Obviousness after *KSR v. Teleflex*

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Background – Patent in Suit

(12) **United States Patent**
Engelgau

(10) **Patent No.: US 6,237,565 B1**
(45) **Date of Patent: *May 29, 2001**

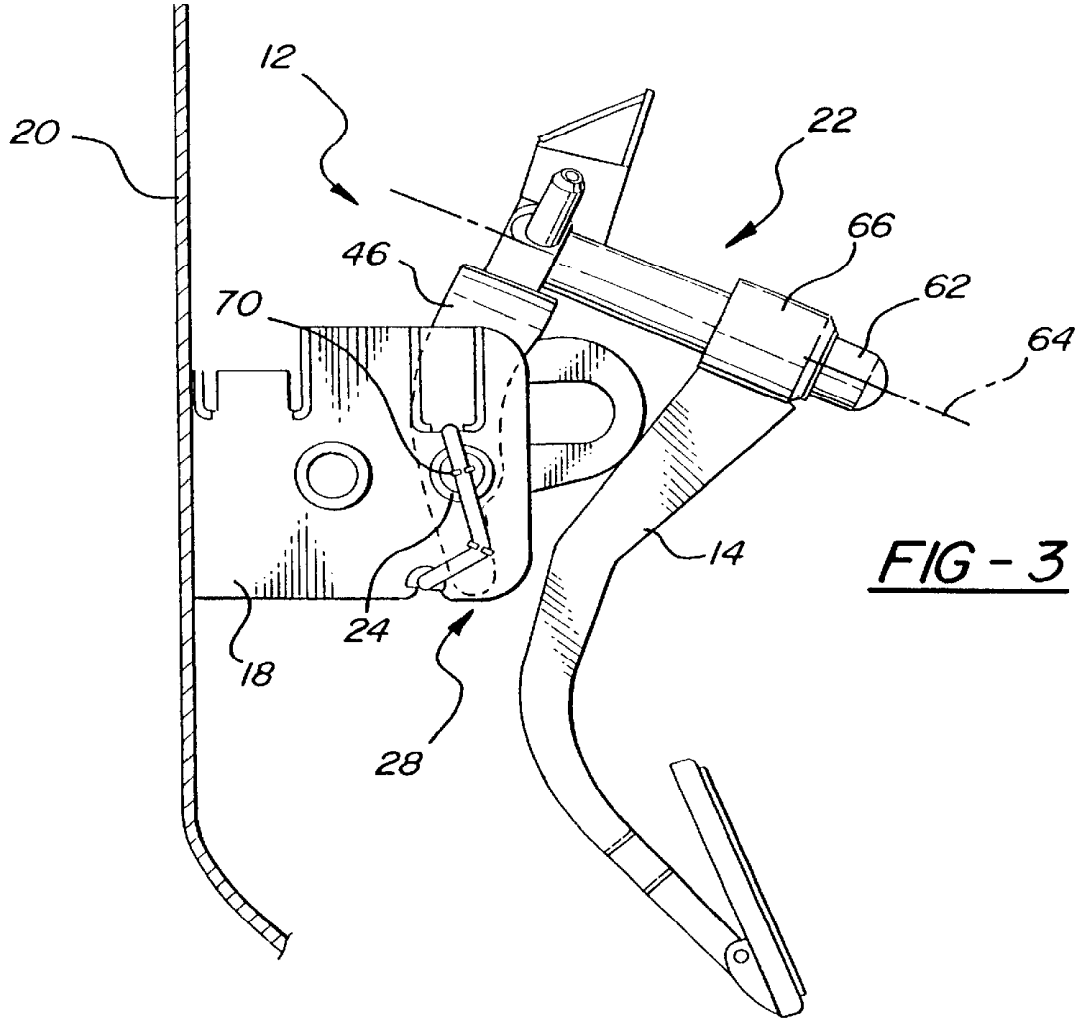


FIG - 3

4. A vehicle control pedal apparatus (12) comprising:

a support (18) adapted to be mounted to a vehicle structure (20);

an adjustable pedal assembly (22) having a pedal arm (14) moveable in force and aft directions with respect to said support (18);

a pivot (24) for pivotally supporting said adjustable pedal assembly (22) with respect to said support (18) and defining a pivot axis (26); and

an electronic control (28) attached to said support (18) for controlling a vehicle system;

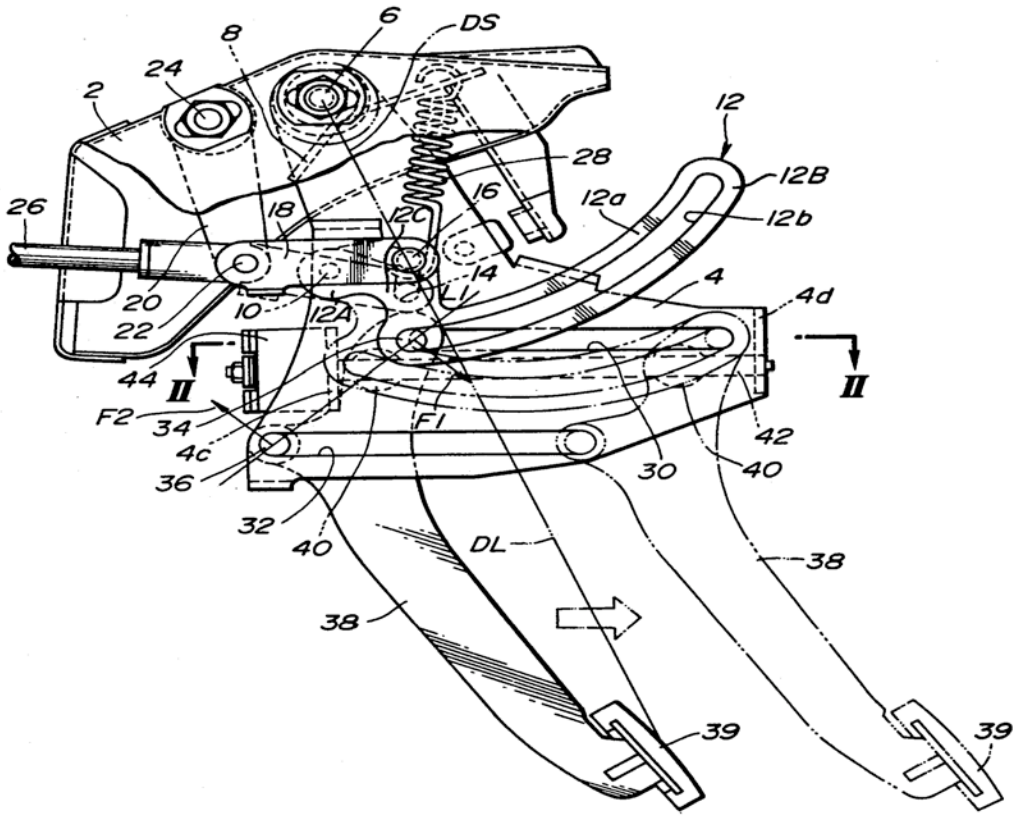
said apparatus (12) characterized by said electronic control (28) being responsive to said pivot (24) for providing a signal (32) that corresponds to pedal arm position as said pedal arm (14) pivots about said pivot axis (26) between rest and applied positions wherein *the position of said pivot (24) remains constant while said pedal arm (14) moves in fore and aft directions with respect to said pivot (24).*

- Background – Prior Art
  - *Asano* – teaches adjustable pedal assembly w/ fixed pivot point

United States Patent [19]
Asano et al.

[11] **Patent Number: 5,010,782**
[45] **Date of Patent: Apr. 30, 1991**

FIG.1



- Background – Prior Art
  - *Asano* – solved problem of variable ratio – force same in any position
  - Not cited

Background – Prior Art

- *Redding* - teaches adjustable pedal assembly w/ movable pivot point
- *Smith* – teaches integrated sensor on fixed location of pedal assembly (to avoid wear problem)
- *Redding* cited w/ *Smith* by examiner to reject similar claims – Claim 4 nonetheless allowed

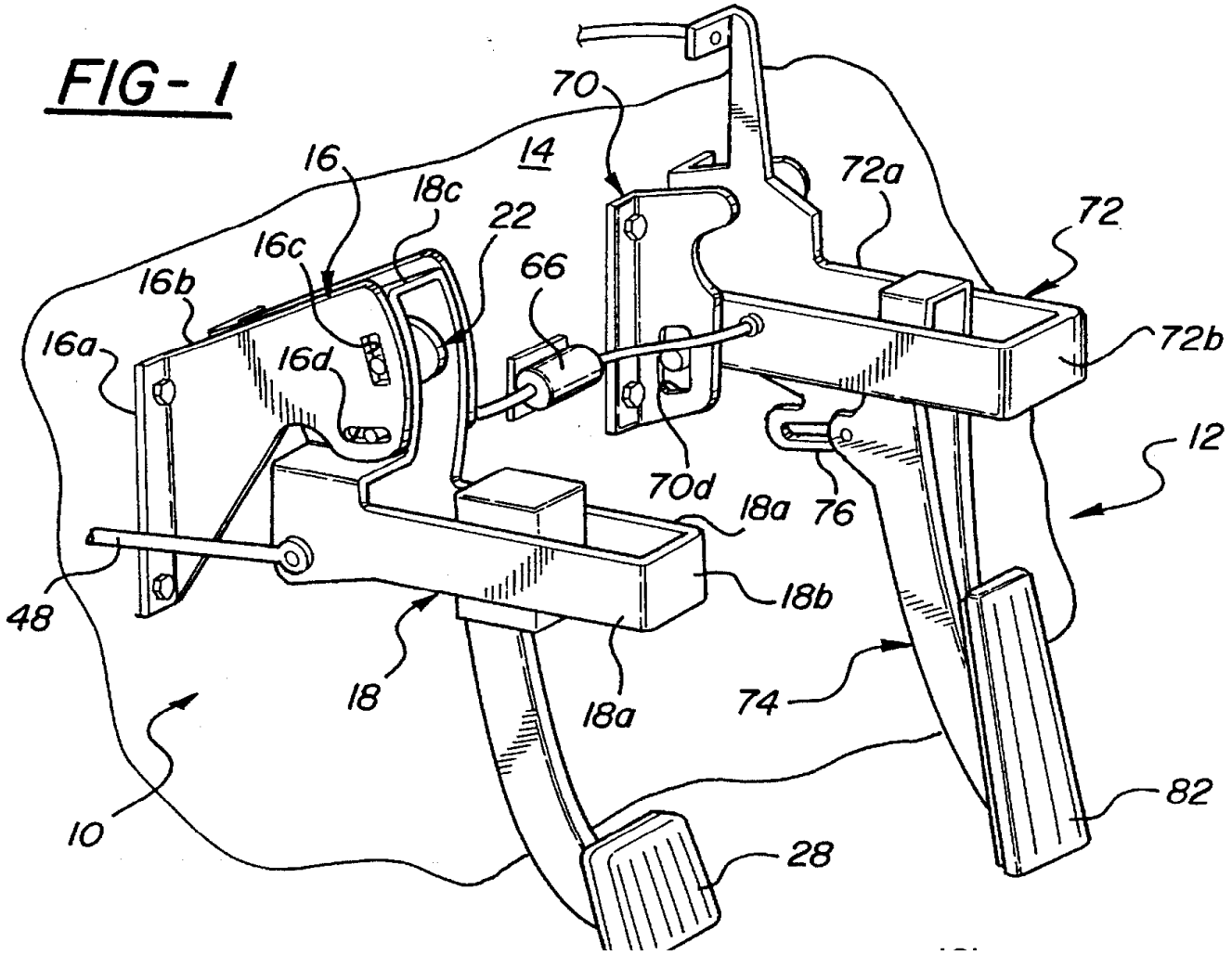
United States Patent [19]

Redding et al.

[11] **Patent Number: 5,460,061**

[45] **Date of Patent: Oct. 24, 1995**

FIG - 1



- Background – Prior Art
  - *Rixon* - teaches sensor in footpad with chafing problem
  - *'068/Chev Truck* – teaches modular sensor on pedal assembly

United States Patent [19]

Rixon et al.

[11] **Patent Number: 5,819,593**

[45] **Date of Patent: *Oct. 13, 1998**

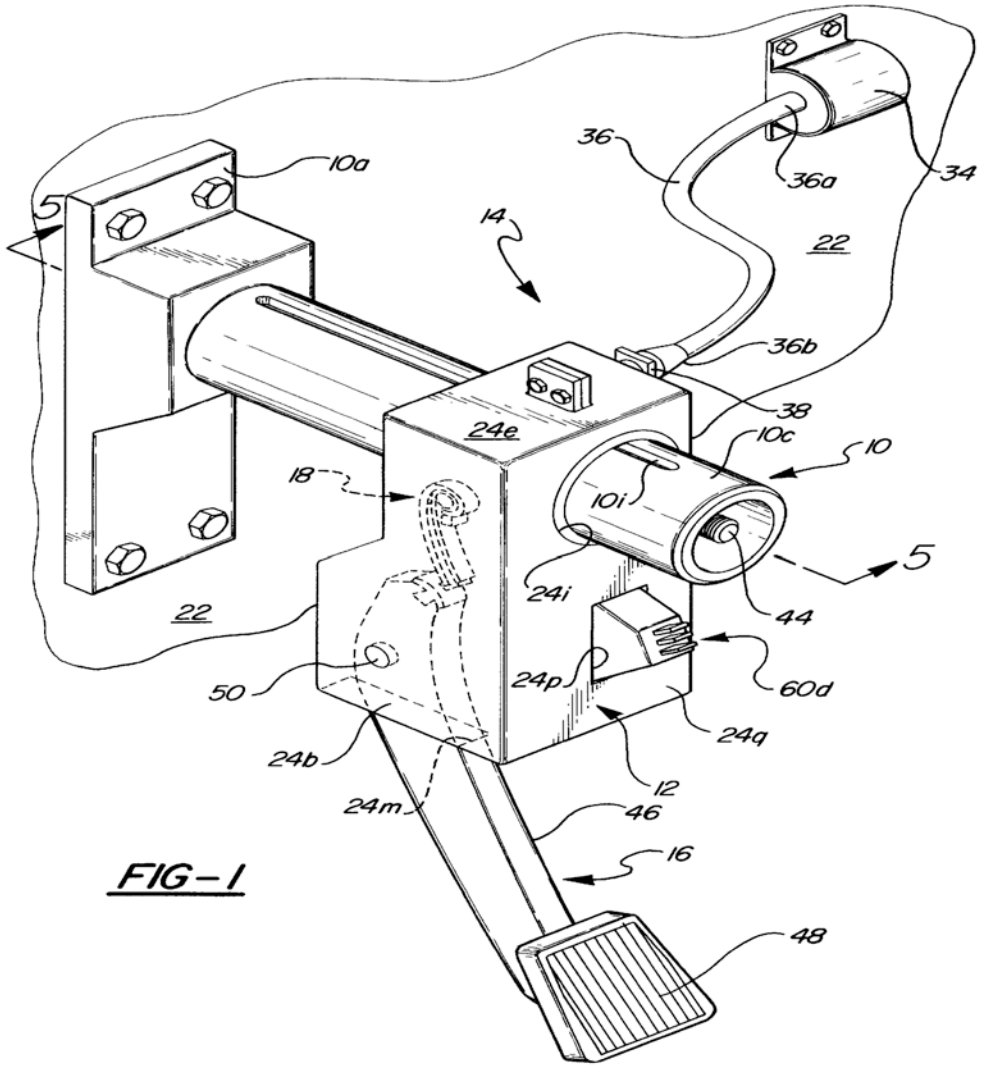
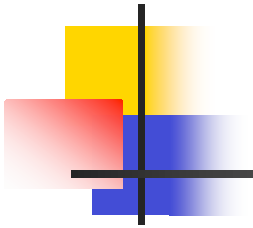


FIG-1

- Background – District Court
  - Granted summary judgment of invalidity
  - *Asano* in combo with *'068/Chev* teaches sensor in fixed pivot

Background – District Court

- TSM test met
- State of art leading to combo
- *Rixon* provided sensor on pad of assembly (w/ chafing problem)
- *Smith* taught solution to chafing was fix at pivot



- Background – Court of Appeals
  - Reversed District Court
  - TSM test not met
  - State of art leading to combo not relevant
  - Chafing problem of *Rixon* and solution of *Smith* of chafing was not relevant

Background of Obviousness Law

Historical Development, 1787-1851

- **U.S. Constitution** (Art. I, §8, cl. 8):
  - Congress may "**promote the Progress** of . . . useful Arts, by securing for limited Times to … Inventors the exclusive Right to their … Discoveries."
- ***Hotchkiss v. Greenwood*** (1851):
  - Essential elements of every invention are **a "degree of skill and ingenuity"; invention is not "the work of the skilful mechanic."**

1950-52

- ***Great Atl. & Pac. Tea Co.*** (1950)
  - invalidated claims that recited ***preexisting*** supermarket check-out counter structures "which only unite[d] old elements with ***no change in their respective functions***" [emphasis added]
- **1952 Patent Statute**:
  - §103(a) A patent may not be obtained … if the differences … **would have been obvious…**
  - no definition of "obvious"
  - no rule for decision

1966

- ***Graham v. John Deere***
  - 1952 Act was intended to codify precedents embraced in *Hotchkiss v. Greenwood,* and "… the general level of innovation necessary to sustain patentability remains the same."
  - The ***standard*** in the Constitution requires innovation, advancement, and things which ***add*** to the sum of useful knowledge.

1966

- **Decision Rule?** Under §103, one determines three factual inquiries and may consider secondary factors. "Against this background, the obviousness or nonobviousness of the subject matter is determined."
- **Difficulties Foreseen**: "What is obvious is **not** a question upon which there is likely to be uniformity of thought in every given factual context."
- **Application**: A PHOSITA "... would immediately see that the thing to do was what Graham did..."

1966

- ***United States v. Adams****:* Patent combining old elements was valid in exceptional circumstances:
  - unexpected operating characteristics;
  - required a PHOSITA to ignore known facts;
  - long-accepted factors deterred any investigation into combination used by Adams;
  - noted experts disbelieved Adams but the invention's significance was subsequently recognized.

1969

- ***Anderson's-Black Rock v. Pavement Salvage***
  - No New or Different Function. "The combination … **did not produce a 'new or different function'***** within the test of validity of combination patents."
  - No synergy.
  - Without invention, filling a long felt need and commercial success are not enough.
  - "…the combination patent **added nothing** to the inherent characteristics or function of the radiant-heat burner."

1976

- ***Sakraida v. Ag Pro***:
  - "this patent simply arranges **old elements** with each performing the **same function** it had been known to perform"; no effect that could "properly be characterized as **synergistic**."
  - Exploiting gravity adds nothing to the sum of useful knowledge where there is **no change in the respective functions** of the elements of the combination.

1989

- ***Bonito Boats v. Thunder Craft*:**
  - §103 precludes patent protection for subject matter that "could **readily be deduced** from publicly available material by a person of ordinary skill in the pertinent field of endeavor."

Amicus Briefs: TSM Opponents

- **U.S. Solicitor Gen'l., Cisco, GM, 14 Law Profs., et al.:** TSM sets the bar too low; need **extraordinary level of innovation** for a patent; allows patents to issue on obvious inventions TSM test supplants *Graham*, which is sufficient and flexible; courts can avoid hindsight.
- **IBM**: keep TSM but add a **rebuttable presumption** that old elements found in references in the "analogous art" would be combined

Amicus Briefs: TSM Proponents

- **ABA, AIPLA, GE, P&G, J&J, duPont** : S.Ct. precedent requires a reason to combine/modify prior art, and TSM does that; TSM comports with *Graham* and is objective, flexible, evidence-based, predictable, and fair; guards against hindsight.
- **IPLAC**: Allowing patents on only major advances discourages the disclosure of incremental improvements; no harm in patenting small advances since patent scope is limited.

Supreme Court Ruling

- 127 S.Ct. 1727
- Reversed Fed. Cir. and found obviousness.
- "We begin by rejecting the rigid approach of the Court of Appeals."
  - TSM was a "helpful insight" of the CCPA to identify a reason for combining prior art.
  - "no necessary inconsistency" between the TSM idea and *Graham,* but TSM cannot become a rigid rule that limits the obviousness inquiry.

Obvious: Not Just Known Elements

- "… a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." [emphasis added]
- must "look with care" at claims for a combination of known devices according to their established functions
- "…Important to **identify a reason** that would have prompted a [PHOSITA] to combine the elements in the way the claimed new invention does."

Predictability of Old Elements

- "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."

Predictable Expectations

- In *Sakraida*, the patent simply arranged "'old elements with each performing the same function it had been known to perform' and yield[ed] no more than one would expect from such an arrangement…'"
- "When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one."

Reason to Combine

- to determine ***whether there was an apparent reason*** to combine the known elements in the fashion claimed by the patent at issue, look to:
  - interrelated teachings of multiple patents;
  - the effects of demands known to the design community or present in the marketplace; and
  - the background knowledge possessed by a PHOSITA.

Explicit Analysis Needed

- Fed. Cir. correctly calls for explicit analysis, with "articulated reasoning" and a "rational underpinning" (citing *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)).

"Ordinary Innovation" --Not Enough

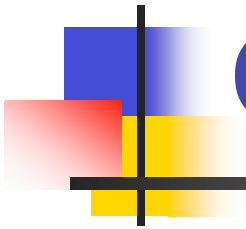
- "… the results of **ordinary innovation** are not the subject of exclusive rights under the patent laws."
- "Granting patent protection to advances that **would occur in the ordinary course without real innovation** retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility."
- In *Adams*, **unexpected results** supported non-obviousness.
- In *Anderson's Black Rock*, the device "did not create some **new synergy**."

Hindsight – Still to be Avoided

- "A factfinder should be aware … of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." (citing *Graham*)

Four Errors of Fed. Cir.

- 1. Error to look at only the problem that the patentee tried to solve.
- 2. Error to assume a PHOSITA attempting to solve a problem will be led to only prior art designed to address that same problem.
- 3. "Obvious to try" can be a valid way to show obviousness.
- 4. Cannot have rigid rules that deny recourse to common sense.



Consequences of *KSR* Decision

Pratical Implications of *KSR*

- Combination patents in predictable arts will be harder to obtain and sustain
- Scope of material information under Rule 1.56 may be broader; duty of candor may be enhanced
- Declaration evidence will focus on predictability rather than explicit teachings or misapplication of TSM
- Teaching away from combination still important
- Increase in patent challenges under §103 (district court, reexam, etc.)

Patent Prosecution After *KSR*

- *KSR* is not expected to have a devastating effect on the ability of applicants to obtain patents.
  - On the one hand, the Court certainly made it easier for examiners to demonstrate an "apparent reason to combine" known elements in various prior art references.
  - On the other hand:
    - The prior art references when combined still must teach or suggest all the claim limitations. MPEP § 2143.
    - The examiner's analysis still must be explicit.

Implications: Patent Prosecution

- Initially, mixed signals from Patent Office
- Memorandum from Margaret A. Focarino, Deputy Commissioner for Patent Operations, strikes moderate tone
- A brake on more aggressive Examiners

Implications: Patent Prosecution

- Focarino memo made four points:
  - The *KSR* opinion reasserts the primacy of four *Graham v. John Deere Co. of Kansas City* factors for determining obviousness;
  - The Court did not overturn the Federal Circuit's "teaching-suggestion-motivation" (TSM) test, which provides a "useful insight" in making an obviousness determination under *Graham*;

Implications: Patent Prosecution

- Focarino memo made four points:
  - The Court did criticize application of the TSM test rigidly to require an explicit showing of teaching, suggestion or motivation to combine prior art references to achieve the claimed invention; and
  - Perhaps most importantly, the Court continued to require that a *prima facie* obviousness case requires an **apparent reason** why a person of ordinary skill in the art would combine the references, and that the analysis must be **made explicit**. (**Boldface** in original).

Implications: Patent Prosecution

- Memo ended with exhortation:

  Therefore, in formulating a rejection under 35 U.S.C. 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. (**Boldface** in original).

Implications: Patent Prosecution

- Statement of John LeGuyader, Director in Technology Center 1600 (Biotech):

  On the day of the KSR decision, walking down the hallway, he could hear examiners excitedly remarking that they could now do "whatever they wanted with obviousness."

Implications: Patent Prosecution

- Statement of John LeGuyader, Director in Technology Center 1600 (Biotech):

  He stressed that this is incorrect, and that examiners were being told that things were more or less status quo.

  Examiners have always been trained to follow the *Graham v. Deere* factors, that that the motivation could also be founded in sound scientific reasoning, which they would need to present.

Implications: Patent Prosecution

- Statement of John LeGuyader, Director in Technology Center 1600 (Biotech):

  That, he added, is still the case, so in his view nothing has changed in terms of examination relative to obviousness.

Patent Prosecution After KSR

- Practice Tips Going Forward:
  - Hold examiners to their burdens of pointing out the claimed elements in the combination of references and providing explicit reasoning as to an apparent reason to combine them.
  - Emphasize drafting practices that will reduce the likelihood of being thwarted by § 103 rejections made possible by *KSR*.

Drafting Applications

- Focus on what the invention accomplishes that the prior art does not.
  - Identify this new functionality when receiving disclosures
- Written Description
  - Tell a convincing story that includes this new functionality.
  - Consider writing a background section that does not explicitly explain the problem solved by the invention.

Drafting Applications

- Claims
  - Look for ways to link elements in a way that highlights that new functionality, reducing the likelihood that an examiner will be able to identify those elements in the prior art.
  - In general, avoid claiming a list of stand-alone prior art elements, since "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions." *KSR* at 13.

Responding to §103 Rejections

- Refuse to accept conclusory assertions by examiners that it would have been obvious to combine certain references.
  - "[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR* at 14.
  - The Court left undisturbed the requirement that an examiner must present a "convincing line of reasoning supporting a rejection." MPEP § 2144.
  - The court reinforced this by stating that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR* at 14.

Responding to §103 Rejections

- Take a step back: 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.

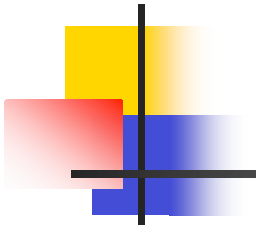
Responding to §103 Rejections

- Where possible, highlight interdependencies between claim elements – especially method steps – to identify elements not found in the prior art.

- Teaching away/Unpredictable results

Pharma/Biotech Implications

- Two important distinctions:
  - Inherent unpredictability of technology
  - Consequently, results frequently surprising/unexpected



Pharma/Biotech Implications

- Example:
  - Novel antibody to novel antigen cannot be obvious
  - Novel antibody to known antigen may be

Pharma/Biotech Implications

- Example:
  - Novel antibody to known antigen may be, depending on additional limitations, including reference to deposit (most limiting), biochemical parameters (such as affinity, concentration, purity, specificity)

Pharma/Biotech Implications

- Example:
  - Genes for unknown protein (e.g., novel member of multigene family) cannot be obvious
  - Gene for known protein may be

Pharma/Biotech Implications

- Example:
  - Gene for known protein may be, depending on scope
  - Perhaps we will need to address unanswered questions from *In re Deuel*

Pharma/Biotech: Patent Prosecution Practice Tips

- Application Drafting Tips:
  - Consider Increased Use of Comparative Examples and "Unexpected Results" Examples
  - Consider Increased Inclusion of Advantages and Secondary Consideration Disclosure
  - Consider Use of "Synergistic in that" type language to illustrate inventive combination is not a "predictable result" or a "predictable function/property"

Pharma/Biotech: Patent Prosecution Practice Tips

- Obviousness Rejection Considerations (the traditional ones still apply):
  - Argue improper hindsight
  - Argue merely obvious to try
  - Argue TSM against proposed combinations of art
  - Argue "no expectation of success" of Examiner's Proposed Combination

Pharma/Biotech: Patent Prosecution Practice Tips

- Consider Use of 1.132 Declarations
  - "Unexpected Results"
  - "Failure of Proposed Combination"
  - "Secondary Considerations"

Implications: Patent Litigation

- Increased likelihood of obviousness challenges
- *For example*, formulation and polymorph/enantiomer patents at particular risk
  - Formulations as combination of elements "old" in the art

Implications: Patent Litigation

- Likely basis for obviousness challenges: PTO applied TSM test too rigidly
- Reduction in presumption of validity
  - TSM test not properly applied
  - Any new art not considered by PTO
  - Absence of secondary considerations
  - "Common sense" approach on fact issues

Implications: Patent Litigation

- Increased use of experts, to establish
  - Level of ordinary skill in the art
  - Teachings of the related art
  - Material fact issues (avoid SJ)
  - Secondary considerations
- Factual issues determinative before CAFC recently (*Syngenta*, *Pfizer*, *Leapfrog*)

District Court Considerations

- interrelated teachings of multiple patents
- the effects of demands known to the design community or present in the marketplace
- the background knowledge possessed by a person having ordinary skill in the art
- *analysis should be made explicit*
- evidence of teaching away from a combination will be useful in establishing nonobviousness going forward

District Court Considerations

- Testimony from experts, POSAs about what would have been *predictable*; common knowledge
- Increase in SJ motions
- Jury instruction on KSR flexible approach
- Factfinder can rely on broader scope of prior art elements in considering obviousness of combination patents

Implications: Federal Circuit

- Follow broad *dicta* in *KSR*
  - *Teva v. Novartis* (March 30, 2007)
- Fed. Cir. has already relaxed rigid application of TSM
  - 2006 *Kahn*, *Alza*, *Dystar* decisions post-*KSR* cert. petition

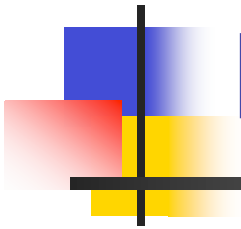
Implications: Federal Circuit

- Will continue relaxed application of TSM consistent with *KSR*

  "Michel added that under his reading of the opinion, the teaching, suggestion or motivation test remains part of the calculation of obviousness, 'but it gives us forceful instruction on the manner in which the test is to be applied.'" (*Legal Times*, May 1, 2007)

Implications: Federal Circuit

- Section 103 rulings likely to be panel-dependent
  - Increased hostility toward incremental advances
- Split decisions (2-1) where
  - combination based on common knowledge or common sense
  - Conclusions on the *predictability* of the results or function of a combination based on conflicting interpretations of prior art



Discussion and Q & A

Thank you!

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