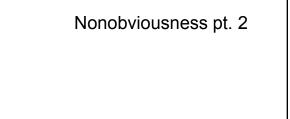
PATENT LAW

Randy Canis

CLASS 6

Nonobviousness pt. 2; Eligibility pt. 3; ST: Public and Private Pair



Obviousness Inquiries

· "Obviousness is a question of law with several underlying factual inquiries: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the field of the invention; and (4) objective considerations such as commercial success, long felt but unsolved need, and the failure of others."

Overcoming Obviousness

Possible options include:

- At least one claimed element is not "familiar"/known/shown in the art.
- The proposed combination of elements does not yield the claimed invention.
- At least one claimed element functions differently from that in the prior art.
- Secondary considerations: long-felt but unsolved need; commercial success; prior art expressions of doubt.

2007 Obviousness Guidelines

- · Purpose of these guidelines was to provide guidance to Examiners in light of the Supreme Court KSR decision.
- · The guidelines were incorporated into the MPEP.
- · The guidelines identified 6 additional lines of reasoning beyond TSM for obviousness rationales.

2007 Obviousness Guidelines

- Combining prior art elements according to known methods to yield predictable results;
 Simple substitution of one known element for another to obtain predictable results;

- predictable results;
 (3) Use of a known technique to improve similar devices, methods, or products in the same way;
 (4) Applying a known technique to a known device, method, or product ready for improvement to yield predictable results;
 (5) Obvious to try—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and
- (6) 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.
- Any rationale employed must provide a link between the factual findings and the legal conclusion of obviousness.

2007 Obviousness Guidelines

- · No limit on approach taken by the Examiner, but the Examiner must make appropriate factual findings to apply the rationales.
- · The analysis supporting obviousness must be made explicit.
- · Rationales must be explained and show how they apply to the facts at hand.
- These guidelines are still viable despite the 2010 guidelines.

2010 Obviousness Guidelines

- Purpose is to provide additional guidance to Examiners in view of decisions by the Federal Circuit
- Does not have the force and effect of law.
- Adopted as of September 1, 2010.

Categorization of Cases in the 2010 Examination Guidelines

- Combining Prior Art Elements
- Substituting One Known Element for Another
- Obvious to Try Rationale
- Consideration of Evidence

Combining Prior Art Elements

- Important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.
- The claimed invention may be nonobvious when the combining step involves such additional effort that no one of ordinary skill would have undertaken it without a recognized reason to do so.
- When a combination invention involves additional complexity as compared with the prior art, the invention may be nonobvious unless an examiner can articulate a reason for including the added features or steps.

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In re Omeprazole Patent Litigation

- · Invention and the Art
 - Applying enteric coatings to a drug in pill form for the purpose of ensuring that the drug did not disintegrate before reaching its intended site of action (omeprazole/Prilosec).
 - Apotex had argued that the claimed invention was obvious because coated omeprazole tablets were known from a prior art reference, and because secondary subcoatings in pharmaceutical preparations generally were also known.

In re Omeprazole Patent Litigation

• Degradation of omeprazole by interaction with the prior art coating had not been recognized in the prior art.

In re Omeprazole Patent Litigation

- Fed. Cir.
 - No reason to modify the initial formulation even though the modification could have been done.
 - Person of skill in the art would have chosen a different modification if the problem had been recognized.

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In re Omeprazole Patent Litigation

PTO

- The proposed modification amounts to extra work and greater expense for no apparent reason.
- Difference between combining prior art elements A & B.
 - Contribution of own properties to final product vs. no expectation to confer any desirable property
- Discovery of previously unknown property.
 No reason to exert additional time or expense to do something extra to solve a problem

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In re Omeprazole Patent Litigation

- · Practice Point
 - When something is not recognized in the prior art, consider arguing that a person of ordinary skill would have to no reason to modify the art as proposed by the examiner.

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Crocs, Inc. v. U.S. Int'l Trade Comm'n.

- Invention and the Art
 - Footwear including a one-piece molded foam base section formed the top of the shoe (the upper) and the sole.
 - Sole. The strap is made of foam and was attached to the foot opening of the upper. The strap could provide support to the Achilles portion of the wearer's foot. The strap was attached via connectors that allowed it to be in contact with the base section, and to pivot relative to the base section
 - Because both the base portion and the strap were made of foam, friction between the strap and the base section allowed the strap to maintain its position after pivoting.
 - Art included a first reference with a shoe that has a corresponding base portion to the claimed invention and a second reference that has heel straps of elastic or other flexible material.

Crocs, Inc. v. U.S. Int'l Trade Comm'n.

• ITC

 Claims were obvious because the prior art of the first reference differed from the claimed invention only as to the presence of the strap, and a suitable strap was taught by a second reference.

Crocs, Inc. v. U.S. Int'l Trade Comm'n.

• Fed. Cir.

- Prior art did not teach foam heel straps.
- The prior art counseled against using foam as a material for the heel strap of a shoe.
- Yielded more than predictable results.
- The loose fit of the heel strap made the shoe more comfortable for the wearer than prior art shoes in which the heel strap was constantly in contact with the wearer's foot.
- heel strap was constantly in contact with the wearer's foot. The foam heel strap contacted the wearer's foot only when needed to help reposition the foot properly in the shoe, thus reducing wearer discomfort that could arise from constant contact.
- The feature was a result of the friction between the base section and the strap that kept the strap in place behind the Achilles portion of the wearer's foot.

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Crocs, Inc. v. U.S. Int'l Trade Comm'n.

• PTO

- Merely pointing to the presence of all claim elements in the prior art is not a complete statement of a rejection for obviousness.
- The rationale that the claimed invention is a combination of prior art elements also includes a finding that results flowing from the combination would have been predictable to a person of ordinary skill in the art.
- If results would not have been predictable, Office personnel should not enter an obviousness rejection using the combination of prior art elements rationale, and should withdraw such a rejection if it has been made.

Crocs, Inc. v. U.S. Int'l Trade Comm'n.

- · Practice Points
 - If possible, identify where the prior art teaches away from the combination proposed by the Examiner.
 - Include benefits of the claimed invention when drafting the specification of the application. The benefits may be deemed to provide a desirable feature such that combination yields more than predictable results.

Sundance, Inc. v. DeMonte Fabricating Ltd.

- Invention and the Art
 - Segmented and mechanized cover for trucks, swimming pools, or other structures.
 - A first prior art reference taught that a reason for making a segmented cover was ease of repair, in that a single damaged segment could be readily removed and replaced when necessary.
 - A second prior art reference taught the advantages of a mechanized cover for ease of opening.

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Sundance, Inc. v. DeMonte Fabricating Ltd.

- Fed. Cir.
 - The segmentation aspect of the first reference and the mechanization function of the second perform in the same way after combination as they had before.

Sundance, Inc. v. DeMonte Fabricating Ltd.

- Practice Point
 - Indicate new functionality or properties of the claimed invention when drafting the specification.

Ecolab, Inc. v. FMC Corp.

- Invention and the Art
 - Method of treating meat to reduce the incidence of pathogens, by spraying the meat with an antibacterial solution under specified conditions.
 - All elements taught in the prior art except a pressure limitation

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Ecolab, Inc. v. FMC Corp.

Fed. Cir.

- There was an apparent reason to combine these known elements—namely to increase contact between the antibacterial solution and the bacteria on the meat surface and to use the pressure to wash additional bacteria off the meat surface.
- An ordinarily skilled artisan would have recognized the reasons for applying the claimed antibacterial solution using high pressure and would have known how to do so.

Ecolab, Inc. v. FMC Corp.

- · Practice Pointer
 - If during a patent search multiple references are identified that collectively have all of the elements of the claimed invention, determine whether the modification of the primary reference would be within the understanding or capability of one of ordinary skill in the art.

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Wyers v. Master Lock Co.

- · Invention and the Art
 - Barbell-shaped hitch pin locks used to secure trailers to vehicles.
 - Several prior art references taught every element of the claimed inventions except for a removable sleeve and an external covering.

Wyers v. Master Lock Co.

• The court noted that Wyers' specification had characterized the claimed invention as being in the field of locking devices, thus at least suggesting that the sealed padlock reference was in the same field of endeavor.

Wyers v. Master Lock Co.

• Fed Cir.

- The scope of analogous art is construed broadly.
- The constituent elements were being employed in accordance with their recognized functions, and would have predictably retained their respective functions when combined.

Wyers v. Master Lock Co.

PTO

 The court explained why a person of ordinary skill in the art at the time of the invention, in view of the facts relevant to the case, would have found the claimed inventions to have been obvious.

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Wyers v. Master Lock Co.

Practice Pointers

- Consider drafting the field portion of the specification narrowly to potentially limit analogous art.
- Challenge conclusory assertions of obviousness.

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DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.

- · Invention and the Art
 - A polyaxial pedicle screw used in spinal surgeries that included a compression member for pressing a screw head against a receiver member.
 - A prior art reference disclosed all of the elements of the claim except for the compression member.

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DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.

• The "predictable result" discussed in *KSR* refers not only to the expectation that prior art elements are capable of being physically combined, but also that the combination would have worked for its intended purpose.

DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.

- Fed Cir.
 - The primary reference teaches away from the proposed combination such that a person of ordinary skill would have been deterred from combining the references as proposed.

DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.

- · Practice Points
 - Argue that the combination would not have been expected to have worked for its intended purpose.
 - Argue that the prior art's teaching undermines the reason being proffered as to why a person having ordinary skill in the art would have combined the known references.
 - Argue that a person of ordinary skill in the art would be deterred from making the combination based on a teaching in the primary reference.

Substituting One Known Element for Another

- · Applicable when
 - POSA capable to make the substitution
 - Result obtained would have been predictable

In re ICON Health & Fitness, Inc.

- Invention and the Art
 - a treadmill with a folding tread base that swivels into an upright storage position, including a gas spring connected between the tread base and the upright structure to assist in stably retaining the tread base in the storage position
 - Prior art included a folding treadmill with all features but a gas spring; a gas spring was found in a bed that folds into a cabinet (i.e., a Murphy Bed)

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In re ICON Health & Fitness, Inc.

- Fed Cir.
 - one skilled in the art would make certain modifications (e.g., sizing) to a device of the prior art to make the identified element work with the elements of the primary reference

In re ICON Health & Fitness, Inc.

• PTO

- Consider the problem to be solved when applying a reference to an invention in a different field of endeavor
- The usefulness of a reference may be narrowly restricted
- If the reference does not teach that a combination is undesirable, then it cannot be said to teach away.
- An assessment of whether a combination would render the device inoperable must not "ignore the modifications that one skilled in the art would make to a device borrowed from the prior art."

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In re ICON Health & Fitness, Inc.

- Practice Points
 - Argue that the disputed element of the secondary reference requires a specific focus of the claimed invention. The specific focus could include selection of the element for the claimed invention, configuration of the element in the claimed invention, and the like. In the specification, provide specific details to argue the specific focus.
 - Argue that the primary reference (or the secondary reference) teaches that the proposed combination is undesirable.
 - Argue that a person having ordinary skill in the art would not make the modification.

Agrizap, Inc. v. Woodstream Corp.

- · Invention and Art
 - A stationary pest control device for electrocution of pests such as rats and gophers, in which the device is set in an area where the pest is likely to encounter it.
 - The prior art was identical to the claimed invention except that the prior art has a mechanical pressure switch instead of a resistive electrical switch.
 - The resistive electrical switch was taught in a prior art hand-held pest control device and a cattle prod.

Agrizap, Inc. v. Woodstream Corp.

• Fed. Cir.

- The prior art concerning the hand-held devices revealed that the function of the substituted resistive electrical switch was well known and predictable, and that it could be used in a pest control device.
- The problem solved by using the resistive electrical switch in the prior art hand-held devices—malfunction of mechanical switches due to dirt and dampness—also pertained to the prior art stationary pest control device.

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Agrizap, Inc. v. Woodstream Corp.

PTO

- A textbook case of when the asserted claims involve a combination of familiar elements according to known methods that does no more than yield predictable results.
- A strong case of obviousness based on simple substitution that was not overcome by the objective evidence of nonobviousness offered.

Agrizap, Inc. v. Woodstream Corp.

- Practice Points
 - Encourage the client to perform a good search and relay to the client the risks and likely outcome with very close references.
 - Include sufficient information in the specification to significantly narrow the claims so that the client can still get a patent.

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Muniauction, Inc. v. Thomson Corp.

- Invention and the Art
 - A method for auctioning municipal bonds over the Internet.
 - The only difference between the prior art bidding system and the claimed invention was the use of a conventional Web browser.

Muniauction, Inc. v. Thomson Corp.

- Fed. Cir.
 - A nexus between the claimed invention and the proffered evidence was lacking because the evidence was not coextensive with the claims at issue; secondary considerations not entitled to substantial weight.

Muniauction, Inc. v. Thomson Corp.

PTO

 Market pressures would have prompted a person of ordinary skill to use a conventional Web browser in a method of auctioning municipal bonds

Muniauction, Inc. v. Thomson Corp.

- · Practice Point
 - When taking invention disclosure, ask the client how the invention differs from merely taking an existing process and putting it on a computer or updating it to known, current technology.

Aventis Pharma Deutschland v. Lupin, Ltd.

- Invention and Art
 - The 5(S) stereoisomer of the blood pressure drug ramipril in stereochemically pure form, and to compositions and methods requiring 5(S) ramipril.
 - A mixture of various stereoisomers including 5(S) ramipril had been taught by the prior art.
 - Issue: would the purified single stereoisomer would have been obvious over the known mixture of stereoisomers?

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Aventis Pharma Deutschland v. Lupin, Ltd.

- · Fed. Cir.
 - Conventional methods could be used on prior art to come up with claimed invention
 - Requiring a clearly stated motivation in the prior art to isolate 5(S) ramipril ran counter to the Supreme Court's decision in *KSR*.

Aventis Pharma Deutschland v. Lupin, Ltd.

PTO

- In chemical cases, structural similarity can provide the necessary reason to modify prior art teachings.
- In the absence of an explicitly stated prior artbased motivation, the kind of teaching that would be sufficient is one that has an expectation of similar properties in light of the prior art can be sufficient, even without an explicit teaching that the compound will have a particular utility.

Aventis Pharma Deutschland v. Lupin, Ltd.

- · Practice Point
 - Clear motivation may not be required in chemical cases when there is structural similarity or an expectation of similar properties.

Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.

· Invention and the Art

- Rabeprazole, a proton pump inhibitor for treating stomach ulcers and related disorders.
- The prior art compound lansoprazole was useful for the same indications as rabeprazole, and differed from rabeprazole only in that lansoprazole has a trifluoroethoxy substituent at the 4-position of the pyridine ring, while rabeprazole has a methoxypropoxy substituent.

Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.

· Fed. Cir.

- Obviousness based on structural similarity can be proved by identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (*i.e.* a lead compound) in a particular way to achieve the claimed compound.
- Motivation can come from a variety of places and need not be explicit
- It is sufficient to show that the claimed and prior art compounds possess a sufficiently close relationship to create an expectation in light of the totality of the prior art, that the new compound will have similar properties' to the old.

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Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.

PTO

- The prior art created the expectation that rabeprazole would be less useful than lansoprazole as a drug for treating stomach ulcers and related disorders because the proposed modification would have destroyed an advantageous property of the prior art compound.
 - Any known compound might possibly serve as a lead compound in an obviousness determination.
- An Examiner may also base an obviousness rejection on a known compound that pharmaceutical chemists would not select as a lead compound due to expense, handling issues, or other business considerations.
- There must be some reason for starting with that lead compound other than the mere fact that the "lead compound" merely exists.

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Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.

- Practice Point
 - Argue against the reason for starting with a different lead compound.

Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.

- Invention and the Art
 - risedronate—the active ingredient of P&G's osteoporosis drug ACTONEL.
 - Risedronate is an example of a bisphosphonate, which is a class of compounds known to inhibit bone resorption.

Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.

- Fed. Cir.
 - If 2-pyr EHDP, argued to be structurally similar to risedronate, is presumed to be an appropriate lead compound, there must be both a reason to modify it so as to make risedronate, and a reasonable expectation of success.
 - Nonobviousness can be shown when a claimed invention is shown to have unexpectedly superior properties when compared to the prior art.

Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.

PTO

- Long felt need is evaluated at the time of filing and not the date an embodiment of the invention was brought to market.
- A single lead compound need not be identified.
- It may be proper to reject a claimed chemical compound as obvious even without identifying a single lead compound.

Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.

- Practice Points
 - Argue that there was no reasonable expectation of success for the selection and modification of the lead compound to obtain the claimed compound.
 - Argue that the proposed modification was not routine and thus no reasonable expectation of success.
 - Describe in the specification or argue unexpected superior properties not found in the art.

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Altana Pharma AG v. Teva Pharms. USA, Inc.

- Invention and the Art
 - The compound pantoprazole, which is the active ingredient in Altana's antiulcer drug PROTONIX.
 - Altana had a prior patent that discussed a compound 12 that was structurally similar to the compound pantoprazole.

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Altana Pharma AG v. Teva Pharms. USA, Inc.

· Fed. Cir.

- Obviousness of a chemical compound in view of its structural similarity to a prior art compound may be shown by identifying some line of reasoning that would have led one of ordinary skill in the art to select and modify the prior art compound in a particular way to produce the claimed compound.
- Reasoning can be drawn from any number of sources and need not be explicit in the prior art of record.
- The prior art need not point to a single lead compound for further development.

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Obvious to Try Rationale

- · Applicable when
 - there is a recognized problem or need in the art;
 - there are a finite number of identified, predictable solutions to the recognized need or problem; and
 - a PSOA could have pursued these known potential solutions with a reasonable expectation of success.

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In re Kubin

- Invention and the Art
 - An isolated nucleic acid molecule where a nucleic acid was encoded in a particular polypeptide.
 - The encoded polypeptide was identified in the claim by its partially specified sequence, and by its ability to bind to a specified protein.
 - A prior art patent to taught the polypeptide encoded by the claimed nucleic acid, but did not disclose either the sequence of the polypeptide, or the claimed isolated nucleic acid molecule.
 - The same prior art disclosed that by employing conventional known methods the sequence of the polypeptide could be determined, and the nucleic acid molecule could be isolated.

In re Kubin

Board

 When there is motivation to solve a problem and 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. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

In re Kubin

- Fed. Cir.
 - Varying of all parameters or trying each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful is not obvious to try

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Takeda Chem. Indus. v. Alphapharm Pty., Ltd.

- Invention and the Art
 - The claimed compound was pioglitazone, a member of a class of drugs known as thiazolidinediones (TZDs) marketed by Takeda as a treatment for Type 2 diabetes.
 - Alphapharm argued that a two-step modification—involving homologation and ring-walking—of a known compound identified as "compound b" would have produced pioglitazone, and that it was therefore obvious.

Takeda Chem. Indus. v. Alphapharm Pty., Ltd.

- · District Court
 - No reason to select compound b as a lead compound among a large number of similar prior art TZD compounds
 - Although the parties agreed that compound b represented the closest prior art, one reference had taught certain disadvantageous properties associated with compound b, which according to the district court would have taught the skilled artisan not to select that compound as a lead compound.

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Takeda Chem. Indus. v. Alphapharm Pty., Ltd.

· Fed. Cir.

– Rather than identify predictable solutions for antidiabetic treatment, the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation. Significantly, the closest prior art compound (compound b, the 6-methyl) exhibited negative properties that would have directed one of ordinary skill in the art away from that compound.

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Takeda Chem. Indus. v. Alphapharm Pty., Ltd.

- PTO
 - Obvious to try does not apply when the factual findings cannot be made.
 - No predictability or reasonable expectation of success associated with the particular modifications necessary to transform compound b into the claimed compound pioglitazone.

Takeda Chem. Indus. v. Alphapharm Pty., Ltd.

- · Practice Points
 - Argue that the prior art taught away from using a particular lead compound.
 - Identify and argue any negative properties or disadvantages associated with the lead compound that would have directed away from the compound.
 - Argue that there was no predictability or reasonable expectation of success in making the modifications to transform the lead compound into the claimed compound.

Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs, Inc.

- Invention and the Art
 - topiramate, used as an anticonvulsant.

Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs, Inc.

 In the course of working toward a new anti-diabetic drug, Ortho-McNeil's scientist had unexpectedly discovered that a reaction intermediate had anticonvulsant properties.

Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs, Inc.

- Fed. Cir.
 - No apparent reason why a person of ordinary skill would have chosen the particular starting compound or the particular synthetic pathway that led to topiramate as an intermediate.
 - No reason to test that intermediate for anticonvulsant properties if treating diabetes had been the goal.

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Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs, Inc.

- PTO
 - Under the Federal Circuit's case law "finite" means "small or easily traversed" in the context of the art in question.
 - Place the inquiry in the context of the subject matter at issue.

Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs, Inc.

- Practice Point
 - When true, argue serendipity as an element of discovery of the claimed invention.

Bayer Schering Pharma A.G. v. Barr Labs., Inc.

- Invention and the Art
 - An oral contraceptive containing micronized drospirenone marketed as YASMIN.
 - Prior art compound drospirenone was known to be a poorly water-soluble, acidsensitive compound with contraceptive effects.
 - Known in the art that micronization improves the solubility of poorly water soluble drugs.

Bayer Schering Pharma A.G. v. Barr Labs., Inc.

 Bayer expected to find that the entericcoated tablet would produce a lower bioavailability than an intravenous injection, while the normal pill would produce an even lower bioavailability than the entericcoated tablet. However, they found that despite observations that drospirenone would quickly isomerize in a highly acidic environment (supporting the belief that an enteric coating would be necessary to preserve bioavailability), the normal pill and the enteric-coated pill resulted in the same bioavailability.

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Bayer Schering Pharma A.G. v. Barr Labs., Inc.

- District Court
 - a person of ordinary skill would have been aware of a particular study's shortcomings, and would have verified the findings as suggested by a treatise on the science of dosage form design, which would have then showed that no enteric coating was necessary.

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Bayer Schering Pharma A.G. v. Barr Labs., Inc.

- · Fed. Cir.
 - The prior art would have funneled the formulator toward two options. Thus, the formulator would not have been required to try all possibilities in a field unreduced by the prior art. The prior art was not vague in pointing toward a general approach or area of exploration, but rather guided the formulator precisely to the use of either a normal pill or an enteric-coated pill.

Bayer Schering Pharma A.G. v. Barr Labs., Inc.

PTO

- Mere existence of a large number of options does not in and of itself lead to a conclusion of nonobviousness.
- Where the prior art teachings lead one of ordinary skill in the art to a narrower set of options, then that reduced set is the appropriate one to consider when determining obviousness using an obvious to try rationale.

Bayer Schering Pharma A.G. v. Barr Labs., Inc.

- Practice Point
 - Argue that the prior art does not teach to narrow down the set of options that can be tried.

Sanofi-Synthelabo v. Apotex, Inc.

- · Invention and the Art
 - Claimed compound is clopidogrel, which is the dextrorotatory isomer of methyl alpha-5(4,5,6,7tetrahydro(3,2-c)thienopyridyl)(2-chlorophenyl) acetate.
 - Clopidogrel is an antithrombotic compound used to treat or prevent heart attack or stroke.
 - The racemate, or mixture of dextrorotatory and levorotatory (D- and L-) isomers of the compound, was known in the prior art.

Sanofi-Synthelabo v. Apotex, Inc.

• The two forms in the prior art had not previously been separated, and although the mixture was known to have antithrombotic properties, the extent to which each of the individual isomers contributed to the observed properties of the racemate was not predicatable.

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Sanofi-Synthelabo v. Apotex, Inc.

· District Court

- In view of the evidence of unpredicted therapeutic advantages of the D-isomer presented in the case, the district court found that any *prima facie* case of obviousness had been overcome.
- When Sanofi ultimately undertook the task of separating the isomers, it found that they had the "rare characteristic of 'absolute stereoselectivity,' " whereby the D-isomer provided all of the favorable therapeutic activity but no significant toxicity, while the L-isomer produced no therapeutic activity but virtually all of the toxicity.

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Sanofi-Synthelabo v. Apotex, Inc.

PTO

– Even when only a small number of possible choices exist, the obvious to try line of reasoning is not appropriate when, upon consideration of all of the evidence, the outcome would not have been reasonably predictable and the inventor would not have had a reasonable expectation of success.

Sanofi-Synthelabo v. Apotex, Inc.

- · Practice Points
 - Argue that the claimed invention exhibits unexpectedly strong therapeutic advantages over the prior art.
 - Argue that the resulting properties of separation of elements was not reasonably predictable.

Rolls-Royce, PLC v. United Technologies

Corp.

- Invention and the Art
 - Fan blade for jet engines.
 Each fan blade has three regions—an inner, an intermediate, and an outer region. The area closest to the axis of rotation at the hub is the inner region. The area farthest from the center of the engine and closest to the casing surrounding the engine is the outer region. The intermediate region falls in between. The count defines a fan blade with a swept-forward inner region, a swept-rearward intermediate region, and forward-leaning outer region.
 - United argued obvious for a person of ordinary skill in the art to try a fan blade design in which the sweep angle in the outer region was reversed as compared with prior art fan blades from rearward to forward sweep, in order to reduce endwall shock.

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Rolls-Royce, PLC v. United Technologies Corp.

- · Fed. Cir.
 - In a proper obvious to try approach to obviousness, the possible options for solving a problem must have been "known and finite."
 - No suggestion in the prior art that would have suggested that changing the sweep angle as Rolls-Royce had done would have addressed the issue of endwall shock.
 - Changing the sweep angle 'would not have presented itself as an option at all, let alone an option that would have been obvious to try.'

Rolls-Royce, PLC v. United Technologies Corp.

PTO

 The obvious to try rationale can properly be used to support a conclusion of obviousness only when the claimed solution would have been selected from a finite number of potential solutions known to persons of ordinary skill in the art.

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Rolls-Royce, PLC v. United Technologies Corp.

- Practice Points
 - Argue that the possible options are not know or are infinite.
 - Argue that the problem is not known and that the proposed modification would not have presented itself as an option.

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Perfect Web Techs., Inc. v. InfoUSA, Inc.

- · Invention and the Art
 - Method for managing bulk e-mail
 - The method required selecting the intended recipients, transmitting the emails, determining how many of the emails had been successfully received, and repeating the first three steps if a predetermined minimum number of intended recipients had not received the e-mail.

Perfect Web Techs., Inc. v. InfoUSA, Inc.

• Fed. Cir.

- Failure to meet a desired quota of e-mail recipients was a recognized problem in the field of e-mail marketing.
- The prior art had also recognized three potential solutions: Increasing the size of the initial recipient list; resending e-mails to recipients who did not receive them on the first attempt; and selecting a new recipient list and sending e-mails to them. The last option corresponded to the fourth step of the invention as claimed.

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Perfect Web Techs., Inc. v. InfoUSA, Inc.

- · Fed. Cir. (cont)
 - There were a "finite number of identified, predictable solutions," and that the obvious to try inquiry properly led to the legal conclusion of obviousness.
 - The final step [of the claimed invention] is merely the logical result of common sense application of the maxim try, try again.
 - Common sense has long been recognized to inform the analysis of obviousness if explained with sufficient reasoning.

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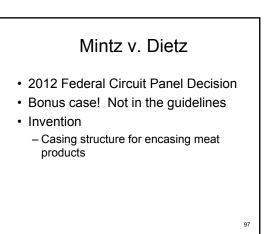
Perfect Web Techs., Inc. v. InfoUSA, Inc.

PTO

 The Federal Circuit noted that although "a reasoned explanation that avoids conclusory generalizations" is required to use common sense, identification of a "specific hint or suggestion in a particular reference" is not.

Perfect Web Techs., Inc. v. InfoUSA, Inc.

- · Practice Point
 - Argue insufficient reasoning to support common sense.



Mintz v. Dietz

Claim 1

- An elongated tubular casing structure for en-casing meat products, said elongated structure having a longitudinal direction and a transverse lateral direction, said casing structure comprising:
 - a stockinette member comprising a closely knit tubular member formed of closely knit threads and having a first stretch capacity;
- a knitted netting arrangement having a second stretch capacity and comprising a first plurality of spaced strands ex-tending in said longitudinal direction and a second plurality of spaced strands extending in said lateral direction;

- Mintz v. Dietz
- the longitudinal and lateral strands of said netting arrangement each intersecting in locking engagement with one another to form a grid-like pattern comprising a plurality of four-sided shapes;
- said strands of said netting arrangement being knit into the threads of said stockinette member, whereby said net-ting arrangement and said stockinette member are integrally formed so that said casing structure comprises an integrally formed structure;
- said first stretch capacity being greater than said second stretch capacity;
- whereby, when a meat product is stuffed into said casing structure under pressure, said meat product forms a bulge within each of said four-sided shapes to thereby define a checker-board pattern on the surface thereof, said stockinette member forming a shield to prevent the adherence of adjacent meat product bulges over said strands of said netting arrangement.

Mintz v. Dietz

 "Within the statutory test to determine if a claimed invention has advanced its technical art field enough to warrant an exclusive right, 'common sense' is a shorthand label for knowledge so basic that it certainly lies within the skill set of an ordinary artisan. With little more than an invocation of the words 'common sense' (without any record support showing that this knowledge would reside in the ordinarily skilled artisan), the district court over-reached in its determination of obviousness."

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Mintz v. Dietz

"The district court has used the invention to define the problem that the invention solves. Often the inventive contribution lies in defining the problem in a new revelatory way. In other words, when someone is presented with the identical problem and told to make the patented invention, it often becomes virtually certain that the artisan will succeed in making the invention. Instead, PCM must prove by clear and convincing evidence that a person of ordinary skill in the meat encasement arts at the time of the invention would have recognized the adherence problem recognized by the inventors and found it obvious to produce the meat encasement structure disclosed in the '148 patent to solve that problem."

Mintz v. Dietz

- Practice Points
 - Check the record to determine whether the examiner supported "common sense" rejection
 - Does the invention overcome a problem not recognized in the art at the time of the invention?

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Consideration of Evidence

- · Examiner should consider all rebuttal evidence
- Applicable when:
 - The results of the claimed invention that includes a combination of prior art references were unexpected.
- Examiner should reweigh obviousness conclusion in light of submitted evidence.
- The evidence need not be knockdown evidence. The Examiner should set forth the facts and
- reasoning if the evidence is deemed insufficient to rebut the prima facie case of obviousness.

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PharmaStem Therapeutics, Inc. v. ViaCell, Inc.

- · Invention and the Art
 - Compositions comprising hematopoietic stem cells from umbilical cord or placental blood, and to methods of using such compositions for treatment of blood and immune system disorders.
 - The composition claims required that the stem cells be present in an amount sufficient to effect hematopoietic reconstitution when administered to a human adult.

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PharmaStem Therapeutics, Inc. v. ViaCell, Inc.

- PharmaStem, had not invented an entirely new procedure or new composition.
- PharmaStem's own specification acknowledged that it was already known in the prior art that umbilical cord and placental blood-based compositions contained hematopoietic stem cells, and that hematopoietic stem cells were useful for the purpose of hematopoietic reconstitution.
- PharmaStem's contribution was to provide experimental proof that umbilical cord and placental blood could be used to effect hematopoietic reconstitution in mice.
- By extrapolation, one of ordinary skill in the art would have expected this reconstitution method to work in humans as well.

PharmaStem Therapeutics, Inc. v. ViaCell, Inc.

- Fed. Cir.
 - Expert testimony was contrary to the inventors' admissions in the specification, as well as prior art teachings that disclosed stem cells in cord blood. PharmaStem's evidence of nonobviousness was outweighed by contradictory evidence.

PharmaStem Therapeutics, Inc. v. ViaCell, Inc.

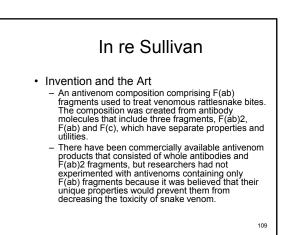
PTO

 Absolute predictability is not a necessary prerequisite to a case of obviousness.
 Rather, a degree of predictability that one of ordinary skill would have found to be reasonable is sufficient.

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PharmaStem Therapeutics, Inc. v. ViaCell, Inc.

- · Practice Point
 - Do not include potentially damaging admissions in the specification.



In re Sullivan

• Rebuttal evidence had not been considered by the Board because it considered the evidence to relate to the intended use of the claimed composition as an antivenom, rather than the composition itself.

In re Sullivan

Fed. Cir.

- While a statement of intended use may not render a known composition patentable, the claimed composition was not known, and whether it would have been obvious depends upon consideration of the rebuttal evidence.
- The Federal Circuit found that the intended use and unexpected property cannot be ignored the unexpected property is relevant and thus the declarations describing it should have been considered.

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In re Sullivan

- PTO
 - Nonobviousness can be shown when a person of ordinary skill in the art would not have reasonably predicted the claimed invention based on the prior art, and the resulting invention would not have been expected. All evidence must be considered when properly presented.

In re Sullivan

- Practice Point
 - Argue on appeal that the Examiner failed to consider all evidence submitted.

Hearing Components, Inc. v. Shure Inc.

- Invention and the Art
 - A disposable protective covering for the portion of a hearing aid that is inserted into the ear canal. The covering was such that it could be readily replaced by a user as needed.
 - Shure argued the claimed invention was obvious over three different combinations of prior art references.

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Hearing Components, Inc. v. Shure Inc.

Fed. Cir.

 Hearing Components had shown a nexus between the commercial success of its product and the patent by providing evidence that "the licensing fee for a covered product was more than cut in half immediately upon expiration" of the patent.

Hearing Components, Inc. v. Shure Inc.

- PTO
 - Examiners should not ignore evidence presented in a timely manner but rather should consider it on the record.
 - All evidence need not be accorded the same weight.
 - Preponderance of the evidence test is the standard.

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Hearing Components, Inc. v. Shure Inc.

- Practice Points
 - Demonstrate a nexus between the the success of a product and the associated claimed invention.
 - Alter licensing fee for a product license to another for a product when the applicable patent expires.

Asyst Techs., Inc. v. Emtrak, Inc.

- · Invention and the Art
 - A processing system for tracking articles such as silicon wafers which move from one processing station to the next in a manufacturing facility.
 - The claims required that each processing station be in communication with a central control unit.
 - The only difference between the claimed invention and the prior art was that the prior art had taught the use of a bus for this communication, while the claims required a multiplexer.

Asyst Techs., Inc. v. Emtrak, Inc. • Fed. Cir.

- Asyst's failure to link that commercial success to the features of its invention that were not disclosed in the prior art undermines the probative force of the evidence.
- While the evidence shows that the overall system drew praise as a solution to a felt need, there was no evidence that the success was attributable to the substitution of a multiplexer for a bus, which was the only material difference between the prior art and the patented invention.
- Evidence of secondary considerations does not always overcome a strong *prima facie* showing of obviousness.

Asyst Techs., Inc. v. Emtrak, Inc.

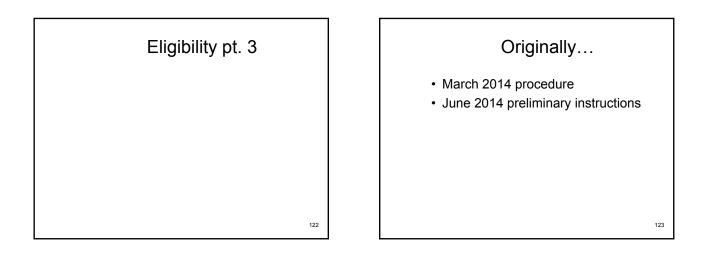
- Practice Point
 - Link the commercial success or long felt need to a claimed feature that distinguishes over the art.

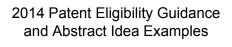
Geo M. Martin Co. v. Alliance Machine Systems Intl LLC

 "The commercial success of a product is relevant to the non-obviousness of a claim only insofar as the success of the product is due to the claimed invention.... Here, Alliance conclusively established that much of George Martin's <u>commercial success was due to Martin's pre-</u> <u>existing market share</u> in the stacker market, which, according to Martin's president, gave it a 'huge advantage' in selling other products because it allowed Martin to sell a 'single-source system.' Thus, this factor carries little weight."

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- Patent office issued guidance on its belief of current state of law as guidance for its examiners in 12/14 and 1/15
- Guidance provides instructions to examiners on how to examine cases for patent eligibility under §101
- Guidance also discusses recent §101 cases

 Federal Register Notice: 2014 Interim Guidance on Patent Subject Matter Eligibility. 2014 Interim Eligibility Guidance Guick Reference Sheet (December 2014) Nature-Based Product Essanghes (December 16, 2014) Abstract Idea Examples (January 27, 2015)

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Effective Date • Effective when published on 12/16/14 • Applies to all applications filed before or after 12/16/14

2014 Patent Eligibility Guidance and Abstract Idea Examples

 "This Interim Eligibility Guidance does not constitute substantive rulemaking and does not have the force and effect of law. This Interim Eligibility Guidance sets out the <u>Office's</u> interpretation of the subject matter eligibility requirements of 35 U.S.C. 101 in view of recent decisions by the Supreme Court and the U.S. Court of Appeals for the Federal Circuit (Federal Circuit), and advises the public and Office personnel on how these court decisions impact the provisions of MPEP 2105, 2106 and 2106.01."

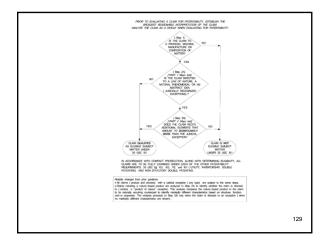
126

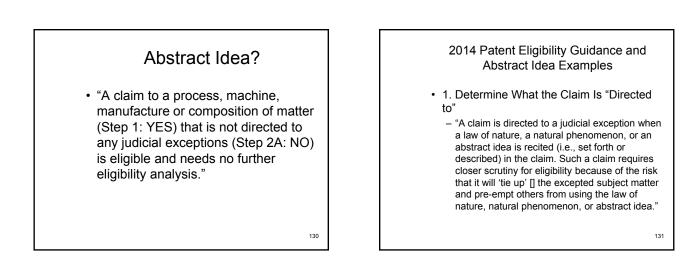
Basis for Appeal or Petition?

 "Rejections will continue to be based upon the substantive law, and it is these rejections that are appealable.
 Failure of Office personnel to follow this Interim Eligibility Guidance is not, in itself, a proper basis for either an appeal or a petition."

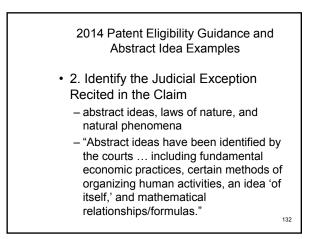


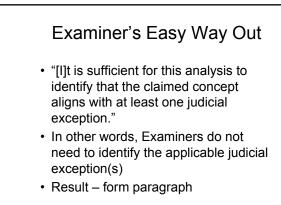
- Superseded sections
 2105
 - 2106(II)(A)
 - 2106(II)(B)
 - 2106.01





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Abstract Ideas

 "Abstract ideas have been identified by the courts by way of example, including fundamental economic practices, certain methods of organizing human activities, an idea 'of itself,' and mathematical relationships/formulas."

Examples of Abstract Ideas

 Mitigating settlement risk (Alice), hedging (Bilski), creating a contractual relationship (buySAFE), using advertising as an exchange or currency (Ultramercial), processing information through a clearinghouse (Dealertrack), comparing new and stored information and using rules to identify options (SmartGene), using categories to organize, store and transmit information (Cyberfone), organizing information through mathematical correlations, managing a game of bingo, the Arrhenius equation for calculating the cure time of rubber (Diehr); a formula for updating alarm limits (Flook); a mathematical jornula relating to standing wave phenomena (Mackay Radio), and a mathematical procedure for converting one form of numerical representation to another (Benson)

2014 Patent Eligibility Guidance and Abstract Idea Examples

- B. Flowchart Step 2B (Part 2 Mayo test)
 - Determine whether any element, or combination of elements, in the claim is sufficient to ensure that the claim amounts to significantly more than the judicial exception.
 - a search for an "inventive concept."

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Additional Features

 "To be patent-eligible, a claim that is directed to a judicial exception must include additional features to ensure that the claim describes a process or product that applies the exception in a meaningful way, such that it is more than a drafting effort designed to monopolize the exception. It is important to consider the claim as whole."

Significantly More

- 1. "Significantly More"
 - Improvements to another technology or technical field;
 - Improvements to the functioning of the computer itself;
 - Applying the judicial exception with, or by use of, a particular machine;
 - Effecting a transformation or reduction of a particular article to a different state or thing;
 - Adding a specific limitation other than what is well-understood, routine and conventional in the field, or adding unconventional steps that confine the claim to a particular useful application; or
 - Other meaningful limitations beyond generally linking the use of the judicial exception to a particular technological environment.

Not Significantly More

- Apply it on a computer
- Insignificant extrasolution activity
- · Linking exception to a particular environment
- "Simply appending well-understood, routine and conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception, e.g., a claim to an abstract idea requiring no more than a generic computer to perform generic computer functions that are well-understood, routine and conventional activities previously known to the industry: 41"

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Footnote 41

 "Id. at 2359 (using a computer to obtain data, adjust account balances, and issue automated instructions); Mayo, 132 S. Ct. at 1300 (telling a doctor to measure metabolite levels in the blood using any known process)."

2014 Patent Eligibility Guidance and Abstract Idea Examples

• "If the claim as a whole does recite significantly more than the exception itself, the claim is eligible (Step 2B: YES), and the eligibility analysis is complete. If there are no meaningful limitations in the claim that transform the exception into a patent-eligible application, such that the claim does not amount to significantly more than the exception itself, the claim is not patent-eligible (Step 2B: NO) and should be rejected under 35 U.S.C. 101."

Examiner's Action

 "In the rejection, identify the exception by referring to where it is recited (i.e., set forth or described) in the claim and explain why it is considered an exception. Then, if the claim includes additional elements, identify the elements in the rejection and explain why they do not add significantly more to the exception."

Guidance Examples

- Example 3 Diamond v. Diehr
- Example 4 Parker v. Flook
- Example 6 Alice Corp. v. CLS Bank

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Summaries of Court Decisions

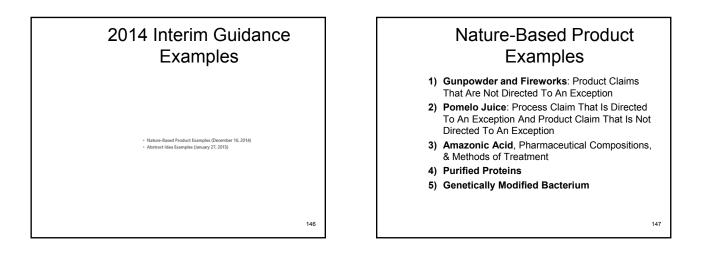
- 1) Supreme Court decisions
- 2) Abstract Idea decisions from Fed. Cir. prior to Alice Corp. (2010-2014)
- Abstract Idea decisions from Fed. Cir. After Alice Corp.

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2014 Interim Guidance Quick Reference Sheet * Pdera Register Notice: 2014 Interim Guidance on Patert Subject Matter Bigbility * 2014 Interim Eighbilty Guidance Quick Reference Sheet (December 2014) Includes form paragraphs that Examiners are using as the basis for their rejections



Nature-Based Product Examples

- 6) Bacterial Mixtures
- 7) Nucleic Acids
- 8) Antibodies
- 9) Cells 10)Food

Examples: Abstract Ideas

Eligible

 Isolating and Removing Malicious Code from Electronic Messages
 E-Commerce Outsourcing System/Generating a Composite Web Page
 Digital Image Processing
 Global Positioning System

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Example 1 Analysis

The claim is then analyzed to determine whether it is directed to any judicial exception. The claimed invention relates to software technology for isolation and extraction of malicious code contained in an electronic communication. The claim is directed towards physically isolating a received communication on a memory sector and extracting malicious code from that communication to create a sanitized communication in a new data file. Such action does not describe an abstract concept, or a concept similar to those found by the courts to be abstract, such as a fundamental economic practice, a method of organizing human activity, an idea itself (standing alone), or a mathematical relationship.

Example 1 Analysis

In contrast, the invention claimed here is directed towards performing isolation and eradication of computer viruses, worms, and other malicious code, a concept inextricably tied to computer technology and distinct from the types of concepts found by the courts to be abstract. Accordingly, the claimed steps do not recite an abstract idea. Nor do they implicate any other judicial exception. Accordingly, the claim is not directed to any judicial exception (Step 2A: NO). The claim is eligible.

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Example 2 Analysis

 This claim recites a system "useful in outsource provider serving web pages offering commercial opportunities," but is directed to automatically generating and transmitting a web page in response to activation of a link using data identified with a source web page having certain visually perceptible elements. The claim does not recite a mathematical algorithm; nor does it recite a fundamental economic or longstanding commercial practice. The claim addresses a business challenge (retaining website visitors) that is particular to the Internet. Example 2 Analysis

The claimed invention differs from other claims found by the courts to recite abstract ideas in that it does not "merely recite the performance of some business practice known from the pre-Internet world along with the requirement to perform it on the Internet. Instead, the claimed solution is necessarily rooted in computer technology in order to overcome a problem specifically arising in the realm of computer networks." No idea similar to those previously found by the courts to be abstract has been identified in the claim. During examination, if the examiner does not identify an abstract idea recited in the claim, the claim should be deemed to be not directed to a judicial exception (*Step 2A: NO*). The claim is eligible.

Example 3 Analysis

"T]he claim as a whole is analyzed to determine if there are additional limitations recited in the claim such that the claim amounts to significantly more than the mathematical operation. There are several additional limitations recited in the claim besides the mathematical operation of generating a blue noise mask. ... the claim uses a processor and memory to perform these steps of calculating a mathematical operation and receiving and storing data. The addition of general purpose computer components alone to perform such steps is not sufficient to transform a judicial exception into a patentable invention."

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Example 3 Analysis

The claim also recites the additional steps of comparing the blue noise mask to a gray scale image to transform the gray scale image to a binary image array and converting the binary image array into a halftoned image. These additional steps tie the mathematical operation (the blue noise mask) to the processor's ability to process digital images. These steps add meaningful limitations to the **abstract idea** of generating the blue noise mask and therefore add significantly more to the abstract idea than mere computer implementation. The claim, when taken as a whole, does not simply describe the generation of a blue noise mask via a mathematical operation and receiving and storing data, but combines the steps of generating a blue noise mask with the steps for comparing the image to the blue noise mask and converting the resulting binary image array to a halftoned image. By this, the claim goes beyond the mere concept of simply retrieving and combining data using a computer.

Example 3 Analysis

Finally, viewing the claim elements as an ordered combination, the steps recited in addition to the blue noise mask improve the functioning of the claimed computer itself. In particular, as discussed above, the claimed process with the improved blue noise mask allows the computer to use to less memory than required for prior masks, results in faster computation time without sacrificing the quality of the resulting image as occurred in prior processes, and produces an improved digital image. These are also improvements in the technology of digital image processing. ... Taking all the additional claim elements individually, and in combination, the claim as a whole amounts to significantly more than the abstract idea of generating a blue noise mask (*Step 2B: YES*). The claim recites patent eligible subject matter.

Example 4

These computer components are recited at **a high level of generality** and add no more to the claimed invention than the components that perform basic mathematical calculation functions routinely provided by a general purpose computer. Limiting performance of the mathematical calculations to a general purpose CPU, absent more, is **not sufficient to transform** the recited judicial exception into a patent-eligible invention.

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Example 4

 However, the claim is further limited to a mobile device comprising a GPS receiver, microprocessor, wireless communication transceiver and a display that receives satellite data, calculates pseudo-ranges, wirelessly transmits the calculated pseudo-ranges to the server, receives location data from the server, and displays a visual representation of the received calculated absolute position from the server. The programmed CPU acts in concert with the recited features of the mobile device to enable the mobile device to determine and display its absolute position through interaction with a remote server and multiple remote satellites. The meaningful limitations placed upon the application of the claimed mathematical operations show that the claim is not directed to performing mathematical operations on a computer alone.

Example 4

• Rather, the combination of elements impose meaningful limits in that the mathematical operations are applied to improve an existing technology (global positioning) by improving the signal-acquisition sensitivity of the receiver to extend the usefulness of the technology into weak-signal environments and providing the location information for display on the mobile device. All of these features, especially when viewed in combination, amount to significantly more than the judicial exception (*Step 2B: YES*). The claim is eligible.

Examples: Abstract Ideas

Ineligible 5)Digital Image Processing 6)The Game of Bingo 7)E-Commerce providing Transaction Performance Guaranty 8)Distribution of Products over the Internet

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Example 5

[T]he claimed method simply describes the concept of gathering and combining data by rectifung steps of organizing information through mathematical relationships. The gathering and combining merely employs mathematical relationships to manipulate existing information to generate additional information in the form of a 'device profile,' without limit to any use of the device profile. This idea is similar to the basic concept of manipulating information using mathematical relationships (e.g., converting numerical representation in <u>Benson</u>), which has been found by the courts to be an abstract idea. Therefore, the claim is directed to an abstract idea (Step 2A: YES). The claim does not include additional elements beyond the abstract idea of gathering and combining data. Therefore, the claim does not amount to more than the abstract idea itself (*Step 2B: NO*). The claim is not patent eligible.

Example 6

 Managing the game of Bingo as recited in the claim can be performed mentally or in a computer and is similar to the kind of 'organizing human activity' at issue in <u>Alice Corp.</u> Although the claims are not drawn to the same subject matter, the abstract idea of managing a game of Bingo is similar to the abstract ideas of managing risk (hedging) during consumer transactions (<u>Bilski</u>) and mitigating settlement risk in financial transactions (<u>Alice Corp.</u>) Claim 1 describes managing the game of Bingo and therefore is directed to an abstract idea (*Step 2A: YES*).

Example 6

[T]he claim is analyzed to determine whether there are additional limitations recited that amount to significantly more than the abstract idea.
 [C]omputer components at each step of the management process perform purely generic computer functions. As such, there is no inventive concept sufficient to transform the claimed subject matter into a patent-eligible application. The claim does not amount to significantly more than the abstract idea itself (*Step 2B: NO*). Accordingly, the claim is not patent eligible.

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Example 7

The claim recites the steps of creating a contract, including receiving a request for a performance guaranty (contract), processing the request by underwriting to provide a performance guaranty and offering the performance guaranty. This describes the creation of a contractual relationship, which is a commercial arrangement involving contractual relations similar to the fundamental economic practices found by the courts to be abstract ideas (e.g., hedging in Bilski). It is also noted that narrowing the commercial transactions to particular types of relationships or particular parts of that commercial transaction (e.g., underwriting) would not render the concept less abstract. Thus, the claim is directed to an abstract idea (Step 2A: YES).

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Example 7

 Analyzing the claim as whole for an inventive concept, the claim limitations in addition to the abstract idea include a computer application running on a computer and the computer network. This is simply a generic recitation of a computer and a computer network performing their basic functions. The claim amounts to no more than stating create a contract on a computer and send it over a network. These generic computing elements alone do not amount to significantly more than the judicial exception (Step 2B: NO). The claim is not patent eligible.

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Example 8

 [T]he claim describes the concept of using advertising as an exchange or currency. This concept is similar to the concepts involving human activity relating to commercial practices (e.g., hedging in Bilski) that have been found by the courts to be abstract ideas. The addition of limitations that narrow the idea, such as receiving copyrighted media, selecting an ad, offering the media in exchange for watching the selected ad, displaying the ad, allowing the consumer access to the media, and receiving payment from the sponsor of the ad, further describe the abstract idea, but do not make it less abstract. The claim is directed to an abstract idea (Step 2A: YES).

Example 8

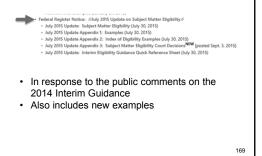
"Viewing the limitations individually, the accessing and updating of an activity log are used only for data gathering and, as such, only represent insignificant pre-solution activity. Similarly, requiring a consumer request and restricting public access is insignificant pre-solution activity because such activity is necessary and routine in implementing the concept of using advertising as an exchange or currency; *i.e.*, currency must be tendered upon request in order for access to be provided to a desired good. Furthermore, the Internet limitations do not add significantly more because they are simply an attempt to limit the abstract idea to a particular technological environment."

Example 8

 Viewing the limitations as a combination, the claim simply instructs the practitioner to implement the concept of using advertising as an exchange or currency with routine, conventional activity specified at a high level of generality in a particular technological environment. When viewed either as individual limitations or as an ordered combination, the claim as a whole does not add significantly more to the abstract idea of using advertising as an exchange or currency (*Step 2B: NO*). The claim is not patent eligible.

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July 2015 Update on Subject Matter Eligibility



Major Themes of Public Comments

- 1) requests for additional examples, particularly for claims directed to abstract ideas and laws of nature;
- further explanation of the markedly different characteristics analysis;
- further information regarding how examiners identify abstract ideas;
- discussion of the prima facie case and the role of evidence with respect to eligibility rejections;
- 5) information regarding application of the 2014 Interim Patent Eligibility Guidance in the Patent Examining Corps; and
- explanation of the role of preemption in the eligibility analysis, including a discussion of the streamlined analysis.

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July 15th Update on Subject Matter Eligibility

Additional Element Consideration

 [E]xaminers are to consider all additional elements both individually <u>and</u> in combination to determine whether the claim as a whole amounts to significantly more than an exception. It is agreed that this instruction is vital to ensuring the eligibility of many claims, because even if an element does not amount to significantly more on its own (e.g., because it is merely a generic computer component performing generic computer functions), it can still amount to significantly more when considered in combination with the other elements of the claim.

Markedly Different Characteristics (MDC) Analysis

 [T]the MDC analysis will be retained in Step 2A, because that location provides three benefits to applicants: it allows many claims to qualify as eligible earlier in the analysis; it provides an additional pathway to eligibility for many claims directed to "product of nature" exceptions; [] and it ensures consistent eligibility analyses across all technologies and claim types.

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Identifying Abstract Ideas

• Because the courts have declined to define abstract ideas, other than by example, the 2014 IEG instructs examiners to refer to the body of case law precedent in order to identify abstract ideas by way of comparison to concepts already found to be abstract.

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Identifying Abstract Ideas

The guidelines associate] Supreme Court and Federal Circuit eligibility decisions with judicial descriptors (e.g., "certain methods of organizing human activities") based on common characteristics. These associations define the judicial descriptors in a manner that stays within the confines of the judicial precedent, with the understanding that these associations are not mutually exclusive, i.e., some concepts may be associated with more than one judicial descriptor. This discussion is meant to guide examiners and ensure that a claimed concept is not identified as an abstract idea unless it is similar to at least one concept that the courts have identified as an abstract idea.

"Fundamental economic practices"

• [U]sed to describe concepts relating to the economy and commerce, such as agreements between people in the form of contracts, legal obligations, and business relations. The term "fundamental" is used in the sense of being foundational or basic, and not in the sense of necessarily being "old" or "well-known."

Common Characteristics

- At least two cases have found concepts relating to agreements between people or performance of financial transactions abstract, such as creating a contractual relationship (buySAFE), and hedging (Bilski).
- At least two cases have found concepts relating to **mitigating risks** abstract, such as hedging (Bilski), and mitigating settlement risk (Alice Corp.).

"Certain Methods of Organizing Human Activity"

• The phrase "certain methods of organizing human activity" is used to describe concepts relating to interpersonal and intrapersonal activities, such as managing relationships or transactions between people, social activities, and human behavior; satisfying or avoiding a legal obligation; advertising, marketing, and sales activities or behaviors; and managing human mental activity.

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"Certain"

• The 2014 IEG uses the term "certain" to qualify this category description, in order to remind examiners that (1) **not all methods of organizing human activity are abstract ideas**, and (2) this category description is not meant to cover human operation of machines.

Common Characteristics

- Several cases have found concepts relating to managing relationships or transactions between people abstract, such as creating a contractual relationship (*buySAFE*), hedging (*Bilski*), mitigating settlement risk (*Alice Corp.*), processing loan information (*Dealertrack*), managing an insurance policy (*Bancorp*), managing a game of Bingo (*Planet Bingo*), allowing players to purchase additional objects during a game (*Gametek*), and generating rule-based tasks for processing an insurance claim (*Accenture*).¹¹
- At least two cases have found concepts relating to satisfying or avoiding a legal obligation abstract, such as tax-free investing (*Fort Properties*) or arbitration (*In re Comiskey*).

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Claim 1 is a claim to a system for generating tasks to be performed in an insurance organization. The system stores information on insurance transactions in a database luce the excurrence of an event the system determined

stores information on insurance transactions in a database. Upon the occurrence of an event, the system determines what tasks need to be accomplished for that transaction and assigns those tasks to various authorized individuals to complete them. In order to accomplish this, the claimed system includes an insurance transaction database, a task library database, a client component for accessing the insurance transaction database, and a server component that interacts with the software components and controls an event processor, which watches for events and sends alerts to a task engine that determines the next tasks to be completed."

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Common Characteristics

- Several cases have found concepts relating to advertising, marketing and sales activities or behaviors abstract, such as using advertising as an exchange or currency (Ultramercial),structuring a sales force or marketing company (In re Ferguson), using an algorithm for determining the optimal number of visits by a business representative to a client (In re Maucorps), allowing players to purchase additional objects during a game (Gametek), and computing a price for the sale of a fixed income asset and generating a financial analysisoutput (Freddie Mac).
- At least two cases have found concepts relating to managing human behavior abstract, such as a mental process that a neurologist should follow when testing a patient for nervous system malfunctions (*In re Meyer*), and meal planning (*DietGoal*).

"An Idea 'Of Itself"

 [U]sed to describe an idea standing alone such as an uninstantiated concept, plan or scheme, as well as a mental process (thinking) that "can be performed in the human mind, or by a human using a pen and paper."

Common Characteristics

- Several cases have found concepts relating to processes of comparing data that can be performed mentally abstract, such as comparing information regarding a sample or test subject to a control or target data (Ambry, Myriad CAFC), collecting and comparing known information (Classen), comparing data to determine a risk level (Perkin-Elmer), diagnosing an abnormal condition by performing clinical tests and thinking about the results (In re Grams),] obtaining and comparing intangible data (Cybersource), and comparing new and stored information and using rules to identify options (SmartGene).
- Several cases have found concepts relating to processes of organizing information that can be performed mentally abstract, such as using categories to organize, store and transmit information (Cyberfone), data recognition and storage (Content Extraction), and organizing information through mathematical correlations (Digitech).
- At least one case has found the steps of displaying an advertisement in exchange for access to copyrighted media to be "an idea, having no particular concrete or tangible form" (Ultramercial).

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"Mathematical relationships/formulas"

• [U]sed to describe **mathematical concepts** such as mathematical algorithms, mathematical relationships, mathematical formulas, and calculations. ... It is also noted that the courts have described some mathematical concepts as laws of nature.

Common Characteristics

- At least five cases have found concepts relating to a mathematical relationship or formula abstract, for example an algorithm for converting binary coded decimal to pure binary (Benson), a formula for computing an alarm limit (Flook), a formula describing certain electromagnetic standing wave phenomena (Mackay Radio), the Arrhenius equation (Diehr), and a mathematical formula for hedging (Bilski).
- Several cases have found concepts relating to performing mathematical calculations abstract, such as managing a stable value protected life insurance policy by performing calculations and manipulating the results (Bancorp), reducing the amount of calculations in known and established computations (FuzzySharp), an algorithm for determining the optimal number of visits by a business representative to a client (In re Maucorps), an algorithm for calculating parameters indicating an abnormal condition (In re Grams), computing a price for the sale of a fixed income asset and generating a financial analysis output (Freddi Mac), and calculating the difference between local and average data values (In re Abele).

Requirements Of A Prima Facie Case

[T]he initial burden is on the examiner to explain why a claim or claims are unpatentable clearly and specifically, so that applicant has sufficient notice and is able to effectively respond. [] For subject matter eligibility, the examiner's burden is met by clearly articulating the reason(s) why the claimed invention is not eligible, for example by providing a reasoned rationale that identifies the judicial exception recited in the claim and why it is considered an exception, and that identifies the additional elements in the claim (if any) and explains why they do not amount to significantly more than the exception.

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Basis for Rationale

• This rationale may rely, where appropriate, on the **knowledge generally available** to those in the art, on the **case law precedent**, on **applicant's own disclosure**, or on **evidence**. Sample rejections satisfying this burden are found in the training materials, particularly the worksheets for Examples 5-8. Once the examiner has satisfied her initial burden, the burden then shifts to the applicant.

Use of Evidence

• The courts consider the determination of whether a claim is eligible (which involves identifying whether an exception such as an abstract idea is being claimed) to be a question of law.[] Accordingly, **courts do not rely on evidence that a claimed concept is a judicial exception**, and inmost cases resolve the ultimate legal conclusion on eligibility without making any factual findings.

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Well-Understood, Routine and Conventional

- For Step 2B, examiners should rely on what the courts have recognized, or those in the art would recognize, as elements that are well-understood, routine and conventional....
- [C]ourts have recognized the following computer functions to be well-understood, routine, and conventional functions when they are claimed in a merely generic manner:
 - performing repetitive calculations; receiving, processing, and storing data; electronically scanning or extracting data from a physical document; electronic recordkeeping; automating mental tasks; and receiving or transmitting data over a network, e.g., using the Internet to gather data.

Examiner Determination

Courts have not identified a situation in which evidence was required to support a finding that the additional elements were well-understood, routine or conventional, but rather treat the issue as a matter appropriate for judicial notice. As such, a rejection should only be made if an examiner relying on his or her expertise in the art can readily conclude in the Step 2B inquiry that the additional elements do not amount to significantly more (Step 2B: NO). If the elements or functions are beyond those recognized in the art or by the courts as being well-understood, routine or conventional, then the elements or functions will in most cases amount to significantly more (Step 2B: YES).

Preemption and Streamlined Analysis

• Current and streamlined approaches still retained

Appendix 1: Examples 21)Transmission Of Stock Quote Data 22)Graphical User Interface for Meal Planning

- 23)Graphical User Interface for Relocating Obscured Textual Information
- 24)Update Alarm Limits
- 25)Rubber Manufacturing
- 26)Internal Combustion Engine
- 27)System Software BIOS

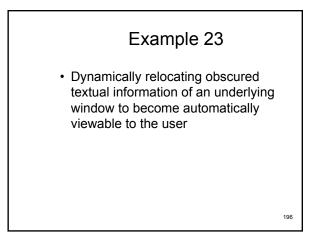
Example 21

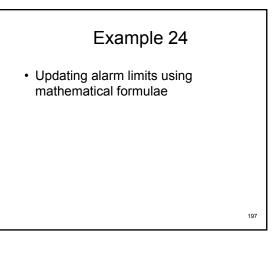
 Stock quote alert subscription service where subscribers receive customizable stock quotes on their local computers from a remote data source

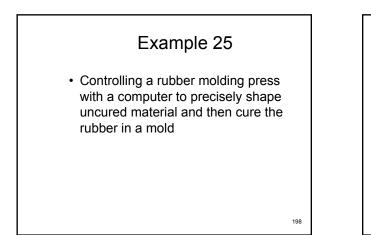
194

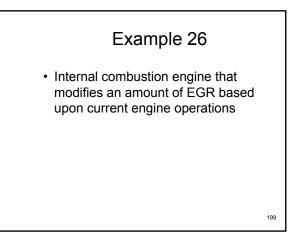
Example 22

 Using visuals to assist users to follow diet programs designed by health professionals for the purpose of modifying diet behavior





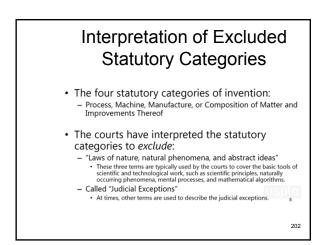




Example 27

 Utilizing a LAN to store BIOS code remotely from the computer

<section-header><section-header><list-item><list-item><list-item><list-item><list-item><list-item><list-item>



Training Directed to Step 1

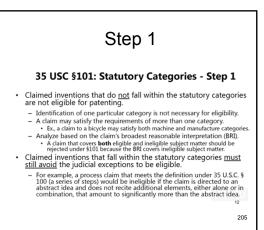
- Step 1 is the claim to a process, machine, manufacture, or composition of matter?
- Yes Step 2 A
- No Claim is not eligible subject matter under §101

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Four Categories 35 USC §101: The Four Categories of Statutory Subject Matter

- Process
- "an act, or series of acts or steps"
 Machine
- "a concrete thing, consisting of parts, or of certain devices and combination of devices"
- Manufacture
- "an article produced from raw or prepared materials by giving these materials new forms, qualities, properties, or combinations, whether by handlabor or by machinery"
 Composition of Matter
 - "all compositions of two or more substances and all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids, for example

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Nonstatutory Example #1

Statutory Categories – Nonstatutory Example

Example 1:

A paradigm for marketing software, comprising: a marketing company that markets software from a plurality of different independent and autonomous software companies, and carries out and pays for operations associated with marketing of software for all of said different independent and autonomous software companies, in return for a contingent share of a total income stream from marketing of the software from all of said software companies, while allowing all of said software companies to retain their autonomy. (In re Ferguson; claim 24) endent

- "Paradigm" is a business model for an intangible marketing company, not a:
- Process: series of steps; 35 U.S.C. § 100
 Machine: a concrete thing consisting of parts or devices
- Manufacture: an article produced from raw or prepared materials
 Composition of matter: a composition of substances or composite article

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Nonstatutory Example #2

Statutory Categories – Nonstatutory Example

• Example 2:



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What about Signals?

Statutory Categories – Signals per se

- · Another example of a claim that does not fit in the categories: A signal with embedded supplemental data, the signal being encoded in accordance with a given encoding process and selected samples of the signal representing the supplemental data, and at least one of the samples preceding the selected samples is different from the sample corresponding to the given encoding process. (*In re Nuijter, claim 14*)
- A transitory, propagating signal like the claim above is not within one of
- A transition propagating signation are the count expert to the four statutory categories.
 The transient electric or electromagnetic transmission is man-made and physical it exists in the real world and has tangible causes and effects but was found not to qualify as a manufacture, or any of the other statutory categories.

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In re Nuijten

- · The issue before the court is whether or not a signal is patentable subject matter. ... The claims [of the present application] seek to patent any 'signal' that has been encoded in a particular manner. Because we agree with the Board that the 'signal' claims in Nuijten's application are not directed to statutory subject matter, we affirm.
- In re Nuijten (Fed. Cir. 2007)

Signals and Computer Readable Media

Signals per se

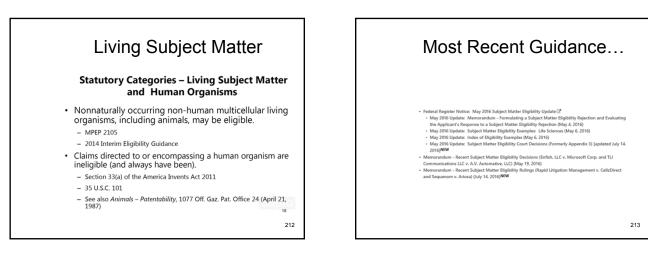
- Computer readable media (CRM), under the broadest reasonable interpretation (BRI), will cover an ineligible signal per se unless defined otherwise in the application as filed.
 - When the specification is silent, the BRI of a CRM and a computer readable storage media (CRSM) in view of the state of the art covers a signal per se. Thus, in this case, a claim to a CRM or CRSM is ineligible unless amended to avoid the ineligible signal embodiment.
 - Some applications, as filed, provide a special definition that explicitly draws a distinction between computer readable <u>storage</u> media, defining it as hardware discs, and computer readable <u>transmission</u> media, defining it as signals *per* se. Thus, in this case, a claim limited to storage media could rely on the special definition and would be eligible.

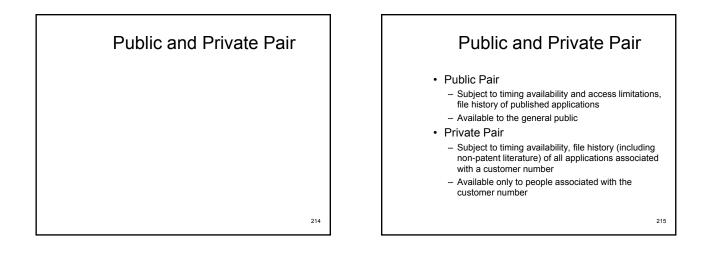
210

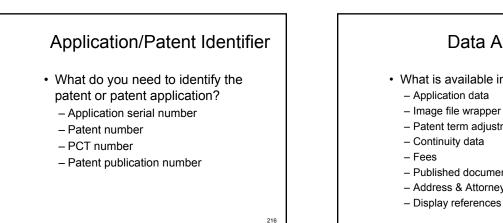
Signals and Computer Readable Media

Signals per se

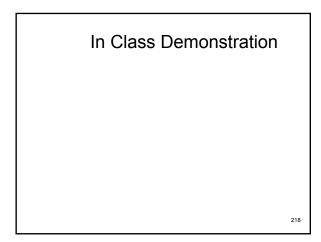
- When the specification is silent (no special definition of a CRM provided in original disclosure):
 - It is acceptable to amend the claims to exclude the signal embodiment by adding "non-transitory" to modify the computer readable media.
 See "Subject Matter Eligibility of Computer Readable Media" (Jan. '10)
- "Non-transitory" is not a requirement, but simply one option. Applicant can choose other ways to amend the claim in accordance with the original disclosure.
 - Not acceptable to just add "physical" or "tangible" Nuijten's ineligible signals were physical and tangible.
- signals were physical and tanguide. Not acceptable to add "storage" absent support in original disclosure because the broadest reasonable interpretation of computer readable storage media based on common usage covers signals/carrier waves. 17













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