

Current Issues in Intellectual Property



Lee C. Heiman
112 S. West Street
Alexandria, Virginia
703-548-6284
www.nathlaw.com

Obviousness, Post-KSR

- ★ Review: The Supreme Court held the TSM test “too rigid”
- ★ Errors in CAFC analysis:
 - ★ Focused on the problem as identified *by the applicant*
 - ★ Limited universe of references to those solving *the same problem*
 - ★ “Obvious to try” may sometimes be enough
 - ★ TSM did not apply “common sense”

Obviousness and Motivation, Post-KSR

KSR Central Inquiries:

- ★ Whether (1) the improvement is “more than the predictable use of prior art elements according to their established functions” *and* (2) there is a **reason** to combine shown
- ★ “When there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.”

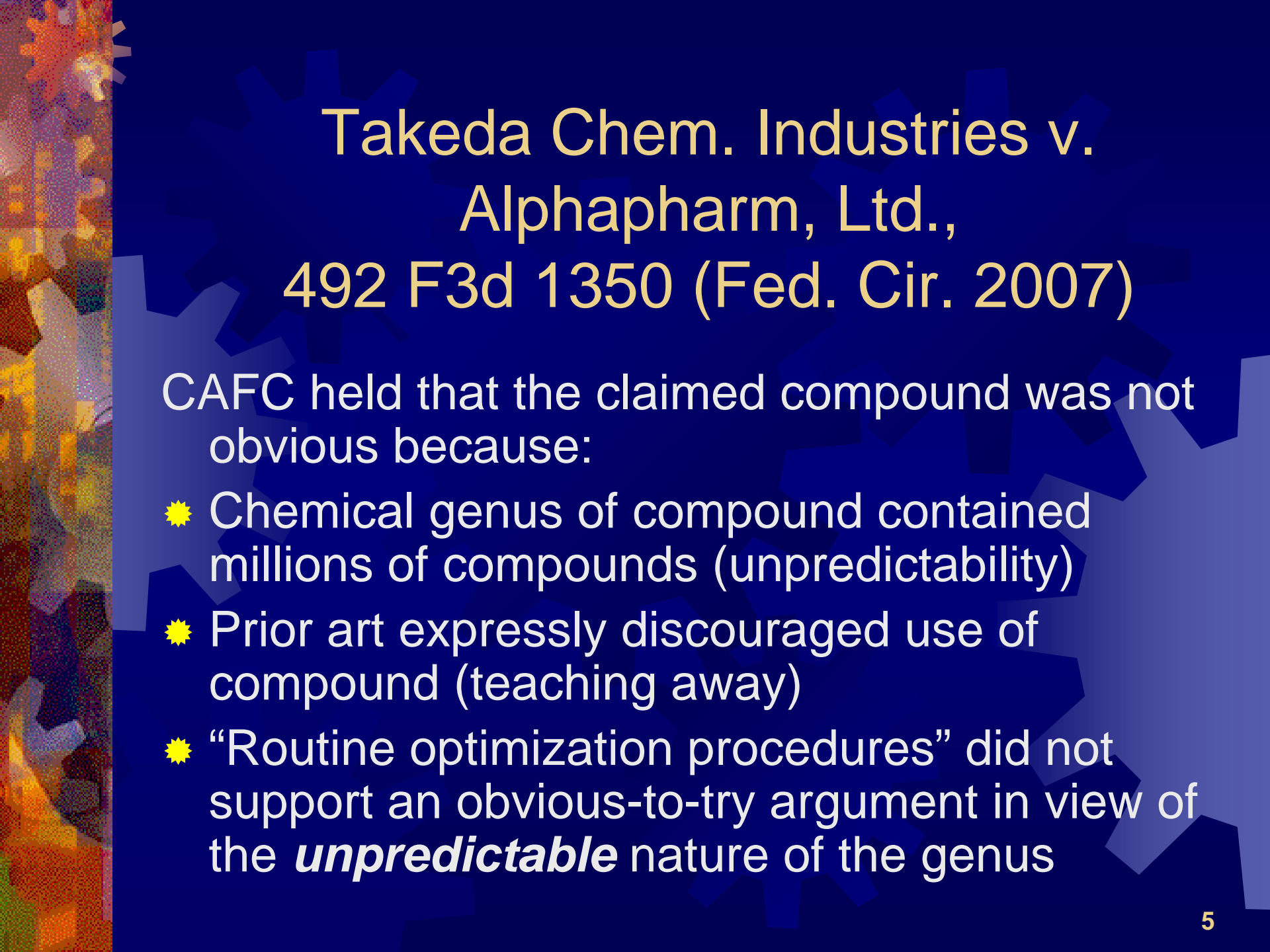
“The rumors of my death have been greatly exaggerated”

-Mark Twain

- ★ At the CAFC, the TSM test appears alive and well... but is this also true at the USPTO?

Takeda Chem. Industries v.
Alphapharm, Ltd.,
492 F3d 1350 (Fed. Cir. 2007)

- ☀ Claim drawn to organic ring compound with a hydrocarbon substituent
- ☀ Closest prior art differed by:
 - ☀ One carbon atom and
 - ☀ Location of substituent group on ring



Takeda Chem. Industries v.
Alphapharm, Ltd.,
492 F3d 1350 (Fed. Cir. 2007)

CAFC held that the claimed compound was not obvious because:

- ✱ Chemical genus of compound contained millions of compounds (unpredictability)
- ✱ Prior art expressly discouraged use of compound (teaching away)
- ✱ “Routine optimization procedures” did not support an obvious-to-try argument in view of the *unpredictable* nature of the genus

Ortho-McNeil Pharm. v. Mylan Lab., Inc., 520 F.3d 1358 (Fed. Cir. 2008)

- ☀ Claim was drawn to a compound (topiramate; TOPAMAX®) invented during a search for new antidiabetic drugs, later determined to have unexpected anticonvulsant properties
- ☀ What is the **reason**, which would have been apparent to POSITA, to use the compound as an anticonvulsant? Mylan argued that a person seeking to develop a *diabetes drug* would design a FBPase inhibitor, and thus would have chosen the claimed compound *as an anticonvulsant* because it had that activity

Ortho-McNeil Pharm. v. Mylan Lab., Inc., 520 F.3d 1358 (Fed. Cir. 2008)

CAFC held that the claimed compound was not obvious because:

- The evidence did not demonstrate a finite (and small in the context of the art) number of options (unpredictability)
- There was no reason shown to select the starting material or the synthetic pathway chosen (unpredictability)
- There was no reason shown to stop at an intermediate and test it for anti-convulsive properties, which were far afield from the original antidiabetic development purpose (unpredictability)
- Only in hindsight was it apparent that the compound had the desired activity (unpredictability)
 - All the evidence cited constitutes independent, not merely cumulative, evidence of nonobviousness

PharmaStem Therapeutics, Inc. v. Viacell, Inc. (Fed. Cir. 2007)

- ★ Claim was drawn to a method of cryopreservation of umbilical cord stem cells useful for hematopoietic reconstitution
- ★ The idea of using cryopreserved cord blood to effect hematopoietic reconstitution was not new at the time of filing. Two of the prior art references...suggest using cord blood for that purpose. Two others...suggest cryopreservation and storage of the cord blood until needed.

PharmaStem Therapeutics, Inc. v. Viacell, Inc. (Fed. Cir. 2007)

- ★ CAFC held that when asserting obviousness based on a combination of prior art references, the patent challenger must show that a skilled artisan
 - “would have had reason to... carry out the claimed process, and
 - “would have had a reasonable expectation of success in doing so.”
- ★ Clear evidence of the former was present in the cited art
- ★ The strong suspicion found in the prior art creates an expectation of success so strong that “no reasonable jury” could find the patent valid
- ★ Proving a theory is not necessarily inventive

Takeaways:

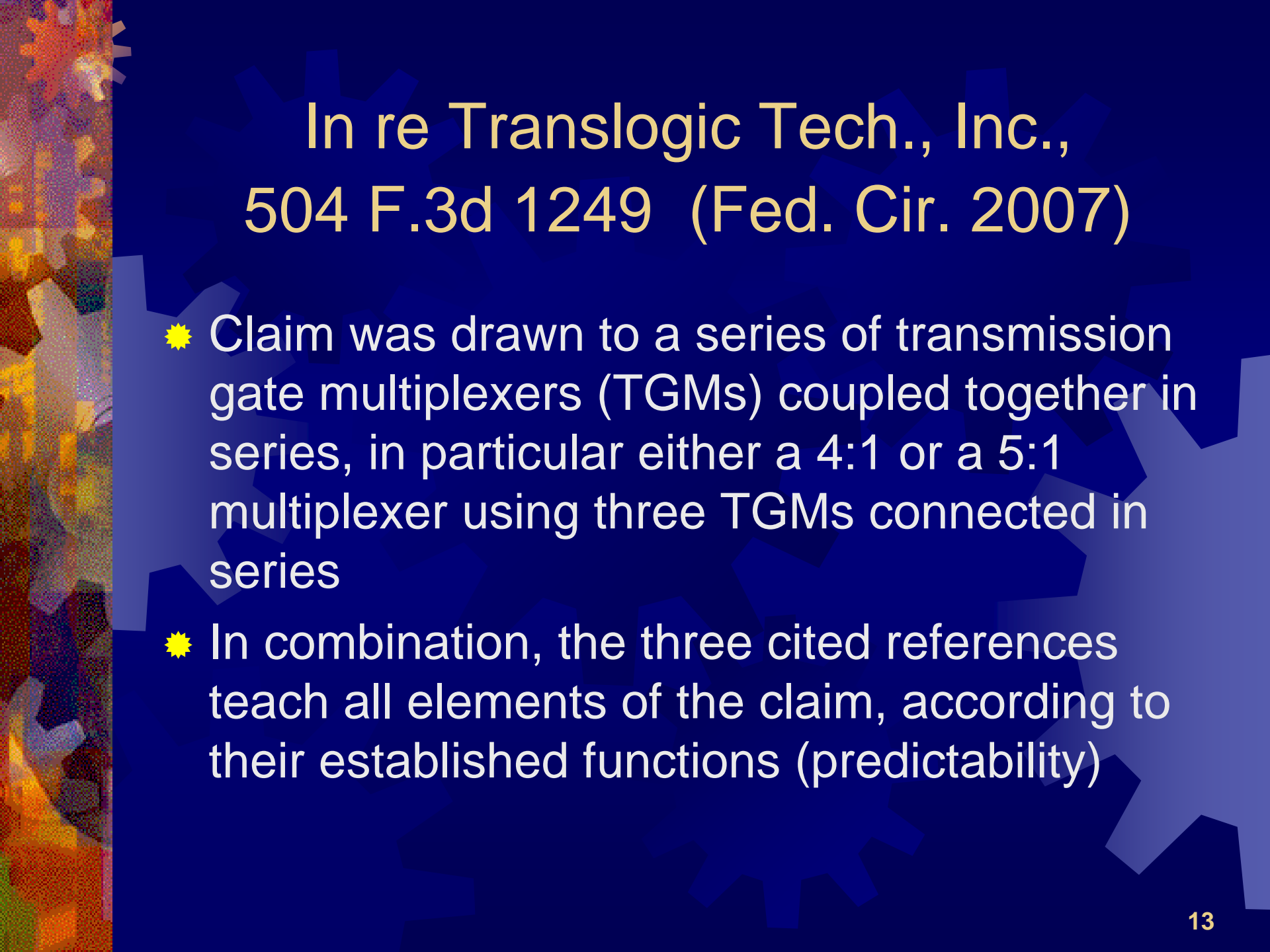
- ★ In the chemical and biotech arts, evidence of unpredictability and related secondary considerations (i.e. unexpectedly superior results, teaching away, long felt but unresolved need, and the failure of others) are still relevant at the CAFC to a showing of non-obviousness
- ★ *But...* unproved theories for solving a problem may make an invention obvious because it was obvious to try

In re Icon Health and Fitness, Inc.,
496 F.3d 1374 (Fed. Cir. 2007)

- ★ Claims were drawn to a treadmill having a gas stabilizing spring aiding the easy opening and closing of the unit
- ★ Gas stabilizing springs were known in other contexts, including the cited art example of a Murphy style bed

In re Icon Health and Fitness, Inc., 496 F.3d 1374 (Fed. Cir. 2007)

- ★ CAFC held that effective prior art must be “reasonably pertinent to the problem addressed” by the patent applicant; i.e. usually references in the same field of technology or that address the same problem
- ★ “Nothing about Icon’s folding mechanism requires any particular focus on treadmills; it generally addresses problems of supporting the weight of such a mechanism and providing a stable resting position.”
- ★ “Analogous art to Icon’s application, when considering the folding mechanism and gas spring limitation, may come from any area describing hinges, springs, latches, counterweights, or other similar mechanisms”
- ★ Did not completely open up what is valid prior art!



In re Translogic Tech., Inc., 504 F.3d 1249 (Fed. Cir. 2007)

- ★ Claim was drawn to a series of transmission gate multiplexers (TGMs) coupled together in series, in particular either a 4:1 or a 5:1 multiplexer using three TGMs connected in series
- ★ In combination, the three cited references teach all elements of the claim, according to their established functions (predictability)

In re Translogic Tech., Inc., 504 F.3d 1249 (Fed. Cir. 2007)

- ✦ Translogic argued that the cited art did not address the same problem to be solved, namely an improved multiplexer circuit
- ✦ Regarding "non-analogous art", the CAFC did not simply follow KSR; it held that prior art which is addressed to a different problem can be used to show the "common knowledge of a person of ordinary skill in the art"
- ✦ cf: *Icon Health and Fitness, Inc*: must the cited art be analogous art

Lexion Medical, LLC v. Northgate Tech. Inc. (Fed. Cir. August 2008)

- ★ Claim was drawn to a method and apparatus for heating and humidifying the gas used to inflate a patient's abdomen during laparoscopic surgery
- ★ The patented product improves upon the prior art by including a recharge port on the humidifier that allows the humidifier's water supply to be replenished during extended surgeries

Lexion Medical, LLC v. Northgate Tech. Inc. (Fed. Cir. August 2008)

- ★ CAFC affirmed the grant of a Motion for Judgment as a Matter of Law on obviousness
- ★ CAFC found obviousness because a recharge port on a humidifier was known, and the results of the combination were predictable

Takeaways:

- ✦ References directed toward solving different problems may be considered to the extent they illustrate "common knowledge."
- ✦ Unpredictability, Unpredictability, Unpredictability (and Unexpected Results)

Obviousness at the USPTO

Examiners seem to be using the result in *Icon* to reject applications, and clear their dockets, based on the “obvious to try” factors:

- a recognized problem or need in the art, which may include a design need or market pressure to solve a problem
- a finite number of identified, predictable potential solutions
- a reasonable expectation of success
- additional findings based on the *Graham* factors

Obviousness at the USPTO

- ★ Question: will the number of Appeals, and reversals, rise? Will it take an Appeal to get an allowance?
- ★ The CAFC is currently reviewing *Ex parte Kubin* (B.P.A.I. 2007), in which the Board, based on its reading of KSR, held a nucleic acid sequence (a composition) obvious because the method for making it was known; this is directly contrary to *In re Duell*



FDA Safe Harbor and Research Tools

“It’s too expensive to buy,
so I’ll beg/borrow/make
my own”

Proveris Scientific Corp. v. Innovasystems, Inc. (Fed. Cir. August 2008)

- ★ Claims were drawn to an apparatus for characterizing aerosol sprays commonly used in drug delivery (i.e. a testing system)
- ★ Innova copied and sold Proveris' apparatus to others engaged in making products (drugs) which would require FDA approval
- ★ Innova took the position that the safe harbor provision under 35 U.S.C. §271(e)(1) should not be limited so as to exclude research instruments and research tools

Proveris Scientific Corp. v. Innovasystems, Inc.

- ★ Question presented: does the safe harbor provision apply to the manufacture, marketing, or sale of a product which is used in the development of FDA regulatory submissions, but is not itself subject to the FDA premarket approval process?
- ★ CAFC held that the section 271(e)(1) safe harbor does not immunize the user of patented products from infringement under such circumstances

Takeaways:

- ✦ This raises the danger of suit for infringement when the product is a research instrument, laboratory reagent, or, arguably, a “research tool” such as an antibody, vector, growth medium, or delivery system
- ✦ If it’s patented, don’t build it, buy it



Thank You



© 2008 Lee C. Heiman