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The GSK Case: An Administrative Perspective

The already voluminous discussion of GSK¹ has not focused sufficiently on the court's reasons for concluding that the PTO continuation rules (for reasons of brevity, I focus here only on continuation rules) probably violate the patent statute. This reasoning is important because the court ruled against GSK's argument that the rules were a bad idea as a policy matter (or, in the language of administrative law, "arbitrary and capricious"). The court's reasoning about the alleged conflict between the statute and the rules contains several errors of administrative law.

With respect to the prospective application of the continuation rules (the very thorny issue of retroactivity in administrative law is best left for another day), analysis of whether the rules are contrary to the patent statute turns on two issues that should be decided sequentially. First, do the rules fall within the scope of the PTO's procedural rulemaking authority? Second, do the rules violate the statute?

One mistake in the court's opinion is that it appears to assume that analysis of the second question can be done without a complete answer to the first. After equivocating briefly on the first question, the court jumps immediately to the alleged inconsistency with section 120 of the Patent Act. In agreeing that GSK has "raised serious concerns" about whether the restrictions on continuations conflict with the Act, the court's opinion relies heavily on *In re Henriksen*.² That 1968 decision by the CCPA overturned a PTO limit on the number of continuation applications entitled to an earlier filing date under Section 120.

But Judge Cacheris should not have avoided deciding the question of substance vs. procedure. If the PTO's rules are in fact procedural, then the question of alleged inconsistency with statutory language does not turn on a 1968 CCPA case that makes no mention of administrative law principles (and, indeed, was decided at a time before it was clear that the Administrative Procedure Act even applied to the PTO). Rather, it turns on the enormous case law that the Supreme Court has

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¹ *Tafas v. Dudas*, 2007 U.S. Dist. LEXIS 80474 (E.D. Va. Oct. 31, 2007).

² *In re Henriksen*, 399 F.2d 253 (C.C.P.A. 1968).

developed under its 1984 decision in *Chevron v. Natural Resources Defense Council*.³ Under *Chevron* and its progeny, an agency acting pursuant to authority delegated to it by Congress (here, procedural rulemaking authority under Section 2(b)(2) of the Patent Act) is entitled to interpret its organic statute so long as Congress has not “directly spoken to the precise question at issue” (*Chevron* step 1) and the agency’s interpretation is reasonable (*Chevron* step 2).

Assuming that *Chevron* applies, it is far from clear that Section 120 “speaks directly” to the limits enunciated in the PTO’s continuation rules. Even if we assume that Section 120 does speak directly to the issue of whether the PTO can impose a bright-line bar, the PTO has argued that it does not intend an absolute limit. According to the PTO, it will evaluate requests for a third continuation application on a case-by-case basis. Importantly, the PTO interpretations of its own regulations are entitled to very strong deference under the Supreme Court decision in *Bowles v. Seminole Rock*.⁴ *Seminole Rock* deference, which was recently reaffirmed in the 1997 Supreme Court case *Auer v. Robbins*, says that an agency interpretation of its own rule is “controlling unless plainly erroneous or inconsistent with the regulation.”⁵

Indeed, the very strong deference of *Seminole Rock* is relevant even if the rules in question are substantive and thus not entitled to the application of *Chevron*. Yet the opinion by Judge Cacheris does not even cite *Seminole Rock*.

These are more than fine lawyerly arguments about details. Given the highly uncertain prospects for patent reform, and the reality that Section 2(b)(2) already gives it some rulemaking authority, the PTO has an understandable desire to engage in “self-help.” Its current and future efforts at self-help must be judged according to the appropriate legal standards.

³ *Chevron U.S. A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984).

⁴ *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410 (1945).

⁵ *Auer v. Robbins*, 519 U.S. 452 (1997)