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Impact Looms Large in Federal Circuit Decision: USPTO and Patentees Still Locked in Showdown Following *Tafas v. Doll*

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On March 20, 2009, the Federal Circuit issued its decision on the USPTO's attempted implementation of four new rules on continuation applications, number of claims, and requests for continued examination ("RCE"). In *Tafas v. Doll*,[1] the panel found that the new rules are procedural rules that are within the scope of the USPTO's rulemaking authority. The panel also affirmed the district court's decision that the rule on continuation applications (Final Rule 78) was invalid on the ground that it was inconsistent with 35 U.S.C. § 120, but vacated the district court's invalidation of the remaining rules, and remanded the case for further proceedings. The Federal Circuit did not address whether the new rules are on their face or as applied in specific circumstances arbitrary and capricious, impermissibly vague or retroactive, or in conflict with the Patent Act on grounds other than those addressed in the decision and whether all USPTO rulemaking is subject to notice and comment rulemaking under 5 U.S.C. § 553. The district court may address these issues on remand. On balance, the ruling potentially gives the USPTO the type of authority to make rules it has been seeking -- the agency arguing that it needs these changes to streamline its processes and reduce its backlog of applications.

Background

On August 21, 2007, the USPTO issued four new rules on Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications.[2] These new rules are designated the "Final Rules."

Final Rules 78 and 114 are directed to continuation applications and RCEs, respectively. Under Final Rule 78, an applicant is entitled to file two continuation applications as a matter of right.[3] Additional continuation applications may be filed only if the applicant files 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."[4] Similarly, Final Rule 114 provides that an applicant is allowed one RCE as a matter of right *within an application family*.[5] A petition similar to Final Rule 78 must also be filed if an applicant seeks to file any additional RCEs.

Final Rules 75 and 265 impose obligations on applicants when the number of claims filed in co-pending applications exceeds five independent and twenty-five total claims.[6] Final Rule 75 requires a submission of an Examination Support Document ("ESD"), if these limits are exceeded.[7] Final Rule 265 sets out the requirements for ESDs, which include a pre-examination prior art search, a list of relevant references, identification of disclosure of claim limitations in each reference, explanation of patentability of each independent claim, and identification of support in the specification.

The Final Rules were to become effective on November 1, 2007. Triantafyllos Tafas, SmithKline Beecham Corporation, and Glaxo Group ("Tafas I") filed suit against the USPTO shortly after the publication of the Final Rules in the Federal Register. In *Tafas v. Dudas*, 511 F. Supp. 2d 652 (E.D. Va. 2007) ("*Tafas I*"), the district court preliminarily enjoined enforcement of the Final Rules. Tafas subsequently moved for summary judgment on the ground that the Final Rules were invalid and sought a permanent injunction. In *Tafas v. Dudas*, 541 F. Supp. 2d 805 (E.D. Va. 2007) ("*Tafas II*"), the district court granted Tafas' motion for summary judgment, on the grounds that the USPTO lacked substantive rulemaking authority and that the Final Rules were substantive. The USPTO subsequently appealed to the Federal Circuit. Among the issues before the Federal Circuit were whether the USPTO has substantive rulemaking authority, whether the Final Rules are substantive or procedural, and whether these rules are valid.

The Federal Circuit's Decision

The opinion of the majority was written by Judge Prost; Judge Bryson wrote a concurring opinion and Judge Rader concurred in part and dissented in part.

Rulemaking Authority
In setting out the analytical framework, the Federal Circuit agreed with the district court that the USPTO is not vested with any general substantive rulemaking power under the Patent Act,[8] citing *Merck & Co., Inc. v. Kessler*,[9] but is vested only the authority to establish regulations that govern "the conduct of proceedings." In addition, *Chevron*[10] deference can be given to the USPTO's interpretation of statutory provisions in relation to its rulemaking within its delegated authority, but not to the USPTO's determination of the scope of its own authority.

Final Rules are Procedural
In determining whether the Final Rules are considered "substantive" or "procedural," the Federal Circuit refused to adopt the analysis used by Tafas that the USPTO intends to deny additional continuation applications and RCEs in almost all circumstances and that the compliance to ESD requirements is impossible and decreases the value of patent rights. According to the opinion, the Final Rules are procedural because they "govern the timing of and materials that must be submitted with patent applications."[11] While an increased burden may be placed on the applicant, the examiner maintains the burden of persuasion in denying patentability.[12] "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."[13] The Federal Circuit therefore concluded that the Final Rules are procedural.

Final Rule 78
The Federal Circuit affirmed the district court's holding that Final Rule 78 is invalid. Invalidity was based on the conclusion that the rule is inconsistent with 35 U.S.C. § 120. Because § 120 unambiguously and plainly states that an application meeting the requirements of the statute shall have the "same effect" as if filed on the date of the priority, adding an additional requirement (*i.e.*, amendments, arguments, or evidence that could not have been submitted earlier) to these requirements is foreclosed by the statute. It was not clear whether the Court would consider limitations on serial continuation applications to be consistent with the statute, but Rule 78 does not address this.

Final Rule 114
The Federal Circuit, however, did not agree with the district court's holding that Final Rule 114 was

inconsistent with 35 U.S.C. § 132(a) and (b). The Federal Circuit rejected arguments that § 132 should be interpreted on a "per application" basis and that Congress intended RCEs to be unlimited in number at an applicant's discretion. The opinion deferred to the USPTO's reasonable interpretation of the statute, which allows the USPTO to "'prescribe regulations' to govern the applicant's ability to request continued examination, which must, in some circumstances, be granted."[14]

Final Rules 75 and 265

Similarly, the Federal Circuit did not agree with the district court's holding that Final Rules 75 and 265 violated 35 U.S.C. §§ 102, 103, 112, and 131. The ESD requirement of these rules, according to the Federal Circuit, is only required if more than five independent or twenty-five total claims are included in a set of co-pending applications. This additional procedural step does not alter the ultimate burdens of the examiner or applicant during application and does not foreclose applicants from successfully submitting ESDs. Concerns regarding exposure to inequitable conduct allegations based on any inadequacy in an ESD were considered not germane.

Concurring and Dissenting Opinions

Judge Bryson's opinion concurred with the outcome, but found the distinction between substantive and procedural rulemaking and the issue of deference to be unnecessary considerations, since, in his view, the statutes as properly interpreted provided the USPTO with the necessary authority.

In the opinion of Judge Rader, none of the Final Rules is valid, and the decision of the district court should have been affirmed.

Implications

The Federal Circuit's decision striking down Final Rule 78 is good news for patent applicants, despite a caveat that the USPTO may still be able to construct a rule limiting the number of serial continuation applications. At a minimum, any implementation of the remaining Final Rules will be further delayed, and it remains to be seen how the issues left open with respect to these rules will be decided on remand. The present decision vacating the district court's invalidation of Final Rules 114, 75, and 265 leaves the fate of these rules uncertain. Implementation of these rules will create challenges for patent applicants. As noted by the Federal Circuit, "[The courts] will be free to entertain challenges to the USPTO's application of the Final Rules." [15] Patent applicants may need to spend more time and money on litigating the application of the Final Rules, perhaps at the expense of focusing on research and development of a new invention. Much could depend on how the new administration and its political appointees decide to handle the rules battle. In addition, the split ruling may prompt a request for the Federal Circuit to review the case *en banc*.

Footnotes

[1] No. 2008-1352, slip op. (Fed. Cir. Mar. 20, 2009).

[2] 72 Fed. Reg. 46,716 (Aug. 21, 2007).

[3] 37 C.F.R. § 1.78(d)(1).

[4] *Id*.

[5] *Id*. § 1.114(f).

[6] 72 Fed. Reg. 46,721.

[7] 37 C.F.R. § 1.75(b)(1).

[8] Section 2(b)(2) of the Patent Act gives the USPTO authority to "establish regulation, not inconsistent with law, which . . . (A) shall govern the conduct of proceedings in the office; . . . (C) shall facilitate and expedite the processing of patent applications, particularly those which can be filed, stored, processed, searched, and retrieved electronically . . . (D) may govern the recognition and conduct of agents,

attorneys, or other persons representing applicants or other parties before the Office . . . ."

[9] *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996).

[10] *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

[11] Slip op. at 14.

[12] Slip op. at 16.

[13] Slip op. at 16-17.

[14] Slip op. at 27.

[15] Slip op. at 15-16.
