

Securing IP rights in nanotechnology



April 14, 2008

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Nanofiber technologies for novel filtration and lighting applications

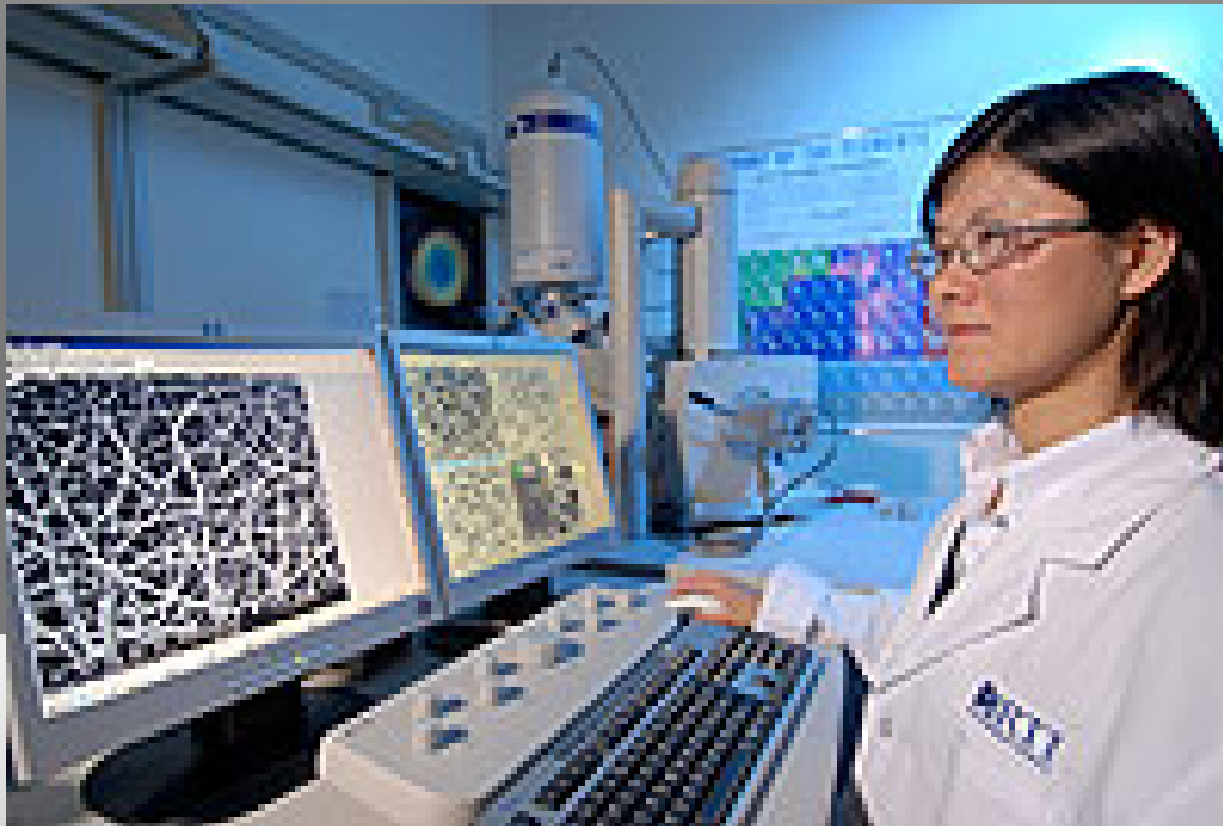
- ★ Working with Research Triangle Institute since 2003 in developing a patent portfolio in nano-fiber and nano-particle production systems, methods, and articles
- ★ Diversity in patent applications and claims, with claims directed to emerging production units, production methods, and novel fiber/particle constructs

Nanofiber technologies for novel filtration applications

- ★ Research conducted at the nanoscale is improving air filters used in homes and in respirators by increasing the filtering efficiency for removing airborne particulates. Nanostructures, such as RTI's nanofibers, with a small size, light weight, and high surface-to-volume ratio, can effectively trap smaller particles than conventional filters.
- ★ The small size of these nanofibers is also advantageous in that they offer less resistance to air flow than do the larger materials commonly used in constructing filters for HVAC systems and respirators. Hence, less energy is required to push air through the filter and the filter can operate with a lower pressure drop.

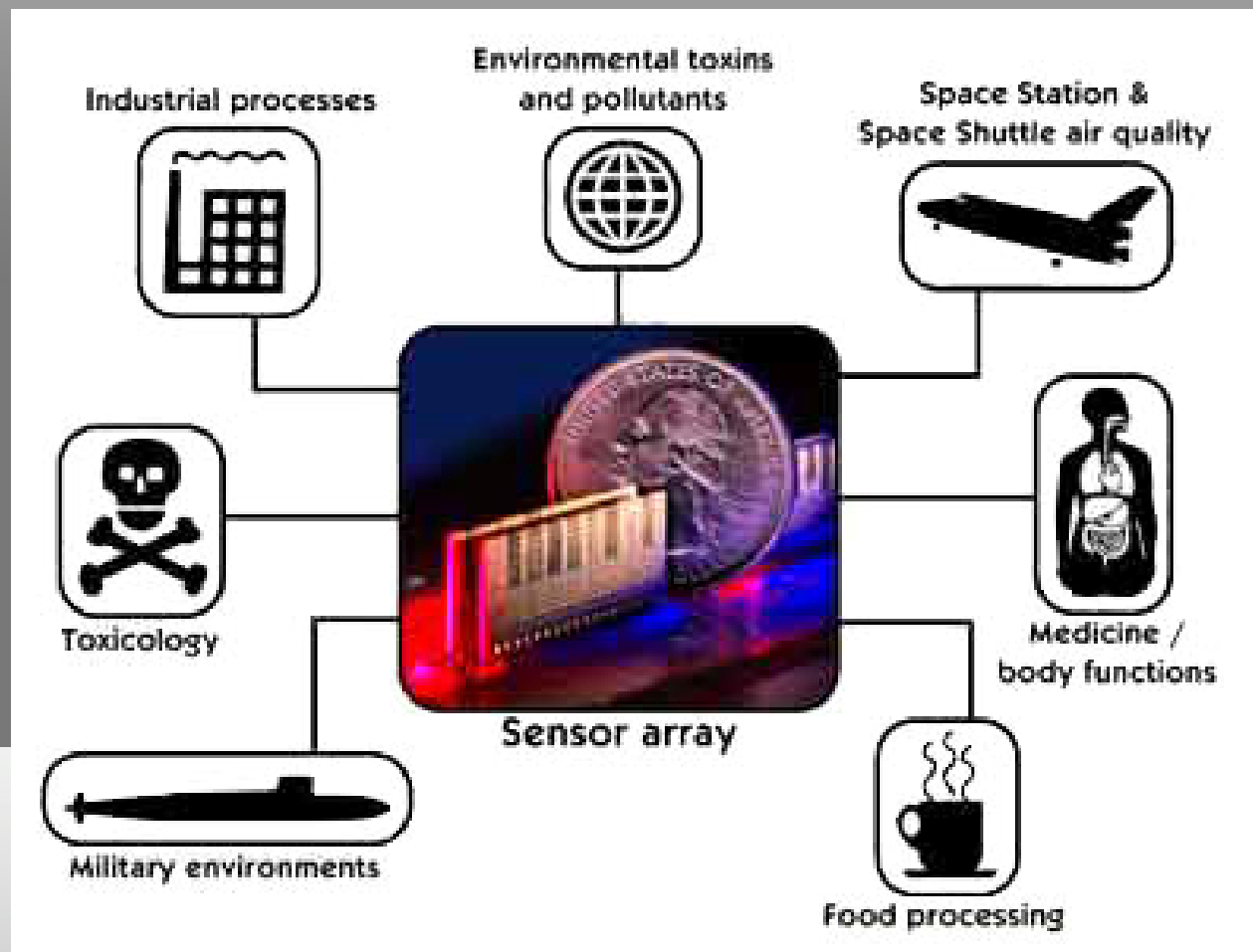
Nanofiber technologies for novel filtration applications

- ✦ RTI researchers have discovered a method of reducing the nanofiber size while maintaining suitable structure and support for the filter



Nanofiber technologies for novel sensing applications

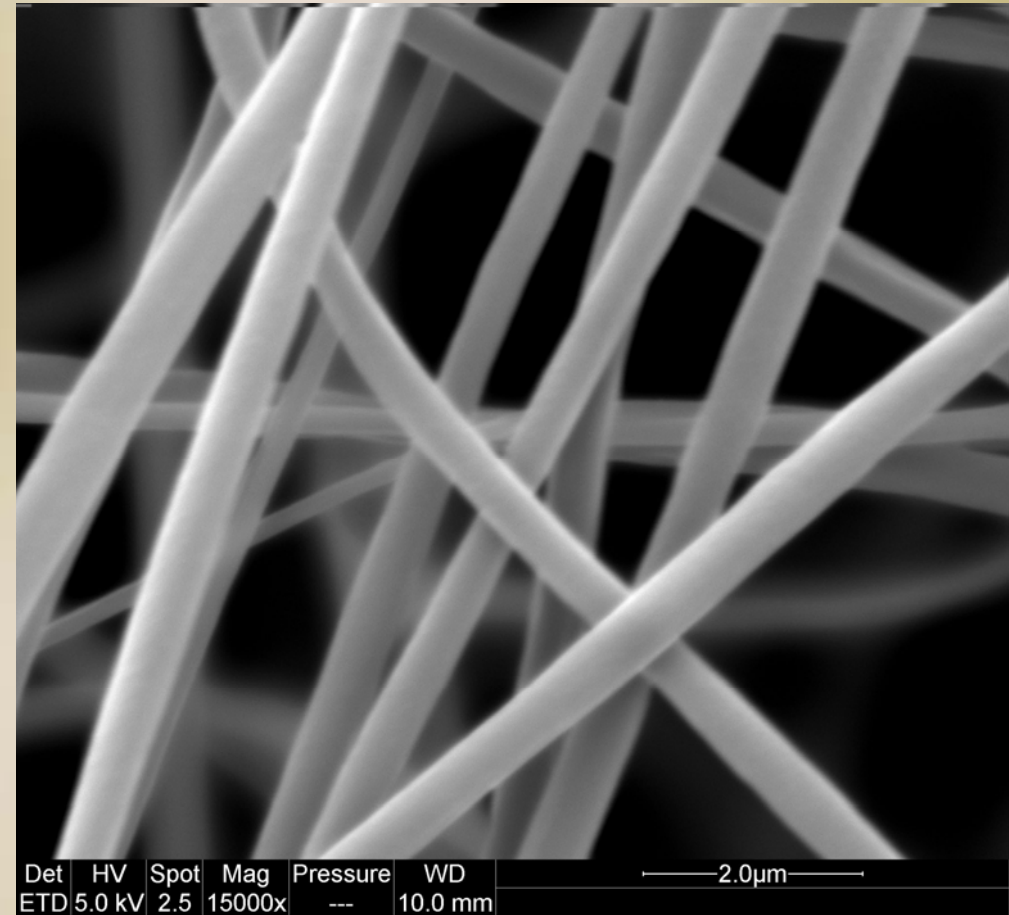
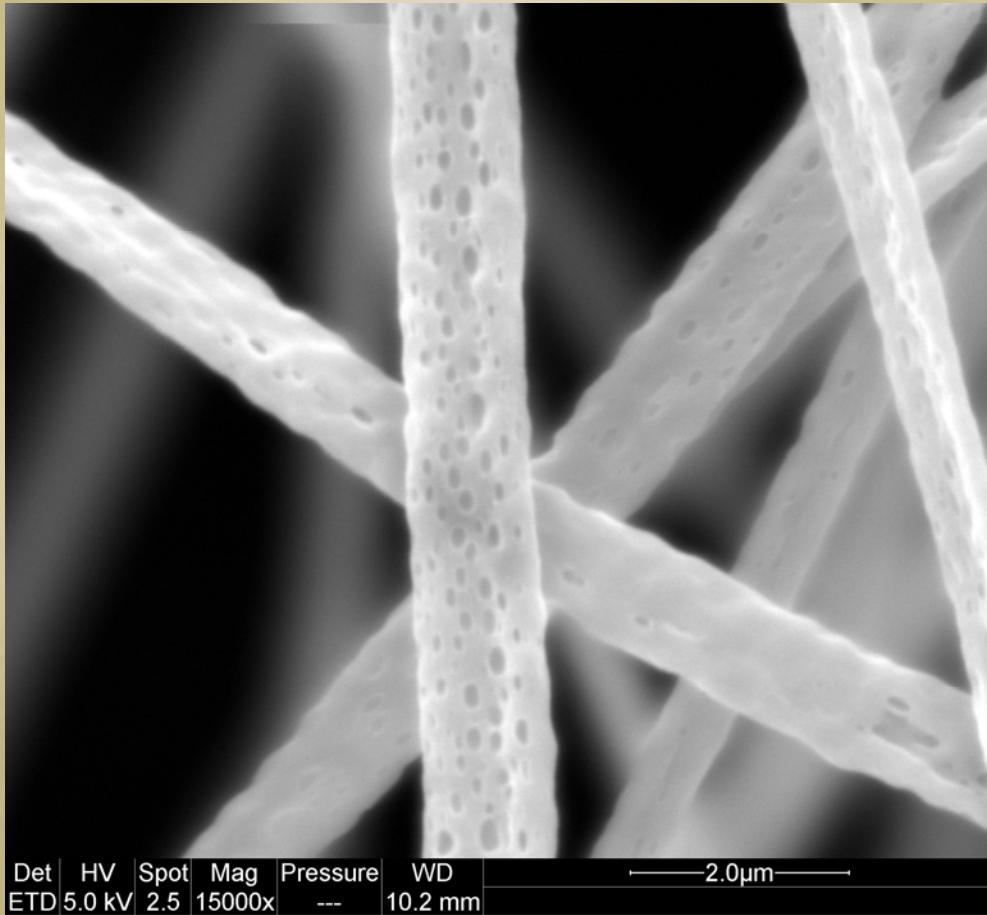
✦ RTI's nanotechnology-based electronic nose



Nanofiber technologies for novel lighting applications

- ★ **DOE Recipient: RTI International**
Title: Photoluminescent Nanofibers for High-Efficiency Solid-State Lighting
Summary: The RTI approach is an improved secondary converter comprised of quantum dots (QDs) embedded in high surface area polymer nanofibers to create a photoluminescent nanofiber (PLN). RTI indicates that PLNs dramatically improve the external quantum efficiency, color rendering properties, and lifetimes of SSL devices incorporating this technology.

Nanofiber technologies for novel lighting applications



Securing IP rights in nanotechnology

★ Diversity in patent applications and claims

★ Prosecution Strategies

- full disclosure of known art in related macro-fiber applications and known nano-fiber properties art

- interview cases with the examiners in person and with the inventors

- convince the examiners of the significance of the invention

KSR Int'l Co. v. Teleflex Inc., 550 U.S. —, 82
USPQ2d 1385 (2007) Reaffirms the *Graham*
Analysis for Obviousness

"In *Graham* [], the Court set out a framework for applying the statutory language of § 103, . . . [T]he factors continue to define the inquiry that controls. If a court, or patent examiner, conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid under § 103." *KSR* at 1391.

EXAMINATION GUIDELINES ON KSR

57526

Federal Register / Vol. 72, No. 195 / Wednesday, October 10, 2007 / Notices

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard (see ADDRESSES) at least 5 days prior to the meeting date.

Dated: October 3, 2007.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. E7-19623 Filed 10-9-07; 8:45 am]
BILLING CODE 3510-23-5

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO-P-2007-0031]

Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 In View of the Supreme Court Decision In *KSR International Co. v. Teleflex Inc.*

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO) is publishing examination guidelines for determining obviousness under 35 U.S.C. 103 in view of the Supreme Court decision in *KSR International Co. v. Teleflex Inc.* These guidelines will assist USPTO personnel to make a proper determination of obviousness under 35 U.S.C. 103 and to provide an appropriate supporting rationale.

DATES: These guidelines are effective October 10, 2007.

FOR FURTHER INFORMATION CONTACT: Contact either Kathleen Kahler Fonda, Legal Advisor (telephone (571) 272-7754; e-mail kathleen.fonda@uspto.gov) or Pinchus M. Laufer, Patent Examination Policy Analyst (telephone (571) 272-7726; e-mail pinchus.laufer@uspto.gov), of the Office of the Deputy Commissioner for Patent Examination Policy. Alternatively, mail may be addressed to Ms. Fonda or Mr. Laufer at Commissioner for Patents, attn: KSR, P.O. Box 1450, Alexandria, VA 22313-1450.

SUPPLEMENTARY INFORMATION: These guidelines are intended to assist Office personnel to make a proper determination of obviousness under 35 U.S.C. 103, and to provide an appropriate supporting rationale in view of the recent decision by the Supreme Court in *KSR International Co. v. Teleflex Inc.* (*KSR*).¹ The guidelines are

based on the Office's current understanding of the law, and are believed to be fully consistent with the binding precedent of the Supreme Court.²

These guidelines do not constitute substantive rule making and hence do not have the force and effect of law. They have been developed as a matter of internal Office management and are not intended to create any right or benefit, substantive or procedural, enforceable by any party against the Office. Rejections will continue to be based upon the substantive law, and it is these rejections that are appealable. Consequently, any failure by Office personnel to follow the guidelines is neither appealable nor petitionable.

To the extent that earlier guidance from the Office, including certain sections of the current Manual of Patent Examining Procedure (MPEP), is inconsistent with the guidance set forth herein, Office personnel are to follow these guidelines. The next revision of the MPEP will be updated accordingly.

I. The *KSR* Decision and Principles of the Law of Obviousness

Teleflex owned a patent claiming technology useful in the gas pedal of a car. The invention at issue in *KSR* was a pedal assembly that could be adjusted to accommodate drivers of different statures. The electronic pedal-position sensor was positioned on the support for the pedal assembly, and the pivot point of the pedal remained fixed regardless of how the pedal assembly was adjusted. This combination of the fixed pivot point for the adjustable pedal and the fixed sensor position on the support resulted in a simpler, lighter, and more compact design.

Teleflex sued *KSR* for infringement. The district court cited references that separately taught adjustable pedals and sensors, and found on summary judgment that Teleflex's patent was invalid for obviousness. On appeal, the Federal Circuit vacated the district court's decision, and remanded the case. The Federal Circuit stated that "the district court's analysis applied an incomplete teaching-suggestion-motivation test" in arriving at the finding of obviousness.³

Upon *KSR*'s petition for review of the Federal Circuit's decision, the Supreme Court reversed, concluding that the district court had correctly determined that the patent was invalid for

obviousness. The Supreme Court reaffirmed the familiar framework for determining obviousness as set forth in *Graham v. John Deere Co.*, but stated that the Federal Circuit had erred by applying the teaching-suggestion-motivation (TSM) test in an overly rigid and formalistic way.⁴ Specifically, the Supreme Court stated that the Federal Circuit had erred in four ways: (1) "By holding that courts and patent examiners should look only to the problem the patentee was trying to solve;"⁵ (2) by assuming "that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem;"⁶ (3) by concluding "that a patent claim cannot be proved obvious merely by showing that the combination of elements was 'obvious to try'";⁷ and (4) by overemphasizing "the risk of courts and patent examiners falling prey to hindsight bias" and as a result applying "rigid preventative rules that deny factfinders recourse to common sense."⁸

In *KSR*, the Supreme Court particularly emphasized "the need for caution in granting a patent based on the combination of elements found in the prior art,"⁹ and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on its precedent that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."¹⁰ The Supreme Court stated that there are "[t]hree cases decided after *Graham* [that] illustrate this doctrine."¹¹ (1) "In *United States v. Adams*, * * * [t]he Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result."¹² (2) "In *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, * * * [t]he two [pre-existing elements] in combination did no more than they would in separate, sequential operation."¹³ (3) "[I]n *Sakurada v. A.G. Pro, Inc.*, the Court derived * * * the conclusion that when

¹ 550 U.S. at __, 42 USPQ2d at 1360.

² *Id.* at __, 42 USPQ2d at 1367.

³ *Id.*

⁴ *Id.*

⁵ *Id.*

⁶ *Id.* at __, 42 USPQ2d at 1365.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ Further developments in the law of obviousness are to be expected in view of *KSR*. Thus, it is not clear which Federal Circuit decisions will retain their viability.

¹² *Teleflex Inc. v. KSR Int'l Co.*, 119 Fed. Appx. 282, 284 (Fed. Cir. 2005).

MPEP GUIDELINES ON KSR

2145

MANUAL OF PATENT EXAMINING PROCEDURE

(2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval). <

If the examiner determines there is factual support for rejecting the claimed invention under 35 U.S.C. 103, the examiner must then consider any evidence supporting the patentability of the claimed invention, such as any evidence in the specification or any other evidence submitted by the applicant. The ultimate determination of patentability is based on the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence. *In re Oenker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The legal standard of "a preponderance of evidence" requires the evidence to be more convincing than the evidence which is offered in opposition to it. With regard to rejections under 35 U.S.C. 103, the examiner must provide evidence which as a whole shows that the legal determination sought to be proved (i.e., the reference teachings establish a *prima facie* case of obviousness) is more probable than not.

When an applicant submits evidence, whether in the specification as originally filed or in reply to a rejection, the examiner must reconsider the patentability of the claimed invention. The decision on patentability must be made based upon consideration of all the evidence, including the evidence submitted by the examiner and the evidence submitted by the applicant. A decision to make or maintain a rejection in the face of all the evidence must show that it was based on the totality of the evidence. Facts established by rebuttal evidence must be evaluated along with the facts on which the conclusion of obviousness was reached, not against the conclusion itself. *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990).

See *In re Pisonetti*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984) for a discussion of the proper roles of the examiner's *prima facie* case and applicant's rebut-

tal evidence in the final determination of obviousness. See MPEP § 706.02(j) for a discussion of the proper contents of a rejection under 35 U.S.C. 103.

2143 >Examples of< Basic Requirements of a *Prima Facie* Case of Obviousness

**>The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395-97 (2007) identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham*. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.

EXEMPLARY RATIONALES

Exemplary rationales that may support a conclusion of obviousness include:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Rev. 6, Sept. 2007

2100-128

MPEP and Guideline Highlights

- ★ Categorization of Seven Kinds of Obviousness Type Rejections and Requirements on Examiner for Prima Facie Obviousness
- ★ Rebuttal Evidence by Applicant
- ★ Three Listed Types of Rebuttal Evidence



Highlights

- ★ The examiners are fact finders
- ★ Once the findings of fact are articulated, office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C. 103. 35 U.S.C. 132 requires that the applicant be notified of the reasons for the rejection of the claim so that he or she can decide how best to proceed.
- ★ Clearly set forth findings of fact and the rationale(s) to support a rejection in an Office Action - - leads to the prompt resolution of issues pertinent to patentability.

Rationales To Support Rejections Under 35 U.S.C. 103

★ *KSR* quoting *In re Kahn* 41 stated that “ ‘[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’ ”

Rationales

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



Rationales (Continued)

- (5) “Obvious to try” —choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success
- (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 would have been predictable to one of ordinary skill in the art
- (7) 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.



1) Combining Prior Art Elements According to Known Methods To Yield Predictable Results

Office personnel must articulate the following:

- (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;
- (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately;
- (3) a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.



1) Combining Prior Art Elements According to Known Methods To Yield Predictable Results (Continued)

- 5) The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention.
 - 6) It can be 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.
- ★ If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.



2) Simple substitution of one known element for another to obtain predictable results

Office personnel must articulate the following:

- (1) a finding that the prior art contained a device (method, product, etc.) which differed from the claimed device by the substitution of some components (step, element, etc.) with other components;
- (2) a finding that the substituted components and their functions were known in the art;
- (3) a finding that one of ordinary skill in the art could have substituted one known element for another, and the results of the substitution would have been predictable; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.



2) Simple substitution of one known element for another to obtain predictable results (Continued)

- 5) **The rationale to support a conclusion that the claim would have been obvious is that the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.**
- 6) **If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.**

Consideration of Applicant's Rebuttal Evidence

- ★ Office personnel should consider all rebuttal evidence that is timely presented by the applicants when reevaluating any obviousness determination. Rebuttal evidence may include evidence of “secondary considerations,” such as “commercial success, long felt but unsolved needs, [and] failure of others, and may also include evidence of unexpected results.



Rebuttal Evidence

- ★ Applicants may submit evidence or argument to demonstrate that:
 - (1) one of ordinary skill in the art could not have combined the claimed elements by known methods (e.g., due to technological difficulties);
 - (2) the elements in combination do not merely perform the function that each element performs separately; or
 - (3) the results of the claimed combination were unexpected.



Rebuttal: Unexpected Results

- ★ *In re Soni* 54 F3d 746 1995
- ★ Consistent with the rule that all evidence of nonobviousness must be considered when assessing patentability, the PTO must consider comparative data in the specification in determining whether the claimed invention provides unexpected results. However, it is well settled that unexpected results must be established by factual evidence. Mere argument or conclusory statements in the specification does not suffice

Rebuttal: Unexpected Results

- ★ In *Takeda v. Alphapharm* 492 F.3d 1350, 83 USPQ2d 1169 (Fed. Cir. 2007)
 - ✦ No reason to choose “compound b” out of “hundreds of millions of TZD compounds” in the prior art disclosure
 - ✦ Review article of 101 TZD compounds (including “compound b”) teaches away from “compound b”
 - ✦ Unexpected reduced toxicity of pioglitazone compared to “compound b”

Rebuttal: Unexpected Results

★ Court Rationale in Takeda v. Alphapharm

- ✦ No “finite number of identifiable, predictable solutions”
- ✦ Prior art provided “broad selection of compounds”
- ✦ Closest prior art compound exhibited negative properties

★ Holding

- ✦ Patent valid – compound nonobvious

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★ TSM test after *KSR v. Teleflex*

- still a valid test
- still commonly used
- attacking the motivation frequently results in new motivation from examiner

TSM Remains a Valid Approach to the *Graham* Inquiries under *KSR*

"When it first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious, the Court of Customs and Patent Appeals captured a helpful insight. . . . There is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis."

KSR at 1396.

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

- ★ The TSM test is just one of a number of valid rationales that may be employed when determining obviousness under 35 U.S.C. § 103.
- ★ The inapplicability of the TSM test does not necessarily result in a conclusion of non-obviousness.

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- ★ From TSM, MPEP indicates that Office personnel must articulate the following:
- ★ (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;
- ★ (2) a finding that there was reasonable expectation of success; and
- ★ (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

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- ★ If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.
- ★ The Courts have made clear that the teaching, suggestion, or motivation test is flexible and an explicit suggestion to combine the prior art is not necessary. The motivation to combine may be implicit and may be found in the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved.

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- ★ In such situations, the proper question is whether the ordinary artisan possesses knowledge and skills rendering him *capable* of combining the prior art references

Practice Tips

- ★ Interview the examiner and include the inventor in the interview
- ★ Use MPEP criteria to request examiner's reasoning for not allowing case beyond the usual conclusory statements
- ★ Present rebuttal evidence
- ★ Consider placing or pointing out secondary evidence
 - When needed to overcome art, or
 - Against future invalidity charges
- ★ Link secondary evidence such as unexpected results to more conventional arguments such as reasonable expectation of success, impermissible hindsight, teaching away
- ★ Engage inventor in identification of unexpected results

