

## LexisNexis® Emerging Issues Analysis

Laurie Axford on

**Tafas v. Doll**

**2009 U.S. App. LEXIS 5806 (March 20, 2009)**

2009 Emerging Issues 3490

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On March 20, 2009, the Federal Circuit issued its opinion in a landmark case that put the U.S. Patent and Trademark Office (USPTO) on one side, and some very large Patentees on the other [[Tafas v. Doll, 2009 U.S. App. LEXIS 5806 \(Fed. Cir. Mar. 20, 2009\)](#)]. Although the decision is being described as “mixed,” it is clearly three parts USPTO and one part Patentee. The proposed new rules at issue in this case involve the permissible number of continuing applications (continuations, continuations-in-part or requests for continued examination (RCEs)) and the maximum number of claims allowed to be filed without supporting patentability in advance. The underlying question addressed by the Federal Circuit was whether or not promulgation of these new rules constituted permissible procedural changes to USPTO practice or impermissible substantive changes to the law. By all counts, this decision is a huge victory for the USPTO in its efforts to reform patent practice and streamline prosecution. However, its ultimate impact on patentees may lead to negative consequences, and may even threaten to undermine innovation in general.

### History

The chronology of major events leading up to this decision is as follows:

- *January 3, 2006*: The USPTO published Federal Register notices proposing a revision to the rules (i.e. the “New Rules”) regarding the number of permissible claims (the “Claims Rules”, [71 FR 61](#)); and proposing limits on continuation applications (the “Continuation Rules”, [71 FR 48](#).)
- *August 21, 2007*: The USPTO published a Federal Register notice setting forth the Final Rules on Claims and Continuations [72 FR 46716](#), which were to become effective November 1, 2008.
- *August 22, 2007*: Dr. Tafas and GlaxoSmithKline (GSK) each filed a complaint ([Triantafyllos Tafas v. Dudas, 2007 U.S. Dist. Ct. Pleadings 846 \(E.D. Va. Sept. 7, 2007\)](#); [Smithkline Beecham Corp. v. Dudas, 2007 U.S. Dist. Ct. Pleadings 846 \(E.D. Va. Oct. 11, 2007\)](#)) in the United States Dis-

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trict Court for the Eastern District of Virginia challenging the proposed New Rules.

- *October 15, 2007*: GlaxoSmithKline filed a Motion for Temporary Restraining Order and Preliminary Injunction ([Smithkline Beecham Corp. v. Dudas, 2007 U.S. Dist. Ct. Motions 846 \(E.D. Va. Oct. 15, 2007\)](#)).
- *October 28, 2007*: The USPTO filed a brief opposing the Motion ([Smithkline Beecham Corp. v. Dudas, 2007 U.S. Dist. Ct. Motions 846 \(E.D. Va. Oct. 28, 2007\)](#)).
- *November 14, 2007*: The USPTO filed its Answer to the Tafas Complaint.
- *April 1, 2008*: Judge Cacheris issued a Memorandum Opinion following a February 8, 2008 hearing granting GSK and Tafas's Motion for Summary Judgment, permanently enjoining the Claims and Continuations Rules ([Tafas v. Dudas, 541 F. Supp. 2d 805 \(E.D. Va. 2008\)](#)).
- *July 18, September 24 and October 15, 2008*: The USPTO filed its Appeal Brief, the Plaintiffs filed their briefs and the USPTO filed its Reply Brief, respectively, with the U.S. Court of Appeals for the Federal Circuit.
- *March 20, 2009*: Following a hearing on December 5, 2008, the Federal Circuit rendered its present opinion ([Tafas v. Doll, 2009 U.S. App. LEXIS 5806 \(Fed. Cir. Mar. 20, 2009\)](#)).

### The “Pros” and “Cons”

The rules that were initially proposed by the USPTO split the patent community in two. On the one hand, much of the technology sector seemed to favor most if not all of the new rules, while smaller companies and firms that represent them were opposed to the new rules. Among the most prominent “pros” were Apple, Cisco, eBay, IBM, Microsoft, Oracle, Micron Technologies and Intel. However, Texas Instruments and Eastman Kodak opposed the new rules, as did the Intellectual Property Owners Association.

One of the loudest critical voices of the New Rules has come from the biotech and pharmaceutical communities, since they tend to file many “variations on a basic theme” patent applications in the same family to keep up with an evolving understanding of the

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complex inventions to which these applications relate. Indeed, the Biotechnology Industry Organization (BIO) considered the District Court's ruling to be a "sound decision" and commented that if the new rules had been allowed to take effect, they would have "inhibited the ability of biotechnology innovators to obtain adequate patent protection on their technologies, significantly decreasing their ability to attract the financing necessary to bring innovative, life-enhancing and life-saving products to market." (BIO President and CEO, Jim Greenwood.)

### Rules at Issue

The proposed Continuation and Claims Rules are as follows:

**Continuations.** *New Rule 78* gives applicants the right to file two continuation or continuation-in-part applications. Additional continuation applications would not be entitled to the earliest filing date of the parent applications unless applicants can show that amendments, arguments or evidence could not have been submitted during prosecution of the prior-filed application.

*New Rule 114* imposes a limit of one RCE per application family.

**Claims.** *New Rule 75* limits the number of claims in an application to five independent claims or 25 total claims, unless applicants provide a detailed examination support document (ESD).

*New Rule 265* sets forth the required contents of the ESD. To comply with *New Rule 265*, the ESD must: 1) include the results of an international prior art search; 2) list the most relevant prior art references; 3) identify which limitations are disclosed by each reference; 4) explain how each independent claim is patentable over the references; and 5) show where each limitation is disclosed in the specification.

### The Heart of the Matter

In the District Court, Plaintiffs argued that implementation of the new rules constituted a substantive change to the Patent Laws, and thus the USPTO lacked the authority to make these changes. The USPTO argued that they were entitled to implement the new rules because they were procedural, an argument that ultimately failed in the District Court.

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In the present opinion authored by Judge Prost, the rulemaking authority of the USPTO was reviewed in light of *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.* [467 U.S. 837](#) (1984). The so-called “Chevron deference” is accorded to an agency to determine the scope of its own authority, if as a threshold matter the agency can demonstrate a “congressional delegation of administrative authority.” (*Adams Fruit Co. v. Barrett*, [494 U.S. 638, 649](#) (1990).) The USPTO argued first that the District Court should have deferred to the USPTO’s interpretation of the scope of its rulemaking authority and granted it “Chevron deference,” and second that even under the District Court’s interpretation of a narrower rulemaking authority, the rules were still proper because they were merely “procedural.”

Thus, the underlying issue in analyzing the propriety of the USPTO’s rulemaking authority was whether or not the New Rules were “substantive” or “procedural.” The District Court took the approach that any rule that affects individual rights and obligations is substantive, citing *JEM Broad. Co. v. FCC*, [22 F.3d 320, 326](#) (D.C. Cir. 1994). Therein, the D.C. Circuit Court held that there is a distinction between agency actions that alter the rights of parties (i.e. substantive) and those that do not alter the rights of parties, but only alter the manner in which the parties assert their rights (i.e. procedural.)

The only remaining issue addressed by the court was whether or not the Final Rules were consistent with the Patent Act.

### The Holding

Judge Prost concluded that when the legal scope of an agency’s rulemaking authority is at issue, the agency should not be given deference to define the metes and bounds of such authority. More specifically, Judge Prost held that the USPTO had not met the initial threshold of demonstrating that it had the administrative authority to institute the new rules in the first place, i.e. that the rules were indeed procedural and not substantive.

Regarding the substantive vs. procedural issue, the Federal Circuit concluded that the New Rules are procedural. The Federal Circuit held that the Final Rules “may ‘alter the manner in which the parties present...their viewpoints’ to the USPTO, but they do not, on their face, ‘foreclose effective opportunity’ to present patent applications for examination” (citing *JEM*, [22 F.3d at 326, 328.](#)) As such, they granted Chevron defer-

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ence to the USPTO's interpretation of the provisions of the Patent Act in putting the rules into effect.

As to New Rules 78 and 114 being procedural, the Federal Circuit reasoned that “applicants who diligently present all of their amendments, arguments, and evidence available at the time of filing will not be limited by New Rule 78,” and likewise “will be granted as many RCEs as they require.”

As to New Rules 75 and 265 being procedural, the Federal Circuit recognized that implementation of these new rules “may put a burden of production on the applicant,” but that this does not require the applicant to prove that the claims are patentable upon submission, and the Examiner still has the burden to “set forth his own prima facie case of unpatentability.”

However, when New Rule 78 was reviewed for consistency with the Patent Act, the Federal Circuit held that it did not comply. More specifically, [35 U.S.C. §120](#) sets forth the requirements for the benefit of priority of a continuation application to an earlier filed application. The Federal Circuit found that New Rule 78 added an additional requirement (i.e. that it not contain amendments, arguments, or evidence that could have been submitted earlier), and was thus foreclosed by the statute.

### **The Loudest Dissent**

Judge Rader's dissent sets forth his opinion that all of the Final Rules are substantive and not procedural. In applying *Chrysler Corp. v. Brown*, [441 U.S. 281](#) (1979), Judge Rader opined that “a rule is ‘substantive’ if it is not an ‘interpretive rule, general statement of policy or rule of agency organization, procedure or practice” (*Id.* at 301), and reasoned that the majority opinion applied too strict a standard that rules are only substantive if they “affect individual rights and obligations.” Finally, Judge Rader noted that, “[t]he Final Rules affect individual rights and obligations, and mark a startling change in existing law and patent policy.”

### **The Devil in the Details**

Regarding the Continuation Rules, the Federal Circuit recognized that it will now be up to the USPTO to interpret when amendments, arguments and evidence “could not have been submitted during the prosecution of the prior-filed application” or “prior to the close of prosecution.” However, during the initial round of comments after the New Rules

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were published, the USPTO said it “intends to deny additional applications in almost all circumstances.” Accordingly, implementation of these rules is bound to create further controversy.

Regarding the Claims Rules and the ESD requirement, the court recognized that the Final Rules would require an additional burden on applicants to conduct a preexamination search of U.S. and foreign patents and non-patent literature, a description of the search and an explanation of its results. Indeed, they recognized that in some cases the USPTO may “apply the rules in a way that makes compliance essentially impossible and substantively deprives applicants of their rights.” Likewise, implementation will undoubtedly lead to further debate.

**The Future**

Further litigation is bound to ensue, and may yet stop implementation of these rules in their present form. Unless further appellate review is granted, the case will be remanded to the District Court consider, among other things:

- Whether any of the rules, either on their face or applied in specific circumstances, are arbitrary and capricious
- Whether any of the rules conflict with the Patent Act in ways not addressed in the Federal Circuit’s opinion
- Whether all USPTO rulemaking is subject to notice and comment under [5 U.S.C. § 553](#)
- Whether any of the rules are impermissibly vague
- Whether the rules are impermissibly retroactive

Appellate review may be sought by any of the Plaintiffs who might choose to file a petition for rehearing or rehearing en banc, or may be sought by petitioning the Supreme Court for review. Another not so trivial fact to consider is that the Obama administration has not yet identified a future leader of the USPTO, and such leader may independently decide not to implement these new rules. In any case, although this recent ruling is significant, its ultimate impact will not be fully understood or appreciated for months if not years to come.

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Ms. Axford is a former director of the San Diego Nucleic Acid Conference, and has served on numerous organizing committees for other scientific and legal conferences. She is also past president of the San Diego Intellectual Property Law Association. She received her B.S. and M.S. from San Diego State University and her J.D. from Thomas Jefferson School of Law.

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