LIMITATIONS ON RCES, CONTINUATIONS & CLAIMS AND THE RELATED APPLICATION DISCLOSURE REQUIREMENT

WHAT'S NEXT?

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The Road to Injunction

- January 3, 2006-USPTO proposed rule changes (71 Fed. Reg. 48)
- August 21, 2007-USPTO publishes final rules (72 Fed Reg. 46716) scheduled to take effect November 1, 2007
- Tafas files suit in E.D. Va.
- GSK files suit in E.D. Va.
- E.D. Va. Decision granting TRO and preliminary injunction (October 31, 2007)

- Final USPTO Rules
- E.D. Va. Court Decision
- Update on Tafas v Dudas since injunction
- Possible Outcomes
- Practice Tips

FINAL USPTO RULES-2+1

- Two continuations or CIPs +1 RCE as a matter of right per application (37 CFR 1.114(f) and 1.78(d)
- If there was a restriction requirement, applicant was entitled to file 2 CONs and 1 RCE per divisional but no CIPs (37 CFR 1.78(d)(1)(iii)
  - Applicant could provide suggested restriction requirement (37 CFR 1.142(c)-must be provided before FAOM and without traverse

5/25 Limit

- 37 CFR 1.75(b)(1) states that an applicant needs to provide an “examination support document” (ESD) in an application exceeding 5 independent or 25 total claims
- The 5/25 limit is a combined limit. This means that if there is more than one application containing even one “patentably indistinct” claims, both applications cannot contain more than a total of 5 independent claims and 25 total claims.

What is an ESD? (37 CFR 1.265)

- Search statement
- Reference list
- Map of claim elements to references
- Detailed patentability explanation
- Support showing for claim elements
- Very expensive
- May create estoppel issues

“Patentably Indistinct”

- Refers to one-way distinctness not two-way distinctness in an obviousness-type double patenting analysis

Presumption of Patentably Indistinct Claim

- Set forth in 37 CFR 1.78(f)(2)
- Would have applied to presently pending applications
- Simultaneously filed applications presumed to have at least one patentably indistinct claim if:
  - Same priority/filing date
  - At least one common inventor
  - Same ownership
  - Substantial overlapping disclosure

Substantial Overlapping Disclosure

- Exists if other application has written description support for at least one claim in the instant application.
- Support may be express or incorporation by reference to another application

Consequences of Presumption

- Applicant must respond as follows:
  - Rebut by explaining how patentably distinct:
    - Showing that claims are directed to separate inventions
    - Pointing to unique claim element(s) in independent claims that patentably distinguish them from claims in other application
  - Submit a terminal disclaimer and, if the other application is pending, explain why there are two pending applications with patentably indistinct claims

Consequences of Presumption- USPTO (37 CFR 1.78(f)(3))

- PTO may require elimination of patentably indistinct claims from one of the applications in absence of good and sufficient reason for there being two commonly owned pending applications with patentably indistinct claims
- Basis: was a restatement of prior rule 37 CFR 1.78(b)- PTO could eliminate "conflicting" claims from all but one application in the absence of "good and sufficient reason for their retention during pendency in more than one application".

Good and Sufficient Reason

- Filing a continuation after allowance of parent, but the allowance was subsequently withdrawn
- Interference declared, and claims not corresponding to count are pursued in a continuation

When is Response to Presumption Due?

- Later of:
  - 4 months from actual filing date
  - 4 months from commencement of national phase
  - Date on which a patentably indistinct claim is presented
  - 2 months from the mailing date of the initial filing receipt in the other application

Application Disclosure Requirements (37 CFR 1.78(f)(1))

- Patents and applications under the following circumstances must be identified in applications not yet allowed:
  - Priority/filing date within two months of the priority/filing date of the application
  - At least one common inventor
  - Same ownership

Timing of submission

- Later of:
  - 4 months from commencement of national phase
  - 2 months from the mailing date of the initial filing receipt in the other application to be identified
  - 4 months from actual filing date
- Duty of disclosure continues until allowance of application

Original Effective Dates

- November 1, 2007 for the RCE and con rules
- 5/25 applied to all applications that had not received a first office action on the merits by November 1, 2007
- Identification requirement would have been waived for applications filed before Nov. 1st for applications/patents having different priority/ filing dates but compliance would have been required by Feb. 1, 2008

ED Va. Court Decision

- Likelihood of Success
  - Limitations on CONs are substantively contrary to 35 U.S.C. 120
  - Retroactive nature of applying the new rules exceeds the USPTO's authority
- No opinion on likelihood of success
  - Limitation on number of RCEs as a matter of right
  - 5/25 Rule
  - Application Disclosure Requirements

Tafas v Dudas
Happenings since 10/31/07

- Plaintiffs motion for discovery denied
- Briefs submitted by both sides in 12/07
- Opposition briefs due January 22, 2008
- Reply briefs due February 1, 2008
- Hearing on parties' motions: February 8, 2008

Amicus Briefs Filed in Tafas v Dudas For GSK

- IPO, AIPLA, Monsanto, PhRMA, Polestar Capital, DC Bar Association, BIO, CropLife America, HGS, Teles AG, Elan Pharmaceuticals, Cantor Fitzgerald Patent Holdings, Washington Legal Foundation, PA biotech organizations,

Amicus Briefs in Favor of USPTO

- Micron Technologies, Public Interest (Public Patent Foundation, Computer & Communications Industry Association, AARP, Consumer Federation of America, Prescription Access, Foundation for Taxpayer and Consumer Rights, Initiative for Medicine, Software Freedom Law Center), various professors (Mark Lemley, Arti Rai, Stuart Benjamin), Intel

Arguments Set Forth In Support Tafas/GSK position

- Retroactive component is improper since rule changes are substantive not procedural and new rules would impair rights a party possesses and imposes new duties w/ respect to transactions completed
- Are arbitrary and capricious-unresponsive to comments; 5/25 rule varied from initial proposal
- Application Disclosure Requirement would be undue burden and exceeds rulemaking authority

Arguments Set Forth Support Tafas/GSK position

- Double patenting component causes USPTO to evade its responsibility
- USPTO doesn't have authority to limit the number of claims
- Limitations on RCEs and CONs are outside of the scope of 35 USC 132 and 120.

Arguments Set Forth in Favor of USPTO

- Not really retroactive since influencing future actions
- Even if retroactive, it is permissible since the rules are merely procedural
- 35 USC 120 and 132 do not necessarily limit no. of CONs and RCEs-limitations are needed to prevent abuses
- Not arbitrary and capricious-used models and provided full disclosure
- No taking since patent application has no rights

Possible Outcomes of Litigation

- GSK and Tafas prevail
- USPTO prevails completely
- Retroactive nature of regulations struck down but USPTO regulations apply to any applications going forward
- Mixed bag
  - Some struck down (e.g. CON/CIP, claim number limitations)
  - Some upheld (e.g. RCE and/or claim number limitations, application identification requirements)

Other Outcomes-USPTO

- Withdraw Rule Package
- Issue modified rule package
  - Possible limitations on RCEs filed as a matter of right
  - Making filing of more than a certain number of RCEs/ CONs/CIPs a less attractive option
  - Clarify ESDs
- When?
  - Likely after final disposition of litigation

Patent Reform Legislation

- H.R. 1908-Passed House of Representatives
- S 1145-Still pending in the Senate

HR 1908

- Gives the USPTO the “authority to promulgate regulations to insure the quality and timeliness of applications and their examination, including circumstances under which an application for patent may claim the benefit under Sections 35 USC 120, 121, and 365(c) of the filing date of prior filed application for patent.”
- Congress has 60 days to disapprove any proposed legislation

S1145

- Does not have HR 1908 provision re rulemaking authority with respect to 35 USC 120, 121 and 365
- Effective Date: 1 yr. after bill is signed
- Only amends 35 USC 3(a) to state that the director has the authority to
  - promulgate such rules, regulations, and orders that the Director determines appropriate to carry out the provisions of this title or any other law applicable to the United States Patent and Trademark Office or that the Director determines necessary to govern the operation and organization of the Office.

Where do We Go From Here?

- Interview Cases Early-at the very least after 1st office action
- If a patent owner is filing multiple applications, make sure that they are filed on different days
- Take inventory of your currently pending applications .
  - Are there applications where you have already filed RCEs?
  - Are there CONs or CIPs where RCEs have been filed in parent applications?

Divisional Applications Can be Your Friend

- Not subject to double patenting
- May have more than one bite at the apple if an application may be deemed to contain more than one invention.
- See in particular MPEP 806.05(j)-Related Products; Related Processes

Examples of Related Products/Processes That Could Be Restricted

- Combination/subcombination,
- Subcombinations usable together,
- Apparatus and product made
- Intermediate-final product
- Distinct products or processes

Distinct Products or Processes

- The inventions as claimed are patentable over each other;
- The inventions as claimed are not obvious variants;
- Inventions as claimed do not overlap in scope, I.e. mutually exclusive; and
- Inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function or effect

Requirements for “Proper” Restriction

- Must be made by the Examiner
- Claims pending must be consonant with Restriction Requirement
- No generic claim can be pending
- Must be made in US case
- Restriction made in parent must be made in subsequent children

Summary

- Possible Outcomes
  - New rules will probably not apply until court decision if in favor of USPTO or effective date of any Patent Reform legislation passed and signed by President Bush.
  - USPTO may withdraw rule package or issue modified rule package

Summary

- Actions by Practitioner
  - Expedite prosecution of currently pending cases-interview and file RCEs where possible.
  - Think strategically about divisional applications
  - Think strategically about filing “related” applications

THANK YOU
STAY TUNED!

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