

## A Review of *Tafas v. Doll*

May 21, 2009

By: Paul M. Rivard  
PharmExec Direct

On March 20, 2009, the US Court of Appeals for the Federal Circuit issued a surprising decision in the closely watched case *Tafas v. Doll*. The three-judge panel largely reversed a lower court's ruling that set aside a controversial set of patent regulations that would sharply restrict the number of continuations, claims, and requests for continued examination that patent applicants may file. The Patent and Trademark Office argued that the regulations would help the agency deal with its growing backlog of applications while providing suitable safeguards that allow applicants to file additional continuations or requests for continued examination when justified. Co-plaintiffs *Tafas* and GlaxoSmithKline argued that the regulations would have devastating consequences in the pharmaceutical industry, where long periods associated with drug discovery and clinical trials frequently require applicants to file a number of continuing applications to secure adequate patent protection for their innovations. The plaintiffs also argued that the alleged safeguards are inadequate because the vast majority of applications would not satisfy the required standards.

Contrary to the lower court's ruling, the majority opinion of the Court of Appeals held that the rules were the type of "procedural" guidelines that the agency is permitted to adopt. However, the appeals court agreed with the lower court that a rule limiting applicants to two continuing applications was invalid, as it conflicted with existing patent laws. The remaining regulations were upheld, including one rule requiring an

"examination support document" when more than five independent claims or 25 total claims are filed, and another limiting applicants to a single request for continued examination in a patent family. Additional requests for continued examination would be available if the applicant is able to make a showing that the request could not have been presented earlier.

Although the Federal Circuit agreed that the "two continuation" rule was invalid, it did so on narrow grounds. The appeals court held that under existing law, the Patent and Trademark Office may not place a limit on the number of continuations that may be filed *while a first application is still pending*. The decision left open the possibility that the agency may be permitted to restrict the number of continuations filed in succession, or, put another way, the number of applications through which an application may claim priority to a first-filed application.

The appeals court discounted plaintiffs' arguments concerning uncertainties in the standards that would be applied for examination support documents and petitions for a second or subsequent request for continued examination. The Federal Circuit explained that applicants would have the opportunity to challenge any abuses in the administration of these rules on a case-by-case basis.

The Federal Circuit noted its decision was limited to reversing the lower court's finding that the rules were

"substantive"—a status the Patent and Trademark Office does not have authority to grant. The case was remanded back to the lower court to consider other possible infirmities in the remaining rules, such as whether the rules are arbitrary or capricious, impermissibly vague, impermissibly retroactive, or in conflict with the patent laws or federal rulemaking procedures.

But before the lower court grapples with these issues, many expect the plaintiffs will ask the Federal Circuit to rehear the appeal *en banc* (by the entire court). This important decision in *Tafas v. Doll*—which will greatly define the role of the Patent and Trademark Office in ongoing patent reform efforts—was issued by a fractured three-judge panel, in which the judges essentially voiced three different opinions on the central issue of whether the rules are substantive or procedural. In the majority opinion, Judge Prost concluded the rules are procedural because they regulate how matters are presented to the Patent and Trademark Office, and do not change the underlying standards for obtaining a patent. Judge Bryson concurred in the result, but asserted that it is not necessary to categorize the rules as substantive or procedural. Judge Rader dissented, and would have affirmed the lower court's decision that all of the rules are impermissibly substantive. Though requests for rehearing *en banc* are rarely granted, the court may find the importance of the case, and the unusual circumstances of the opinion, justify such a rehearing.

A number of issues remain to be decided before the rules potentially can go into effect—and depending on how these issues are resolved, it is entirely possible that the rules may never go into effect. In addition to the issues that may require further litigation, another question is whether the new Administration will continue to pursue the rules, which were enacted in the face of near-universal opposition from the patent community. New leadership at the Patent and Trademark Office can be expected to revisit whether the rules are in the pub-

lic interest, and are an appropriate way for the agency to handle its backlog of applications.

Regardless of the fate of these particular rules, for the time being the Federal Circuit has handed the Patent and Trademark Office significant power to promulgate rules that, although “procedural,” nonetheless may have significant impact on the cost and availability of obtaining patent protection. If the agency’s new leadership decides to continue pursuing rules aimed at reducing

the number of filings and claims, the pharmaceutical industry may need to revisit its patent strategies and prepare for the added expense of navigating a new regulatory framework.

*Paul Rivard is a principal shareholder of Banner & Witcoff in Washington, DC. This article reflects the opinion of the author and should not be attributed to the firm Banner & Witcoff or to any of its clients.*