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In a Split-Panel Decision, Federal Circuit Upholds the Invalidity of Just One of the Four Challenged PTO Rules

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Judges: Rader (concurring-in-part and dissenting-in-part), Bryson (concurring), Prost (author)

[Appealed from E.D. Va., Senior Judge Cacheris]

In *Tafas v. Doll*, No. 08-1352 (Fed. Cir. Mar. 20, 2009), the Federal Circuit, in a split-panel decision, affirmed the district court's grant of SJ that Final Rule 78 is inconsistent with 35 U.S.C. § 120 and vacated the district court's grant of SJ with respect to Final Rules 75, 114, and 265.

The PTO issued new rules in August 2007. Four of the new rules (collectively the "Final Rules") were at issue in this appeal. Final Rules 78 and 114 pertain to continuation applications and requests for continued examination ("RCEs"). Final Rule 78 governs the availability of continuation and continuation-in-part applications. Under Final Rule 78, an applicant is entitled to file two continuation applications as a matter of right. If an applicant wishes to pursue more than two continuation applications, he must file a petition "showing that the amendment, argument, or evidence

sought to be entered could not have been submitted during the prosecution of the prior-filed application." 37 C.F.R. § 1.78(d)(1)(vi). If the applicant cannot make the requisite showing, the PTO will accept the application for examination but will "refuse to enter, or will delete if present, any specific reference to a prior-filed application." *Id.* § 1.78(d)(1). The effect of this is to remove the application from the scope of 35 U.S.C. § 120, which would otherwise entitle the application to the filing date of the prior-filed application. Final Rule 114 provides for similar treatment of RCEs. Under the rule, an applicant is allowed one RCE as a matter of right. 37 C.F.R. § 1.114(f). For each additional RCE, the applicant must file a petition "showing that the amendment, argument, or evidence sought to be entered could not have been submitted prior to the close of prosecution in the application." *Id.* § 1.114(g). The limitation on RCEs is applied on the basis of application families rather than individual applications. *Id.* § 1.114(f).

The two other rules, Final Rules 75 and 265, were intended to address the PTO's difficulty in examining applications that contain a large number of claims. Final Rule 75 requires an applicant who submits either more than five independent claims or twenty-five total claims to provide the examiner with information in an examination support document ("ESD"). 37 C.F.R. § 1.75(b)(1). The requirements for ESDs are set forth in Final Rule 265. To comply with Final Rule 265, an applicant must

conduct a preexamination prior art search, provide a list of the most relevant references, identify which limitations are disclosed by each reference, explain how each independent claim is patentable over the references, and show where in the specification each limitation is disclosed in accordance with 35 U.S.C. § 112, ¶ 1. 37 C.F.R. § 1.265(a).

“We do not believe that requiring applicants to raise all then-available amendments, arguments, and evidence by the second continuation application or the first RCE is so significant a burden that applicants will be effectively foreclosed from obtaining the patent rights to which they are entitled.” Slip op. at 15.

Shortly after the Final Rules were published in the Federal Register, Triantafyllos Tafas, Smithkline Beecham Corporation, and Glaxo Group Limited (collectively “Tafas”) filed suit against the PTO. The district court preliminarily enjoined enforcement of the Final Rules. *Tafas v. Dudas*, 511 F. Supp. 2d 652 (E.D. Va. 2007). Tafas moved for SJ that the Final Rules are invalid and sought a permanent injunction against their enforcement, alleging that the Final Rules were impermissibly substantive, inconsistent with law, arbitrary and capricious, incomprehensibly vague, impermissibly retroactive, and procedurally defective. The district court granted the motion for SJ, finding the Final Rules were “substantive rules that change existing law and alter the rights of applicants such as [Tafas] under the Patent Act.” *Tafas v. Dudas*, 541 F. Supp. 2d 805, 814 (E.D. Va. 2008). The PTO appealed to the Federal Circuit.

On appeal, the Federal Circuit first addressed whether the PTO’s rulemaking authority is subject to a substantive/procedural distinction. The Court found that 35 U.S.C. § 2(b)(2) does not vest the PTO with any general substantive rulemaking power. “A substantive declaration

with regard to the Commissioner’s interpretation of the patent statutes, whether it be section 101, 102, 103, 112 or other section, does not fall within the usual interpretation of [the language in section 6, the predecessor of § 2(b)(2)].” Slip op. at 7 (alteration in original) (citing *Merk & Co. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996)). The Court concluded that the decision of Congress to replace § 6(a) with § 2(b)(2), which contains the same grant of authority to regulate “the conduct of proceedings in the Office,” is indicative that Congress did not intend to give the PTO substantive rulemaking authority, and further, that Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change.

The Court next turned to whether the PTO’s interpretations of statutes pertaining to the PTO’s delegated authority are entitled to *Chevron* deference. Concluding that the PTO’s interpretations of statutes that pertain to the PTO’s delegated authority, i.e., procedural rules promulgated under § 2(b)(2) or § 132(b), are entitled to *Chevron* deference. Therefore, when reviewing rules within the PTO’s delegated authority, the Court held that it would give *Chevron* deference to the PTO’s interpretation of statutory provisions that relate to the exercise of delegated authority.

The Federal Circuit then turned to whether the Final Rules were substantive or procedural in nature. While the Court did not purport to set forth a definitive rule for distinguishing between substance and procedure, it concluded that the Final Rules challenged here are procedural, finding, in essence, that they governed the timing of and materials that must be submitted with patent applications. The Court held that although the Final Rules may “alter the manner in which the parties present . . . their viewpoints” to the PTO, they do not, on their face, “foreclose effective opportunity” to present patent applications for examination. Slip op. at 14 (alteration in original).

Applying this rationale to Final Rules 78 and 114, the Court stated that it “[did] not believe that requiring applicants to raise all then-available amendments, arguments, and evidence by the

second continuation application or the first RCE is so significant a burden that applicants will be effectively foreclosed from obtaining the patent rights to which they are entitled." *Id.* at 15. Moreover, although the PTO published responses to questions raised during the notice and comment proceedings indicating that the PTO intends to deny additional applications in almost all circumstances, the Court declined to rely on these responses. The Court noted that the responses were not binding on the courts, which will be free to review the PTO's application of the Final Rules under the standard set forth in 5 U.S.C. § 706.

With respect to the ESD requirement of Final Rules 75 and 265, the Court noted that once a satisfactory ESD is submitted, examination will proceed in precisely the same manner as it would have in the absence of the rule. While the rule may put a burden of production on the applicant, the examiner maintains the burden of persuasion. The Court found that a procedural rule does not become substantive simply because it requires the applicant to exert more effort to comply, so long as the effort required is not so great that it effectively forecloses the possibility of compliance. In response to arguments that compliance with the ESD requirement is both impossible in requiring a worldwide search of prior art without regard to scope, time, or cost, the Court found that Final Rule 265 only requires applicants to conduct a reasonable, cost-effective search. Moreover, to the extent the PTO applies the rules in a way that makes compliance essentially impossible, judicial review will be available under § 706.

The Court regarded as "too speculative" the proposition that even the most diligently prepared ESD will inevitably open an applicant to inequitable conduct allegations, entailing costly litigation and a possible finding of unenforceability. The Court declined to decide that an otherwise valid PTO rule that requires applicants to provide information is void because the Court might in the future apply the inequitable conduct doctrine in such a way that honest applicants who comply in good faith will nevertheless lose their patent rights. In response to the argument that ESDs will decrease the

value of patent rights because the statements therein will limit claim scope through prosecution history estoppel, the Court held that it did not believe applicants have a right to remain silent throughout prosecution in order to maximize their advantage in later litigation.

Having found the Final Rules to be procedural, the Federal Circuit next turned to their consistency with the Patent Act. Agreeing with the district court, although on narrower grounds, the Federal Circuit held that Final Rule 78 was inconsistent with the statutory mandate that qualifying applications "shall have" the benefit of the priority date of the initial application as set forth in § 120. The Court found that the use of "shall" indicates the requirements are exclusive, and that all applications that meet these requirements must receive the benefit provided by § 120. The Court therefore concluded that Rule 78 was invalid as it attempted to add an additional requirement that the application not contain amendments, arguments, or evidence that could have been submitted earlier.

Overtaking the district court's decision, the Federal Circuit found Final Rule 114 valid and not in conflict with the Patent Act. The Court found that § 132, which uses the singular form of "application," did not unambiguously dictate that the provisions be applied on a per application basis. The Court therefore concluded that Final Rule 114 can properly be applied on a per family basis. Further, the Court found § 132(b)'s mandate that "[t]he director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant" not to unambiguously require the PTO to grant unlimited RCEs. The Court therefore deferred to the PTO's interpretation of § 132(b). Section 132(a) requires the PTO to continue examination if "the applicant persists in his claim for a patent." The PTO argued that subsection (a) provides for the "reexamination" of an application at the applicant's request after the initial examination provided in § 131, and in contrast, "continued examination" under subsection (b) occurs after the reexamination provided for in subsection (a) is complete. The Federal Circuit found the PTO's explanation

distinguishing § 132(a) and § 132(b) “reasonable,” and therefore deferred to the PTO interpretation that § 132(a) does not require it to grant unlimited RCEs. The Court found that under these interpretations, Final Rule 114 did not to conflict with § 132.

The Federal Circuit also held Final Rules 75 and 265 valid, and not in conflict with the Patent Act or the Court’s precedent holding that applicants have no duty to search the prior art. The Court noted that the rule simply required an ESD be submitted if more than five independent or twenty-five total claims were included in certain sets of copending applications. The Court reasoned that because it could not conclude that Final Rules 75 and 265, on their face, effectively foreclosed applicants from successfully submitting ESDs, it could not conclude that these rules place an absolute limit on claim numbers in violation of § 112, ¶ 2. In response to Tafas’s argument that the Final Rules are inconsistent with the Court’s inequitable conduct cases, the Court found that there was no persuasive reason to prohibit the PTO from requesting the information required by Final Rule 265. Finally, agreeing with the district court that the PTO bears the initial burden of proving unpatentability, the Court disagreed that the ESD requirement shifts that burden. The Court found that while creating an additional procedural step for the submission of applications, the ESD requirement did not alter the ultimate burdens of the examiner or applicant during examination.

Accordingly, the Court concluded that Final Rules 75, 78, 114, and 265 are procedural rules that are within the scope of the PTO’s rulemaking authority. Further, the Court concluded that Final Rule 78 conflicts with 35 U.S.C. § 120, and thus affirmed the district court’s grant of SJ that Final Rule 78 is invalid. The Court also vacated its grant of SJ with respect to Final Rules 75, 114, and 265, and remanded for further proceedings consistent with its opinion. The Court expressly declined to address the following issues: whether any of the Final Rules, either on their face or as applied in any specific circumstances, are arbitrary and capricious; whether any of the Final Rules conflict with the Patent Act in ways not specifically addressed in the Court’s opinion;

whether all PTO rulemaking is subject to notice and comment rulemaking under 5 U.S.C. § 553; whether any of the Final Rules are impermissibly vague; and whether the Final Rules are impermissibly retroactive.

In a concurring opinion, Judge Bryson agreed with the majority that the regulations in this case are of the type that Congress authorized in § 2(b). Judge Bryson likewise concluded that the issue here comes down to whether the challenged regulations are consistent with other provisions of the Patent Act. Agreeing that Final Rule 78 is invalid for the reasons given by the majority, Judge Bryson noted the narrow scope of the Court’s decision. The Court held that Final Rule 78 is invalid because it limits the number of continuation applications that may be filed and applies that limit even if all of the continuation applications are filed while the first application is still pending. In Judge Bryson’s view, while that is a sufficient reason to invalidate Final Rule 78, it does not answer the question as to whether the rule is invalid as applied to serial continuances, i.e., a series of continuances in which each was copending with its immediate predecessor, but in which only the second in the series was copending with the first application.

Under current law, all continuances in such a series, if they satisfy the other requirements of § 120, are deemed to have the same effective date as the first application. In Judge Bryson’s view, Rule 78 would change that practice. As to serial continuances, § 120 provides that an application for continued prosecution is entitled to the benefit of an earlier priority date when it is copending with “an application similarly entitled to the benefit of the filing date of the first application.” That portion of § 120 has been understood to confer upon patent applicants the right to file any number of successive continuation applications after the first application has been abandoned or issued as a patent. Judge Bryson found that it would not be unreasonable to construe the phrase “an application similarly entitled” to mean an application that satisfies all the preceding requirements set forth in § 120, including the requirement of copendency with the initial application. Judge Bryson noted that the

question remains open as to whether a revised rule that addressed only serial continuances and limited such continuances to only two—the first copending with the original application and the second copending with the first—would be struck down as reflecting an impermissible interpretation of § 120.

“The Final Rules affect individual rights and obligations, and mark a startling change in existing law and patent policy.” Rader Dissent at 7.

In a dissenting opinion, Judge Rader agreed with the majority’s ultimate conclusion regarding Final Rule 78 but disagreed with the majority’s decision with respect to Final Rules 74, 114 and 265. In Judge Rader’s view, the Final Rules are substantive, not procedural, and thus the PTO exceeded its statutory rulemaking authority in promulgating these rules. According to Judge Rader, this case asks the Court to ensure that the PTO has not exceeded its rulemaking authority, and it therefore makes no sense to classify a rule as “procedural” or “interpretative,” as either of those labels would lead to the same conclusion that the rule is nonsubstantive.

To Judge Rader, a case-by-case question of degree must guide the assessment of the substantive nature of the PTO’s Final Rules. He stated that the Final Rules are not incidental inconveniences of complying with an enforcement scheme, but rather, substantive rules that “affect individual rights and obligations, and mark a startling change in existing law and patent policy.” Rader Dissent at 7.

Judge Rader then considered each rule. He agreed with the majority’s ultimate conclusion with respect to Final Rule 78, finding that the rule contravenes the language of § 120. In Judge Rader’s view, the majority opinion ignored that the “substantive effect” of failing to meet this

new petition and showing obligation—the loss of priority date—is “sufficiently grave” to make this rule substantive. Likewise, Judge Rader found the impact and reach of Final Rule 114 would significantly affect patent prosecution. Because they require more than adherence to existing law, Judge Rader stated Final Rules 78 and 114 are substantive.

With respect to Final Rule 75, Judge Rader found this rule alters obligations under 35 U.S.C. §§ 102, 103, 112, and 131. In Judge Rader’s view, placing a mechanical cap on the number of claims in an application hinders an applicant’s right and obligation to particularly point out and distinctly claim the subject matter that the applicant regards as his invention. Judge Rader stated that “limiting an applicant to five independent claims ignores the varying scopes and methods of claiming inventions across different technologies.” *Id.* at 12. He further noted that an inventor’s incentive to disclose is commensurate with the protection available, and Final Rule 75 frustrates the quid pro quo contemplated by the Patent Act.

Finally, regarding Final Rule 265, Judge Rader found the ESD requirement improperly shifts the burden of proving patentability onto the applicant in direct conflict with the Court’s interpretation of § 102. Judge Rader noted that although the Court has upheld the PTO’s authority to request such information as may be reasonably necessary to properly examine or treat the matter, this requirement relates to information that is already in the applicant’s possession; it does not impose an affirmative duty to perform a prior art search or opine regarding patentability over the closest reference. In Judge Rader’s view, Final Rule 265 shifts the burden of proving patentability onto the applicant, and this shift significantly alters practice before the PTO, representing a change in existing law or policy. Finding the satisfaction of the ESD requirement to require more than adherence to existing law and amounting to more than the incidental inconveniences of complying with an enforcement scheme, Judge Rader concluded that Final Rule 265 was substantive.

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Abbreviations

ALJ Administrative Law Judge
ANDA Abbreviated New Drug Application
APA Administrative Procedures Act
APJ Administrative Patent Judge
Board Board of Patent Appeals and Interferences
Commissioner Commissioner of Patents and Trademarks
CIP Continuation-in-Part
DJ Declaratory Judgment
DOE Doctrine of Equivalents
FDA Food and Drug Administration
IDS Information Disclosure Statement
ITC International Trade Commission
JMOL Judgment as a Matter of Law
MPEP Manual of Patent Examining Procedure
PCT Patent Cooperation Treaty
PTO United States Patent and Trademark Office
SJ Summary Judgment
TTAB Trademark Trial and Appeal Board

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