Providing explicit rationales in rejections under 35 U.S.C. 103
A refresher for TC1600 examiners

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A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.
35 U.S.C. 103 and the law of obviousness

• The Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966), articulated factors to be considered when analyzing prior art under 35 U.S.C. 103.

• The Court later reaffirmed and relied upon this standard in *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007).
  – The *KSR* Court suggested seven possible rationales for obviousness, but that list is not exhaustive.

• The key to supporting any rejection under 35 U.S.C. 103 is a clear articulation of the reason(s) *why* the claimed invention would have been obvious.

See MPEP 2141 (II), (III)
Graham v. Deere factual inquiries

1. Determine the scope and content of the prior art.
2. Ascertain the differences between the prior art and the claimed invention.
3. Resolve the level of ordinary skill in the pertinent art before the effective filing date of the claimed invention.
4. Evaluate any objective evidence relevant to the issue of obviousness.

See MPEP 2141 (II)
Making a rationale for modifying the prior art

• Once all of the *Graham* factors have been considered, any 103 rejection made must address findings of fact and then provide a rationale for combining or modifying the references.

• Each rejection must contain an explicit rationale clearly explaining why it would have been obvious to combine or modify the teachings of the references.

• Each included claim must be explicitly addressed in the rejection, although it is not necessary to rewrite the entire rejection for each claim.

See MPEP 2143
Rationale for modifying prior art

• “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*, 550 U.S. at 419.

• The *KSR* Court reaffirmed that the *Graham v. Deere* factors are to be used when determining obviousness and discussed a number of possible rationales that can be used consistently with the *Graham* inquiries.

• The list of rationales from *KSR* is not exhaustive. See MPEP 2141 (I), 2143
Rationale for modifying prior art

• The rationale may be—but need not be—implicitly contained in the prior art.
• Factors other than the disclosures of the cited prior art may provide a basis for a finding of obviousness.
• It will often be the case that a conclusion of obviousness may be supported by more than one line of reasoning, although examiners are not required to provide multiple lines of reasoning in a rejection.

See MPEP 2141 (I), (III); 2143
Rejection must give an explanation

• For each rationale deployed in an obviousness rejection, examiners must explain why the person of ordinary skill in the art would have found the proposed modification obvious.
  – This is true for every obviousness rationale.

• Conclusory statements about obviousness that are unaccompanied by a reasoned statement explaining them are insufficient to establish a prima facie case.

See MPEP 2141 (I), (III); 2143
Exemplary obviousness rationales identified in *KSR*

- Combining prior art elements according to known methods to yield predictable results
- Simple substitution of one known 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

See MPEP 2143 (I)
Exemplary obviousness rationales identified in *KSR*

- Choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success (“obvious to try”)
- 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
- Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention (“TSM”)

See MPEP 2143 (I)
Additional sources of reasoning to support an obviousness finding

- Overlapping, approaching, and similar ranges, amounts, and proportions
- Optimization within prior-art conditions or through routine experimentation
- Legal precedent
- Art-recognized equivalence of compositions or processes for same purpose as each other

See, for example, 2144.04-2144.09
Legal precedent as source of supporting rationale

• When a line of reasoning drawn from legal precedent is relied upon to explain an obviousness rejection, the examiner must show how that line of reasoning applies to the facts of the application under consideration.

• Case law should not be the sole basis for obviousness.

• Common examples in TC1600
  – Automating a manual activity
  – Changes in size, shape, or sequence of adding ingredients
  – Purifying an old product

See MPEP 2144.04
Obviousness of ranges, amounts, and proportions

- When claimed ranges overlap or lie within prior-art ranges, a *prima facie* case of obviousness exists, **but** examiners must explain **why** the ranges in each included claim overlap or lie within the art’s ranges.

- A *prima facie* case of obviousness exists where the claimed ranges or amounts do not overlap with the prior art but are merely close, **but** examiners must explain **why** the ranges in each included claim are close to the art’s ranges.

- Ranges in dependent claims must be particularly explained as well, although it may not be necessary to rewrite the rejection for each claim.

- The same standard applies for ranges, amounts, and proportions.

See MPEP 2144.05 (I)
Optimization within prior-art conditions or by routine experimentation

- Generally, differences in concentration or temperature do not support patentability, but there must be an articulated rationale explaining why routine optimization renders each included claim obvious.

- Routine optimization can be supported by any valid rationale for an obviousness finding, including “obvious to try.”

- The presence of a result-effective variable would be one, but not the only, motivation for the skilled artisan to optimize the prior art’s conditions.

- Examiners must make findings of relevant facts and present their underpinning reasoning in sufficient detail.

See MPEP 2144.05 (II)
Art-recognized equivalence for same purpose

• It is *prima facie* obvious to combine two compositions that the art teaches as being useful individually for the same purpose as each other, **but** there must be an explanation of the art’s recognition of each composition’s utility as of the relevant date.

• If the prior art recognizes two compositions or processes as equivalents, they can be substituted for each other, **but** there must be an explanation of *why* the art recognized them as equivalents as of the relevant date.
  
  – The mere fact of functional or mechanical equivalence is insufficient if the art did not recognize that equivalence before the effective filing date.
  
  – There is no requirement that the art expressly suggest substituting one component or process for another.

See MPEP 2144.06
Rationales relying on common knowledge in the art

• Examiners may rely on common knowledge in the art without providing a reference, but examiners must explicitly provide a clear and unmistakable line of technical reasoning to do so.

• Any statement of a technical or scientific fact that is unsupported by documentary evidence qualifies as official notice.

• Official notice is appropriate only where the facts asserted are capable of instant and unquestionable demonstration as being well-known.
  – Whenever possible, cite a reference to support statements of technical or scientific fact.

See MPEP 2144.03
Rationales relying on common knowledge in the art

- It is never appropriate to rely on common knowledge as the principal evidence upon which a rejection is based.
- “Absent some articulated rationale, a finding that a combination of prior art would have been ‘common sense’ or ‘intuitive’ is no different than merely stating the combination ‘would have been obvious.’

See MPEP 2144.03 (A)
Summary: providing explicit rationales

• Rejections must contain an explicit, clear articulation of the reasons why the claimed invention would have been obvious.
  – Obviousness rejections must explain that the claimed invention would have been obvious because at least one particular rationale applies.
  – Examiners must explain why the limitations of each claim included in a rejection would have been obvious and why the claim as a whole would have been obvious.
  – Regardless of the applicable rationale, examiners must explain how the rationale applies to the facts of the case.

See MPEP 2141, 2143
Discussion examples
Discussion examples

• All discussion examples presume the absence of any evidence of nonobviousness.
  • **Example 1**: Removing microbes from meat
  • **Example 2**: Ear-treatment formulation
  • **Example 3**: Pharmaceutical counterion
  • **Example 4**: Codon optimization
Example 1: Removing microbes from meat

A method of treating a meat product to reduce a microbial population in the meat product, the method comprising the steps of:

spraying an aqueous antimicrobial treatment composition onto said meat product at a pressure of at least 50 psi at a temperature of up to about 60°C resulting in a contact time of at least 30 seconds, the antimicrobial composition comprising at least two ppm of one or more peroxycarboxylic acids having up to 12 carbon atoms; and at least 20 ppm of one or more carboxylic acids having up to 18 carbon atoms; and

achieving at least a one log$_{10}$ reduction in the microbial population.
Example 1: Limitation at issue

A method of treating a meat product to reduce a microbial population in the meat product, the method comprising the steps of:

spraying an aqueous antimicrobial treatment composition onto said meat product at a pressure of at least 50 psi at a temperature of up to about 60°C resulting in a contact time of at least 30 seconds, the antimicrobial composition comprising at least two ppm of one or more peroxycarboxylic acids having up to 12 carbon atoms: and at least 20 ppm of one or more carboxylic acids having up to 18 carbon atoms; and

achieving at least a one log_{10} reduction in the microbial population.

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Example 1: Prior art

- Patent A teaches the entire claimed method, including “rapidly spraying” the claimed antimicrobial agent onto poultry.
- Patent A does not teach that the pressure was 50 psi or greater, as the claim requires.
- Patent B teaches spraying a different antimicrobial agent onto poultry at a pressure anywhere from “20 to 150 psi to cause a spray of medium particle size to impact the inside and outside of the poultry with sufficient force for good cleaning.”
- Patent B explains how to modify its apparatus such that the spray pressure can be changed in order to achieve good cleaning.
Example 1: Simple combination—adequate rationale

It would have been obvious to combine Patent B’s high-pressure washing with Patent A’s meat-treatment method because Patent A’s method applies an antimicrobial composition to reduce microbes, while Patent B’s high-pressure washing achieves that same outcome. In this combination, both Patent A’s meat-treatment method and Patent B’s high-pressure washing are performing the same functions they would if they were separate. The person of ordinary skill in the art would have found it obvious to combine the elements because ordinarily skilled artisans would have recognized the reasons for applying Patent A’s composition using Patent B’s high pressure and would have known how to do so. The person of ordinary skill in the art would further have predicted that the combination would remove microbes from meat because Patent B teaches that its spraying step effectively cleans meat.
Example 1: Optimization within prior-art conditions—**inadequate rationale**

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. It would therefore have required only routine optimization to find the best spray pressure for Patent A’s method.

This rationale does not explain why it would have been routine optimization to arrive at the claimed invention and why a person of ordinary skill in the art would have had a reasonable expectation of success in carrying out Patent A’s method with the claimed pressure range.
Example 1: Optimization within prior-art conditions—adequate rationale

Routine optimization of Patent B’s high-pressure washing would have led to the claimed range of a pressure of at least 50 psi because Patent B teaches that washing at 20-150 psi achieves the reduction of microbes desired in Patent A. The person of ordinary skill in the art would have found it obvious to optimize within the range taught by Patent B because Patent B teaches that this entire range reduces microbial levels on meat and also teaches how to optimize the spray pressure.
Example 1: Overlapping ranges—adequate rationale

The claimed method requires a spray pressure of at least 50 psi, which overlaps with the range of Patent B because Patent B teaches washing at 20-150 psi. Because the claimed range overlaps with the range disclosed by the prior art, a *prima facie* case of obviousness exists.
Example 1: Teaching-suggestion-motivation—adequate rationale

The person of ordinary skill would have had a reasonable expectation of success in selecting a spray pressure of 50 psi, which is within Patent B’s 20-150 psi range, in Patent A’s meat-cleaning method because Patent A requires “rapid spraying” to remove microbes and Patent B teaches that 20-150 psi removes microbes. The skilled artisan would have been motivated to select Patent B’s spray pressure because the references both teach that it is desirable to remove microbes from meat, while Patent B expressly suggests a pressure range including 50 psi for accomplishing this removal.
Example 2: Ear-Treatment

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 2: Ear-Treatment formulation

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 2: Prior art

• Reference A teaches using ear drops containing ciprofloxacin to treat middle-ear infections.

• Reference A identifies ciprofloxacin as a gyrase inhibitor, a class of compounds it finds are less likely than other antibiotics to be toxic to the ear.

• Reference B teaches that the art recognized both ciprofloxacin and ofloxacin as gyrase inhibitors suitable for application to the ear.
Example 2: Simple substitution—adequate rationale

The skilled artisan would have expected success in substituting Reference B’s ofloxacin for the ciprofloxacin in Reference A’s ear-treatment method because Reference A teaches that gyrase inhibitors are useful for treating ear infections and Reference B teaches that ofloxacin is a gyrase inhibitor. The skilled artisan could have substituted one compound for another because Reference B teaches that the compounds were both known to be suitable for application to the ear. The person of ordinary skill in the art would have found it obvious to make the substitution because ordinarily skilled artisans would have predicted that ofloxacin would be safe and effective based on the compounds’ shared activity.
Example 2: Close structural similarity—inadequate rationale

Ofloxacin and ciprofloxacin are structurally similar, differing at only two sites on their shared core structure. Therefore, the person of ordinary skill in the art would have found it obvious to substitute ofloxacin for ciprofloxacin in Reference A’s method.

This rationale does not explain why it would have been routine optimization to arrive at the claimed invention and why a person of ordinary skill in the art would have had a reasonable expectation of success in substituting Reference B’s ofloxacin for Reference A’s ciprofloxacin.
Example 2: Close structural similarity—adequate rationale

Ofloxacin and ciprofloxacin are structurally similar, differing at only two sites on their shared core structure. The person of ordinary skill in the art would have found it obvious to substitute ofloxacin for ciprofloxacin in Reference A’s method because Reference B identifies these structurally similar compounds as also sharing gyrase-inhibitor activity. The skilled artisan could have substituted one compound for another because Reference B teaches that the compounds were both known to be suitable for application to the ear.
Example 2: Teaching-Suggestion-Motivation—adequate rationale

The person of ordinary skill would have had a reasonable expectation of success in selecting Reference B’s ofloxacin as the agent in Reference A’s ear-treatment method because Reference A teaches that ciprofloxacin, a gyrase inhibitor, is an effective agent for treating ear infections and Reference B teaches that ofloxacin is a gyrase inhibitor. The skilled artisan would have been motivated to select Reference B’s ofloxacin as the active agent because Reference A teaches that gyrase inhibitors are effective against ear infections and are not toxic to the ear.
Example 3: Pharmaceutical counterion

The besylate salt of amlopidine.
Example 3: Limitation at issue

The **besylate** salt of amlopidine.
Example 3: Prior art and evidence

- Patent A teaches amlopidine and pharmaceutically-acceptable acid addition salts and specifically names 12 non-cyclic non-toxic acid addition salts.
- All of Patent A’s working examples of salts are amlopidine maleate.
- Reference B discloses 53 FDA-approved commercially-marketed anions useful for making pharmaceutically acceptable salts.
- Reference B specifically names besylate, a cyclic anion, but teaches that only 0.25 percent of approved drugs as of the time of the invention were besylate salts.
- Reference C established that amlopidine maleate would be predicted to be chemically unstable because of maleate’s double bond; besylate has no double bond.
- Reference C shows that aryl sulfonic acids like besylate increase the solubility of pharmaceuticals with reactive amine groups.
- Reference C shows that the choice of counterion does not affect the therapeutic effectiveness of amlopidine.
- Reference C explains that formulation stability is desirable and suggests optimizing stability by modifying the counterion selection.
Example 3: Simple substitution—adequate rationale

The skilled artisan would have expected success in substituting Reference B’s besylate for the maleate exemplified in Reference A’s pharmaceutical formulation because Reference B teaches that besylate is an FDA-approved counterion and Reference C teaches that anions similar to besylate are compatible with compounds like amlodipine. The person of ordinary skill in the art would have found it obvious to make the substitution because ordinarily skilled artisans would have predicted that besylate salts of amlodipine could be prepared and that changing the counterion would not affect the therapeutic effectiveness of the drug.
Example 3: Optimization within prior-art conditions—**inadequate rationale**

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. It would therefore have required only routine optimization to find the best counterion for Reference A’s amlodipine.

This rationale does not explain **why** it would have been routine optimization to arrive at the claimed invention and **why** a person of ordinary skill in the art would have had a reasonable expectation of success in preparing Reference A’s amlodipine with the claimed besylate counterion.
Example 3: Optimization within prior-art conditions—adequate rationale

Routine optimization of Patent A’s pharmaceutical composition would have led to the claimed besylate counterion because Reference B teaches that besylate is one of several anions known to be useful in pharmaceutical compositions. The person of ordinary skill in the art would have found it obvious to optimize the formulation’s stability by selecting from the set of counterions taught by Reference B because Reference B teaches that these counterions are suitable for pharmaceutical formulations and establishes that preparing the salts would have required only routine experimentation. Furthermore, Reference C identifies formulation stability as a desirable parameter to optimize and suggests doing so by modifying the counterion selection.
Example 3: Teaching-Suggestion-Motivation—adequate rationale

The person of ordinary skill would have had a reasonable expectation of success in formulating the besylate salt of amlodipine because Patent A contemplates multiple counterions for amlodipine and Reference B identifies besylate as an FDA-approved anions useful in pharmaceutical formulations generally. The skilled artisan would have been motivated to select besylate from the list in Reference B because Reference C identifies problems with the conventional maleate salt and explains why besylate avoids those problems. The skilled artisan would have been further motivated to select besylate as the counterion for amlodipine because aryl sulfonic acids were known to increase solubility of reactive-amine-containing pharmaceuticals.
Example 4: Codon optimization

A fertile transgenic maize plant comprising:

   a foreign DNA sequence encoding a *Bacillus thuringiensis* insecticidal protein toxic to European corn borer stably incorporated into the plant's genome, the foreign DNA comprising a nucleic acid coding sequence modified from the nucleic acid coding sequence of the native *Bacillus thuringiensis* gene encoding the insecticidal protein [Bt] to increase expression of [Bt] in the transgenic plant;

   wherein the transgenic plant expresses [Bt] in plant leaf tissue at greater than about 1-5 ng [Bt] per mg soluble leaf protein, and the leaf tissue causes mortality to European corn borer, and

   wherein the foreign DNA nucleic acid coding sequence has a G+C content of at least . . . 60 percent.
Example 4: Limitation at issue

A fertile transgenic maize plant comprising:

   a foreign DNA sequence encoding a *Bacillus thuringiensis* insecticidal protein toxic to European corn borer stably incorporated into the plant's genome, the foreign DNA comprising a nucleic acid coding sequence modified from the nucleic acid coding sequence of the native *Bacillus thuringiensis* gene encoding the insecticidal protein [Bt] to increase expression of [Bt] in the transgenic plant;

   wherein the transgenic plant expresses [Bt] in plant leaf tissue at greater than about 1-5 ng [Bt] per mg soluble leaf protein, and the leaf tissue causes mortality to European corn borer, and

   wherein the foreign DNA nucleic acid coding sequence has a G+C content of at least about 60 percent.
Example 4: Prior art

- Patent A teaches that when plants are engineered to express Bt protein, they effectively generate their own insecticide because Bt is toxic to insects.

- Patent A describes a method for improving Bt expression in plants by selecting codons preferred by the native plant.

- Patent A’s working examples all use tobacco plants, but Patent A teaches that its methodology and results would be “equally applicable in other plant species.”

- Patent A teaches that the native Bt gene is 38 percent G+C.

- Patent A teaches it is only necessary to change the first 25 codons or so but also speculates that changing all codons “might still be expected” to improve expression.

- Reference B teaches that the coding regions of corn genes tend to be high in G+C.

- A synthetic Bt gene with a coding region consisting entirely of corn-preferred codons would necessarily have a G+C content of over 60 percent.
Example 4: Optimization within prior-art conditions—inadequate rationale

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. It would therefore have required only routine optimization to arrive at a Bt-encoding sequence with a G+C content of at least about 60 percent.

This rationale does not explain why it would have been routine optimization to arrive at the claimed invention and why a person of ordinary skill in the art would have had a reasonable expectation of success in applying Patent A’s method to corn plants to arrive at the claimed G+C content level.
Example 4: Optimization within prior-art conditions—adequate rationale

Routine optimization of the G+C content of Patent A’s Bt-encoding DNA sequence would have led to the claimed range of at least 60 percent because Patent A teaches selecting plant-preferred codons and suggests doing so for the entire coding sequence. The person of ordinary skill in the art would have found it obvious to optimize all of the codons to the claimed G+C content because Reference B teaches that corn prefers high levels of G+C and that optimizing every codon necessarily results in more than 60 percent G+C.
Example 4: Teaching-suggestion-motivation—adequate rationale

The person of ordinary skill would have had a reasonable expectation of success in selecting Reference B’s high G+C content for providing Patent A’s Bt-encoding nucleic-acid sequence in corn because Patent A suggests optimizing the entire sequence, while Reference B teaches that optimizing every codon in the Bt sequence for corn would necessarily result in the claimed G+C content. The skilled artisan would have been motivated to select Reference B’s high G+C content because Reference B teaches that corn prefers high G+C content and Patent A teaches that expressing Bt in plants aids in insect resistance.
Summary

• An obviousness rejection must explain why the invention as a whole would have been obvious over the cited prior art.
• Clear obviousness rejections permit applicants, examiners, and reviewers to understand why a claim has been rejected.
Thank you!

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