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**

PETITION FOR REHEARING *EN BANC* OF MARCH 20, 2009 DECISION

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FEDERAL CIRCUIT RULE 35(b) STATEMENT OF COUNSEL

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

- *Chrysler Corp. v. Brown*, 441 U.S. 281 (1979);
- *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991); and
- *Cooper Technologies Co. v. Dudas*, 536 F.3d 1330 (Fed. Cir. 2008).

Based on my professional judgment, I further believe that this appeal requires an answer to the following precedent-setting questions of exceptional importance:

I. Whether the Panel majority erred in rejecting the test for determining whether a Patent and Trademark Office (“PTO”) rule is “substantive,” as set forth in the controlling precedent of *Chrysler, supra*; *Animal Legal Defense Fund, supra*; and *Cooper Technologies, supra*.

II. Whether the Panel majority erred in holding that the challenged Final Rules, 72 Fed. Reg. 46,716 (Aug. 21, 2007), fall within the PTO’s limited, non-substantive rulemaking authority.



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ARGUMENT IN SUPPORT OF PETITION

I. Introduction

The patent statute specifies that whoever invents a new, useful and non-obvious invention is entitled as of right to a patent. *See* 35 U.S.C. § 101; *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). The patent laws are thus unlike most Federal laws, which generally do not presume an individual's right to a Federal entitlement absent proof to the contrary. And, Congress, mindful of the Constitutional foundation of patent rights, strictly limited the PTO's rulemaking authority to only procedural matters.¹

GlaxoSmithKline ("GSK") seeks *en banc* review of a fragmented panel's decision that certain rules² issued by the PTO fall within its limited non-substantive rulemaking authority. The challenged rules limit an applicant's right to file requests for continued examination (Rule 114), and condition the presentation of more than a specified number of claims on compliance with requirements not

¹ Under 35 U.S.C. § 2(b)(2), the PTO "may establish regulations, not inconsistent with law, which ... shall govern the conduct of proceedings in the Office." The panel unanimously affirmed that this provision "does not vest the USPTO with any general substantive rulemaking power." *Tafas and GSK v. Doll*, 559 F.3d 1345, 1352 (Fed. Cir. 2009) (hereinafter, "*Op.*").

² Although the panel incorrectly found Final Rule 78 to be within the ambit of the PTO's non-substantive rulemaking authority, the panel correctly struck Final Rule 78 as inconsistent with 35 U.S.C. § 120. GSK does not seek review of the portion of the panel's ruling striking down Final Rule 78.

imposed by the patent statute (Rules 75 and 265) (collectively, the “Final Rules”). Two judges agreed that PTO has authority to issue Rules 114, 75, and 265, but disagreed on the applicable legal framework and rationale. The dissenting judge used a third approach and concluded that the Rules were substantive and thus beyond the PTO’s limited authority.

Both opinions that comprise the majority conflict with established precedent of this Court and the Supreme Court governing when a rule is substantive. The opinions also conflict with each other, leaving the PTO and patent applicants wholly uncertain about this Court’s test for deciding whether PTO rules are lawful. The conflict between the majority opinions and binding precedent, and the need to remove the uncertainty this has created as to the legal standard for measuring the legality of PTO rules, warrants *en banc* review.

Equally to the point, as shown *infra* and in numerous *amicus* filings, the Final Rules will operate to limit the number, scope, and character of the patents the PTO grants. They do so by limiting the range of patentability issues an applicant may raise during an application’s examination, *inter alia*, by foreclosing or severely restricting access to measures provided by statute (*e.g.*, the authority to request continued examination or the right to present claims), or by curtailing the authority provided in the statute to present patent claims. The Final Rules are not, as the principal opinion suggests, merely mechanisms to “govern the timing of and

materials that must be submitted with patent applications,” *Op.* at 1356, but measures that significantly affect applicants’ rights and obligations under the Patent Act. *Op.* at 1368 (Rader, J., dissenting) (hereinafter “*Dissent*”). The Final Rules are thus substantive.

If the determination that the Final Rules are procedural were to stand, the PTO’s rulemaking authority would exceed the limited scope of authority that Congress conferred on the PTO to promulgate procedures governing only the *conduct* of examinations and will affect applicants’ *substantive* rights to a patent covering the full scope of their inventions – aspects Congress reserved for itself.

The principal opinion improperly and incorrectly dismissed *Chrysler Corp. v. Brown*, 441 U.S. 281, 289 (1979), as irrelevant in the course of finding the Final Rules non-substantive. *See also Animal Legal Defense Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991) (“*ALDF*”); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336 (Fed. Cir. 2008); *Dissent* at 1368-70. In particular, it incorrectly – and without authority – concluded that “the inquiry set forth in *Chrysler* and used in *Animal Legal Defense Fund* and *Cooper Technologies* may be useful in defining the boundary between interpretive and substantive rules, [but] it is not dispositive on the issue of whether the Final Rules are procedural.” *Op.* at 1355. But the line between substantive and procedural rules delineated in *Chrysler* is particularly

important to enforce, given the PTO's narrow rulemaking authority, and both the principal opinion and the concurring opinion erred in rejecting its use in this case.

That the Final Rules are substantive is underscored by the unprecedented number of *amicus* filings in the district court and in this Court explaining the harmful effects the Final Rules will have on statutory rights to patent protection and thus on innovation and investment in a broad spectrum of enterprises and industries. Whether and how those rights should be altered is a task reserved to Congress and the political process, not one delegated to the PTO.

Both the general test for determining the limits of the PTO's rulemaking authority and the specific application of that test to the Final Rules are questions of overriding importance. The general test will govern all future PTO rulemakings. The majority opinions conflict with each other and with controlling Supreme Court precedent. If either approach becomes the law of this Circuit, the PTO will have a vastly expanded power to issue substantive rules that alter the availability and character of patent rights under the guise of procedural changes – a power at odds with the express congressional design of 35 U.S.C. § 2 (b)(2). This Court should thus grant the petition for rehearing *en banc*.

II. The Panel Decision Conflicts With Binding Precedent In Finding That The Final Rules Are Within The Scope Of The PTO's Delegated Rulemaking Authority.

A. The panel correctly recognized that § 2(b)(2) of the Patent Act does not vest the PTO with the power to issue “substantive” rules. *Op.* at 1352 (“This principle is amply supported by our precedent”); *see id.* at 1352 n.3; *see also Dissent* at 1368. In determining that the Final Rules are not substantive, however, the principal opinion rejected the Supreme Court’s *Chrysler* test – a test which this Circuit has adopted and applied repeatedly.

In *Chrysler*, the Supreme Court defined a “substantive rule – or a ‘legislative-type rule,’ as one ‘affecting individual rights and obligations.’” 441 U.S. at 302 (citation omitted). That Court explained that “[t]his characteristic is an important touchstone for distinguishing those rules that may be ‘binding’ or have the ‘force of law.’” *Id.*

This Circuit has repeatedly endorsed the *Chrysler* test to determine whether rules, including PTO rules, are substantive. *See, e.g., ALDF*, 932 F.2d at 927 (internal quotation marks omitted) (citing *Chrysler*); *Cooper Techs.*, 536 F.3d at 1336; *Tunik v. MSPB*, 407 F.3d 1326, 1344 (Fed. Cir. 2005); *Schism v. United States*, 316 F.3d 1259, 1281 (Fed Cir. 2002) (en banc); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996). In *ALDF*, this Circuit applied the *Chrysler* test to PTO rules, defining a substantive rule as one that “effects a change in

existing law or policy which affect[s] individual rights and obligations.” 932 F.2d at 927 (internal quotation marks omitted)(citing *Chrysler*). In *Merck*, too, this Circuit applied the *Chrysler/ALDF* test to PTO actions. 80 F.3d at 1550.

In 1999, Congress recodified prior § 6(a) of the Patent Act as current § 2(b)(2) without any substantive change in the relevant text.³ See American Inventors Protection Act of 1999 (“AIPA”), Pub. L. No. 106-113, sec. 4712, § 2(b)(2), 113 Stat. 1501, 1501A-573. Congress thus presumptively affirmed the PTO’s lack of substantive rulemaking authority and the *Chrysler/ALDF* test for identifying “substantive” rules. See *Lorillard v. Pons*, 434 U.S. 575, 580 (1978) (“Congress is presumed to be aware of an administrative or judicial interpretation of a statute ... when it re-enacts a statute without change.”).

In *ALDF*, this Court adopted the *Chrysler* standard in reviewing PTO rules, thereby serving the statutory goal of circumscribing the PTO’s authority. The PTO’s power is limited to internal housekeeping matters; it cannot alter inventors’ basic rights to receive patents if they otherwise satisfy the Patent Act’s conditions. Thus, it makes perfect sense to declare PTO rules *ultra vires* whenever they affect

³ Congress has repeatedly refused to delegate to substantive rulemaking authority to the PTO. See, e.g., H.R. 1333, 107th Cong. § 4 (2001); H.R. 2795, 109th Cong. § 5 (2005); S. 1145, 110th Cong. § 11 (2007); S. 3600, 110th Cong. §§ 9, 10 (2008).

“individual rights and obligations.” *Chrysler*, 441 U.S. at 302. Yet, neither the principal opinion nor the concurring opinion applied the *Chrysler/ALDF* test to determine whether the Rules are lawful. That decision thus conflicts with Circuit precedent. For this reason alone, *en banc* review is warranted.

B. The majority opinions not only conflict with established precedent, they also set forth conflicting legal approaches for addressing whether PTO rules are within its rulemaking authority. The principal opinion concludes that the Rules at issue are procedural because they “do not, on their face, ‘foreclose effective opportunity’ to present patent applications for examination.” *Op.* at 1356 (quoting *JEM Broad. Co. v. FCC*, 22 F.3d 320, 326, 328 (D.C. Cir. 1994)).⁴ Judge Bryson’s concurring opinion also fails to employ the *Chrysler/ALDF* test, but it does not adopt the principal opinion’s approach. He declines to address the

⁴ The principal opinion also advances a false dichotomy between “procedural” and “interpretive” rules, and attempts to portray *Chrysler* and *ALDF* as relating only to *interpretive* rules. *Op.* at 1354-55. See also *Dissent* at 1369 (finding *Chrysler*’s reasoning “in no way” limited to distinguishing between interpretive and substantive rules, but between substantive and non-substantive rules). Yet, in *Chrysler*, the Supreme Court made clear that the “central distinction” among agency rules “is that between ‘substantive rules’ on the one hand and ‘interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice’ on the other.” *Chrysler*, 441 U.S. at 301. The *Chrysler* Court provided a flexible test for distinguishing between substantive and non-substantive rules: “[The Court] need not decide whether [] regulations are properly characterized as ‘interpretive rules.’ It is enough that [] regulations are not properly promulgated as substantive rules” *Id.* at 315.

substance/procedure dichotomy and instead engages in an ad hoc inquiry about whether the specific Rules at issue are within the congressional delegation to the PTO. The dissent, as noted, urges the application of the *Chrysler/ALDF* test.

As a consequence of the decision's structure, it is unclear which legal framework governs the important question whether any particular set of PTO rules are within the Agency's lawful authority. The resulting uncertainty will disrupt the operations of the PTO, damage the economic interests of inventors and patent applicants, and undermine incentives for innovation by American industry. The need for certainty about the legal test for determining the legality of PTO rules amply justifies rehearing *en banc*.

C. Finally, the Final Rules "drastically change the existing law and alter an inventor's rights and obligations under the Patent Act." *Dissent* at 1374. Analyzed under the *Chrysler/ALDF* test, the Final Rules are substantive.

1. Rule 114 effectively restricts an applicant to a single request for continued examination per "application family," even though Congress unambiguously stated that the RCE provisions of § 132(b) apply to "all applications" filed after June 8, 1995. AIPA, Pub. L. No. 106-113, § 4405(b)(1), 113 Stat. at 1501A-560 to 561. The principal opinion claims that this limit does "not, on [its] face 'foreclose effective opportunity' to present patent applications for examination." *Op.* at 1356. In reality, Rule 114 has precisely such an effect.

Congress established RCEs to allow an applicant to continue the examination of an application without having to file an additional application, with the consequent delays to and disruption of the examination process. There is no other purpose for this authority. The RCE authority mitigates the effects of the PTO's longstanding policy of pressuring Examiners to issue "final" rejections as early as possible during an examination. Once the "final" rejection threshold has been crossed, an applicant cannot present, as a matter of right, additional evidence or claim amendments, even though doing so may be necessary to secure the patent rights to which the applicant is entitled under the Patent Act. Despite this, if Rule 114 functions as the PTO intends, an applicant will never be able to file an RCE in any member of an application family if that applicant has previously filed an RCE in any other family member. The effect of the Rule is that many applicants will not secure any patent rights, or not the full scope of rights, to which the inventor is constitutionally and statutorily entitled. This change is far more than a timing restriction.

The principal opinion misperceives the character and purpose of the RCE authority when it concludes that by "requiring applicants to raise all then-available amendments, arguments, and evidence by . . . the first RCE is [not] so significant a burden that applicants will be effectively foreclosed from obtaining the patent rights to which they are entitled." *Op.* at 1356. Yet, the circumstances that might

trigger the need to file an RCE are inextricably tied to the specific events that occur *during* examination of each application. In other words, an applicant *cannot know* if there will be a need to file a future RCE in another member of an application family when the “first” RCE is filed.

Final Rule 114 does permit an applicant to file additional RCEs by filing a petition that establishes that “the amendment, argument or evidence could not have been submitted prior to the close of prosecution in the application.” But the very purpose of Rule 114 is to limit the number of requests for continued examinations that are made, and to thereby reduce the PTO’s backlog. *See id.* at 1350 (“Final Rule 78 and Final Rule 114 ... were issued to address the ‘large and growing backlog of unexamined patent applications.’”) (citing 72 Fed. Reg. 46,716, 46,717 (Aug. 21, 2007)).⁵ The PTO’s plan as stated in the Federal Register publication of the Final Rules is to deny the overwhelming majority of petitions; otherwise, Rule 114 could have no impact on its backlog. Simply put, Rule 114 will substantively limit the ability of an inventor to obtain the full measure of patent rights to which

⁵ Perversely, the practical effects of ESD requirements as imposed by Rules 75 and 265 will be to significantly *increase* the workload of the PTO by requiring assessment of compliance with the formal requirements of these rules, and in addressing petitions, appeals, and litigation concerning decisions made concerning compliance with these rules.

the inventor is entitled under the statute. Congress did not delegate such policy choices to the PTO – it specifically reserved them for itself.

2. The Patent Act imposes no upper limit on the number of claims an applicant may present for examination. *See* 35 U.S.C. § 112 (“one or more claims”); *see also Dissent* at 1372. This Circuit’s precedent similarly recognizes that there is no limit on the number of claims an applicant may present for examination (so long as the applicant avoids unduly multiplying the claims). *See, e.g., In re Wakefield*, 422 F.2d 897, 900 (C.C.P.A. 1970).⁶

Final Rules 75 and 265 are designed to limit the number of claims an applicant presents for examination. They do this by requiring an applicant who presents more than the specified number of claims to provide the PTO with an examination support document (ESD). The majority characterized this ESD requirement as procedural, calling it a mere shift in a “burden of production on the applicant.” *Op.* at 1357. It plainly is not.

⁶ Congress also has expressly provided the Director with two statutory mechanisms to regulate the number of claims an applicant may present for examination. First, the Director may restrict examination to a subset of the claims presented in an application to those that define a single invention; an applicant must file another application to obtain examination of claims that define patentably distinct inventions. *See* 35 U.S.C. § 121. Second, the Director may collect fees for “Excess Claims.” *See* 35 U.S.C. § 41(a)(2). This express authority reinforces that rules governing the number of claims an applicant may submit for examination are substantive, rather than procedural, in character.

The majority fails to appreciate the substantive impact that the ESD requirement will have on applicants. The principal opinion suggests that “once a satisfactory ESD is submitted, examination will proceed in precisely the same way as it would in the absence of the rule” and that “an examiner is not permitted to substantively reject claims on grounds that the ESD did not prove the claims are patentable.” *Op.* at 1357. Yet, Rule 265 provides no concrete guidance, particularly as to the scope of the search required.⁷ Non-compliance with vague, unknowable ESD requirements will result in suspension or termination of the examination, a loss of rights that is plainly substantive.

The principal opinion also dismissed the implications of the ESD requirement on claim scope and inequitable conduct. As to the former, it asserted that applicants have no right to “remain silent” during examination, and it opined that the latter concern should be resolved through reform of the rules governing disclosure or the law of inequitable conduct. *Op.* at 1358. The approach reflected in the principal opinion of dealing with the fatal vagueness of the ESD regulation is to suggest that applicants prosecute and litigate patents at their peril based on

⁷ The PTO cannot explain how to comply with Rule 265’s preexamination search requirements. In response to critical comments, the PTO only stated that “[i]f applicant follows the search guidelines set forth in the MPEP, then the preexamination search *should* be sufficient.” GSK App. Br. at 51-52 (quoting JA136; emphasis added).

their own self-imposed search limitations. The fiction of this assumption is that it is reasonable to rely on a standard which relies on this Court to tell applicants, on a case-by-case basis, whether their ESD-mandated search was adequate or if they committed inequitable conduct in preparing, providing and continually updating that ESD during examination. This is an unacceptable approach. Industry needs business certainty at the front end of the examination process to make well reasoned decisions based on clear rules. Patent applicants cannot play the high risk game of going forward with millions of dollars of investment without any assurance that the investment will be adequately protected.

As a practical matter, many applicants, to avoid the real and substantial risks created by the ESD requirement, will limit the number of claims they present to match the PTO's prescribed limits. Yet, "Placing an arbitrary limit on the number of claims in an application drastically affects an applicant's rights and obligations under the Patent Act." *Dissent* at 1372. By limiting an inventor's ability to fully claim an invention, the Rules will diminish the inventor's incentive to disclose the full scope of the technological advance. In other words, "Rule 75 frustrates the quid pro quo contemplated by the Patent Act." *Id.* at 1373.

The ESD requirement is also inconsistent with the Patent Act because it improperly shifts the burden of examination onto applicants. Sections 102 and 131 of the Patent Act provide, respectively, that "[a] person shall be entitled to a

patent” and “[t]he Director shall cause an examination to be made of the application.” “Thus, the PTO bears the burden of putting forth a prima facie case of unpatentability.” *Dissent* at 1373. Rule 265, by imposing an affirmative duty to perform a prior art search and opine on patentability, has a substantive effect and goes beyond the authority the PTO has been delegated by Congress.

III. Conclusion

The questions presented here are exceptionally important. The panel’s expansion of the PTO’s rulemaking authority and its conflicting views as to the proper analysis for determining whether a rule falls within the PTO’s authority create uncertainty, threaten to stifle innovation, and significantly affect a wide array of industries. Congress did not authorize the PTO to make such substantive changes by rulemaking. This Court should rehear the case *en banc*.

Dated: June 3, 2009

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