Continuation/Claim Rules Update *and* Life After KSR v. Teleflex

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OCTOBER 31, 2007 PRELIMINARY INJUNCTION

- History
  - GSK sued USPTO to stop implementation of rules
    - Filed in E.D. Va on October 9, 2007 and amended on October 15, 2007
    - A wide variety of people and organizations expressed to the court their opposition to the PTO rules (AIPLA, Sen. Charles Schumer, HEXAS, Elan Pharma, former USPTO Commissioner Harry Manbeck, IBM)
    - Consolidated with a similar suit by an individual inventor (Mr. Tafas)

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- Plaintiff's Complaint Pleaded
  - Temporary Restraining Order and Preliminary Injunction to stop implementation of rules
  - Declaratory Judgment that Rules are contrary to law
  - Request to vacate the final rules

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- Order
  - Plaintiff's motion for Preliminary Injunction is GRANTED
  - Defendants (Jon Dudas/USPTO) are preliminarily enjoined from
    - implementing all portions of the rules
    - issuing any other new regulations to limit the number of continuing applications, RCEs, and claims that can be filed/examined
  - Order expires once the merits of the case have been fully decided
    - We do not yet know when this will occur, but the next step is a scheduling conference to determine the briefing and trial schedule to decide the merits of the case in the District court
    - Many U.S. attorneys believe that this will happen in early 2008
    - Regardless of this result, there might be an appeal to the Federal Circuit
    - In this case, it is unclear if or when the final rules will become effective
  - Other procedural matters were also decided

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- Opinion
  - Background discussion
    - Notes that GSK is a large company; explains GSK's strategy for filing patent applications (genus and many species)
    - Explains difference between USPTO practice under old rules vs. new rules
    - Discusses history of this rulemaking

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- Standard of Review by Court
  - Applies substantive law of Federal Circuit: 4 factors
    1. Likelihood of plaintiff's success on merits
    2. Irreparable harm if injunction is NOT granted
    3. Balance of hardships between the parties
    4. Public interest
  - Accepts *amicus* briefs and expert testimony
    - *Amicus* parties are filing in a timely manner, and court will consider the briefs, but will not consider legal issues or arguments not made by the parties themselves
    - Expert testimony permitted due to complexity of the terminology and rules
    - USPTO argued for a variety of reasons that this information should not be considered
    - However, the Court dismissed USPTO's motions to prevent this information from being considered

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- Consideration of 4 factors
  - 1. Likelihood of Success on Merits
    - GSK argued that
      - (a) USPTO lacked authority to issue substantive rules, because Congress did not authorize USPTO to do so;
      - (b) the specific rules exceed the plain language of 35 USC;
      - (c) rules are improperly applied retroactively (apply legal consequences to past events)
      - (d) ESD requirement is unconstitutionally vague
    - USPTO argued that rules are simply procedural and not truly substantive, and even if there are substantive outcomes, USPTO is still authorized to implement the rules
    - Court agrees that GSK has demonstrated a *likelihood of success on the merits*

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- Consideration of 4 factors
  - 2. Irreparable harm to GSK if no injunction
    - GSK argued that
      - (a) about 2000 GSK applications would have their rights changed under the new rules
      - (b) lack of ability to file continuations and further claims
      - (c) harm is that if the rules are not enjoined but later held invalid, GSK will lose investment capital, and patent rights covering medical inventions, such that potentially helpful drugs will be lost to both GSK and the public
      - (d) as *quid pro quo* for strong patent protection, inventors surrender the trade secret rights in their inventions
    - USPTO argued that GSK's harms are speculative and does not provide any specific patent applications or exact monetary loss
    - Court agrees that GSK has demonstrated a *likelihood of suffering irreparable harm*

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- Consideration of 4 factors
  - 3. Balance of hardships between parties
    - GSK argued that
      - (a) USPTO's training costs are "sunk", and were based on implementing rules they might not go into effect
      - (b) PTO's assertion of reduced backlog are exaggerated
      - (c) GSK will suffer instantly from the uncertainty of patent protection if the rules are not enjoined, in addition to the costs
    - USPTO argued that they have already trained staff and changed computer systems in view of the new rules, and it is difficult to undo or suspend operation in view of the rules…and that a preliminary injunction would cause costly computer problems and increase the likelihood of errors in USPTO
    - Court found that although USPTO might have some hardships, the *immediate* uncertainty and loss of investment by GSK *tilts the balance in GSK's favor*

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- Consideration of 4 factors
  - 4. Public Interest
    - GSK argued that
      - (a) preserving status quo (old rules) maintains stability for patent holders
      - (b) *amicus* briefs more fully explain about the harm to the public interest from the new rules in many industries
      - (c) again refers to the tradeoff of abandoning trade secret rights
    - USPTO argued that public interest is benefited by immediate implementation in view of efficiency and timeliness, and that applicants who are already trying to comply with the new rule will face uncertainty
    - Court agrees that uncertainty of implementing potentially invalid new rules is *against public interest*

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- Next steps
  - USPTO might appeal District Court's Order of October 31, 2007
    - Must be filed within 60 days of October 31, 2007
    - "Abuse of discretion" standard
    - We do not know when this could happen, or what the result might be
  - There will be a scheduling conference to fix a date for the hearing of the case on the merits, probably in late 2007
    - Some practitioners believe the hearing might occur in early 2008, but we do not know for sure yet
      - USPTO has requested additional time in view of involvement of GSK, many expected *amicus* briefs, and less urgency due to the injunction
    - At this time, the District Court might uphold or invalidate some or all of the rules
    - Depending on the results, the case might be appealed to the Circuit level, and the preliminary injunction could be withdrawn or maintained if this occurs
      - USPTO could restart the ENTIRE rulemaking process from the first step (notice, comment period, etc)
  - It is unclear how long this process might take

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- What to do?
  - Follow “old rules” until further notice
    - Do not file SRR, ESD, list of related applications, list of claims supported by parent in CIP, etc
    - Right to file unlimited continuations, RCEs, claims, until further notice
  - Be prepared for possible implementation of new rules
    - If rules are upheld, transitional practice effect is still unclear
    - Maintain previous preparations for related applications
    - It is unknown as to what will happen on the merits, or how long it will take for the rules to be instated or canceled

Highlights of KSR and Aftermath

- Some argue that *KSR* is the most important case since *Graham v. John Deere Co*., which was the Supreme Court's 1966 decision on the obviousness standard for granting patents.
- A higher standard of inventiveness will now be needed to obtain and uphold the validity of patents.

Highlights of KSR and Aftermath (Cont.)

- It will be harder to convince the Patent Office that a particular invention is non-obvious and therefore patentable.
- The legal test for obviousness will undoubtedly be much more subjective as applied by the U.S. Patent Office and the Federal Circuit (CAFC).

Highlights of KSR and Aftermath (Cont.)

- The Supreme Court in *KSR* did not specifically set forth a new standard, but rather criticized the "teaching, suggestion, or motivation" (TSM) standard relied upon by the CAFC.
- The Supreme Court decision in *KSR* causes a ripple effect which will most likely take many years to settle down so that the Patent Bar, the Patent Office and the Federal Courts all have a clear understanding of its impact.

Highlights of KSR and Aftermath (Cont.)

- In the meantime, the purpose of this brief presentation is to understand:
  - 1) how KSR will affect patent prosecution before the U.S. Patent and Trademark Office;
  - 2) how KSR will affect patent litigation; and
  - 3) who will benefit and who will not after KSR

Brief Summary of the Supreme Court's KSR decision

- The Supreme Court in KSR reaffirmed *Graham v. John Deere Co.*, as the case which controls the obviousness standard.
- The KSR Court stated that the CAFC erred when it applied the TSM standard in an overly rigid and formalistic way.

Brief Summary of the Supreme Court KSR decision (Cont.)

- More specifically, the KSR Court stated that the CAFC erred in the following manner:
  1) "By holding that Courts and Patent Examiners should look only to the problem the patentee was trying to solve;"
  2) By assuming "that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem;"

Brief Summary of the Supreme Court KSR decision (Cont.)

3) By concluding “that a patent claim cannot be proved obvious merely by showing that the combination of elements was ‘obvious to try’”; and

4) By overemphasizing “the risk of Courts and Patent Examiners falling prey to hindsight bias” and by doing so denying “fact finders recourse to common sense.”

Brief Summary of the Supreme Court KSR decision (Cont.)

- Under the prior TSM test, the teaching, suggestion or motivation may be found in the prior art, in the nature of the problem, or in the knowledge of a person having ordinary skill in the art.
- However, according to KSR, the TSM standard is merely one of a number of valid rationales that may be relied upon to determine obviousness, but is not the only one.

Brief Summary of the Supreme Court KSR decision (Cont.)

- Accordingly, after KSR, if the TSM standard cannot be applied, then Examiners should consider one or more additional rationales in order to support their conclusion of obviousness.
- Said another way, not finding TSM would not thereby permit the Examiner to find non-obviousness and thus allow a particular claim.

Brief Summary of the Supreme Court KSR decision (Cont.)

- Nevertheless, KSR indicated that it is important to **identify a reason** that would have prompted a person having ordinary skill in the art to combine elements in the way the claimed invention does.

Brief Summary of the Supreme Court KSR decision (Cont.)

- The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield **predictable results**…
- "If a person of ordinary skill can implement a **predictable variation**, §103 likely bars its patentability."
- "…a court must ask whether the improvement is more than the **predictable** use of prior art elements according to their established functions."

Patent Prosecution After KSR

- An Examiner must clearly articulate a reason or rationale to support his obviousness rejection under 35 U.S.C. §103.
- The Examiner's rationale should be based on state of the art and, as before, cannot rely on impermissible hindsight bias which would normally be gleaned by reading Applicant's application.

Patent Prosecution After KSR (Cont.)

- Examiners still must deal with all of the claim recitations in a particular claim in their rejection.
- However, the prior art is not limited to the applied references
  - The specialized understanding of one of ordinary skill in the art, as well as the common understanding of a laymen must be considered.
  - For example, Examiners may rely on official notice, common sense, design choice, and ordinary ingenuity.

Patent Prosecution After KSR (Cont.)

- Importantly, whenever an Examiner makes a finding of obviousness based on, for example, common sense or design choice, the Examiner must provide an explanation as to why the differences between the prior art reference and the claimed invention would have been obvious to one of ordinary skill in the art.

Patent Prosecution After KSR (Cont.)

- Again, it is important to note as articulated by the Supreme Court in KSR, the Examiner must **identify a reason** why the claimed invention would have been obvious.

Applicant's response to §103 Rejections (Cont.)

- Based on the KSR decision, the Patent Office most likely will rely on the following rationales which were suggested by the Supreme Court's decision:
  1) Combining prior art elements according to known methods to yield predictable results;
  2) Substituting one known element for another to obtain predictable results;
  3) Using a known technique to improve similar devices in the same way;
  4) Applying a known technique to a known device ready for improvement to yield predictable results;
  5) "Obvious to try" – that is, choosing from a set number of identified, predictable solutions together with a reasonable expectation of success;
  6) Work which is known in one field of endeavor may prompt variations of its use in the same field of endeavor or a different one if the variations are predictable to one having ordinary skill in the art; and
  7) The teaching, suggestion, or motivation standard (TSM).

Applicant's response to §103 Rejections

- When faced with an obviousness rejection under §103, Applicant must present a reasoned position explaining why he believes the Patent Office has erred in its conclusion of obviousness.
- Applicant's rebuttal evidence may include evidence of secondary considerations such as commercial success, long felt but unsolved needs, failure of others, and unexpected results.

Applicant's response to §103 Rejections (Cont.)

- Of particular importance is the fact that if Applicant argues that there is no teaching, suggestion, or motivation (TSM) to combine various prior art, the Patent Office will most likely respond that the KSR decision now prevents an argument that a specific teaching, suggestion or motivation is required to support a conclusion of obviousness.

Applicant's Response to §103 Rejections

- Practitioners should ask themselves:
  - What is accomplished by the invention that is not accomplished by the prior art, even taken together?
- As before KSR, argue on a common-sense level about differences between the prior art and the claimed invention.

Applicant's Response to §103 Rejections (Cont.)

- Wherever possible, highlight interdependencies between claimed elements – especially method steps – to identify elements not found in the prior art.
- Teaching away/unpredictable results
- Whenever possible, utilize Rule 132 Declarations in order to show:
  - the non-combinability of various references;
  - the Examiner's misunderstanding of a particular technology and thus the combination of references; or
  - new and unexpected results achieved by the claimed invention

Patent Litigation After KSR

- Increase likelihood of obviousness challenges.
- For example, in the CAFC's first post KSR precedential decision, *Leapfrog Enterprises Inc. v. Fishcer-Price Inc.*, the Federal Circuit found the patent to be invalid as obvious.
- In *Leapfrog*, the CAFC wrote "an obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why such combinations would have been obvious where others would not."

Patent Litigation After KSR (Cont.)

- There may be a reduction in the presumption of validity
  - TSM test is not properly applied
  - Any new art not considered by the PTO
  - Absence of any secondary considerations
  - “Common sense” approach on the factual issues
- Increased use of experts, to establish:
  - Level of ordinary skill in art
  - Teachings of the related art
  - Material fact issues
  - Secondary considerations

Who Will Benefit and Who Will Not After KSR

- Larger established companies may obtain relief from the annoyance of “patent trolls”
  - The higher standard of inventiveness now needed to obtain and sustain patents under KSR may prevent patent trolls from obtaining patents on combination inventions
- Those who challenge patents will benefit since the new standard will most likely make it easier to invalidate patents
- Those who wish to seek more favorable terms in licensing negotiations or in existing licenses will benefit

Who Will Benefit and Who Will Not After KSR (Cont.)

- Those who wish to rely on the reexamination process should benefit from the higher standard after KSR
  - Since a re-exam opens all the claims of patent application to reexamination, Examiners may strike out more claims if not all of the claims based on the higher standard of obviousness

Who Will Benefit and Who Will Not After KSR (Cont.)

- Those who will not benefit after KSR
  - independent inventors and start-up businesses may have much more difficulty getting financial backing with a new tougher obviousness standard
  - Investors may be less likely to invest large sums of money where there is uncertainty as to whether a particular invention is non-obvious
- All patent applicants in general will most likely have on average a lengthier patent prosecution involving more office actions and more appeals to the Board of Patent Appeals and Interferences

THANK YOU