Patent Law

Prof. Roger Ford
October 11, 2017
Class 13 – Nonobviousness:
Life after *KSR*

Recap

Recap

→ Nonobviousness: introduction

→ *Graham*

→ *KSR*

Today's agenda

Today's agenda

→ Obviousness after *KSR*

→ (review of pre-AIA § 102(e))

Obviousness after *KSR*

Nonobviousness

→ The basic *Graham* test

- 1. Scope and content of the prior art are examined.
- 2. Differences between prior art and claims are ascertained.
- 3. Level of ordinary skill in the art is resolved.
- 4. Obviousness is determined.
- 5. Also, secondary considerations might be considered. (More on this later.)

Nonobviousness

→ Federal Circuit: Look for a teaching, suggestion, or motivation to combine elements

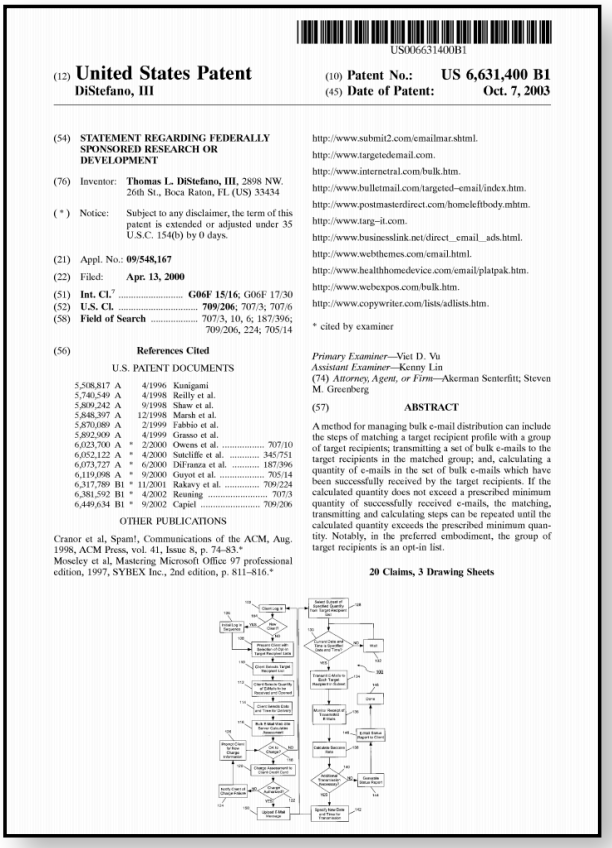
- Motivation: hindsight bias

→ Supreme Court: Not so fast; there are lots of reasons someone of ordinary skill in the art might combine elements

- Market forces
- Common sense

Perfect Web

→ An example of how the Federal Circuit has, sometimes, embraced *KSR*



US006631400B1

(12) **United States Patent**
DiStefano, III

(10) **Patent No.: US 6,631,400 B1**
(45) **Date of Patent: Oct. 7, 2003**

(54) **STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT**

(76) Inventor: **Thomas L. DiStefano, III**, 2898 NW. 26th St., Boca Raton, FL (US) 33434

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/548,167**

(22) Filed: **Apr. 13, 2000**

(51) **Int. Cl.**[7] **G06F 15/16**; G06F 17/30

(52) **U.S. Cl.** **709/206**; 707/3; 707/6

(58) **Field of Search** 707/3, 10, 6; 187/396; 709/206, 224; 705/14

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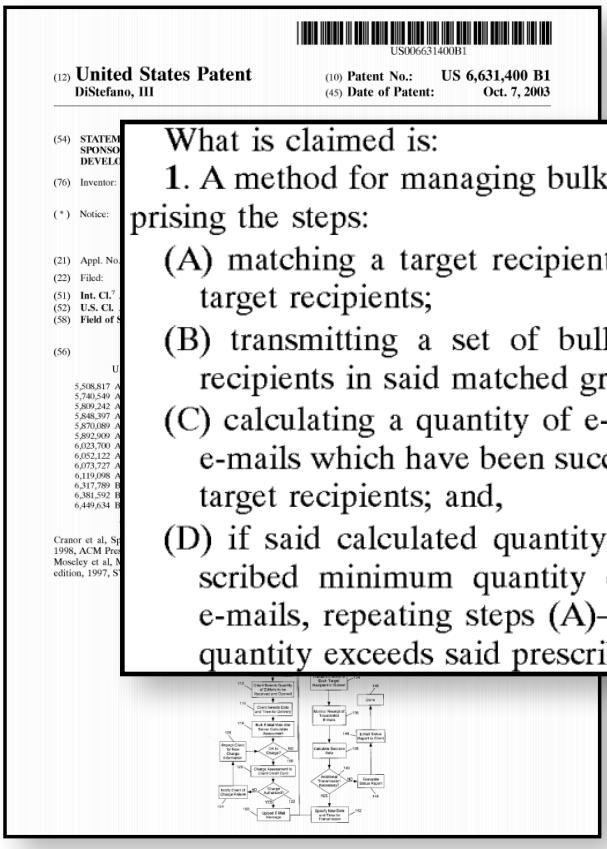
(57) **ABSTRACT**

A method for managing bulk e-mail distribution can include the steps of matching a target recipient profile with a group of target recipients; transmitting a set of bulk e-mails to the target recipients in the matched group; and, calculating a quantity of e-mails in the set of bulk e-mails which have been successfully received by the target recipients. If the calculated quantity does not exceed a prescribed minimum quantity of successfully received e-mails, the matching, transmitting and calculating steps can be repeated until the calculated quantity exceeds the prescribed minimum quantity. Notably, in the preferred embodiment, the group of target recipients is an opt-in list.

20 Claims, 3 Drawing Sheets

U.S. Patent No. 6,631,400

→ "Statement regarding federally sponsored research or development"



US006631400B1

(12) **United States Patent**
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What is claimed is:

1. A method for managing bulk e-mail distribution comprising the steps:

(A) matching a target recipient profile with a group of target recipients;

(B) transmitting a set of bulk e-mails to said target recipients in said matched group;

(C) calculating a quantity of e-mails in said set of bulk e-mails which have been successfully received by said target recipients; and,

(D) if said calculated quantity does not exceed a prescribed minimum quantity of successfully received e-mails, repeating steps (A)–(C) until said calculated quantity exceeds said prescribed minimum quantity.

U.S. Patent No. 6,631,400

nt

or

ent"

Perfect Web

→ How would this have come out pre-*KSR*?

Perfect Web

→ How would this have come out pre-*KSR*?

- The court would have looked for some teaching in the prior art to combine steps (A) through (C) with step (D)
- (Though really such a document probably would have been anticipating)

Perfect Web

→ After *KSR*:

- Common sense suggests that if your goal is to have a certain number of emails be read, and your first try doesn't reach that number, try again

Perfect Web

→ Why did Perfect Web appeal? What is its argument?

Perfect Web

→ Why did Perfect Web appeal? What is its argument?

- There's no evidence in the record for this sort of post-hoc reasoning
- This resort to "common sense" basically invites courts to make it up as they go

Perfect Web

→ So does that argument have merit?

Perfect Web

→ So does that argument have merit?

- Maybe!
- Court's response: A court can resort to "logic, judgment, and common sense available to a person of ordinary skill"

Perfect Web

→ So does that argument have merit?

- Here, the level of skill is "a high school education and limited marketing and computer experience"
- Cases with more complicated technology might require expert opinion or record evidence of a teaching, suggestion, or motivation

Perfect Web

→ *Mintz v. Dietz & Watson:* Common sense "is a shorthand label for knowledge so basic that it certainly lies within the skillset of an ordinary artisan"

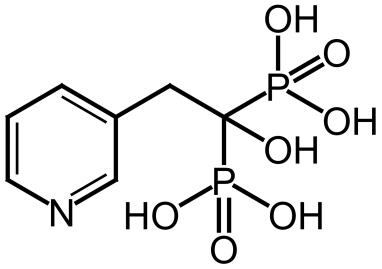
"Updating" patents

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

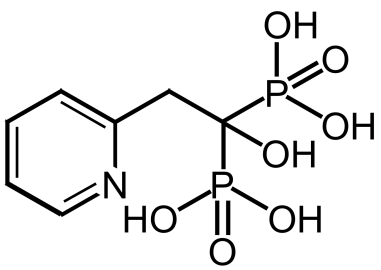
- *Leapfrog Enterprises v. Fisher-Price*
- *Muniauction v. Thomson*
- After *KSR*: "Applying modern electronics to older mechanical decides has been commonplace in recent years."
- "Accommodating a prior art mechanical device that accomplishes [a goal] to modern electronics would have been reasonably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

P&G v. Teva

→ Tech: risedronate, a drug to treat osteoporosis



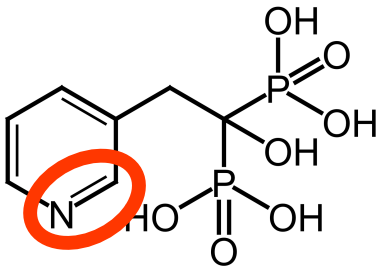
risedronate



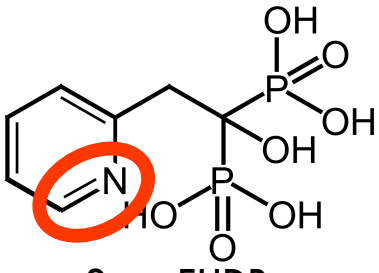
2-pyr EHDP
(prior art)

P&G v. Teva

→ Tech: risedronate, a drug to treat osteoporosis



risedronate



2-pyr EHDP
(prior art)

P&G v. Teva

→ Procedural aside:

- This is a Hatch-Waxman case, not a normal infringement case
- Normally, one infringes a patent by making, using, selling, offering for sale, or importing the invention

P&G v. Teva

→ Procedural aside:

- Hatch-Waxman Act: designed to increase development of generic pharmaceuticals
- A generic pharmaceutical company can tell the maker of a branded drug that it will start selling a generic
- That is a technical act of infringement that lets the branded drug maker sue

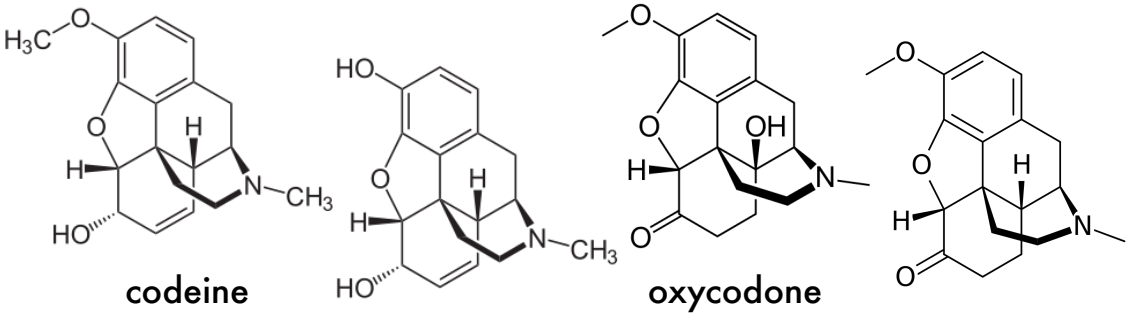
P&G v. Teva

→ Chemistry patents don't usually involve combinations of elements

- Courts instead look to variants of the same basic structure for obviousness

P&G v. Teva

→ In chemistry, structurally similar drugs often have similar properties



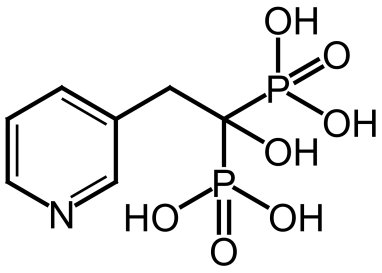
P&G v. Teva

→ So instead of looking for a motivation to combine, we look for a motivation to start with a lead compound and modify it to give the patented product

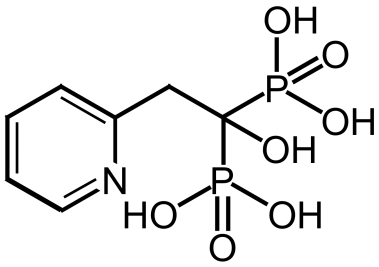
- Here, 2-pyr EHDP → risedronate

P&G v. Teva

→ So why wouldn't someone start with 2-pyr EHDP and try moving the hydroxy-ethane-diphosphonate group around the ring?



risedronate



2-pyr EHDP
(prior art)

P&G v. Teva

→ Two distinct problems:

- There's no reason to expect someone of ordinary skill in the art to select 2-pyr EHDP as their starting point, since there are dozens of potential compounds
- Even if they did think that's a good starting point, there's no reason they would expect modifying it to work

P&G v. Teva

→ Isn't this first explanation just "obvious to try"?

P&G v. Teva

→ Isn't this first explanation just "obvious to try"?

- Sometimes things that are obvious to try are obvious, when there aren't many possibilities and they provide reasonable guidance
- Sometimes, though, there are too many things, or the field is too unpredictable, to expect success

P&G v. Teva

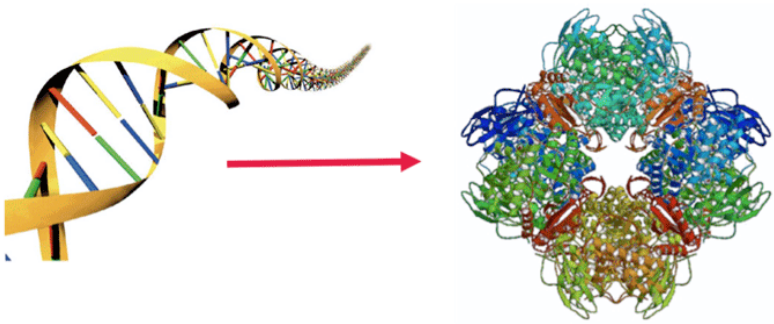
→ The big problem is lack of predictability

- Chemistry is often highly unpredictable
- (But sometimes it's not!)

In re Kubin

→ Technology

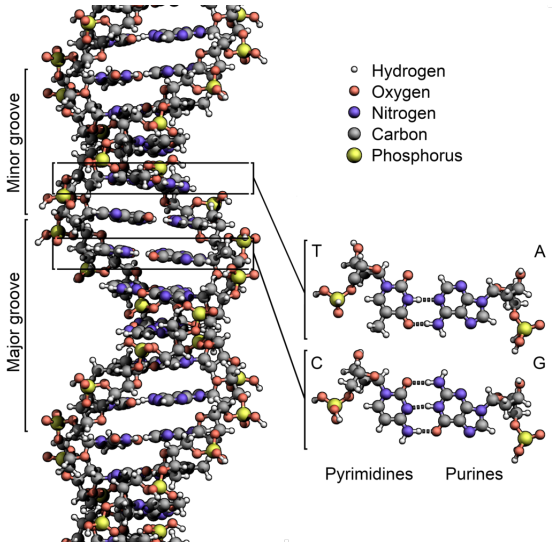
- Genes (DNA) encode proteins



In re Kubin

→ Technology

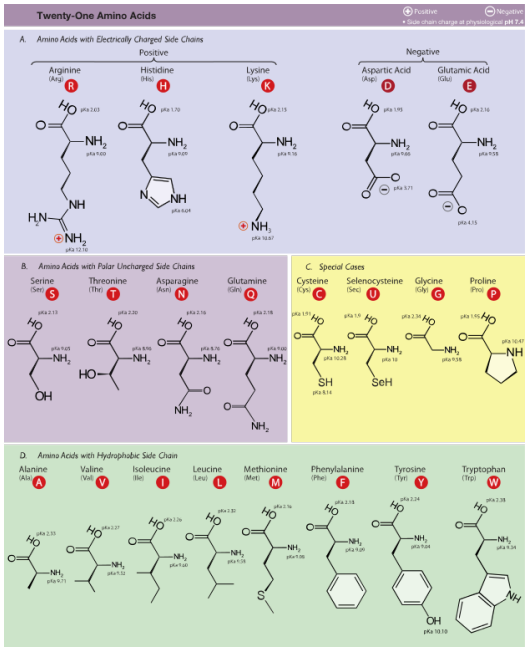
- DNA: string of nucleotides (guanine, adenine, thymine, or cytosine)



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		TAA	Stop	TGA	Stop
TTG		TCG		TAG		TGG	Trp
CTT	Leu	CCT	Pro	CAT	His	CGT	Arg
CTC		CCC		CAC		CGC	
CTA		CCA		CAA	Gln	CGA	
CTG		CCG		CAG		CGG	
ATT	Ile	ACT	Thr	AAT	Asn	AGT	Ser
ATC		ACC		AAC		AGC	
ATA		ACA		AAA	Lys	AGA	Arg
ATG	Met	ACG		AAG		AGG	
GTT	Val	GCT	Ala	GAT	Asp	GGT	Gly
GTC		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

→ 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 *Kubin* is an outlier:

- *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."
- Result: *KSR* has had less practical impact on the pharmaceutical industry

St. Jude Medical

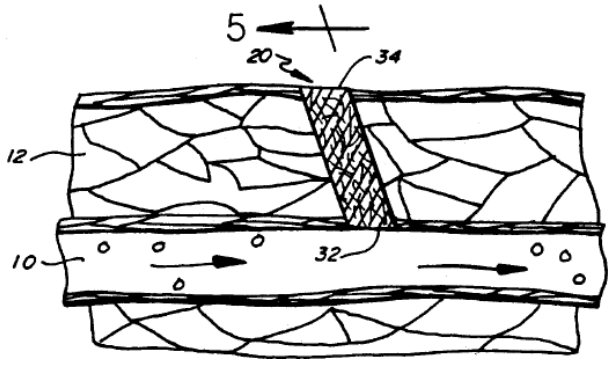
→ Another post-*KSR* case

→ 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:

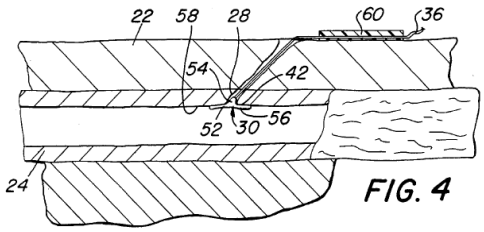


FIG. 4

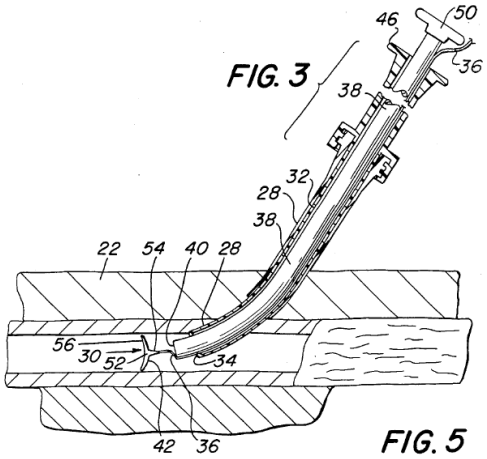


FIG. 3

FIG. 5

St. Jude Medical

→ Invention:

- Combine balloon catheter (as a guide) and plug

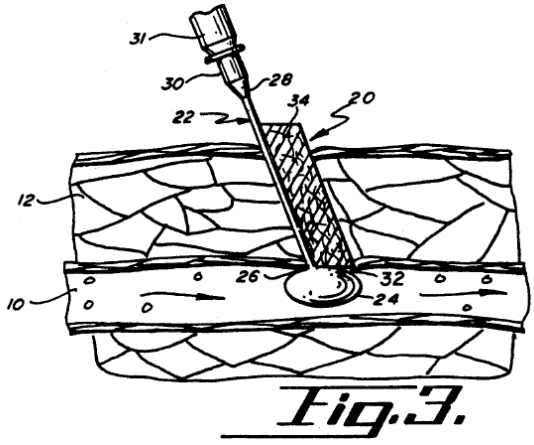


Fig.3.

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."

MPEP § 2141

After *KSR*

→ How big a change?

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"

"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*

(review of § 102(e))

Next time

Next time

→ Nonobviousness III: the level of skill in the art; objective indicia of nonobviousness; the scope and content of the prior art