

# Patenting Strategies for Nanotechnology Inventions: Establishing that the Invention Was Not Obvious

FOR:  
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## Topics For Today

- Legal Analysis – Patents – in Context
- The Statute - What is Obviousness?
- Factors from Case Law - How do we get past examiner rejections under §103?
- Lessons from Prosecution History
- 2010 KSR Guidelines Update
- Examiner Rejections and Practitioner Arguments in Traverse
- US Patent No. 7,776,817 Case History of §103(a) Claim Rejections
- The way forward?
- Your Questions...



# Legal Analysis – Patents – in Context

Patentability - New, Useful and **Non-obvious**

Bar Dates – By statute, cannot obtain a patent if...

Breadth of Claims – “Prior Art” of others can limit you to narrow claims

Infringement detection - Can you detect if others are practicing your invention?

Third party rights - Joint ownership reduces value; work-around: assignments, licenses, etc.

Government rights – if applicable (i.e. Federal Acquisition Regulations (FAR) contracts or University research)

“Subject Invention” – under the FAR, USG can have rights...

“Authorization and Consent” – under the FAR, USG can give you permission to infringe any and all US patents. Remedy of patent owner v. the USG in the Federal Court of Claims...

“Bayh-Dole Act” – University research sponsored by the USG...can limit transfer rights.

Appropriate protection?

Patent, Trademark, Copyright, Trade Secret or Defensive Publication



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# The Statute - What is Obviousness?

- The standard for obviousness is initially set forth in 35 U.S.C. 103(a) which states in relevant part: "A patent may not be obtained though the invention is not identically disclosed or described [in the prior art], if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."



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# Factors from Case Law - How do we get past examiner rejections under §103?

The U.S. Supreme Court case Graham v. John Deere 383 U.S. 1, 17-18 (1966) set forth the basic factual inquiries to determine obviousness. They are:

- (1) ascertaining the scope and content of the prior art;
- (2) ascertaining the differences between the claimed invention and the prior art; and
- (3) resolving the level of ordinary skill in the pertinent art.

The Court also identified six indicia of nonobviousness:

- (1) evidence of commercial success;
- (2) long-felt but unresolved need;
- (3) failure of others;
- (4) unexpected results;
- (5) skepticism of experts; and
- (6) copying by others.



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# More Factors from Case Law

- In 2007, the U.S. Supreme Court revisited the obviousness standard in KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007) and abrogated the strict TSM test as but one of several factors. In all the court identified seven exemplary rationales supporting an obviousness rejection (See also the MPEP §2141 et seq)
- (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 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;
- (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; and
- (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. (This is the old TSM test)





# Lessons from Prosecution History

- Quite often we see in Office Actions that the Examiner does not expressly point to one of the exemplary rationales listed in KSR (nor is he required to do so). Instead, from reading the examiner's rationale, we must determine what factors she may be relying on. Chief among the most problematic are:
  - Obvious to try rationale - that we merely chose from a finite number of possible ... and obtained a predictable solution.
  - Additionally, as you can see, a number of the exemplary obviousness rationales refer to predictable results.



# 2010 KSR Guidelines Update

- Grouped cases into four categories for the examiner corps. The first three track roughly with three found in the 2007 KSR Guidelines:
- 1) Combining prior art elements – examiner must identify reason to so combine.
- 2) Substituting one known element for another – analogous art – OSA capable of making the substitution and the result would have been predictable See MPEP §2143(B)
- 3) Obvious to try – courts are now applying the KSR “finite number of identified predictable solutions” in a manner that places particular emphasis on predictability and the reasonable expectations of OSA. May be proper when possible options are known and finite. See Rolls Royce v. UTC, 603 F.3d 1324, 1328-29 (Fed. Cir. 2009).
- 4) New for the 2010 Guidelines – Consideration of evidence during prosecution. Even though all evidence must be considered in an obviousness analysis, evidence of nonobviousness may be outweighed by contradictory evidence in the record or by what is in the specification. See PharmaStem v. Viacell, 491 F.3d 1342 (Fed. Cir. 2007).



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# Examiner Rejections and Practitioner Arguments in Traverse

- Examiners must still state their Prima Facie case for rejecting claims under §103 as obvious. “Simply stating the principle without providing an explanation of its applicability to the facts of the case at hand is generally not sufficient...” (See 2010 KSR Guidelines Update)
- Since KSR, practitioners have shifted their nonobviousness arguments but still applicable are: teaching away from the claimed invention by the prior art, lack of a reasonable expectation of success, and unexpected results.



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# Examples from Class 977 Nanotechnology Patents

## US Patent No. 7,776,817 Case History

- Issued on Aug 17, 2010 directed to Neuregulins for prevention and treatment of damage from acute assault on vascular and neuronal tissue and as regulators of neuronal stem cell migration.
- After making Applicant elect a species for prosecution (Restriction Requirement) in First Office Action, in rejecting Claims in prosecution, among other grounds, the examiner cited §103(a).



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# US Patent No. 7,776,817 Case History – First Office Action

- At page 4 of Non-Final (the first) Office Action, the examiner rejected Claims 7,8,10 and 20-21 as obvious under §103(a) in view of a combination of other references.
- Examiner said it would have been obvious to OSA to determine optimal ranges of time and dosage to administer...
- Because disclosure did not specify “criticality” of the claimed ranges of time and dosage, “optimization within prior art conditions or through routine experimentation” is obvious to OSA.



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# US Patent No. 7,776,817 Case History – Applicant’s Response

- To First office Action – Applicant argues in traverse that the “examiner has failed to establish a prima facie case of obviousness, since (the references in combination) do not teach or suggest all the limitations of Claims 7 and 8.”
- Applicant also includes other Remarks and tenders (by right) a set of Amended Claims.



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# US Patent No. 7,776,817 Case History – Office Action made Final

- Examiner issues the next OA and makes Final (of note - entry of amendments to Claims no longer by Applicant's right – now only with permission of examiner).
- Rationale – arguments not persuasive, well established that neuregulin promotes neural development... also well known that organophosphates comprising insecticides or pesticides produce neuronal damage and degeneration. MPEP 2144 states “rationale to modify or combine the prior art does not have to be expressly stated ... may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to OSA.” Goes on to write that it is obvious to perform “simple substitution.”



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# US Patent No. 7,776,817 Case History – Applicant’s Response to Final

- Applicant had tendered amendments to Claims 7,8 and 10, yet examiner maintained §103 rejections. In attacking examiner’s *obvious to substitute* argument, applicant writes that “EGF-like domain has been found in a large number of animal proteins having completely different functions.”
- The applicant cites a BPAI decision re: DNA... and stresses that “given the fact that biotechnology is an unpredictable art, the cited references would not render it obvious that...” also that “the scientific knowledge and legally established standards do not provide OSA, at the time the invention was made, a reasonable expectation of success.”
- Applicant then files a RCE to keep case alive...
- Examiner accepts, then issues another Restriction Requirement... Species III elected...



# US Patent No. 7,776,817 Case History – Next OA

- By RCE made non-final – examiner stays on with §103 rejections “...obvious to modify method of administration of neuregulin as taught by Xu et al. with administration of neuregulin as taught by Shimkets...” and says OSA would have been motivated to so combine. “Thus the claimed invention was prima facie obvious over the combined teachings of the art.”



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# US Patent No. 7,776,817 Case History – Response to OA

- After telephonic interview where Applicant said that the Xu reference was the work of applicant...
- Attacks prima facie case: “all words” must be considered, and “a clear articulation” must be provided by examiner.



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# US Patent No. 7,776,817 Case History – Notice of Allowance

- Finally – appears scope narrowed from Neuregulin to Neuregulin-1.
- With last set of claim amendments and with examiner now considering arguments against Shimkets reference as persuasive.
- Applicant had submitted exhibits with last response to bolster his arguments.



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# The Way Forward, and... Your Questions?

- Attack §103 rejections on all fronts at once and stay on course. Keep the examiner honest and make him/her meet the standards in the rules for identifying and defending with clear rationale all obviousness rejections under §103 and per the MPEP Chapter 2100.
- Thanks for your attention and interest in this area of the law.
- If you think of something later, feel free to call us at:  
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