

News from our Intellectual Property, Life Sciences and Technology Transactions Groups

Round 2: Federal District Court Permanently Enjoins Enforcement of New Patent Rules

In what would have been one of the most anticipated, analyzed and, perhaps, most feared acts of the United States Patent and Trademark Office (USPTO) in recent years, the USPTO was set to implement sweeping revisions to its rules on November 1, 2007 (the "Final Rules").¹ The USPTO's plans were upset, however, when pharmaceutical manufacturer GlaxoSmithKline and inventor Triantafyllos Tafas sued the USPTO last fall and obtained a temporary injunction preventing the Final Rules from taking effect on time.²

Following the temporary injunction proceedings, the parties moved directly to summary judgment on the same issues. Earlier this week, the plaintiffs prevailed. On April 1, 2008, Judge James C. Cacharis ordered the Final Rules permanently enjoined.³ The fight may not be over, however, as at least one commentator is reporting that the USPTO will appeal the judgment to the Federal Circuit.⁴

The Final Rules made significant changes to several aspects of the patent application process. A *Cooley Alert* published on September 12, 2007, available at www.cooley.com/news/alerts.aspx?ID=000040765420, detailed those changes. In short, the Final Rules limited an applicant to two continuing applications and one request for continued examination (RCE) per applicant family, absent a petition justifying more. The Final Rules also limited an application to no more than five independent claims and twenty-five claims (the "5/25 Rule")

without the filing of an examination support document (ESD).

In enjoining the Final Rules, the Court held that the USPTO lacks substantive rulemaking authority under the Patent Act,⁵ and that the Final Rules were substantive in nature. Therefore, the USPTO had violated the Administrative Procedures Act (APA),⁶ and the Final Rules were "in excess of [the USPTO's] statutory jurisdiction [and] authority."⁷

In an attempt to save the Final Rules, the USPTO had aggressively argued that the distinction between "substantive rules" and "procedural rules" was not important.⁸ Instead, it sought to frame the issue as whether the Final Rules fell within its grant of authority under the Patent Act because "they 'govern the conduct of proceedings in the Office' by 'facilitat[ing] and expedit[ing]' the application process."⁹ The Court rejected this argument, concluding that the distinction between substance and procedure was important and controlling. It cited both the language of the statute and Congress' historical reluctance to make an express grant of the power the USPTO was claiming here as convincing evidence that the USPTO could not make substantive rules.¹⁰

The Court specifically examined the Final Rules relating to continuation applications, RCEs, and the 5/25 Rule. It held each to be a substantive rule, defining such as "any rule that 'affect[s] individual rights and obligations.'"¹¹

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The limit on continuation applications is substantive because it creates a “hard limit” that “changes existing law and deprives applicants of their valuable rights” to an unlimited number of continuation applications as granted under Section 120 of the Patent Act.¹²

The limit of one RCE per application family is substantive for two reasons. First, it is “a clear departure from the plain language of the statute,” which obligates the USPTO to provide for the continued examination of each application (and not of each application family).¹³ Second, and more importantly in the eyes of the Court, the language of the Patent Act demonstrates that Congress intended an unlimited number of RCEs to be filed at the discretion of the applicant and not of the USPTO.¹⁴

The 5/25 Rule is substantive in nature because the Court of Customs and Patents Appeals “has consistently held that the Patent Act does not place any mechanical limits on the number of claims an applicant may file.”¹⁵ The ability to overcome the 5/25 Rule by filing an ESD was not an acceptable solution in the eyes of the Court, because the ESD requirements shift the examination burden away from the USPTO and on to the applicant.¹⁶ This shift alters applicants’ rights under several sections of the Patent Act and “manifestly changes existing law.”¹⁷

Having held that the Final Rules were substantive rules, and that nothing in the Patent Act grants the USPTO the power to make substantive rules, the Court sided with the plaintiffs and against the USPTO. The parties and more than two dozen *amici curiae* (friends of the court) raised and argued several other issues in connection with the Final Rules. Judge Cacheris declined to address these arguments once he concluded that the Rules were substantive and beyond the authority of the USPTO, saying “one who judges least, judges best.”¹⁸

As noted above, there are early indications that the USPTO will appeal this decision. But even without appellate reversal, the plaintiffs’ victory may be temporary. Congress is contemplating legislation that could give the USPTO the very authority that Judge Cacheris concluded it now lacks.¹⁹

If you have questions or would like to discuss any issues concerning patent law, please feel free to contact one of the attorneys listed above. ■

NOTES

¹ The USPTO published the “Final Rules” in the Federal Register on August 21, 2007 (72 Fed. Reg. 46, 716-843).

² *Tafas v. Dudas*, No. 1:07-cv-00845, slip op. (E.D. Va. Oct. 31, 2007). The opinion may be accessed through the Court’s website at www.vaed.uscourts.gov/opinions/index.htm.

³ *Tafas v. Dudas*, No. 1:07-cv-00846, slip op. (E.D. Va. Apr. 1, 2008).

⁴ See Dennis Crouch, *Patently-O: patent law blog*, available at www.patently.com/patent/.

⁵ See 35 U.S.C. § 2(b)(2).

⁶ 5 U.S.C. § 706(2).

⁷ *Tafas* at 25 (quoting 5 U.S.C. § 706(2)).

⁸ See *Tafas* at 14.

⁹ *Id.* at 14-15 (quoting 35 U.S.C. § 2(b)(2)).

¹⁰ *Id.* at 11-16.

¹¹ *Id.* at 17 (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979)).

¹² *Id.* at 20.

¹³ *Id.*

¹⁴ *Id.* at 21.

¹⁵ *Id.* at 22.

¹⁶ *Id.* at 25.

¹⁷ *Id.*

¹⁸ *Id.* at 10.

¹⁹ The House of Representatives passed the Patent Reform Act in Sept. of 2007. That bill grants the USPTO substantive rulemaking authority. See Patent Reform Act, H.R. 1908, 110th Cong. § 14 (2007). However, the Senate’s Bill, S. 1145, does not grant that power. See S. 1145, 110th Cong. (2007). While the Senate Judiciary Committee sent the bill to the full Senate in July of 2007, there has been no vote. The House and Senate bills continue to be amended, and it is not clear which position, if either, will emerge as the final result.