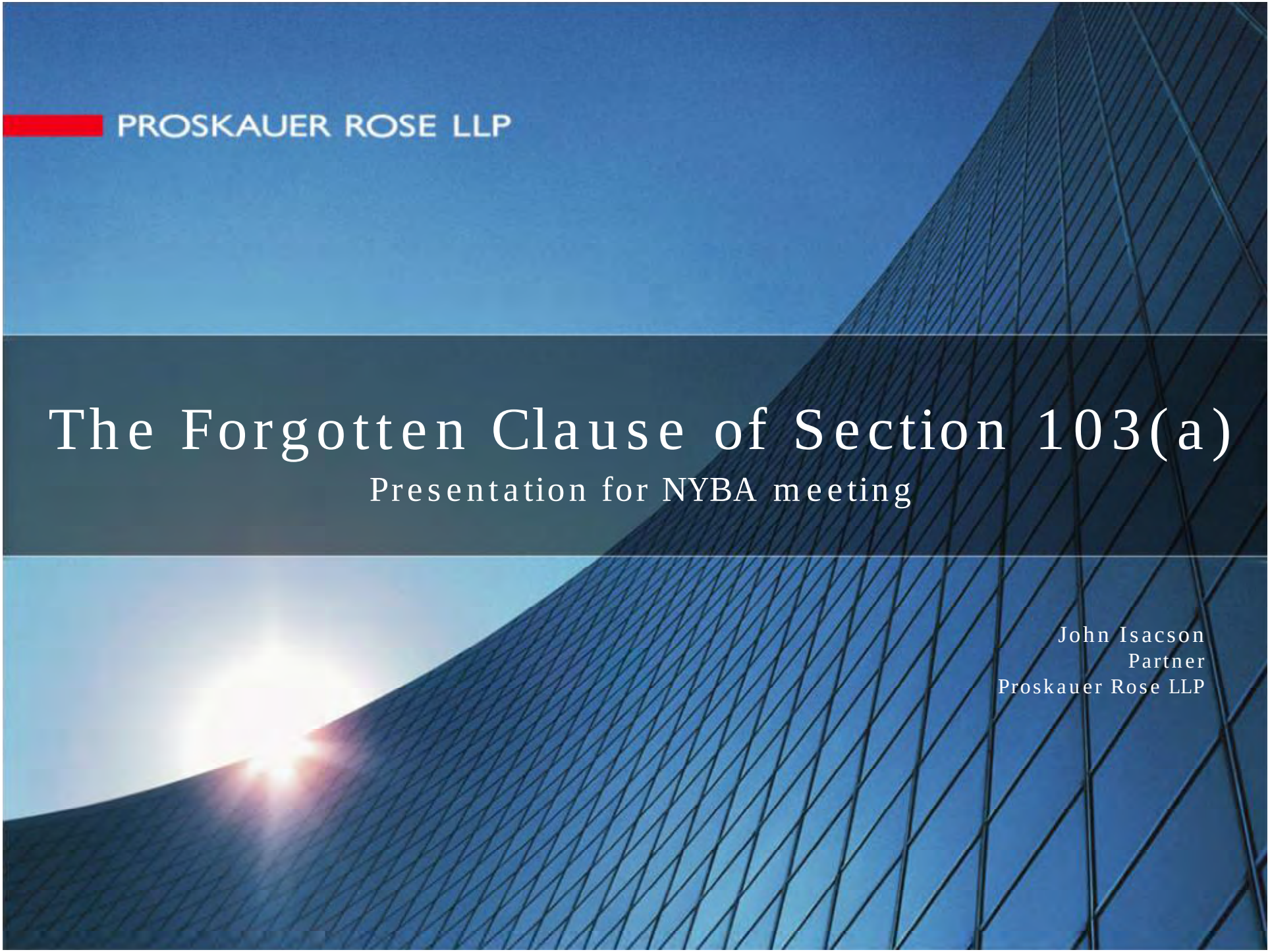

The Forgotten Clause of Section 103(a)

Presentation for NYBA meeting

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Partner
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Patentability shall not be negatived by the manner in which the invention was made.

Last sentence of 35 USC 103(a).

"[I]t is immaterial whether it resulted from long toil and experimentation or from a flash of genius."

Report of House Judiciary Committee on H.R. 7794 (1952).

- Moderates the "extreme degrees of strictness" in previous decisions.

- Marks "some change of attitude more favorable to patents".

P.J. Federico, Commentary on the New Patent Act (1954)

Briefly discussed in footnote 8 of *Graham v. John Deere Co.*

- *Graham* involved a spring clamp mechanism for plow shanks.
- The way the mechanism was made was not in issue.

KSR Int'l v. Teleflex, Inc.

- Relies on *Graham,* and concerned adjustable automotive pedals.
- Combining familiar elements according to known methods is likely to be obvious.
- Where a technique has been used to improve one device, the skilled person would recognize that it could be used for similar devices.
- The skilled person can pursue known options within their technical grasp.
- TSM is too rigid for obviousness (tacit repudiation of Federico).
- No mention of the negatived clause.

The life sciences often involve “long toil and experimentation”.

Life Science patenting post-*KSR*

- "[I]nventors merely used routine research methods…." *Pharmastem Therapeutics v. Viacell* (Fed. Cir. 2007) (citing *KSR*).

- Judge Newman noted in dissent the importance of "persistent and skilled investigation," and cited the negatived clause of 103(a).

Ex Parte Kubin, Board Appeal 2007-0819

- NAIL polypeptide was known in the art.
- "[A]n obvious method of obtaining nucleic acid encoding NAIL may be all that is required to show [that the genus is obvious]."
- Obvious to try can be appropriate.
- Isolating NAIL cDNA was not innovation, but rather of ordinary skill and common sense.
- No mention of the negatived clause.

USPTO Obviousness Guidelines, 72 Fed. Reg. 57526

Rationales for finding obviousness:

- Combining prior art elements by known methods.
- Use of a known technique to improve a similar device.
- Applying a known technique to a known device.
- Obvious to try.
- *Kubin* is discussed in Example 3.
- No mention of the negatived clause.

Rebuttal evidence noted by USPTO

- Cannot combine elements by known methods.
- Elements in combination do not merely perform the function that each performs separately.
- Unexpected results.

Other arguments

1. Invoke the negatived clause.

2. Secondary considerations: long felt but unmet need, failures of others, surprising results, praise by the field, commercial success, etc.

3. Thematic and factual flow can be particularly persuasive.

*****

Obviousness in view of KSR

TC1600-Specific Examples

The Basic Approach to Determining Obviousness Remains the Same

- ***KSR International Co. v. Teleflex Inc.,*** **550 U.S. —, 82 USPQ2d 1385 (2007)**
- **An examiner is <u>still</u> required to provide a reasoned statement of rejection grounded in the *Graham* inquiries. He or she must articulate a reason or rationale to support the obviousness rejection.**
- **See *KSR* at 1396 ("To facilitate review, [the obviousness] analysis should be made explicit.") (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).**

Any Reasoned Argument Grounded in *Graham* May Form the Basis for a *Prima Facie* Case of Obviousness

- "If a court, or patent examiner, conducts [the *Graham*] analysis and concludes the claimed subject matter was obvious, the claim is invalid under § 103." *KSR* at 1391.

- "The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents." *KSR* at 1396.

The Examiner as Fact Finder

- Examiners act as fact finders when resolving the *Graham* inquiries.
- Examiners must articulate findings of fact to support the obviousness rejection being made.

Key Points

- **Examiners must account for all claim limitations in their rejections by explaining how each limitation is disclosed or rendered obvious by the reference(s) applied**

Key Points

- **Prior art is not limited to the four corners of the documentary prior art being applied.**
  - **Prior art includes both the specialized understanding of one of ordinary skill in the art, and the common understanding of the layman.**
  - **It includes "background knowledge possessed by a person having ordinary skill in the art. . . . [A] court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR* at 1396.**

Making a *Prima Facie* Case of Obviousness

Examiners must:

- **Resolve the *Graham* inquiries**
- **Articulate appropriate factual findings**
- **Explain the reasoning that provides a nexus between the factual findings and the legal conclusion of obviousness**

Rationales

- One or more of the rationales set forth in the following slides may be relied upon to support a conclusion of obviousness
- The list of rationales provided herein is not intended to be an all-inclusive list
- The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reasons why the claimed invention would have been obvious.

Rationales Supporting a *Prima Facie* Case of Obviousness

- Combining prior art elements according to known methods to yield predictable results
- Simple substitution of one known, equivalent element for another to obtain predictable results
- Use of known technique to improve similar devices (methods, or products) in the same way
- Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results

Rationales Supporting a *Prima Facie* Case of Obviousness

- "Obvious to try" – choosing from a finite number of predictable solutions
- 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 would have been predictable to one of ordinary skill in the art
- Teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings

Example 1

- **Claims**
  - **A therapeutic composition comprising hematopoietic stem cells obtained from umbilical cord blood and a cryopreservative**
  - **A method for hematopoietic or immune reconstitution comprising cryopreservation of hematopoietic stem cells obtained from umbilical cord blood , thawing, and administering said cells to a human**

Example 1

- **Prior Art**
  - **Reference identifies the presence of stem cells in umbilical cord blood**
  - **Reference teaches that stem cells in umbilical cord blood could be cryopreserved and thawed**
  - **Reference suggests the use of stem cells from cord blood for transplantation and hematopoietic reconstitution**

Example 1

- **Evidence**
  - **Declarations by expert asserting**
    - **Prior art used "flawed nomenclature"**
    - **Problems with prior transplants of analogous stem cells (blood, marrow)**
    - **Surprise by those in the art at the success of the invention**

Example 1

- **Evidence**
  - **Statements in the specification defining both stem cells and progenitors are consistent with art-recognized definitions of stem cells and progenitors**

Example 1

- **Conclusion**
  - **It would have been obvious to one of ordinary skill in the art at the time the invention was made to collect, cryopreserve, store and administer hematopoietic stem cells from umbilical cord blood to an individual in need of hematopoietic reconstitution with a reasonable expectation of success because the prior art suggests that umbilical cord blood may be successfully used in hematopoietic reconstitution and may be successfully cryopreserved without loss of viability of the stem cells contained therein**

Pharmastem Therapeutics, Inc. v. Viacell, Inc., 491 F.3d 1342, 83 USPQ2d 1289 (Fed. Cir. 2007)

- **Court's Analysis**
  - Could not reconcile expert testimony with statements in the specification
  - Did not agree with expert that terminology was "flawed"
  - Prior art references to "stem cells" were consistent with Applicants' statements in the specification
  - Citing KSR, determined that invention was confirmation of what was already believed to be true

Example 2

- **Claim**
  - **The besylate salt of amlodipine**

Example 2

- **Prior Art**
  - **Patent disclosing amlodipine and pharmaceutically-acceptable acid addition salts and specifically names hydrochloride, hydrobromide, sulphate, phosphate, acid phosphate, acetate, maleate, fumarate, lactate, tartrate, citrate, and gluconate salts**
  - **Reference disclosing 53 FDA-approved commercially-marketed anions useful for making pharmaceutically acceptable salts and specifically names besylate as one of those salts whose frequency of use was 0.25%**

Example 2

- **Evidence**
  - **Inventor declaration asserting that the besylate salt of amlodipine possessed good solubility, stability, non-hygroscopicity and processability which were "unpredictable both individually and collectively" and was superior to prior art amlodipine maleate salt**

Example 2

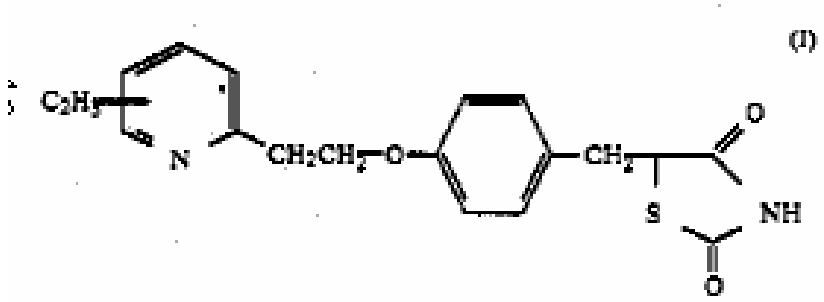
- **Conclusion**
  - **It would have been obvious to one of ordinary skill in the art at the time the invention was made to choose from a finite number of predictable pharmaceutically acceptable salt options of amlodipine with a reasonable expectation of success of producing a functional amlodipine formulation**

Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 82 USPQ2d 1321 (Fed. Cir. 2007)

- **Court's Analysis**
  - **Suggestion, teaching or motivation does not have be explicit and "may be found in any number of sources, including common knowledge, the prior art as a whole or the nature of the problem itself", citing Dystar Textilfarben GMBH v. C.H. Patrick Co., 464 F.3d 1356 (Fed. Cir. 2006)**
  - **Formulations must be tested by routine procedures to verify expected properties**

Example 3

- **Claim**
  - **5-4-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl-2,4-thiazolidinedione (a thiazolidinedione (TZD) with the ethyl group at the 5-position pyridyl ring)**



Example 3

- **Prior Art**
  - **Patent disclosing an effective anti-diabetic compound, "Compound 42" (out of 60), which differs from the claimed compound in two ways**
    - **methyl in place of ethyl**
    - **substitution in the 6-position instead of the 5-position**
  - **References discussing the conventional practices of homologation and ring-walking**

Example 3

- **Prior Art**
  - **Review article of 101 TZD compounds, which specifically singles out "Compound 42" as having negative side effects of increasing body weight and percentage brown fat**

Example 3

- **Evidence**
  - **Compound 42 produced significant toxicity to the liver and heart as well as a decrease in the number of erythrocytes, a sign of potential toxicity to bone marrow**
  - **Claimed compound showed no statistically significant toxicity**

Example 3

- **Conclusion**
  - **The claimed compound would <u>not</u> have been obvious to one of ordinary skill in the art at the time the invention was made due to evidence of teaching away and unexpected properties**

Takeda Chemical Industries v. Alphapharm Pty, Ltd., 492 F.3d 1350, 83 USPQ2d 1169 (Fed. Cir. 2007)

- **Court's Analysis**
  - **No "finite number of identifiable, predictable solutions"**
  - **Prior art provided "broad selection of compounds"**
  - **Closest prior art compound exhibited negative properties**

Highlights and Guidance

- **Evidence is critical to the determination of obviousness**
  - **Example 1 - Applicants' statements in specification were consistent with the prior art and inconsistent with expert testimony**
  - **Example 2 – Evidence of unexpected results may be insufficient to overcome a conclusion of obviousness**
  - **Example 3 - Evidence of "teaching away" combined with unexpected results were sufficient to outweigh evidence of obviousness**

Example 4

- **Claim**
  - Solid oral dosage form comprising
  - (a) coated famotidine granules
  - (b) $Al(OH)_3$ or $Mg(OH)_2$ granules
  - wherein the coating on the famotidine is impermeable to the $Al(OH)_3$ or $Mg(OH)_2$

Example 4

- **Prior Art**
  - **Reference disclosed combination of uncoated histamine H_2 receptor antagonists (e.g. famotidine) and antacids**
  - **Reference disclosed coating granulated medicaments to mask taste of active ingredient**
  - **Reference acknowledged the bitter taste of cimetidine (a famotidine analog)**

Example 4

- **Evidence**
  - **Other modes of taste-masking were preferable due to cost of coated granules**

Example 4

- **Conclusion**
  - **It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply a known taste-masking technique to mask the expected bitter taste of famotidine by coating the famotidine granules with the predictable expectation that the formulation will be more palatable**

McNeil-PPC, Inc. v Perrigo Company, 516 F. Supp.2d 238 (S.D. N.Y. July 3, 2007)

- **Court's Rationale**
  - **The combination of coated famotidine and the antacids provided no more than predictable results, citing KSR**
  - **Costs alone are not indicative of non-obviousness**

Example 5

- **Claim**
  - A formulation comprising
  - (a) a core comprising omeprazole plus an alkaline reacting compound (ARC);
  - (b) an inert subcoating, which is soluble or rapidly disintegrates in water, disposed on the core region,
  - (c) an outer layer disposed on the subcoating comprising an enteric coating

Example 5

- **Prior Art**
  - **References disclose drugs formulated in a core with a subcoating and enteric coating but do not disclose omeprazole**
  - **References disclose omeprazole but do not disclose coatings or an alkaline reacting compound**
  - **References describe subcoating techniques but do not disclose omeprazole – subcoatings should not be used with moisture-sensitive drugs**

Example 5

- **Evidence**
  - **Omeprazole is acid labile, sensitive to heat, moisture, solvents and light**
  - **Expert testimony of "multitude of possible paths and dead-ends" in formulation attempts**

Example 5

- **Conclusion**
  - **It would not have been obvious to one of ordinary skill in the art at the time the invention was made to formulate omeprazole with an alkaline reacting compound and then sub-coat and enterically coat the combination**

In re Omeprazole Patent Litigation, 490 F. Supp. 2d 381 (S.D. N.Y. June 1, 2007)

- **Court's Analysis**
  - **Prior art compounds that were subcoated and coated were not comparable to omeprazole**
  - **Prior art taught away from the subcoated formulation**
  - **Prior art disclosure to omeprazole formulations did not disclose stability problems**

Highlights and Guidance

- **Recognition of problems in the prior art as well as answers to problems in the prior art may lead to a finding of obviousness**
  - **In Example 4, single problem is solved with predictable results**
  - **In Example 5, numerous variables suggested that the results would not be predictable**

Example 6

- **Claim**
  - **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**

Example 6

- **Prior Art**
  - Reference disclosed p38 protein (same protein as NAIL) and methods of isolation by using mAbs as well as methods of obtaining the polynucleotide sequence but does not disclose the sequence of p38
  - Reference disclosed the nucleic acid sequence of the highly conserved murine version of p38 and identified a human homologue

Example 6

- **Conclusion**
  - **One of ordinary skill in the art would have been motivated to isolate and identify the claimed nucleotide sequence based on the prior art disclosure of the p38 protein by applying conventional methodologies**

Ex parte Kubin, 83 USPQ2d 1410 (Bd. Pat. App. & Int. 2007)

- **Board's Analysis**
  - State of the art has advanced
  - Reliance on KSR – "obvious to try" in view of limited methodologies available to isolate NAIL cDNA
  - Methodologies had reasonable expectation of success

Highlights and Guidance

- **Advancements in the state of the art may render that which was once unpredictable to become predictable**
  - **Regularly review the state of the art that is examined**
  - **Take of note of changes in the state of the art**

Example 7

- **Claim**
  - An antivenom pharmaceutical composition for treating a snakebite victim, comprising
    - Fab fragments which bind specifically to a venom of a snake of the Crotalus genus essentially free from contaminating Fc
    - and a pharmaceutically acceptable carrier,
    - which neutralizes the lethality of the venom of a snake of the Crotalus genus

Example 7

- **Prior Art**
  - **Reference teaches whole antibodies purified from horse serum for use as an antivenom for treatment of rattlesnake bites**
  - **Reference teaches producing Fab fragments from whole antibodies for use in immunoassays to detect textilotoxin**

Example 7

- **Evidence**
  - Declaration discussing state of the art of antivenoms which, since 1969, have only been commercially available as whole antibodies or F(ab)2 fragments
  - Declaration stating that those in the art would not have considered Fab fragments as antivenoms because they are cleared faster than whole antibodies or F(ab)2 fragments

Example 7

- **Evidence**
  - **Declaration discussing success of whole antibody antivenom dependent on extra disulfide bond allowing whole antibody to bind to repeating protein antigens - Fab fragment does not contain such a bond but surprisingly binds and neutralizes venom**
  - **Declaration showing decreased adverse immune reactions**

Example 7

- **Conclusion**
  - **To be determined!**
  - **Federal Circuit vacates decision of the Board that affirmed the Examiner's conclusion of obviousness**
  - **Remanded to the Board for evaluation of rebuttal evidence**

In re Sullivan, 498 F.3d 1345, 84 USPQ2d 1034 (Fed. Cir. 2007)

- **Court's Analysis**
  - **The Board asserted that the declarations related only to use and expressly declined to give any meaningful consideration to them because the claims were drawn to the composition**
  - **The court found that the board erred in failing to consider rebuttal evidence**

Highlights and Guidance

- **Do not ignore any terms in a claim**
  - **Determine whether any claimed function requires or implies a structural limitation**
  - **Explain how the prior art renders obvious the functional limitation, i.e. how the invention rendered obvious by the prior art is suitable for and/or capable of carrying out the claimed function**

Example 8

- **Claim**
  - **A method for treating otopathy which comprises the topical otic administration of an amount of ofloxacin or a salt thereof effective to treat otopathy in a pharmaceutically acceptable carrier to the area affected with otopathy**

Example 8

- **Prior Art**
  - **Reference teaches lack of ototoxicity of ciprofloxacin when used to treat middle ear infections**
  - **Reference teaches that ofloxacin and ciprofloxacin are both gyrase inhibitors and belong to the same family of compounds**

Example 8

- **Conclusion**
  - **It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute ofloxacin for ciprofloxacin in the treatment of otopathy with a predictable expectation of successful treatment due to the compounds' structural and functional similarities**

Daiichi Sankyo Co. v. Apotex, Inc., 501 F.3d 1254, 84 USPQ2d 1285 (Fed. Cir. 2007)

- **Court's Analysis**
  - **District Court erred in the determination of the level of skill**
  - **By finding the level of skill in the prior art to be too high, prior art teaching was dismissed by the District Court**

Highlights and Guidance

- **Resolving the level of ordinary skill may be explicit or implicit in view of the prior art applied**
- **When making an obviousness rejection, examiners are only *required* to make an explicit statement addressing the level of ordinary skill in the art when the level of ordinary skill is not clear in light of the cited prior art (Union Carbide Corp. v. American Can Co., 724 F.2d 1567, 1573 (Fed. Cir. 1984))**

Example 9

- **Claim**
  - **The 5(S) stereoisomer of ramipril substantially free of other isomers**

Example 9

- **Prior Art**
  - **References teach that related ACE-inhibiting therapeutic compounds (BPP5a, captopril, and enalapril) are most therapeutically active in the S configuration**
  - **"Parent" patent disclosing structurally similar compounds and teaching that when diastereomeric products result from the synthetic procedures, the diasteriomeric products can be separated by conventional chromatographic or fractional crystallization methods**

Example 9

- **Evidence**
  - **Synthesis of a mixture of the 5(S) stereoisomer with the 4(S)(R) stereoisomer of ramipril by competitor pharmaceutical company (which qualified as prior art under 102(g))**

Example 9

- **Conclusion**
  - **It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce and isolate the 5(S) stereoisomer of ramipril with a reasonable expectation of success**

Aventis v. Lupin, 499 F.3d 1293, 84 USPQ2d 1197 (Fed. Cir. 2007)

- **Court's Analysis**
  - **District Court erred in requiring clear and convincing showing of motivation, citing KSR**
  - **Obviousness flowed from recognition of the properties of similar prior art compounds combined with recognition of the presence of the claimed isomer in the prior art mixture**

Example 10

- **Claim**
  - **Substantially pure (S) enantiomer of escitalopram oxalate**

Example 10

- **Prior Art**
  - **Reference taught racemate of escitalopram as a SSRI and predicted enhanced potency of the (R) enantiomer but did not disclose the process of separation of the racemate**

Example 10

- **Evidence**
  - **Chiral HPLC was a relatively new and unpredictable technique at the time of the invention**
  - **Author of prior art reference had attempted to use chiral HPLC to separate racemate of escitalopram but failed**
  - **Failure by inventor to resolve escitalopram racemate by diasteriomeric salt formation**

Example 10

- **Conclusion**
  - **It would not have been obvious to one of ordinary skill in the art at the time the invention was made to produce the substantially pure (S) enantiomer of escitalopram oxalate with a reasonable expectation of success**

Forest Laboratories v Ivax Pharmaceuticals, 501 F.3d 1263, 84 USPQ2d 1099 (Fed. Cir. 2007)

- **Court's Analysis**
  - **District Court's finding that the prior art reference was not enabling with regard to the isolation of (S) enantiomer was not in error**

Highlights and Guidance

- **Evidence**
  - **Consider the invention as a whole and all of the evidence presented**
  - **The question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious**

Example 11

- **Claim**
  - **A transgenic corn plant that produces a Bt protein where the foreign DNA nucleic acid coding sequence has a G+C content of at least about 60%**

Example 11

- **Prior Art**
  - **Published patent application describing a method for improving Bt expression in tobacco plant genes by selecting codons that are rich in G+C to increase expression efficiency of the Bt protein and asserting that the methodology would be equally applicable in other plant species**

Example 11

- **Evidence**
  - **Declaration showing total sales of transgenic corn and asserting commercial success**

Example 11

- **Conclusion**
  - **It would have been obvious to one of ordinary skill in the art to modifying the Bt DNA sequence by selecting codons for the Bt amino acid sequence that are rich in G+C with a reasonable expectation of improved expression of Bt in by the corn plant and optimizing the percentage G+C to produce desired expression**

Syngenta Seeds v. Monsanto, (Fed. Cir. 2007)

- **Court's Analysis**
  - **A non-precedential decision after KSR**
  - **District Court correctly used the Graham factors**

Highlights and Guidance

- **When deciding questions of obviousness**
  - **Determine the facts**
  - **Weigh the evidence – including secondary considerations**
  - **Articulate rationales**
  - **Explain conclusions**

Post-KSR:
What do we do now???

Wendy Rieder, Esq.
General Counsel and
VP, Intellectual Property and Legal Affairs

May 19, 2008

Synta Pharmaceuticals Corporate Profile

- Public company with ~175 employees
  - IPO February 2007
- Lead drug candidate, elesclomol (formerly STA-4783)
  - Synta is conducting a global, pivotal Phase 3 study for metastatic melanoma (SYMMETRY℠ trial)
  - Partnership with GSK announced October 2007 ($1.01 B)
- R&D focused company with a diverse pipeline
  - 3 clinical stage programs (elesclomol, apilimod and STA-9090)
  - 2 earlier stage programs (CRAC inhibitors and vascular disrupting agents)
- 600+ patent filings worldwide
  - >20 issued US patents
  - >90 pending US patent applications
- See Synta's 2007 Annual Report filed with the SEC on March 20, 2008 for further details

SYNTA

Our Experience with Obviousness Rejections

- Before KSR, obviousness rejections were common but relatively straightforward to overcome
  - Examiner's argument often flawed by lack of suggestion or motivation to combine references
  - Evidence of unexpected results usually persuasive
- Post-KSR, obviousness rejections have been made more frequently and are tougher to overcome
  - Examiner's reliance on general knowledge, analogy to similar products or methods, or just common sense to bridge the gap between the claimed invention and the prior art
  - Difficult to persuade the Examiner to withdraw the rejection absent spectacular unexpected results
  - Prior art that "teaches away" from the claimed invention remains an effective means to overcome obviousness rejections

SYNTA

Our Views of the Impact of KSR

- Significantly raised the bar of patentability by making a *prima facie* case of obviousness easier to establish
  - Motivation to combine references does not have to be explicitly found in the prior art
  - Examiner can merely allege that it is reasonable to combine
  - The general trend appears to be calling obvious anything that a PHOSITA does that has a reasonable expectation of success
  - "Obvious to try" is apparently becoming the standard
- Issued patents are now more susceptible to attack based on obviousness. Potential ammunition includes:
  - Prior art references not cited during prosecution that show analogous discoveries
  - Admissions of obviousness by the patentee (in patent file wrapper, publications, regulatory filings and elsewhere)
  - Expert testimony evidencing the knowledge of a PHOSITA

Post-KSR Adjustments to Our Approach

- Include more disclosure and more on-the-record discussion specifically designed to support non-obviousness
  - Experimental data and scientific rationale
  - Different theories of non-obviousness (improved activity, solubility, safety, etc.)
  - Discussion of a broader range of prior art references and how our invention compares
- Ensure that an IP attorney reviews all disclosures (including regulatory filings) prior to release for ill-chosen language regarding potential points of obviousness
- Conduct more prior art searches, understand our place in the landscape as best we can and submit all potentially relevant prior art to USPTO for consideration
  - add more claims of varying type and scope for extra protection
  - claim subject matter that was initially disclosed but not claimed
  - file CIP, if additional disclosure might help support non-obviousness

SYNTA

Concluding Thoughts

- KSR has changed the way we need to think about obviousness
- By adjusting our strategy going forward, we will improve our chances of obtaining issued US patents that can withstand obviousness attacks
- Overcoming obviousness rejections on the record and presenting prior art for consideration by the USPTO will strengthen the issued patent
- Including a variety of claims will be helpful if the patent is attacked for obviousness later
- Be vigilant about avoiding statements that could provide support for an obviousness claim

SYNTA