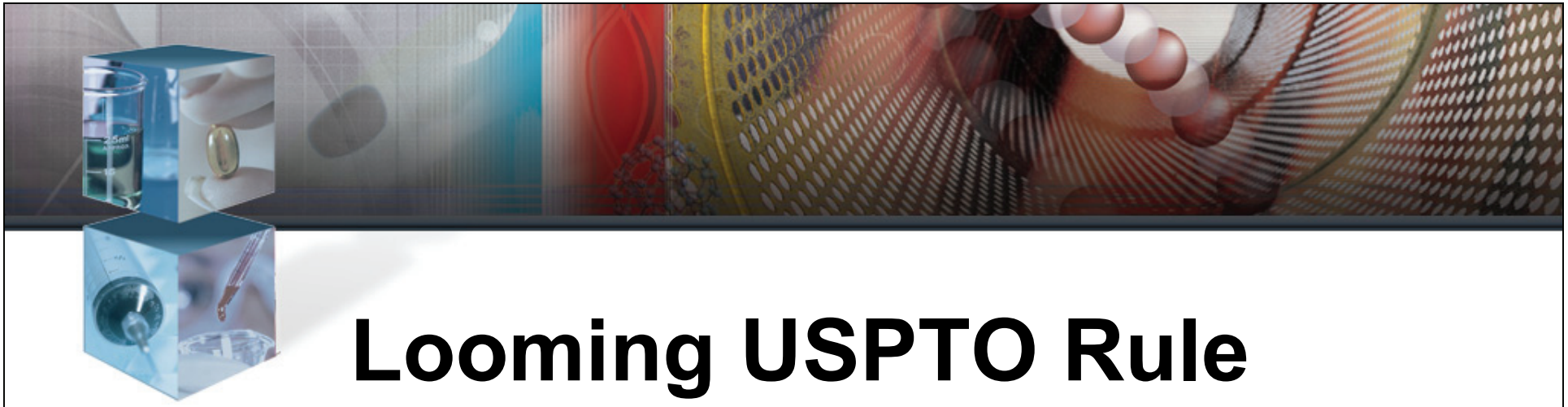

Looming USPTO Rule Changes and Legislative Reform

Dr. Rouget F. (Ric) Henschel
RHenschel@Foley.com

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Genesis: A Call for Reform

- 2003: U.S. Federal Trade Commission report "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy“
- 2004: National Academy of Sciences report “A Patent System for the 21st Century” (National Academies Press)
- 2004: "Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What To Do About It" (Princeton University Press)
  - Authors say the Federal Circuit court (formed in 1980) and USPTO self-funding (in early 90s) caused:
    - Easier patenting ->
    - Higher examiner workloads ->
    - Lower-quality patents that stifle innovation

Why Revise USPTO Rules?

- USPTO says its goal is:
  - "Better focused and effective examination" and
  - "Reducing the backlog of patent applications"
    - See the USPTO notice of the final rules: "Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications; Final Rule" 72 Fed. Reg. 46716 (http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html)
- Question: Who else besides the USPTO considers the new rules a good idea?

Principle Rule Changes

- Limits on continuations
- Limits on number of claims
- Examination support document
- Scrutiny of related applications

Continuations Now

- Unlimited continuations
- Unlimited Requests for Continued Examination ("RCE")
- There is an effective limit to this: A patent expires 20 years from its filing date

Continuations Under New Rules

- Maximum of 2 continuations and 1 RCE
  - PER FAMILY
- Complex exceptions allow for some "gaming" of system
  - Divisional applications are treated as a separate family
- Additional continuations/RCEs permitted by petition (showing new amendment, argument or evidence could not have been presented earlier)

Continuations Under New Rules

- **Proposed For Continuation-in-Part Applications:**
  - Must identify claims in CIP that are entitled to priority claim
  - Inaction yields loss of priority: Unidentified claims do NOT benefit from parent filing date

Claiming Rules Now

- Unlimited number of claims
- No limit on total claims (independent plus dependent)
- No limit on dependent
- Practical limit: Cost rises as with number of claims

Claiming Under New Rules

- 5 independent and 25 total claims
  - PER FAMILY
- More claims?
  - Must file Examination Support Document (ESD)
  - Estimated cost: $20-$100

Related Applications-New Rules

- Must identify all commonly owned co-pending applications with at least one common inventor and with priority dates within two months of each other
- Implication: Must notify all law firms prosecuting your applications

Preliminary Injunction Issued

- A U.S. district court blocked enactment of the rules because the relevant factors favored plaintiff GSK:
  - likelihood of success on the merits(!)
  - irreparable harm absent injunction
  - balance of hardships between USPTO and GSK
  - public interest

GSK v. Dudas

- GSK challenged the rules as:
  - (1) beyond the USPTO's limited rulemaking authority,
  - (2) contrary to 35 U.S.C. § 120, which does not limit the number of continuation applications,
  - (3) retroactive, effecting the prior *quid pro quo* between Applicant and the government,
  - (4) vague, and
  - (5) arbitrary and capricious.

Likelihood of Success on the Merits

- The court found GSK was likely to succeed on its arguments that:
  - limiting the number of continuations does not comply with 35 U.S.C. § 120
  - the new rules are substantive rule changes beyond the USPTO's authority
  - retroactive effect violates the *quid pro quo* of patents
  - some new rules are vague

Irreparable Harm, Balance of Hardships, Public Interest

- Irreparable harm to GSK:
  - Implementing the rules immediately could cause GSK to lose certain patent rights based on the limited ability to file continuations; not recoverable, if the rules are later found invalid, on inventions disclosed to the public.
  - Harm to GSK investments could reduce incentive to file applications.
- Balance of hardships favors GSK:
  - PTO faces costs in retraining Examiners and retooling computers, but harm to GSK outweighs this.
- Public Interest Favors GSK
  - Implementing rules that may be overturned causes more uncertainty than keeping the status quo while court considers rules' validity.

GSK Silent On Some Issues

- Decision does not discuss
  - Related Application requirements
  - Requiring identification of CIP claims
- Limited discussion of allowing 1 RCE

Pending Legislation

- Legislation in Congress could clarify the new rules and the PTO's rule making authority.
- S.1145 is awaiting a vote in the Senate. This bill could override any court decision and enact the rules.
- A similar bill has already passed in the House.

Pending Legislation

- First-to-file replaces first-to-invent (except for derivation)
- Post-grant opposition introduced (lower-cost alternative to litigation)
- Interference proceedings disappear
- Patent Trial and Appeal Board replaces “Board of Patent Appeals and Interferences”

Pending Legislation

- Damages limited to "economic value" of invention's improvement over prior art
- Willfulness infringement would require one of:
  - detailed written notice from patentee;
  - intentional copying; OR
  - blatant violation of injunction

What do I do now?

- Remain vigilant of GSK lawsuit and patent reform bill
  - USPTO could prevail, in whole or in part
  - Legislation could overturn an outcome favorable to GSK
- Evaluate your readiness to act under a "worst-case scenario"
- Identify your most important inventions and review relevant applications

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Thank You!