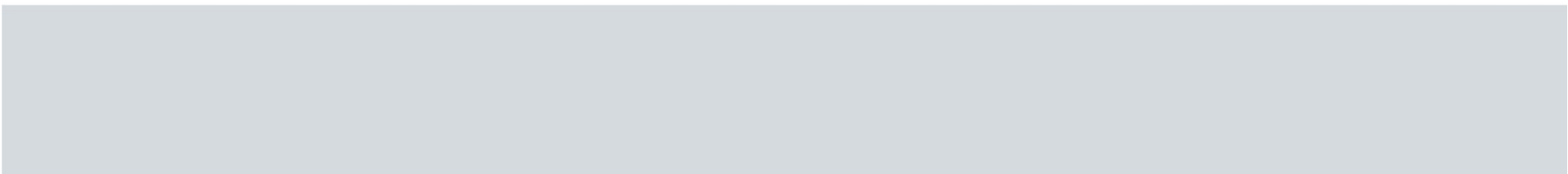


Enablement in the Chemical Arts

Carlyn A. Burton
Osha Liang LLP
October 21, 2009

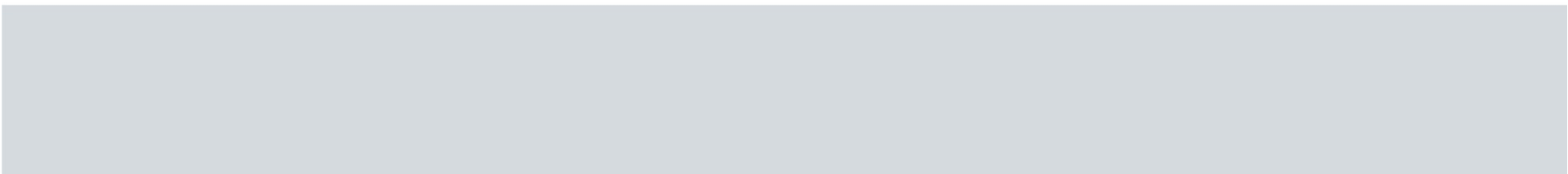
Overview – The Patent Bargain

- An inventor must, through a patent specification, place the public in possession of his invention, so that the public may exploit and otherwise receive the benefit of the invention upon the patent's expiration.
 - Requirements under 35 U.S.C. § 112:
 - Written Description
 - Enablement
 - Best Mode
- 

35 U.S.C. 112, ¶ 1

- The specification shall contain a written description of the invention, and of the manner and process of making and using it, ***in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same***, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The Enablement Requirement

- The invention will be freely available to the public once the patent term expires
 - The specification must contain more than vague intimations of general ideas that may or may not be workable
 - The specification must enable a person of ordinary skill in the art how to make and use the full scope of the claimed invention without undue experimentation.
- 

How is Enablement Determined?

- Is the experimentation necessary to make or use the invention undue or unreasonable?
 - Unless information is well known in the art, the application must itself contain this information.
 - For information not present in the application, the applicant can only rely on the ordinary level of skill in the art to fill in the gaps omitted from the disclosure
 - In determining whether a claim is enabled, the examiner considers only the state of the art as of the application filing date and not developments arising during the pendency of the application.

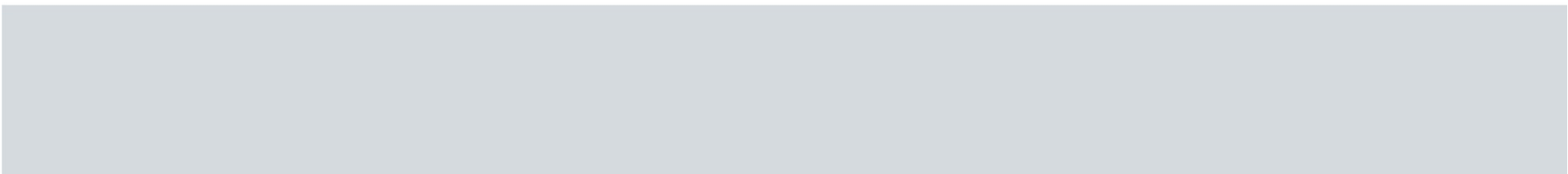
Undue Experimentation

- Quantity of experimentation necessary
- Amount of direction or guidance presented
- Presence or absence of working examples
- Nature of the invention
- State of the prior art
- Relative skill of those in the art
- Predictability or unpredictability of the art
- Breadth of the claims

-*In re Wands*, 858 F.2d 731
(Fed. Cir. 1988)



Undue Experimentation – The Threshold Factors

- Quantity of experimentation necessary
 - Amount of direction or guidance presented
 - Presence or absence of working examples
 - Nature of the invention
 - State of the prior art
 - Relative skill of those in the art
 - ***Predictability or unpredictability of the art***
 - ***Breadth of the claims***
- 

The Threshold Factors

- The other factors are much less relevant when:
 - the art is predictable
 - the claims are narrow enough to only encompass examples described in the specification

When the art is predictable

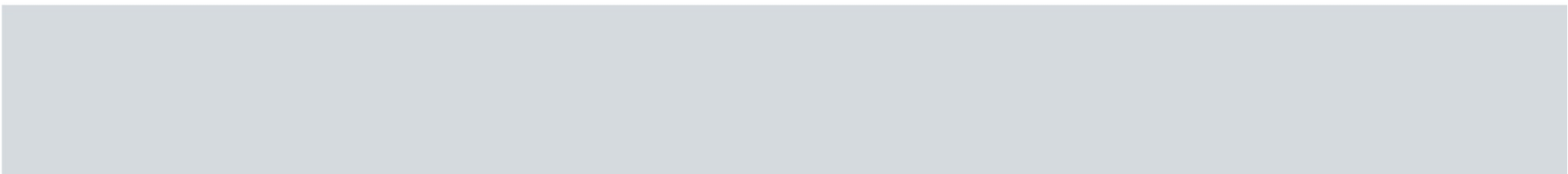
- In the predictable arts, disclosure of a single embodiment will be enabling “in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws.”

-*In re Fisher*, 427 F.2d 833
(C.C.P.A. 1970)

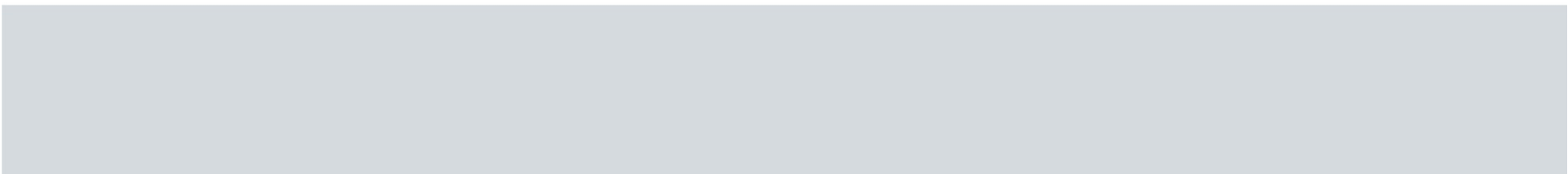
Reliance on Knowledge of One Skilled in the Art

- In “predictable” arts, a patentee can rely on the knowledge of one skilled in the art to fill in any gaps or pieces missing from the specification and still fulfill the enablement requirement.
- In the “unpredictable” arts, a patentee cannot as easily rely on the knowledge of one skilled in the art, because one skilled in the art might not necessarily be able determine what was missing due to the “unpredictability” of the subject matter.

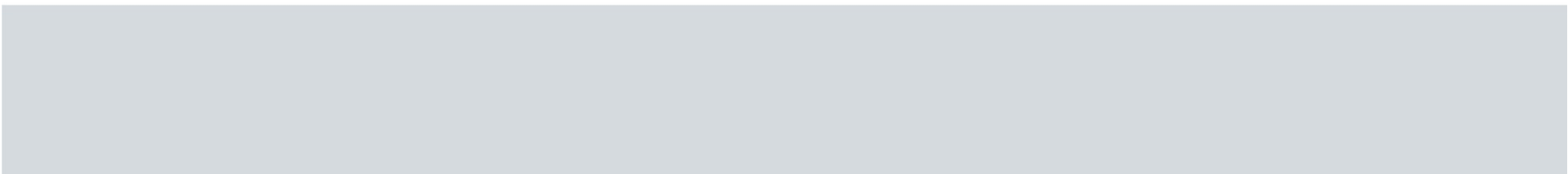
What are Predictable and Unpredictable Arts?

- Electrical arts: can easily predict what occurs when circuits are combined
 - Mechanical arts: can use thermodynamics to predict how much power a new engine will produce
 - In comparison to the mechanical and electrical arts
 - Chemistry
 - Biotechnology
- 

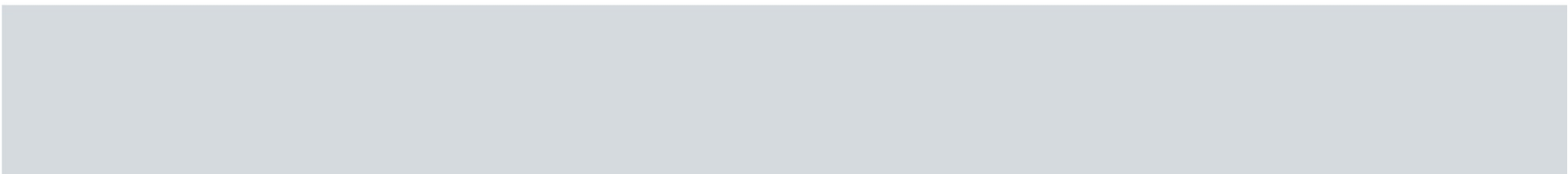
Even when the art is predictable

- Recent Federal Circuit cases in the “predictable arts” have required full scope enablement
 - Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371 (Fed. Cir. 2007)
 - Auto. Tech. Int’l Inc., v. BMW, 501 F.3d 1274 (Fed. Cir. 2007)
 - Sitrick v. DreamWorks, LLC, 516 F.3d 993 (Fed. Cir. 2008)
- 

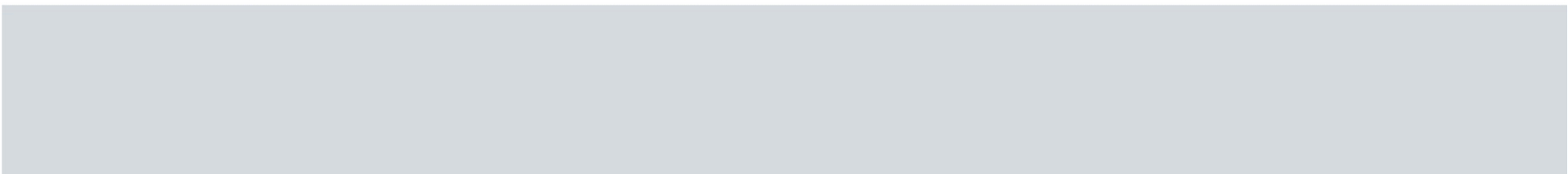
Why the Chemical Arts are Unpredictable

- Environmental factors can have a drastic effect on reaction pathways
 - Small changes in bonding or the addition of an atom or a molecule to a chemical structure can have dramatic macroscopic and microscopic effects.
- 

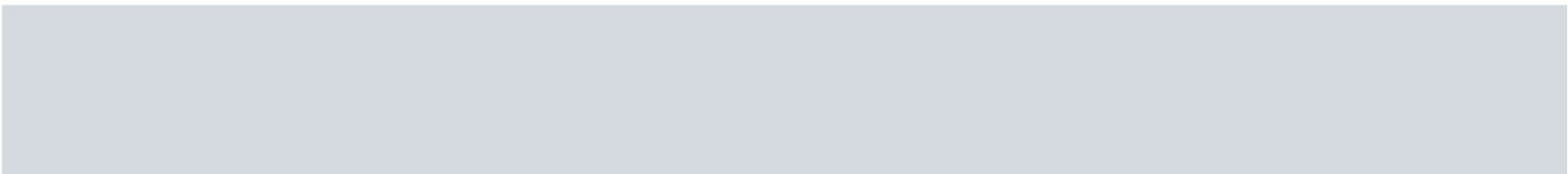
Why the Chemical Arts are Unpredictable: Examples

- The addition of a side-group onto the polymer chain tends to turn a flexible polymer such as butadiene into a brittle polymer such as styrene.
 - The change of a double bond between atoms to a single bond transforms an unsaturated fat to one that is saturated.
- 

Unpredictability in the Chemical Art

- Three examples of where the issue of enablement often arises
 - No disclosure of how to make a chemical compound
 - Little or no information on how to use the compound
 - The scope of the method claim is broader than the teaching in the specification
- 

Example 1: Lack of “How to Make”

- Where a chemical compound claim is presented, and there is no disclosure of how to make this chemical compound.
 - To meet the enablement requirement:
 - At least one method for making and using is disclosed proportional to the claimed invention
 - Disclosure of starting materials and apparatus
- 

Example 1: Lack of “How to Make”

- *In re Howarth*
 - Preparation of the claimed derivatives of clavulanic acid is disclosed; however, the specification includes no disclosure of how to make the starting material, clavulanic acid.
 - The Court:
 - The existence of a foreign patent directed to clavulanic acid does not necessarily mean that the information is within the knowledge of one of ordinary skill in the art.
 - This rejection could have been eliminated by simply including a reference to the foreign patent.

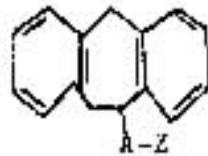
Example 2: Lack of “How to Use”

- Disclosure of a class of compounds without indicating an intended use.
- Disclosure of compounds without the disclosure of the properties of the class of compounds that make the compounds useful.
- To meet the enablement requirement:
 - When a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for non-enablement based on how to use.

Example 2: Lack of “How to Use”

- ***In re Fouche***

- 1. A dibenzo (a, d) cycloheptadiene derivative of the formula:



and its acid addition salts and quaternary ammonium derivatives in which A is a divalent, saturated aliphatic hydrocarbon chain of 2 to 5 carbon atoms, such that at least 2 carbon atoms separate the radical Z from the dibenzocycloheptadiene ring, and Z is a member selected from the group consisting of amino, monoalkylamino, dialkylamino, in which the alkyl radicals contain 1 to 5 carbon atoms each, and 1-pyrrolidinyl, piperidino, morpholino, 1-piperazinyl, and 4-alkyl-1-piperazinyl in which the alkyl radical contains 1 to 5 carbon atoms, and such rings substituted by at least one alkyl radical of 1 to 5 carbon atoms each.

Example 2: Lack of “How to Use”

- The *Fouche* Court:
 - The examiner noted that the definition of Z in the claim was by a Markush group including both aliphatic and heterocyclic members. His position was that the specification did not enable the use of those compounds within the claim having heterocyclic moieties.
 - The specification contained no mention of the heterocyclic members other than the brief listing of the members within the Markush group.

Example 2: Lack of “How to Use”

- The *Fouche* Court cont'd:
 - It is not to be expected that the heterocyclic compounds claimed will necessarily exhibit the same properties as those of the exemplified open chain amines.
 - While this position could have led to a rejection under § 101, it also leads to a rejection under the how-to-use provision of § 112, since if such compositions are in fact useless, appellant's specification cannot have taught how to use them.

Example 3: Broad Method of Use Claim

- Where a method of use claim is presented, and the scope of that claim is broader than what is taught in the specification
- The law requires that the disclosure inform those skilled in the art how to use, not how to find out how to use for themselves.
- Others should not be required to investigate which part of the claimed invention was operable and which part was inoperable.
- The claim is invalid if the number of inoperative combinations in a method of use claim is high, forcing undue experimentation.

Example 3: Broad Method of Use Claim

- It seems that there is an even higher standard of disclosure of utility when confronted with method of use claims as compared to chemical compound claims.
- To meet the enablement requirement:
 - If the field is unpredictable, “guidance” as to how to determine which embodiment will work should be included.

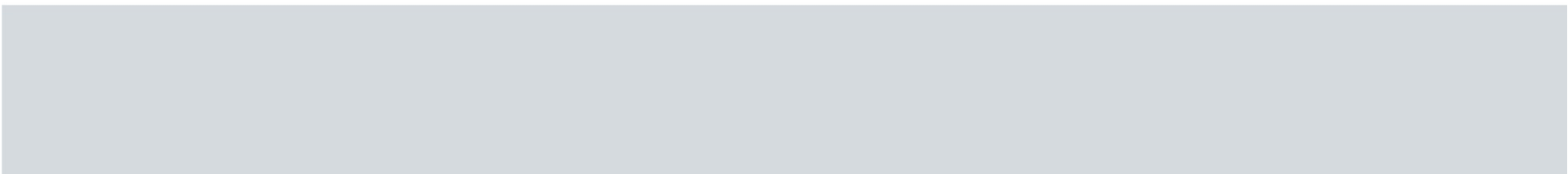
Example 3: Broad Method of Use Claim

- *Ex Parte Paul Stevens*
 - Claim 1:
 - A composition suitable for parenteral or subcutaneous administration to mammalian hosts for therapeutic or prophylactic treatment of cancer comprising a mixture, in pharmacologically effective amounts, of IL-2 from a mammalian species and at least one monoclonal antibody that binds selectively to human breast tumor cells.
 - The Court:
 - “As will be evident upon inspection of the claims reproduced above, appellants’ invention involves a composition and process for treating cancer. By appellants’ express acknowledgement, there is no actual evidence of the effectiveness of the claimed composition and process in achieving that utility.”

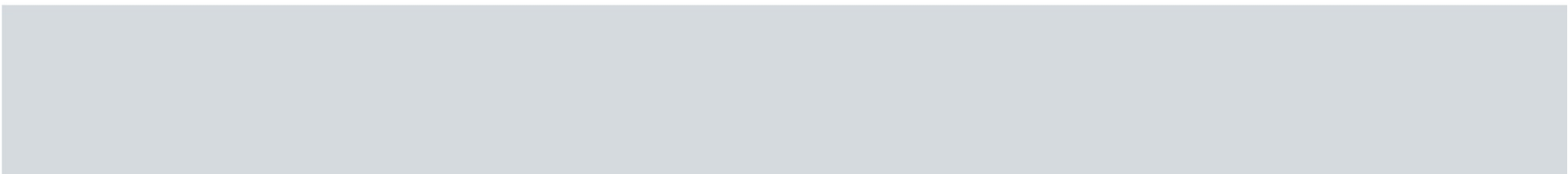
Where is the current trend?

- Lack of enablement infrequently applied
 - In examination or litigation
- Recent “full scope” enablement in even predictable arts might result in greater number of challenges in all cases
- Will this push the enablement bar even higher in unpredictable arts?
- Recent *en banc* review of separate enablement and written description requirements

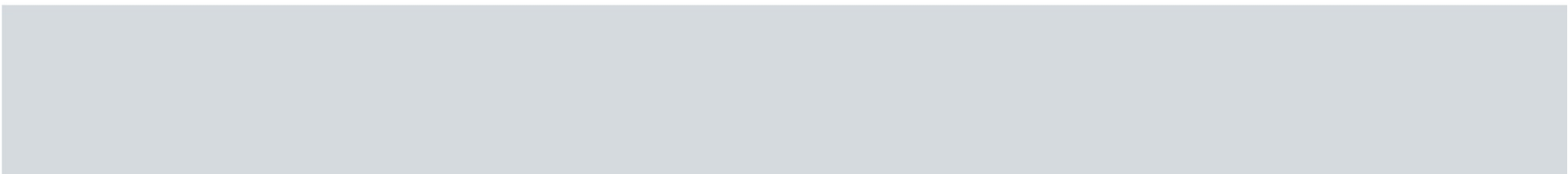
Does *KSR* have an effect?

- Traditionally, a person of ordinary skill in the art is not a person of extraordinary skill or an innovator, but is a “plodder”
 - Under *KSR*, the POSITA is a creative individual with problem solving ability
 - Does this mean that the more creative post-*KSR* POSITA can more readily fill in the gaps than a plodder?
 - Can the required experimentation be pushed out of the label “undue”?
- 

Recommendations

- References can be incorporated within an application's specification so as to provide the necessary "how to make or use"
 - While working examples are not required, they can often prevent enablement rejections
 - A single working example in the specification for a claimed invention is enough to preclude a rejection which states that nothing is enabled since at least that embodiment would be enabled.
- 

Recommendations

- Inclusion of sub-genus and species claims that may be more likely to survive an enablement challenge, particularly if there are working examples
 - Where a Markush group is recited, it is necessary to enable one skilled on the art to make and use at least one composition employing each member of the Markush group.
- 

Any Questions?

Carlyn Burton: cburton@oshaliang.com