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INTELLECTUAL PROPERTY LAW

Intellectual Property Advisory:

Federal Circuit Hears Arguments in Patent Continuation Rules Appeal

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On Friday, December 5, 2008, a three-judge panel of the U.S. Court of Appeals for the Federal Circuit heard arguments in a case involving a controversial patent rules package that would limit the number of continuing applications, claims, and requests for continued examination that may be filed in patent cases. The U.S. Patent and Trademark Office ("USPTO") appealed the April 2008 ruling of the U.S. District Court for the Eastern District of Virginia that permanently enjoined the rules and declared them "null and void as 'otherwise not in accordance with law' and 'in excess of statutory jurisdiction and authority'" under the Administrative Procedures Act.

The case is *Tafas v. Dudas*, Appeal No. 2008-1352. The consolidated plaintiffs-appellees are Triantafullos Tafas, an individual inventor, and GlaxoSmithKline (GSK), the world's second largest pharmaceutical company. John M. Desmarais of Kirkland & Ellis argued for GSK, while Steven Moore of Kelley Drye & Warren argued for Tafas. James Toupin, General Counsel for the USPTO, argued for the government. The panel included Circuit Judges Rader, Bryson, and Prost.

Rules: Substantive or Procedural?

A key issue in the appeal is whether the new rules set forth by the USPTO are "substantive" or "procedural." Rules are considered substantive if they "'effect a change in existing law or policy' which 'affect individual rights and obligations.'" *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920,

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927 (Fed. Cir. 1991). The appellees argued the rules are clearly substantive under this standard, and that the Patent Act "does not grant the Commissioner the authority to issue substantive rules." *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996).

The USPTO argued that the rules fall within the Patent Act's grant of rulemaking authority in 35 U.S.C. § 2(b)(2), which authorizes the USPTO to "establish regulations, not inconsistent with law, which shall govern the conduct of proceedings in the Office." The USPTO asserted that the proposed rules relate to proceedings before the Patent and Trademark Office and are not inconsistent with current law. Further, the USPTO argued that as an administrative agency, it is entitled to *Chevron* deference in its interpretation of the statute. *See Chevron U.S.A., Inc., v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

Limits on Number of Continuing Applications

One of the most contentious provisions in the rules would limit applicants in most instances to filing two continuations in a given patent family. GSK argued that such "hard limits" on the number of continuations are contrary to 35 U.S.C. § 120, which has been held to contain no limit on the number of earlier applications to which priority may be claimed. *In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977). When asked by Judge Rader about the nature of the harm caused by the two continuation limit, GSK argued the rules provide insufficient opportunity to protect inventions in the pharmaceutical industry due to the lengthy periods associated with drug discovery and clinical trials. GSK also argued that the provision for petitioning for additional continuations is inadequate because the petitions ordinarily would be denied or altogether unavailable. Such petitions require a showing that claims or evidence could not have been presented earlier.

The USPTO argued the rules provide ample opportunity to present claims, and do not place a "hard limit" on the number of continuations because additional continuations are available whenever justified. When Judge Rader asked whether the USPTO considered the concerns raised by the pharmaceutical industry, the USPTO pointed out that in response to the notice and comment process, the rules were amended to provide for two continuations, instead of one as was originally proposed. When used together with procedures under the Patent Cooperation Treaty, the rules would enable prosecution to be stretched over a period of about 10 years, according to the USPTO.

Limits on Number of Claims

Other provisions in the rules, namely Rules 75 and 265, set limits on the number of total claims and independent claims applicants may file without filing an Examination Support Document (ESD). The appellees argued that these rules conflict with several provisions of Title 35 including Sections 102, 103, 112, and 131. The appellees contended that Section 112, ¶ 2 grants applicants a right to pursue "one or more claims" in patent applications, which does not contemplate a mechanical limit on the number of claims. Further, the appellees urged Sections 102, 103, and 131 are also violated by shifting the burden to the applicant when an application exceeds 5 independent and/or 25 total claims (5/25). In particular, the statute places the burden on the USPTO to demonstrate why an applicant is not entitled to a patent under Sections 102, 103, 131 etc. Rules 75 and 265 improperly shift this burden to the applicant, according to the appellees. The appellees also asserted the ESD requirements were vague and impractical. During the argument, Judge Rader also raised concerns regarding the practicality of applicants, and patent practitioners in particular, using ESDs under the new rules. He questioned whether practitioners would place themselves at risk of claims of inequitable conduct down the road in litigation of the patent as a result of statements (or potential misstatements) in an ESD.

The USPTO argued that Rules 75 and 265 do not place any hard or mechanical limits on the number of claims. Instead, the rules merely require applicants to give reasonable assistance to the examiner when the application exceeds 5/25 claims. According to the USPTO, applicants may still file any number of claims that they choose in a given application. Additionally, the USPTO pointed out that Rules 75 and 265 and other new rules at issue were drafted in response to a growing backlog of applications. The USPTO contended that by requiring applicants to give reasonable assistance to Examiners in cases with excessive numbers of claims, the rules would assist the USPTO in reducing its backlog of applications

Limits on Number of Requests for Continued Examination

The appellees argued that Rule 114, which limits the number of Requests for Continued Examination (RCE) per "application family," violates Section 132(b) of the Patent Act in two ways. First, the appellees argued that the mechanical limit on RCEs contradicts the express language of Section 132(b), which states that the USPTO "shall" prescribe regulations to provide for continued examination "at the request of the applicant." Second, the appellees claimed that by imposing a limit based on an "application family" rather than an "application," Rule 114 violates the Patent Act. Although the rules provide an opportunity to petition for additional RCEs, the appellees contended that this option is essentially meaningless because the USPTO has indicated it will deny the petitions in all but the rarest circumstances.

The USPTO contended that Section 132(b) simply obligates the USPTO to issue implementing regulations for continued examination, but does not specify the conditions and requirements for continued examinations. The USPTO asserted that this task instead is left to the USPTO through its prescribed exercise of rulemaking authority. Further, the USPTO argued that the availability of unlimited RCEs has contributed to its backlog of applications, and that the rules will help stem abuses of the patent system.

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