United States Court of Appeals

FOR THE FEDERAL CIRCUIT

TRIANTAFYLLOS TAFAS,

Plaintiff-Appellee,

—and—

SMITHKLINE BEECHAM CORPORATION (d/b/a GlaxoSmithKline), SMITHKLINE BEECHAM PLC, and GLAXO GROUP LIMITED (d/b/a GlaxoSmithKline),

Plaintiffs-Appellees,

—v.—

JOHN L. DOLL, 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

BRIEF OF AMICUS CURIAE NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF APPELLEES' PETITIONS FOR PANEL REHEARING AND REHEARING EN BANC

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June 16, 2009

CERTIFICATE OF INTEREST

In accordance with Fed.Cir.R. 29(a) and 47.4, the undersigned counsel of record for amicus curiae New York Intellectual Property Law Association hereby certifies the following:

- 1. The name of every party or amicus curiae represented by me or by the other below-identified attorneys in connection with this proceeding is: New York Intellectual Property Law Association.
- 2. The name of the real party in interest (if such party is not named in the caption of this brief) is: New York Intellectual Property Law Association.
- 3. The parent companies, subsidiaries (except wholly-owned subsidiaries), and affiliates of the party or amicus curiae represented by me and that have issued shares to the public, are: <u>None</u>.
- 4. The names of all law firms and partners or associates that appeared for the parties or *amici* now represented by me in the trial court or agency and who are expected to appear in this Court are indicated below.

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STATEMENT OF IDENTITY, INTEREST, AND AUTHORITY OF AMICUS CURIAE UNDER FED. R. APP. P. 29(c)(3)

The New York Intellectual Property Law Association ("NYIPLA") submits this brief as amicus curiae in support of the Plaintiffs-Appellees' petitions requesting a panel rehearing or rehearing en banc. This brief focuses on the portion of the panel decision¹ reversing the district court's judgment enjoining the United States Patent and Trademark Office ("PTO's") enactment of rules 75 and 265.2 These rules unduly and unnecessarily burden patent applicants for exceeding an arbitrary number of claims, whether presented in a single application or in a group of commonly owned applications containing one or more "indistinct claims," by requiring submission of a so-called Examination Support Document ("ESD"). The district court correctly held that the PTO has no statutory authority to enact such rules because their impact on the rights of inventors would be so unduly adverse as to constitute impermissibly substantive and hence *ultra vires* rulemaking meriting no judicial deference. The panel's decision reversing the district court is contrary to precedent and would validate future actions by the PTO to carry out still more legislative "rulemaking" that would substantively change other areas of patent law and the long-standing rights of patent applicants. For the reasons set forth herein, this Court should grant Appellees' petitions for a rehearing and affirm the district court's judgment.

¹ Tafas v. Doll, 559 F.3d 1345 (Fed. Cir. 2009), rev'g in part Tafas v. Dudas, 541 F. Supp. 2d 805 (E.D. Va. 2008).

NYIPLA was informed that other *amici* would submit briefs addressing other aspects of the March 20, 2009 panel decision not discussed in detail here.

In accordance with Fed. R. App. P. 29(a), all parties to this appeal, through their respective counsels of record, orally consented on or about June 5, 2009 to the submission of this brief.

Amicus curiae NYIPLA and its counsel appearing in this proceeding represent that they have authored this brief, that no party or counsel for a party in this proceeding authored any part of this brief, and that no person other than the NYIPLA, its members or its counsel, including any party or counsel for a party, made any monetary contribution intended to fund the preparation or submission of this brief. The arguments set forth in this brief were approved on or about June 12, 2009 by an absolute majority of the total number of officers and members of the Board of Directors of the NYIPLA (including such officers and Board members who did not vote for any reason including recusal), but may not necessarily reflect the views of a majority of the members of the NYIPLA or of the organizations with which those members are affiliated. After reasonable investigation, the NYIPLA believes that no officer, or member of its Board or of its Amicus Briefs Committee who voted in favor of this brief, or any attorney in the law firm or corporation of such officer, Board or Committee member, or attorney who aided in preparing this brief, represents a party in this litigation. Some officers, Board or Committee members or other attorneys in their respective law firms or corporations may represent entities, including other amici, which have an interest in other matters that may be affected by the outcome of this proceeding.

The NYIPLA is a bar association of approximately 1,600 attorneys whose professional interests and practices lie mainly in the areas of patents, copyrights, trademarks, trade secrets and other forms of intellectual property. A

more detailed description of the NYIPLA's history and activities is included in its amicus brief filed with this Court on October 3, 2008 in support of Plaintiff's-Appellees' earlier reply to the PTO's appeal from the district court's decision.

The NYIPLA supports ongoing review of the PTO's practices and procedures aimed at improving the patent examination process and the quality of patents issued by the agency. The NYIPLA is mindful of the PTO's need to manage the ever-increasing number of patent applications filed and pending each year, as well as the "large and growing backlog of unexamined patent applications." But the PTO's attempt to do this by foreclosing applicants from exercising their rights under the Patent Act is not a valid option. The NYIPLA believes that whatever challenges the PTO faces stem from issues that can and should be addressed by statutorily permissible rulemaking and applying existing rules that are intended to curb abuses in the filing of patent applications. If this is not sufficient, the remedy must come from Congress.⁴

³ 72 Fed. Reg. 46717, 46790 (Aug. 21, 2007).

⁴ Food and Drug Administration v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000) (an agency may not engage in rulemaking that exceeds the authority granted it by Congress).

ARGUMENT IN SUPPORT OF APPELLEES' PETITIONS

The panel erred in its application of Supreme Court and Federal Circuit precedent characterizing a PTO rule as impermissible "substantive" rulemaking if it impacts a party's rights and obligations by changing existing law and policy, and causes inconveniences that more than "incidental ...[to] complying with an enforcement scheme." The changes to patent practice that would be imposed by enforcement of the new rules would be profound and deserve reexamination in a rehearing by the Court.

The Court Should Rehear Its Decision Reversing The District Court's Injunction Against The Implementation of the PTO's 5/25 Claim Limit And ESD Rules

The NYIPLA presents this amicus brief in support of a panel rehearing or rehearing en banc as to Final Rules 114, 75, and 265, but addresses rules 75 and 265 with greater specificity. In the three-judge panel decision, the majority and concurring judges found that the PTO had not exceeded its authority as to challenged Final Rules, but could not agree on the applicable framework and rationale. The third judge, in a dissenting opinion and following established precedent, argued that the *Chrysler Corporation's* "affecting individual rights and

Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications; Final Rule, 72 Fed. Reg. 46716 - 46843 (Aug. 21, 2007). The particular Final Rules addressed in this amicus brief are 37 C.F.R. § 1.75(b)(1) - (5) (limiting the number of claims in patent applications to 25 total claims including 5 independent claims in the absence of an "Examination Support Document" or "ESD"); and 37 C.F.R. § 1.265 (requirements for ESDs).

The fractured nature of the panel decision provides little guidance as to when an agency's rules constitute impermissible substantive rule-making; the absence of a clear standard in and of itself warrants review in a panel rehearing or rehearing en banc.

obligations" test should apply.⁷ The dissent applied a case-by-case test and concluded that the Final Rules not only "affect individual rights and obligations" but also change existing patent law and policy.⁸ Noting existing case law, the dissent stated that the challenged Final Rules are not mere "incidental inconveniences of complying with an enforcement scheme." He therefore deemed the Final Rules substantive in nature and beyond the PTO's limited authority. Given the conflict between the panel decision and established precedent, the NYIPLA urges this Court to grant a panel rehearing or rehearing en banc.

The changes caused by the challenged Final Rules would have significant and negative consequences on the substantive rights of patent applicants. The PTO's pre-existing rules governing the number of claims in patent applications¹¹ and the PTO's examination of patent applications¹² are well-established hallmarks of the U.S. patent system; they are grounded on and consistent with fundamental

⁷ Tafas v. Doll, 559 F.3d at 1369 (citing Chrysler Corp. v. Brown, 441 U.S. 281 (1979)) (Rader, J., dissenting)

⁸ *Id.* at 1369-70.

Id. at 1370 (citing to Chamber of Commerce v. Dep't of Labor, 335 U.S. App. D.C. 370 (D.C. Cir. 1999); Animal Legal Defense Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991); Cooper Technologies Co. v. Dudas, 536 F.3d 1330 (Fed. Cir. 2008).

¹⁰ *Id.* at 1371.

³⁷ C.F.R. § 1.75 currently states that "(a) [t]he specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention or discovery;" "(b) [m]ore than one claim may be presented provided they differ substantially from each other and are not unduly multiplied;" and (c) "[o]ne or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the subject application." [Emphasis added].

³⁷ C.F.R. § 1.104(a)(1) currently states that "[o]n taking up an application for examination . . ., the *examiner shall* . . . *make* <u>a thorough investigation of the</u> <u>available prior art</u> relating to the subject matter of the claimed invention." The examination shall be complete with respect both to compliance of the application . . . with the applicable statutes and rules and to the patentability of the invention as claimed . . .". [Emphasis added].

precepts set forth in the Patent Act.¹³ The Final Rules, however, would impose undue restrictions and obligations that effectively alter these long-established statutory rights of patent applicants.

According to the Patent Act, controlling judicial precedent, and this Court's March 20, 2009 holding, the PTO may promulgate only those rules -- whether procedural or interpretive -- that implement provisions of the Patent Act that are germane to the agency's administrative function, and do not materially diminish the existing rights of those having matters before the agency. Correlative to this fundamental precept is the core principle that Appellees seek judicial affirmation in their Petitions, namely, that the PTO may enact <u>no rule</u> that is legislative and hence substantive in the sense of altering those rights.

The rights that would be jeopardized by the Final Rules include the statutory rights of patent applicants under 35 U.S.C. § 102(a), (b), (d), (e) and (g)(2); 35 U.S.C. § 112, beginning with the second sentence; and 35 U.S.C. § 131, and the PTO's existing administrative rule in 37 C.F.R. § 1.104(a)(1). Congress delegated to the PTO the responsibility for granting and issuing patents solely in a manner consistent with what is now 35 U.S.C. § 2(a), and for examining patent applications and conducting other proceedings solely in a manner consistent with § 2(b). These statutes, and § 2(b)(2) in particular, cabin the PTO's rulemaking authority and form the statutory framework that protects patent applicants' substantive rights under the Patent Act from *ultra vires* rulemaking.

With respect to the number of claims in an application, see 35 U.S.C. § 112, second paragraph *et seq.* 35 U.S.C. § 131 imposes *an unconditional obligation* upon the PTO to examine each and every patent application.

In seeking to alter the substantive rights that patent applicants have long enjoyed under these statutes, the PTO has taken upon itself to construe -- and would have this Court construe -- those statutes in a way that is not only at odds with their plain wording and intendment, but also unreasonable in a practical sense. In doing so, the PTO has exceeded its authority as an administrative agency. Its actions are *ultra vires* and entitled to no deference.

Whether labeled "procedural" or "interpretive," the Final Rules are unlawful because they are substantive in nature. They would change important precepts of existing law and would alter the rights and interests of applicants, rather than address the procedure in which their applications are presented for examination.

Here, the panel erred in failing to recognize the degree to which Final Rules 75 and 265 would affect individual rights and obligations. Final Rule 75(b)(1)-(5) (the "5/25 Rule") restricts inventors to twenty-five claims (including five (5) independent claims) unless they submit an ESD. The ESD would have to identify all of the features in each of the claims that are disclosed by references uncovered in a broad search of the prior art that the applicant will be required to carry out in the first instance, and explain in detail how the subject matter defined in each claim is patentable over the references reported in the ESD.

By effectively placing an arbitrary limit on the number of claims permitted by the PTO to be filed in an application, these rules are substantive. As observed by the dissent, this limitation alters the obligations under 35 U.S.C. §§ 102, 103, 112, and 131¹⁴ and is contrary to precedent that suggests no limit on the

Sections 102, 103, and 112 place no limits on the number of permissible claims; an applicant "shall" be entitled to a patent for inventions satisfying the requisite

number of claims."¹⁵ Further, by limiting the number of claims, Final Rule 75 ignores the various ways of claiming inventions across different fields and technologies, some of which require a greater number of claims due to an invention's nature or complexity. ¹⁶ In addition, the incentive to disclose is commensurate with the level of protection (or number of claims) afforded to the inventor; capping the number of claims that an inventor may seek discourages full disclosure of the innovation. ¹⁷

The ESD requirement would unlawfully shift the responsibility for assessing patentability from the PTO to the applicant; this would fundamentally alter patent law and policy. Under existing law, the statutory task of evaluating applications falls exclusively upon the examiner under 37 C.F.R. § 1.104, ¹⁸ which implements the command of 35 U.S.C. § 131 that the PTO assess the patentability of claimed inventions. Shifting this burden to the applicant (to provide a detailed explanation of how each of the independent claims is patentable over the cited references) significantly alters practice before the PTO, represents "a change in existing law or policy", and most importantly, amounts to more than an "incidental inconvenience" to the applicant. First, placing such a burdensome obligation on the applicant may unnecessarily subject him to potential inequitable conduct

conditions for patentability, upon examination. Placing a limit on the number of permissible claims hinders an applicant from particularly pointing out and claiming his invention with "one or more claims", as required by section 112. See also Tafas v. Doll, 559 F.3d at 1372

Id. at 1372 (citing *In re Wakefield*, 422 F.2d 897, 900 (CCPA 1970) ("[A]n applicant should be allowed to determine the necessary number and scope of his claims"), and *In re Chandler*, 319 F.2d 211, 225 (CCPA 1963)).

¹⁶ *Id.* at 1373.

¹⁷ *Id.*

¹⁸ *Supra* at fn. 11.

allegations, for rejecting some prior art as less pertinent.¹⁹ Also, sections 102 and 131 provide that an applicant "shall" be entitled to a patent if certain conditions of patentability are satisfied, and that it "shall" be the examiner who causes an examination of the application, not the applicant.²⁰ Indeed, this Court has held that an applicant need not conduct a prior art search; and certainly it has not imposed a duty on the applicant to prove patentability.²¹

Contrary to the PTO's assertion that an ESD would serve as a "launch pad" for additional searching within the PTO, examiners (whose performance evaluations are determined in large part by the number of case "disposals" they achieve in each calendar quarter), would be inclined to rely unduly, if not entirely, on what an applicant submits by way of prior art. Congress has unambiguously made the PTO responsible for examining the application and searching for (and analyzing) the prior art with or without input from the applicant.

The impropriety of requiring ESD's is further reinforced by the fact that the fees associated with the filing of an application include money paid by the applicant for the examiner's search for prior art to be applied against the claimed invention. Moreover, such fees include a surcharge for presenting claims in excess of three independent and twenty total claims; hence, the PTO is already receiving increased revenue from applicants who submit additional claims for examination. By also having to review and characterize the prior art, the applicant is in effect paying for the dubious privilege of wearing two hats – that of the applicant and that

¹⁹ See also Tafas v. Doll, 559 F.3d at 1373.

Id

Id. (citing Frazier v. Roessel Cine Photo Tech, Inc., 417 F.3d 1230, 1238 (Fed. Cir. 2005) and In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992)).

of an examiner.

CONCLUSION

For all of the reasons herein set forth, amicus curiae NYIPLA respectfully urges the Court to grant Appellees' petitions for panel rehearing or rehearing en banc in order to reconsider its decision reversing the district court's judgment, permanently enjoining the PTO from implementing the Final Rules, a judgment widely applauded by the patent community.

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Pursuant to Fed. R. App. P. 25(b), (c), and (d), I, Charles E. Miller, being

duly sworn, depose and certify that I am not a party to the present action, I am over

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FOR PANEL HEARING OR REHEARING EN BANC

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The undersigned hereby certifies that:

- 1. This brief complies with the type-volume limitations of Fed. R. App. P. 29(d) and 32(a)(7)(B) because it contains 2709 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed.Cir.R. 32(b).
- 2. This brief complies with the type-face requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionately-spaced type-face using Microsoft Office Word 2003 in 14-point Times New Roman type-style.

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