Nonobviousness Part 2

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9. The method of providing user interface displays in an image forming apparatus which is really a bogus claim included amongst real claims, and which should be removed before filing; wherein the claim is included to determine if the inventor actually read the claims and the inventor should instruct the attorneys to remove the claim.

Beau Ties

Classic Markush Claim (Class 6)

• “… Wherein X is selected from the group consisting of A, B, C, D ...”
  • e.g., “A suit of attire, including an article of clothing, wherein said article of clothing is selected from the group consisting of shirt, sweater, or sweatshirt. . . .”

An article of clothing, selected from the group consisting of
• Shirts
• Shoes
• Pants

A chemical entity selected from the group consisting of
• Carbon
• COOH
• CH(6)
**Hatch-Waxman**

Unaffordable prescription drugs: the real legacy of the Hatch-Waxman Act

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**Potential Approach to Analyzing Validity over Prior Art**

- Does pre-AIA or post-AIA §102 apply?
- Which materials are prior-art candidates?
- Does each prior-art candidate have an effective date before a relevant critical date?
- Given above, what claim language might need construction to evaluate validity?
- Under likely constructions, are the claims anticipated by any single prior-art candidate?
- Under likely constructions, are the claims obvious over any potential prior-art combination?

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**Nonobviousness Analysis**

- **Basics:** Claimed invention “as a whole” must have been nonobvious at time of invention (pre-AIA) or before effective filing date (post-AIA), to an ordinary artisan knowing all prior art
- **4 Graham Factors to structure inquiry**
  - Prior art’s scope & content
  - Differences from prior art
  - Skill level in art
  - Secondary considerations
- **Challenge of Articulating Nonobviousness or Obviousness**
  - Your job on the exam is to make the case!

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**Background**

- The patent at issue attempted to solve a problem in paving asphalt roads—the joint between the new section of asphalt and old, cold sections tends to bond poorly
- Previously, two machines were used: one to spread and shape the new deposit of asphalt and a second containing a radiant-heat burner, which would soften the cold asphalt
- The claimed invention combined, on a single machine chassis, the spreading/shaping equipment and the radiant-heat burner

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Fig.1

Fig.2.

J. Douglas’ opinion for the Court

• “putting the burner together with the other elements in one machine, though perhaps a matter of great convenience, did not produce a 'new or different function’”

• “[commercial success] without invention will not make patentability”

• Relies on Graham: “[t]he patent standard is basically constitutional, Article I, § 8, of the Constitution” … Congress may not "enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby.”

Dann v. Johnston (1976)

Background

• Business method patent: “machine system for automatic record-keeping of bank checks and deposits.”

J. Marshall’s opinion for the Court:

• “[T]he mere existence of differences between the prior art and an invention does not establish the invention's nonobviousness. The gap between the prior art and respondent's system is simply not so great as to render the system nonobvious to one reasonably skilled in the art.”

Sakraida v. Ag Pro, Inc. (1976)

Background

• The patent in this case covered “a water flush system to remove cow manure from the floor of a dairy barn,” using a combination of conventional, well-known elements

J. Brennan’s opinion for the Court

• ”simply arranges old elements with each performing the same function it had been known to perform, although perhaps producing a more striking result than in previous combinations.”

In re Dembiczak (Fed. Cir. 1999)

Background

• “a large trash bag made of orange plastic and decorated with lines and facial features, allowing the bag, when filled with trash or leaves, to resemble a Halloween-style pumpkin, or jack-o'-lantern.

• “As the inventors note, the invention solves the long-standing problem of unsightly trash bags placed on the curbs of America, and, by fortuitous happenstance, allows users to express their whimsical or festive nature while properly storing garbage, leaves, or other household debris awaiting collection.”

• “Embodiments of the invention—sold under a variety of names, including Giant Stuff-A-Pumpkin, Funkins, Jack Sak, and Bag-O-Fun—have undisputedly been well-received by consumers, who bought more than seven million units in 1990 alone.”

In re Dembiczak (Fed. Cir. 1999)

J. Clevenger’s opinion for the Court

• Motivation-to-combine test = “best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis”

• Potential “evidence of a teaching, suggestion, or motivation”:
  • “prior art references”
  • “knowledge of one of ordinary skill”
  • “nature of the problem”

KSR v. Teleflex (2007)
**KSR v. Teleflex (2007)**

**Background**

1970s: Prior art with “adjustable pedal assemblies” “using cable-actuated throttle controls” (“CTCs”)

Mid-1990s: Development of “computer-controlled engines requiring … electronic throttle controls” (“ETCs”)

1998: KSR “chosen … to supply adjustable pedal systems” with CTCs; “sworn” '565 invention date

1999: Engelgau files application leading to ‘241 patent

2000: KSR “chosen by [GM] to supply adjustable pedal assemblies” for vehicles “requir[ing]” ETC

2000: Engelgau files continuation leading to ‘565 patent

2000-01: KSR combines prior pedal assembly “with an off-the-shelf pedal position sensor”

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**J. Kennedy’s opinion for the Court**

- Rejects the “rigid approach” of the Federal Circuit
  - “our cases have set forth an expansive and flexible approach”

- “Reason to Combine” standard embraced
  - Requires a court to look to “interrelated teachings of multiple patents”
  - Such “analysis should be made explicit.”
  - Is this just “motivation to combine” repackaged as a legal Q?

- Objective: any “reason” can suffice
  - No restriction to reasons relating to problems actual inventor looked to solve

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**Modern-Day Nonobviousness**

- §103 Ordinary Artisan Standard
- 4 Graham Factors
- Reason-to-Combine Analysis (KSR)
  - RTC “analysis should be made explicit.”
  - Objective analysis: any reason known in art can suffice!
  - Suspicion of “predictable combinations” and mere “upgrades”
  - Rejection of the “rigid” approach of the Federal Circuit
USPTO and KSR

- “In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done.”
- “Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.”
- The prior art reference(s) need not teach or suggest all the claim limitations; however, Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art.

In re Kubin (Fed. Cir. 2009)

Background
- Patent examiner: NAIL protein was in the prior art (Valiante patent for the p38 protein)
  - Valiante teaches that “[t]he DNA and protein sequences for the receptor p38 may be obtained by resort to conventional methodologies known to one of skill in the art.” Example 12 of Valiante’s patent further describes a five-step cloning protocol for ‘isolating and identifying the p38 receptor’.
- BPAI agrees: Claimed invention was obvious, importance of NAIL protein would have motivated people in the field to isolate and clone the gene sequence

NK cells and NAIL protein

- NK cells are cytotoxic lymphocytes that play a major role in fighting tumors and viruses
- NAIL (Natural killer cell Activation Inducing Ligand) is a surface protein that acts as a cell binding site; when the right trigger binds with it (e.g., CD48), cell activity is stimulated
- Goal: Stimulate NK cells into fighting cancer

NAIL Protein: partial amino acid sequence

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HuNAIL MGQWTVTLLLLKLVQKGCQSQADHVWSIDGVPQLQNSIQTVBD50
Mu284 MGQWTVTLLLLKLVQKGCQSQADHVWSIDGVPQLQNSIQTVBD50
IWWKLLPSQNGFPHILKWRNGLPGSTS-98
VQMXXQGSHKIBILWYNQGSNVSQFDGYGFPALGKSAR100
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In re Kubin (Fed. Cir. 2009)

J. Rader’s opinion for the Court

• Deuel statement, “[T]he existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNAs,” is no longer good law after KSR

In re Kubin (Fed. Cir. 2009)

J. Rader’s opinion for the Court

• “the prior art teaches a protein of interest [NAIL/p38], a motivation to isolate the gene coding for that protein, and illustrative instructions to use a monoclonal antibody specific to the protein for cloning this gene”
• “a skilled artisan would have had a resoundingly ‘reasonable expectation of success’ in deriving the claimed invention in light of the teachings of the prior art”

B&W Tobacco (Fed. Cir. 2001)

2 Parts of the Motivation-to-Combine Test

• motivation
• “reasonable likelihood of success”
  • not just “‘obvious to try’”

Nonobviousness in Chem/Bio: From Deuel to Kubin

In re Deuel (Fed. Cir. 1995)

• “[T]he existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious . . . .”
• To establish obviousness, “[t]here must . . . be prior art that suggests the claimed compound . . . .”

In re Kubin (Fed. Cir. 2009)

• “Insofar as Deuel implies the obviousness inquiry cannot consider that the combination of the claim’s constituent elements was ‘obvious to try,’ the Supreme Court in KSR unambiguously discredited that holding.”

Arkie Lures (Fed. Cir. 1997)

Background

• Larew “made samples by hand” of “salty-tasting lure” made of plastisol
• “[M]anufacturers of plastic lures expressed strong doubts about the feasibility of manufacturing such a device,” and “about its properties”
• The Gene Larew Salty Frog “was an immediate commercial success”
**Arkie Lures (Fed. Cir. 1997)**

J. Newman’s opinion for the Court

- **Skill Level?**
  - Larew’s experts:
    - Biology professor who worked as “a consultant to the fishing tackle industry”
    - “Custom manufacturer of soft-bodied plastic fishing lures”

- **Prior Art**
  - “salty bait”
  - “plastisol lures”
  - “organic fish attractants in plastic lures”

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**Arkie Lures (Fed. Cir. 1997)**

J. Newman’s opinion for the Court

- **Differences from prior art**
  - What differences does the Court identify?
  - “Objective indicia”
    - What is the objective evidence of nonobviousness, and how convincing is it?

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**Arkie Lures (Fed. Cir. 1997)**

J. Michel’s dissent

- Larew patent is obvious
- Known in the prior art:
  - “fish are attracted to certain smells and tastes”
  - “salt was just such an attractor, even in small quantities”
- Not known: adding salt to plastisol lure

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**Hybritech, Inc. v. Monoclonal Antibodies Inc.**

**Hybritech v. Monoclonal Antibodies (Fed. Cir. 1986)**

**Background**

- Immunoassay: diagnostic test for detecting the presence of antigens in body fluids
- Prior art: diagnostic assay procedures using polyclonal antibodies in “sandwich assays”
- Sandwich assays using human or animal (polyclonal) antibodies were fast and simple, but required “enormous quantities” of antibodies
- At issue: patent for sandwich assay using monoclonal antibodies
- District Court: patent is obvious; prior art references predicted the use of monoclonal antibodies in immunoassays
Hybritech v. Monoclonal Antibodies (Fed. Cir. 1986)

J. Rich’s opinion for the Court

- Objective evidence of commercial success
  - Hybritech’s diagnostic kits had a substantial market impact
  - Market leader (25% share) even with multiple competitors
- Disagrees with District Court in two instances:
  - “sudden availability” – took “at least three years” from adequate supply of monoclonal antibodies and Hybritech kits
  - “disproportionate sums on marketing” – Hybritech spends 25-30% of income on marketing, industry standard is between 17-32%

“Causal Nexus”

- Federal Circuit jurisprudence requires a “causal nexus” between secondary considerations like “commercial success” and the claimed invention
  - “an invention can be wildly successful in the marketplace and still be obvious”
- Was a “causal nexus” established in Hybritech? Isn’t it more plausible that the commercial success of Hybritech and similar firms is more directly connected to the work of Kohler and Milstein that had just recently entered the public domain?

Application of the “Causal Nexus”

Prilosec and Nexium

- AstraZeneca’s omeprazole (Prilosec) was widely promoted as “the purple pill” after its launch in 1989.
- As Prilosec’s market exclusivity was ending, AstraZeneca launched the prescription-only follow-on product esomeprazole (Nexium) as “the new purple pill” in 2001 to encourage patients accustomed to taking Prilosec to switch to Nexium.
- Notably, when AstraZeneca began to sell omeprazole without a prescription as Prilosec OTC, the company changed the color of its product to salmon pink.
Application of the “Causal Nexus”

- Is there a causal nexus between the commercial success of esomeprazole (Nexium) and the invention?
  - Omeprazole (Prilosec, whose patent expired) was a blockbuster drug, extremely successful, an improvement over existing treatments, and with few side effects (Nexium may owe its commercial success to its predecessor Prilosec).
  - The S-enantiomer of omeprazole (hence esomeprazole) is thought to be the active form of the drug, with the R-form biologically inactive.
  - Racemic mixtures are hard to separate.
  - Implied: limited incentive to isolate/patent esomeprazole.
  - Remember: “an invention can be wildly successful in the marketplace and still be obvious.”