

Patent Law

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October 17, 2016

Class 12 – Nonobviousness:
Life after *KSR*; objective indicia

Recap

Recap

- Nonobviousness: introduction
- *Graham*
- *KSR*

Today's agenda

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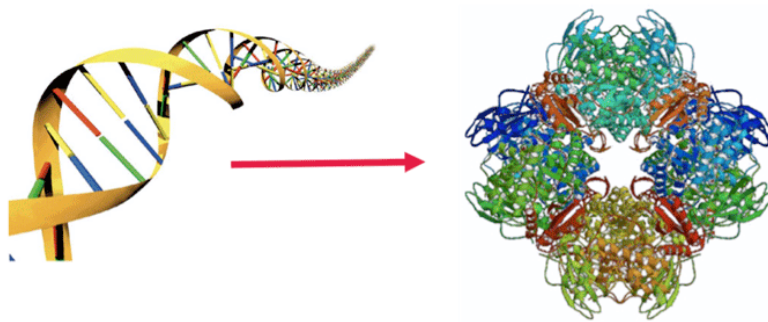
- Obviousness after *KSR*
- Objective indicia of nonobviousness

**Obviousness
after *KSR***

In re Kubin

→ Technology

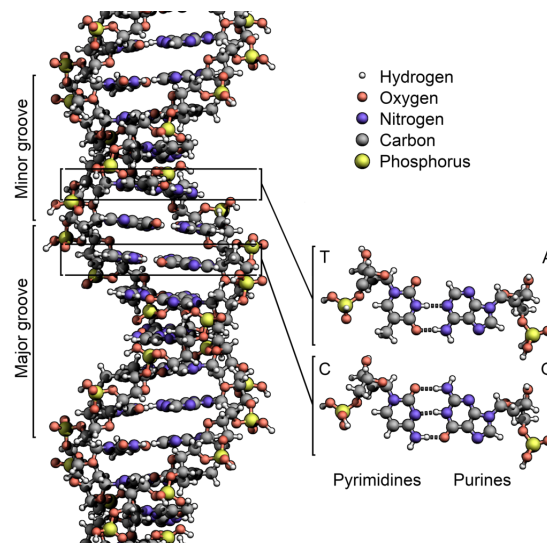
- Genes (DNA) encode proteins



In re Kubin

→ Technology

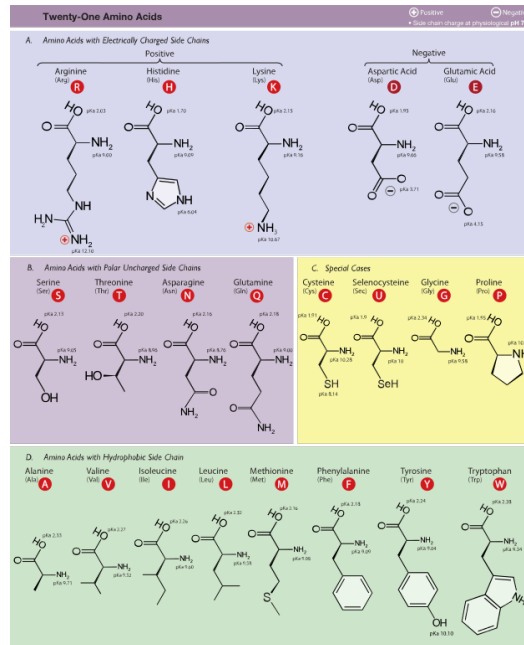
- DNA: string of nucleotides (guanine, adenine, thymine, or cytosine)



In re Kubin

→ Technology

- Protein: string of amino acids (21 in all)



In re Kubin

→ Technology

- Every triplet of nucleotides encodes a specific amino acid (or an instruction like "STOP")

TTT	Phe	TCT	Ser	TAT	Tyr	TGT	Cys
TTC		TCC		TAC		TGC	
TTA	Leu	TCA	Ser	TAA	Stop	TGA	Stop
TTG		TCG		TAG		TGG	Trp
CTT		CCT	Pro	CAT	His	CGT	Arg
CTC	Leu	CCC		CAC		CGC	
CTA		CCA		CAA	Gln	CGA	
CTG		CCG		CAG		CGG	
ATT		ACT	Thr	AAT	Asn	AGT	Ser
ATC	Ile	ACC		AAC		AGC	
ATA		ACA		AAA	Lys	AGA	Arg
ATG	Met	ACG		AAG		AGG	
GTT		GCT	Ala	GAT	Asp	GGT	Gly
GTC	Val	GCC		GAC		GGC	
GTA		GCA		GAA	Glu	GGA	
GTG		GCG		GAG		GGG	

In re Kubin

→ Technology

- So, DNA encodes protein (DNA → protein)
- Going from protein to DNA requires a little more reverse-engineering

In re Kubin

→ Patent

- Claim 73: "An isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide at least 80% identical to amino acids 22-221 of SEQ ID NO:2, wherein the polypeptide binds CD48."
- In other words, the claim covers a category of DNA molecules that encode a category of proteins (NAIL and similar)

In re Kubin

→ Prior art: Valiante patent

- Discloses p38 protein – same as NAIL protein
- Does not disclose DNA to make that protein

In re Kubin

→ Prior art: Valiante patent

- Does say “The DNA and protein sequences for the receptor p38 may be obtained by resort to conventional methodologies known to one of skill in the art”
- Discloses conventional five-step protocol for cloning DNA molecules encoding p38/NAIL

In re Kubin

→ Applying KSR

- Combination of familiar elements?
- Using known methods?
- To yield predictable results?

In re Kubin

→ Applying TSM test

- Teaching, suggestion, or motivation to combine?

In re Kubin

→ “Obvious to try”?

- Two classes of cases
- Varying all parameters or trying every possibility until something works
- Exploring a promising new approach, where the prior art offers only general guidance

In re Kubin

→ What happened to predictability?

In re Kubin

- What happened to predictability?
 - Court: in the context of biotech, this is super-predictable
 - It's too broad a brush to say a field is predictable or unpredictable

In re Kubin

- But: *Eisai Co. v. Dr. Reddy's Labs*:
 - "To the extent an art is unpredictable, as the chemical arts often are, *KSR*'s focus on these 'identified, predictable solutions' may present a difficult hurdle because potential solutions are less likely to be genuinely predictable."
 - M&D 679: "Because of analyses like the one above, *KSR* has had less practical impact on the pharmaceutical industry...."

“Updating” patents

→ Common scenario: take something that has long been done, and do it – with a computer! – or, – on the internet!

- *Leapfrog Enterprises v. Fisher-Price*
- *Muniauction v. Thomson*
- After *KSR*: “Applying modern electronics to older mechanical devices has been commonplace in recent years.”
- “Accommodating a prior art mechanical device that accomplishes [a goal] to modern electronics would have been reasonably obvious to one of ordinary skill in [the art].”

St. Jude Medical

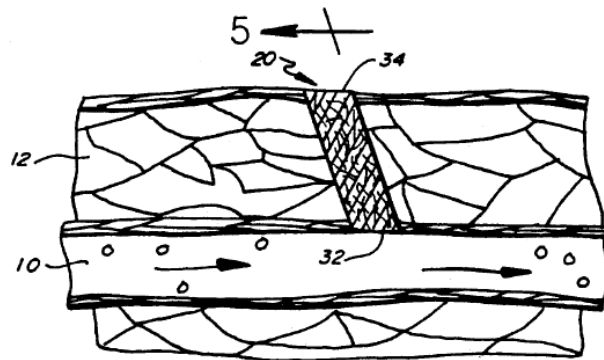
→ Another post-*KSR* case

→ Tech

- Prior art: different ways to close a puncture in a blood vessel after using a catheter
- In-vessel catheter and solid plug (gelfoam stick)
- But both can stick into the blood vessel and block blood flow

St. Jude Medical

→ Prior-art plug:



St. Jude Medical

→ Prior-art insert:

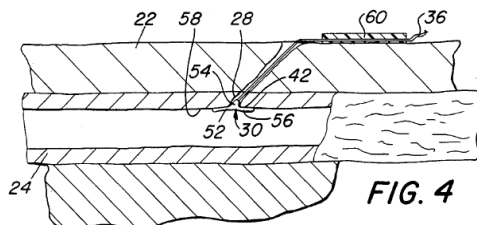


FIG. 4

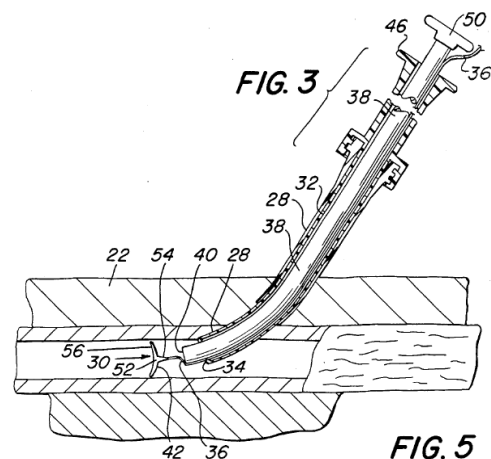
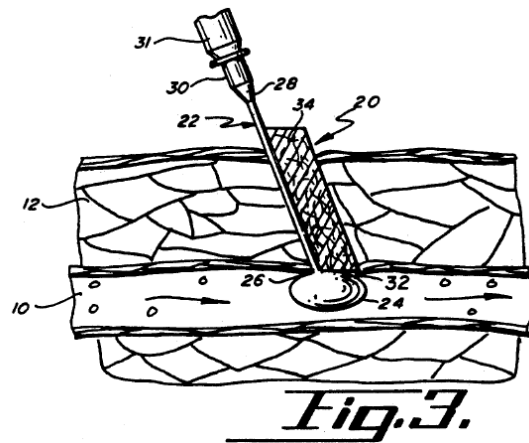


FIG. 5

St. Jude Medical

→ Invention:

- Combine balloon catheter (as a guide) and plug



St. Jude Medical

→ Applying KSR

- Combination of familiar elements?
- Using known methods?
- To yield predictable results?

After *KSR*

→ Does TSM test survive?

- Yes, in many cases
- But to far-more-limited effect
- More things count as teaching, suggestion, or motivation

After *KSR*

→ New teachings, suggestions, and motivations

- Predictability
- Exogenous technical developments
- Exogenous legal developments
- Routine experimentation
- Market forces
- Common sense

After *KSR*

→ Procedural changes

- Expert testimony may not be enough to create a genuine issue of fact
- Willingness to resolve questions on summary judgment

“Exemplary rationales that may support a conclusion of obviousness include:

(A) Combining prior art elements according to **known methods to yield predictable results**;

(B) **Simple substitution** of one known element for another to obtain predictable results;

(C) Use of **known technique to improve similar devices** (methods, or products) in the same way;

(D) **Applying a known technique to a known device** (method, or product) ready for improvement to yield predictable results;

(E) “**Obvious to try**” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on **design incentives or other market forces** if the variations are predictable to one of ordinary skill in the art;

(G) Some **teaching, suggestion, or motivation** in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.”

After *KSR*

→ How big a change?

“There is absolutely no doubt that the Supreme Court’s decision in *KSR* **largely took away objectivity, instead supplanting it with a subjective test**. Ever since the Federal Circuit and the Patent Office have **struggled to get objectivity back into the test**. **The Federal Circuit has largely been successful**, with at least several notable exceptions. With nearly 7,000 patent examiners, most of whom are not lawyers, **the Patent Office has not been quite so successful despite their best efforts**. Many patent examiners continue to provide conclusory obviousness rejections seemingly unaware of the fallacy of their logical constructs.”

Gene Quinn, *KSR the 5th Anniversary:
One Supremely Obvious Mess*

After *KSR*

→ Jason Rantanen, *The Federal Circuit's New Obviousness Jurisprudence: An Empirical Study*:

- Less favorable to patentees
- TSM test has formally disappeared
- TSM concept has endured in the form of “reason to combine” analysis, though more forgiving
- Federal Circuit routinely relies on language from *KSR* about “whether the improvement is more than the predictable use of prior-art elements according to their established functions”
- Federal Circuit often looks to “common sense”

**Objective indicia
of nonobviousness**

Objective indicia of nonobviousness

- Objective indicia of nonobviousness
- Secondary indicia of nonobviousness
- Objective considerations of nonobviousness
- Secondary considerations of nonobviousness

Objective indicia of nonobviousness

- Commercial success of the invention
- Long-felt (but unmet) need for the invention
- Failure of others to develop the invention
- Professional skepticism of the invention
- Unexpected results
- Prior art “teaching away” from the invention
- In favor of obviousness: Simultaneous (or near-simultaneous) invention by multiple inventors

Objective indicia of nonobviousness

→ What do these add over ordinary
considerations of nonobviousness?

Objective indicia of nonobviousness

- What do these add over ordinary
considerations of nonobviousness?
- Less susceptibility to hindsight bias
 - More objectivity

Arkie Lures

→ Tech

- Plastic fishing lure with embedded salty compound
- Turns out, fish like salt, and so are less likely to let go of a lure

Arkie Lures

→ What are the secondary considerations of nonobviousness?

Arkie Lures

→ What are the secondary considerations of nonobviousness?

- No one in the industry thought it would work
- Salt causes problems when embedded in plastic
- Ruins surface texture
- Causes explosions (!!)

“The question is not whether salt ‘could be used,’ as the district court concluded, but **whether it was obvious to do so** in light of all the relevant factors. The beliefs of those in the field at the time, including **beliefs that the plastisol lure would lose its surface qualities, texture, and strength, as well as the manufacturing uncertainties**, are the position from which the decisionmaker must view the invention.”

“It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements. Indeed, **the years of use of salty bait and of plastic lures, without combining their properties, weighs on the side of unobviousness of the combination.** Mr. Larew persisted against the accepted wisdom, and succeeded. The evidence that the combination was not viewed as technically feasible must be considered, for **conventional wisdom that a combination should not be made is evidence of unobviousness.**”

Arkie Lures, Merges & Duffy at 686

Arkie Lures

- So do we want to give Mr. Larew a patent?
 - Does he satisfy the patent bargain?

Objective indicia of nonobviousness

→ Exogenous regulatory change

- *Richardson-Vicks Inc. v. Upjohn Co.*: There was a long-felt need for a combination ibuprofen/pseudoephedrine cold medicine
- Court: The long-felt need was irrelevant because the odds of getting regulatory approval were low until the FDA announced a change

Objective indicia of nonobviousness

→ Exogenous regulatory change

- *WMS Gaming Inc. v. Int'l Game Tech.*: New slot machine was obvious because it was illegal until it came out
- Court: no, it was illegal until it was invented, like all slot machines



Next time

Next time

→ **Nonobviousness III: the scope
and content of the prior art**