

**Keywords: Administrative Procedure Act, APA, Substantive Rule, Procedural Rule, 2+1 Rule, 5/25 Rule**

**General: The U.S.P.T.O. does not have substantive rulemaking authority. Substantive rules are those rules which affect an individual's rights and obligations.**

*Triantafyllos Tafas v. Jon W. Dudas*  
Case no. 1:07-CV-846 (E.D. Va. April 1, 2008)

## **I. Facts**

On January 3, 2006, the United States Patent and Trademark Office (the "Office") issued two notices in the Federal Register that related to proposed rule changes. The proposed rules set out changes to the patent examination process that would limit the number of continuing applications, Requests for Continued Examinations ("RCEs"), and claims that an applicant could file as a matter of right. The Office justified the rule changes on the ground that the number of claims in applications and the number of continuation applications filed had crippled the Office's ability to examine newly-filed applications. After the comment period ended, the Office published the Final Rules on August 21, 2007.

Final Rules 78 and 114 (collectively, the "2+1 Rule") permit an applicant to file two continuation or continuation-in-part ("CIP") applications and one RCE as a matter of right after an initial application. Additional filings, such as a third continuation or CIP, or a second RCE, could be filed with a "petition and showing" explaining why the amendment, argument, or evidence could not have been previously presented.

Final Rule 75 (the "5/25 Rule") permits an applicant to present a total of five independent claims or twenty-five total claims for examination without providing additional information. If either limitation is exceeded, the applicant would have to provide an "examination support document" ("ESD") to assist the Examiner's examination of the claims.

Rule 78 also requires that applicants identify related patent applications and sets forth a rebuttable presumption that applications meeting certain conditions contain patentably indistinct claims. Thus, applicants could not evade the requirements of the 2+1 Rule or the 5/25 Rule by attempting to simultaneously prosecute indistinct applications.

Tafas duly filed a complaint pursuant to the Administrative Procedure Act ("APA") against the Office seeking preliminary and permanent injunctions prohibiting the Office from implementing the Final Rules on various grounds. GlaxoSmithKline ("GSK") filed a similar complaint. On October 15, 2007, GSK moved for a temporary restraining order and a preliminary injunction enjoining implementation of the Final Rules, which was granted by the Court. Subsequently, all parties filed respective motions for Summary Judgment.

## **II. Issues**

- A. Does the Office have authority to issue substantive rules?
- B. Is the 2+1 Rule substantive in nature?
- C. Is the 5/25 Rule substantive in nature?

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### III. Discussion

- A. No. 35 U.S.C. § 2(b)(2) empowers the Office to “establish regulations, not inconsistent with the law” to “govern the conduct of proceedings in the Office.” In view of the § 2(b)(2), the Office argued that there was no distinction to be drawn between “substantive” and “procedural” regulations and argued that the issue was instead whether the rules at issue were within the scope of § 2(b)(2). The Court, however, found that the balance of the relevant case law supported the existence of the substantive/procedural rule distinction. In particular, the case law with regard to § 2(b)(2) limits the Office’s rulemaking authority to rules governing the “conduct of proceedings” before the Office (i.e., to procedural rules), as set forth in 35 U.S.C. § 2(b)(2)(A).

Further, even though 35 U.S.C. § 2(b)(2)(B) requires notice and comment in accordance with 5 U.S.C. § 533 and this requirement is typically associated with the promulgation of substantive rules, this requirement may also be required by statute, as it is here. Thus, the Court interpreted § 2(b)(2) to mean that the USPTO may establish regulations that govern the proceedings in the Office that are not inconsistent with the law (i.e., procedural rules) and that such rules are promulgated after notice and comment in accordance with 5 U.S.C. § 533. The requirement of notice and a comment period does not create substantive rulemaking authority by implication. Thus, the Court found that 35 U.S.C. § 2(b)(2) does not permit the USPTO to promulgate substantive rules and that any rules deemed substantive would be null and void.

- B. Yes. In view of the case law, the Court defined a “substantive rule” as being “any rule that ‘affect[s] individual rights and obligations.’” In addition, the Court agreed with the Office that, in view of the case law, procedural rules with collateral substantive consequences were within the Office’s rulemaking authority under 35 U.S.C. § 2(b)(2).

Under the previous rules, an applicant could file an unlimited number of continuations, CIPs, or RCEs. The 2+1 Rule does completely prohibit an applicant from filing two or more continuations or CIPs. However, the Court determined that the Office intended to deny additional applications in almost all circumstances and that the “could not have been submitted” standard of petition and showing requirement effectively imposed a hard limit on additional applications. Thus, the 2+1 Rule effectively changes existing law and deprives applicants of their rights under 35 U.S.C. § 120 to an unlimited number of continuation and CIP applications.

With regard to the limitation placed on RCEs, the Court noted that the 2+1 Rule placed a limit on RCEs as of right on the basis of application family rather on the basis of each individual application. The Court states that such a limitation is a clear departure from the plain language of the statute “which states that the USPTO must provide for the continued examination of each *application*.” In addition, the 35 U.S.C. § 132(b) states: “[t]he Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant.” The Court found the use of the word “shall” and the phrase “at the request of the applicant” to be indicative that Congress intended to allow for an unlimited number of RCEs and to empower the applicant, not the USPTO, to determine whether an RCE would be filed. The 2+1 Rule, however, limits the number of RCEs to one per application family as a matter of right and imposes the stringent “could not have been submitted” standard of petition and showing requirement for any additional RCEs, thereby effectively imposing a hard limit on the filing of further RCEs.

For these reasons, the Court found the 2+1 Rule to be substantive in nature and, thus, null and void.

- C. Yes. Under the current law, the Patent Act does not mechanically limit the number of claims an applicant may file. The 5/25 Rule, however, imposes a mechanical limit on the number of claims allowed in each application unless the Applicant provides additional information in the form of an ESD. Absent satisfaction of the ESD requirement, the Office will abandon an otherwise meritorious application having more than the allowed number of claims.

The Court viewed the ESD requirement as more than a mere request for additional information and instead viewed this requirement as shifting the examination burden from the Office to the applicant. In particular, the rule governing ESDs demands that the applicants conduct a broad search and provide a detailed explanation of how each independent claim is patentable over the cited references. This requirement is at odds with existing Federal Circuit case law that applicants have no duty to conduct prior art searches and no duty to disclose art of which the applicant could have been aware. In addition, 35 U.S.C. §§ 102, 103, and 131 have been read as placing the burden of examination and the burden of proof with regard to unpatentability on the USPTO.

Therefore, the Court concluded that requiring applicants to perform prior art searches and by shifting the examination burden to the applicants, the ESD requirement changes existing law and alters the applicant's rights under 35 U.S.C. §§ 102, 103, and 131. Thus, under the 5/25 Rule applicants are subject to new substantive responsibilities if they wish to file more than 5 independent claims or more than 25 total claims.

Therefore, the Court found the 5/25 Rule to be substantive in nature and, thus, null and void.

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**Relevant Statutes**

**35 U.S.C. § 2 Powers and duties.**

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(b) SPECIFIC POWERS.- The Office-

- (1) shall adopt and use a seal of the Office, which shall be judicially noticed and with which letters patent, certificates of trademark registrations, and papers issued by the Office shall be authenticated;
- (2) may establish regulations, not inconsistent with law, which-
  - (A) shall govern the conduct of proceedings in the Office;
  - (B) shall be made in accordance with section 553 of title 5;
  - (C) shall facilitate and expedite the processing of patent applications, particularly those which can be filed, stored, processed, searched, and retrieved electronically, subject to the provisions of section 122 relating to the confidential status of applications;
  - (D) may govern the recognition and conduct of agents, attorneys, or other persons representing applicants or other parties before the Office, and may require them, before being recognized as representatives of applicants or other persons, to show that they are of good moral character and reputation and are possessed of the necessary qualifications to render to applicants or other persons valuable service, advice, and assistance in the presentation or prosecution of their applications or other business before the Office;
  - (E) shall recognize the public interest in continuing to safeguard broad access to the United States patent system through the reduced fee structure for small entities under section 41(h)(1) of this title; and
  - (F) provide for the development of a performance-based process that includes quantitative and qualitative measures and standards for evaluating cost-effectiveness and is consistent with the principles of impartiality and competitiveness;

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**35 U.S.C. § 112 Specification.**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

### **35 U.S.C. § 120 Benefit of earlier filing date in the United States.**

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application. No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.

**35 U.S.C. § 131 Examination of application.**

The Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor.

**35 U.S.C. § 132. Notice of rejection; reexamination.**

(a) Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention.

(b) The Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant. The Director may establish appropriate fees for such continued examination and shall provide a 50 percent reduction in such fees for small entities that qualify for reduced fees under section 41(h)(1) of this title [35 USC 41(h)(1)].