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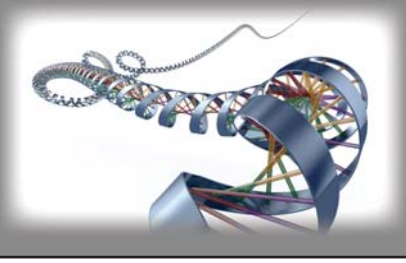

Bradley Arant Boult Cummings LLP

Tafas v. Doll – The Federal Circuit Court Weighs In

In a much anticipated opinion, on March 20, 2009, the Federal Circuit Court of Appeals affirmed-in-part, reversed-in-part and remanded the United States Patent Office's ("PTO") appeal of the District Court of Eastern Virginia's (the "District Court") summary judgment invalidating the PTO's controversial rules package concerning limitations on the number of continuation applications, requests for continued examinations ("RCEs") and effectively limiting the number of claims that can be filed in a patent application (the "Proposed Rules").

All of the Proposed Rules were found to be "procedural" rather than substantive, but the Federal Circuit Court of Appeals held that Proposed Rule 78 was invalid as it contradicted 35 U.S.C. § 120.

Background

As previously discussed in the December 2008 edition of the Life Sciences Newsletter, the PTO is faced with a backlog of patent applications numbering somewhere between 760,000 and 1,000,000 applications. In an effort to effectively stem the tide of newly filed and continuing applications as well as simplify examination of pending applications, the PTO proposed four (4) new rules in August of 2007 (Rules 75, 78, 114 and 265).

Rule 78 and Rule 114 pertained to continuation applications and requests for RCEs. Continuation applications allow patent applicants to claim all of the inventions disclosed in their original application and maintain the priority filing date of the original (or "parent") application for the continuation applications. Continuation applications are needed if the applicant faces a restriction requirement from the PTO where the PTO believes that that the applicant has impermissibly claimed more than one invention. Continuation applications are also used when an applicant later discovers that a potentially patentable invention that was disclosed in the original application was not claimed. In this case, a later filed continuation application is filed to protect this invention. RCEs may be used in similar circumstances.

Under Rule 78, an applicant could file two (2) continuation applications as a matter of right and if the applicant wished to file an additional continuation, the applicant had to file a petition showing that the amendment, argument, or evidence sought to be entered could not have been submitted during the prosecution of the prior-filed application. If the applicant could not make that showing, then the additional continuation applications lost priority to the prior-filed applications. Rule 114 proposed to impose similar limitations on RCEs by limiting an applicant to one RCE as a matter of right.

Rule 75 and Rule 265 required an examination support document ("ESD") for applications including more than five (5) independent claims or twenty-five (25) total claims. The ESD includes a pre-examination prior art search, a list of the most relevant references and limitations disclosed by each reference, an explanation of how each independent claim is patentable over the submitted references and an analysis of how each limitation of the claims is disclosed and enabled by the specification.

Dr. Tafas, an individual inventor from Connecticut, filed suit against the PTO seeking to enjoin the enactment of the Proposed Rules in August of 2007. Dr. Tafas was later joined by pharmaceutical giants SmithKline Beecham and Glaxo Group. The District Court granted the Plaintiffs' motion for preliminary injunction thereby preventing the PTO from enacting the Proposed Rules in October of 2007. The District Court subsequently granted the Plaintiffs' motion for summary judgment permanently enjoining the PTO from enacting the Proposed Rules in April of 2008. The District Court found that the Proposed Rules were substantive changes to existing law and because the PTO lacked substantive rulemaking authority, the Proposed Rules exceeded the PTO's statutory authority and were invalid. Specifically, the District Court found that the Proposed Rules created limits on continuation applications, RCEs, and claims that were inconsistent with several sections of the Patent Act, as well as precedent from this court and its predecessor, the Court of Customs and Patent Appeals. The PTO appealed the District Court's ruling to the Federal Circuit Court.

The PTO's Arguments on Appeal

The PTO argued that the District Court improperly refused to give the Proposed Rules (and the PTO's rulemaking authority)

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so-called *Chevron* deference. Under *Chevron*, a reviewing court must determine: (1) whether the statute is ambiguous or there is a gap that Congress intended the agency to fill and (2) whether the agency's interpretation of a statute is reasonable or permissible. If the statute is unambiguous, and the interpretation runs contrary to the statute, then the interpretation is considered unreasonable as the text of the statute prevails. If an agency's interpretation is reasonable, then the court will defer to the agency's reading of the statute. Under this line of argument, the PTO believed that the distinction between its substantive and procedural rule making powers is subject to the PTO's own interpretation of that distinction and that the court should defer to the PTO's opinion on its rule making authority.

Next the PTO argued that even if the substantive/procedural framework is proper, the proposed rules are procedural and within in the PTO's rule making authority and were valid.

The Decision

The Federal Circuit Court began by holding that 35 U.S.C. § 2(b) gives the PTO authority to "establish regulations, not inconsistent with the law, which . . . (A) shall govern the conduct of proceedings in the office; . . . (C) shall facilitate and expedite the processing of patent applications, particularly those which can be filed, stored, processed, searched, and retrieved electronically . . . (D) may govern the recognition and conduct of agents, attorneys, or other persons representing applicants or other parties before the Office . . . ." The PTO is also required – under 35 U.S.C. §132(b) – to "prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant." Although, the statutes did not provide any "general substantive rulemaking power" to the PTO, the court nonetheless granted *Chevron* deference to the PTO's interpretation of "statutory provisions that relate to the exercise of delegated authority." Accordingly, the Federal Circuit Court held that the District Court erred in failing to accord the PTO *Chevron* deference with respect to the PTO's interpretations of various sections of the Patent Act, and the PTO's belief that the continuation and claims rules were consistent with such interpretations. The Federal Circuit Court found that "the PTO's interpretations of statutes that pertain to the PTO's delegated authority are entitled to *Chevron* deference." Thus, for rules that are within the scope of the Office's delegated authority (*i.e.*, procedural rules promulgated under 35 U.S.C. §§ 2(b) (2) and 132(b)), the Federal Circuit Court held that the District Court must "give *Chevron* deference to the PTO's interpretation of statutory provisions that relate to the exercise of delegated authority."

The Federal Circuit Court then examined each of the Proposed Rules to determine whether the rule was procedural or substantive.

The Federal Circuit Court then found that each of the Proposed Rules was procedural, and therefore, within the PTO's rule making authority if the rule did not conflict with the statutory framework of the Patent Act. The Federal Circuit Court relied upon *JEM Broad. Co. v. FCC*, a D.C. Circuit Court opinion recognizing that rules resulting in the loss of "substantive rights," could be procedural if they did not foreclose effective opportunity to make one's case on the merits. The Federal Circuit Court concluded that Rule 78 and Rule 114 are procedural because "[i]n essence, they govern the timing of and materials that must be submitted with patent applications," adding that while the rules "may 'alter the manner in which the parties present . . . their viewpoints' to the USPTO, . . . they do not, on their face, 'foreclose effective opportunity' to present patent applications for examination."

With respect to Rules 75 and 265, Judge Prost states that:

> Once a satisfactory ESD is submitted, examination will proceed in precisely the same manner as it would have in the absence of the rule. It is important to note that an examiner is not permitted to substantively reject claims on grounds that the ESD did not prove that the claims are patentable.

As a result, the Rules 75 and 265 were found to be procedural under a *JEM* analysis. However, the Federal Circuit Court noted that the search requirement of Rule 265 "does not necessarily require a visit to every library in every corner of the world," but rather only requires "[a] reasonable, cost-effective search." The implementation of Rules 75 and 265 will also lead to an inevitable increase in the number of lawsuits filed by applicants against the USPTO. While the Federal Circuit Court was "mindful of the possibility that the USPTO may in some cases attempt to apply the rules in a way that makes compliance [with Rules 75 and 265] essentially impossible and substantively deprives applicants of their rights," the Federal Circuit Court notes that in such circumstances, "judicial review will be available." The Federal Circuit Court also dismissed the concern that "even the most diligently prepared ESD will inevitably open the applicant to inequitable conduct allegations that will entail costly litigation and a possible finding of unenforceability," as being "too speculative to void the rules." The Federal Circuit Court noted that the ESD requirement is unlikely to cause any inequitable conduct problem for applicants. "[D]oubt about the judiciary's ability to apply its own doctrine in a way that yields fair results and discourages frivolous allegations should not preclude the USPTO from promulgating rules that are within its statutory authority."

Next, the Federal Circuit Court found that only one (1) of the Proposed Rules contradicted the Patent Act. Rule 78 was found to be inconsistent with 35 U.S.C. § 120, albeit on "narrower grounds" than the District Court's holding. In particular, the Federal Circuit Court stated that while "Section 120 unambiguously states that an application that meets four requirements 'shall have the same effect, as to such invention, as though filed on the date of the prior application,'" new Rule 78 "attempts to add an additional requirement -- that the application

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not contain amendments, arguments, or evidence that could have been submitted earlier -- that is foreclosed by the statute." The other Proposed Rules are not in conflict with the Patent Act.

In conclusion the Federal Circuit Court affirmed the District Court's ruling that Rule 78 was invalid, but reversed the District Court's ruling that Rule 75, 114 and 265 were invalid and remanded the case to the District Court. The Federal Circuit Court did not dissolve the injunction preventing the valid Proposed Rules from being implemented.

The Future

The Proposed Rules' future is uncertain at the moment. Given that the injunction entered by the District Court is still in place, the PTO cannot implement the "valid" Proposed Rules without dissolving the injunction. It is possible that the PTO will ask the District Court to do just that in the near future and move forward. The Federal Circuit Court also listed several issues that remain to be determined on remand: whether any of the Proposed Rules are arbitrary and capricious; whether any of the Proposed Rules conflict with the Patent Act in ways not addressed; whether all PTO rulemaking was subject to notice and comment rulemaking; whether any of the Proposed Rules are impermissibly vague; and whether the Final Rules are impermissibly retroactive. The only certain outcome of the decision is the prospect of more litigation. The Life Sciences Practice Group at Bradley Arant Boult Cummings will continue to stay abreast of these developments.

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