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The Best April Fools' Day Non-Prank

Permanent Injunction Of the Final Rules

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On April 1, 2008, Judge James C. Cacheris of the U.S. District Court for the Eastern District of Virginia permanently enjoined rules promulgated by the U.S. Patent and Trademark Office ("USPTO"). News of the federal ruling spread like wildfire among the patent community, quickly leading to e-mails wondering whether the ruling was an elaborate April Fools' Day joke. It was not. Now there are concerns (or hopes) about the implications of the ruling on other USPTO proposed rules as well as the impact Patent Law Reform in Congress could have on the ruling.

The judgment addresses rules first proposed by the USPTO on Jan. 3, 2006 (the "Proposed Rules") and published on Aug. 21, 2007 as "Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications," 72 Fed. Reg. 46,716-843 (the "Final Rules"). The patent community responded to the Proposed Rules en masse, submitting hundreds of disapproving written comments. The rules were widely viewed with trepidation, with the patent community criticizing the rules for potentially increasing the cost of the patent process and shifting burdens of the patent examination process to the applicant, thereby unfairly limiting patents and patent claims.

The Final Rules set forth changes to the patent examination process that would limit the number of continuing applications, Requests for Continued Examination ("RCEs"), and claims that an applicant could file as a matter of right. Among other things, the Final Rules include the "2+1 Rule" and "5/25 Rule." Under the 2+1 Rule, as a matter of right, an applicant could only file two continuation or continuation-in-part applications, plus a single RCE, after an initial application. Under the 5/25 rule, an applicant could only present a total of five independent claims and 25 total claims for examination without providing any further information about those claims.

The effective date for the Final Rules was Nov. 1, 2007. Plaintiffs Smithkline Beecham Corporation d/b/a GlaxoSmithKline et al. ("GSK") and Triantafyllos Tafas ("Tafas") separately filed complaints seeking, among other things, preliminary and permanent injunctions prohibiting the USPTO from implementing the Final Rules and a declaratory judgment that the Final Rules violate the Constitution, the Patent Act, the APA, and the Regulatory Flexibility Act. The court granted a preliminary injunction enjoining implementation of the Final Rules on Oct. 31, 2007. The plaintiffs and the defendants each moved for summary judgment. The defendants contended that the Final Rules were procedural because they did not affect any core patentability requirements, that they were necessary in view of the backlog of applications, and that no property rights were taken because none vested until a patent issues.

Summary Judgment Granted

On April 1, 2008, summary judgment was granted to GSK and Tafas, and the injunction was made permanent. The court held that the USPTO does not have substantive rule-making authority and that the Final Rules were substantive in nature. The court voided the Final Rules as "otherwise not in accordance with law" and "in excess of statutory jurisdiction [and] authority."

The first issue looked at by the court was whether the USPTO has authority to make substantive rules. In looking at this issue, the court criticized the USPTO's attempt to erase the distinction between procedural and substantive rule-making authority: "Despite this attempt to abolish the substantive/procedural distinction, however, the balance of the case law in the Federal Circuit and the Supreme Court indicates that the distinction exists, and that it is pertinent to this dispute. Both *Merck* and *Animal Legal Defense Fund* acknowledge the divide, and the law in those cases is clear: Section 2(b)(2)'s authority is limited to rules governing the 'conduct of proceedings' before the Office, the USPTO does not have the authority to issue substantive rules, and it does not have the authority to make substantive declarations interpreting the Patent Act … Accordingly, the Court finds that Section 2(b)(2) does not permit the USPTO to

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promulgate substantive rules, and any rules that may be deemed substantive will be declared null and void."

After determining that the USPTO does not have substantive rule-making authority, the court found that the Final Rules were substantive in nature. The court explained: "According to the USPTO, the Final Rules are procedural in nature because, rather than altering the substantive requirements for novelty, nonobviousness, or definiteness, they instead aim to curb repetitive filings requiring applicants to justify those excess filings and to assist the agency in examining burdensome applications."

In the Final Rules, the USPTO dressed up the 2+1 Rule and the 5/25 Rule to give the appearance of procedural outs. Specifically, the USPTO provided for petitions to permit more than two continuation or continuation-in-part applications, petitions to permit more than one RCE, and Examination Support Documents ("ESDs") for permitting more than 5/25 claims. The court dismissed this dressing up of the rules.

In discussing the 2+1 rule, the court found that the effect of the rule was a hard ban: "Though Final Rule 78 does not completely prohibit applicants from filing more than two continuation or continuation-in-part applications ..., the 'could not have been submitted' standard of the petition and showing requirement effectively imposes a hard limit on additional applications."

In discussing the 5/25 rule, the court found that the effect of the rule was an undue shifting of examination burden to the applicant: "The USPTO contends that Final Rules 75 and 265 simply establish a procedure by which applicants may submit more than five independent or twenty-five total claims, and that the abandonment of an application that fails to comply with the ESD requirement is no more than a procedural step. This argument fails, however, because these rules go far beyond merely requiring additional information. Instead, the ESD requirement changes existing law and alters the rights of applicants under the current statutory scheme by shifting the examination burden away from the USPTO and onto the applicants."

In rejecting the USPTO's argument that the Final Rules were procedural in nature, the court noted that the Federal Circuit has interpreted the Patent Act as placing the burden on the Patent Office for initially establishing a case of unpatentability. The court then reasoned that the Final Rules improperly shifted this initial burden to the applicant and such shifting changes existing law and alters applicants' rights: "The 2+1 Rule and the 5/25 Rule, which limit continuing applications, RCEs, and claims, and the ESD requirement, which shifts the examination burden onto applicants, constitute a drastic departure from the terms of the Patent Act as they are presently understood. By so departing, the Final Rules effect changes in GSK's and Tafas's existing rights and obligations."

[I]f the ruling is upheld on appeal, other proposed USPTO rules may be vulnerable to challenge.

Notice of Appeal

On May 7, 2008, the USPTO filed notice that it is appealing the ruling. Even if the appeal is successful, the case would likely be returned to district court to rule on each individual regulatory change — a lengthy process. It is not clear that a new administration, taking office in 2009, would want to continue an attempt to push through unpopular rules.

However, if the ruling is upheld on appeal, other proposed USPTO rules may be vulnerable to challenge. Most notably, proposed rules relating to Information Disclosure Statements ("IDSs") and appeals may be vulnerable. The proposed IDS rules impose an ESD requirement, similar to that of the 5/25 rule, if more than 25 references are cited. An assessment could be made of the IDS rules that the requirement of an ESD for citing more than 25 references (when combined with risks of misconduct if an applicant does not cite relevant references) improperly shifts the examination burden away from the USPTO and onto applicants. Following the court's reasoning, the IDS rules thus may be substantive, and the USPTO does not have the authority to make substantive rules.

Patent Reform Legislation is currently pending before Congress. H.R. 1908 was passed by the House of Representatives on Sept. 7, 2007. S.1145 was reported out of the Senate Judiciary Committee on July 19, 2007 (but is not yet passed). Each of the bills increases the USPTO's rule-making authority. The House bill confirmed the authority of the USPTO to promulgate rules on continuation applications and adds additional congressional review procedures for any rules published related to this new authority. The Senate bill, in contrast, increases the USPTO rule-making authority only in giving the USPTO fee-setting authority. Patent reform legislation was introduced at least in part to address pendency problems in the USPTO — something the USPTO also purported to address in the Final Rules. The USPTO could use the ruling to show that it cannot solve the pendency problem because it does not have substantive rule-making authority. If such a position pushes Congress to give the USPTO such authority, the ruling could be in jeopardy.

Conclusion

The April 1 ruling is one welcomed by the patent community in overturning rules that many thought would compromise an applicant's ability to protect its invention. What becomes of the ruling, whether it is upheld on appeal, whether it becomes the basis for challenging other rules, and whether it becomes the basis for modifying the Patent Reform Legislation will doubtless be watched with great interest.