UNITED STATES
PATENT AND
TRADEMARK OFFICE

Chemical Non-Statutory Double Patenting Examples

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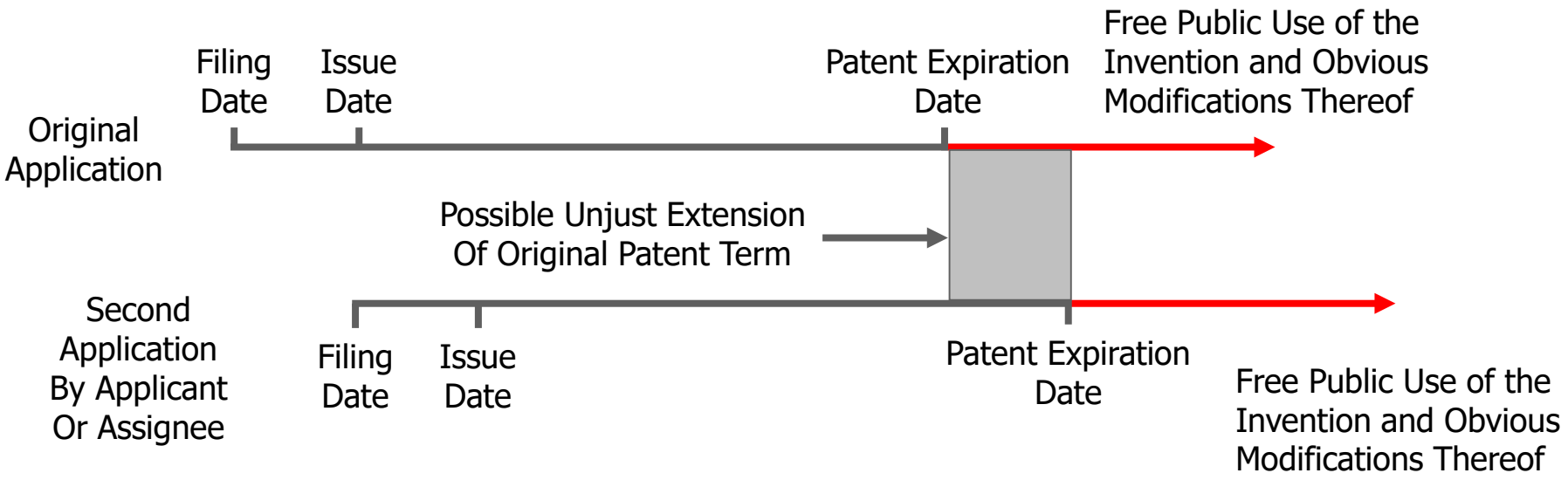
A Graphical Representation of the Problem



The Purpose Behind the Policy

Double Patenting

- Prevents unjustified extension of exclusive rights
- After expiration, public should be able to:
  - » Freely use the claimed invention
  - » Freely use obvious modifications of the
  - » claimed invention

Focus on the Claims

- Claims of the Potentially Conflicting Patent or Application vs. Examined Claims
- The Scope of the Claimed Invention Must be Clearly Determined by Giving the Claims the Broadest Reasonable Interpretation Consistent with the Specification

Proper Uses of Disclosure

- Look at the Specification to Construe the Scope of the Claimed Invention
  - Dictionary for claim terminology
  - Portions of the disclosure which provide support for the claims in the potentially conflicting patent or application

Example Situation I

A Method Renders

Product Obvious

Example 1

Claim Under Examination:

Claim 1. A compound represented by Formula I.

Example 1

Issued Patent:

Same inventors, not prior art to the application being examined.

Claim 1. A method for preparing an edible product, comprising adding a compound of Formula I to a natural or commercial edible product.

Example 1:
Analysis and Conclusion

There is no restriction on the record in either application.

The compound of formula 1 is required to practice the method of the issued patent.

The method of the issued patent should be used to reject the compound of formula 1 under non-statutory double patenting.

Example Situation II

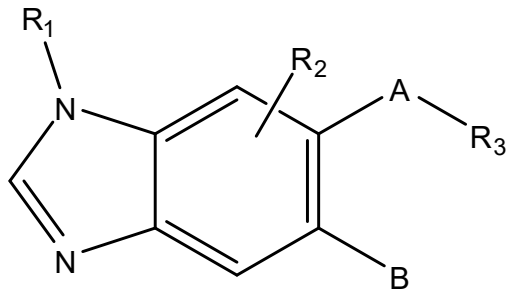
Product Renders

Method Obvious

Example 2

Claim under examination:

A method for treating contact dermatitis or psoriasis which method comprises administering to a patient in need thereof a benzimidazole compound of formula I,

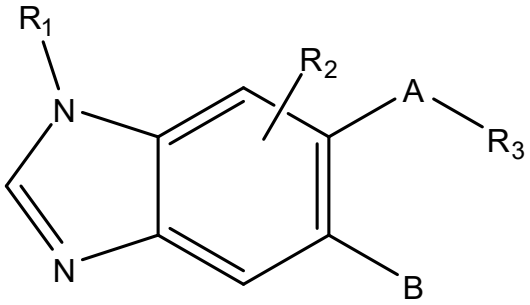


wherein R1 is hydrogen or alkyl; R2 is halogen; R3 is hydrogen, or alkyl; A is alkylene; and B is $CONH_2$.

Example 2

An issued U.S. Patent with the same inventors not prior art to the application being examined, claims:

A benzimidazole compound of formula I,



wherein R1 is hydrogen or alkyl; R2 is halogen; R3 is hydrogen, or alkyl; A is alkylene; and B is $CONH_2$.

2. A pharmaceutical composition for treating contact dermatitis comprising a compound of formula (I) according to claim 1 and a pharmaceutically acceptable carrier.

Example 2

There is no restriction on record in either application.

The intended use recitation of the issued pharmaceutical claim renders the method of using the compound to treat contact dermatitis obvious.

Non-Statutory-Type Double Patenting rejection should be made.

Example 3

Claim under examination:

A method for supplementing a patient's potassium levels comprising administering to said patient an extended release dosage unit containing 10mEq to 20mEq potassium chloride crystals between about 20 to about 60 mesh and a coating consisting of compound A.

Example 3

Issued Patent, same inventorship, not prior art to the application being examined:

No restriction was made.

Claim 1. An extended release dosage unit containing 10mEq to 20mEq potassium chloride crystals between about 20 to about 60 mesh and a coating consisting of compound A.

Example 3

Prior Art reference A:

- Administering potassium chloride to patients suffering from potassium depletion is well established in the art.
- Current efforts in the art focus on minimizing adverse reactions to potassium through use of controlled release formulations.

Example 3

It would have been obvious to use the extended release composition of the issued patent to supplement a patient's potassium level as taught by the prior art reference.

An non-statutory double patenting rejection should be made over the issued claim in view of the prior art reference.

Example Situation III

Product Does Not Render Method Obvious

Example 4

Claim under examination:

1. A method for producing a complex of type Z, comprising:

   (a) contacting a compound of class Y, a metal salt, and a diamine to form a mixture, and

   (b) recovering the type Z complex from the mixture.

Example 4

An issued U.S. patent with the same inventors, not prior art to the application being examined:

1. A compound having chemical formula I.

Example 4

The specification of the issued patent teaches:

- The compound of formula I is a compound of class Y
- The compound of formula I can be used to produce a complex of type Z by contacting with a metal salt and a diamine to form a mixture and recovering the type Z complex from the mixture.

Example 4

Conclusion:

- No non-statutory double patenting rejection can be made
- The specification of the issued patent cannot be used as art
- The issued claim to the starting material does not identically disclose the instantly claimed method of using the compound nor render it obvious.

Example Situation IV

Genus

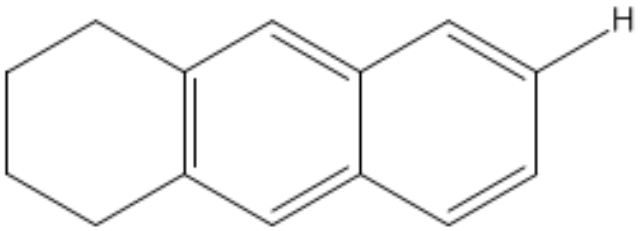
and

Species

Example 5

Claim under examination

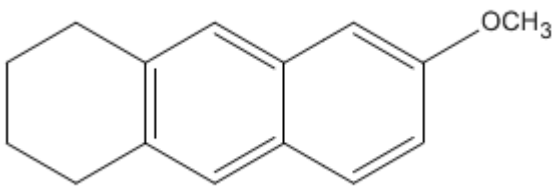
A compound of formula (I):



Example 5

Issued Patent X, same inventorship with the current application but is not prior art:

Claim 1: A compound of Formula (I):



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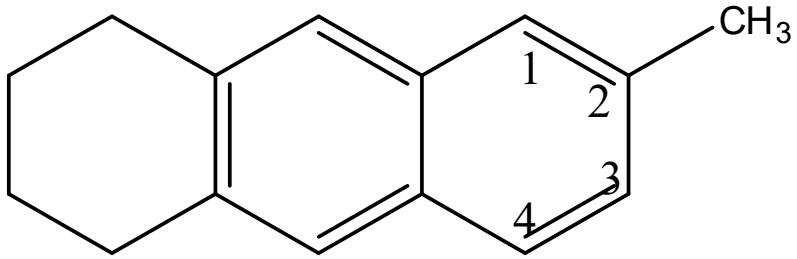
Example 5

Issued Patent Specification:

The Disclosure of issued patent teaches position 2 may be methyl or alkoxy groups.

Specifically disclosed in the patent disclosure, but not claimed, is a compound of formula (II)



Example 5 Analysis

Compounds of the class to which the formula (I) compound belongs would have been expected to have the same activity regardless of whether there is a hydrogen or a methyl group at position 2.

Substitution of a H for a methyl group would have been considered obvious.

Substitution of a hydrogen for an alkoxy group, however would not have been considered obvious since, upon analysis, an alkoxy group would have been expected to confer different properties.

Example 5 Conclusion

No non-statutory double patenting rejection can be made.

While the specification of the issued patent includes a structure with a methyl at position 2, the specification cannot be used to render the substitution of a hydrogen obvious.

When making a non-statutory double patenting rejection, the specification may be used only to ensure proper claim interpretation.

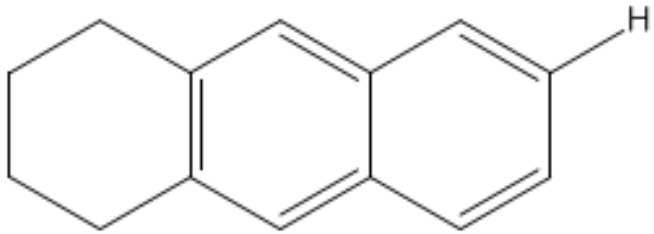
Double patenting involves a comparison of claimed inventions

An examiner may not rely on information that is in the specification but not in the claims

Example 6

Claim under examination

A compound of formula (I):



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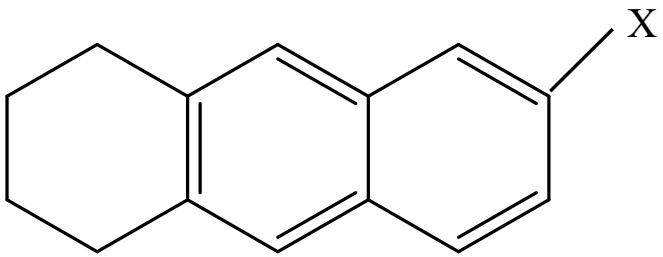
Example 6

Issued Patent X, same inventorship, not prior art to the application being examined:

Claim 1: A compound of Formula (I):



wherein X is selected from the group consisting of methyl or alkoxy groups.

Example 6 Analysis

Compounds of the class to which the formula (I) compound belongs would have been expected to have the same activity regardless of whether there is a hydrogen or a methyl group at position 2.

Substitution of a H for a methyl group would have been considered obvious.

Substitution of a hydrogen for an alkoxy group, however would not have been considered obvious since, upon analysis, an alkoxy group would have been expected to confer different properties.

Example 6 Conclusion

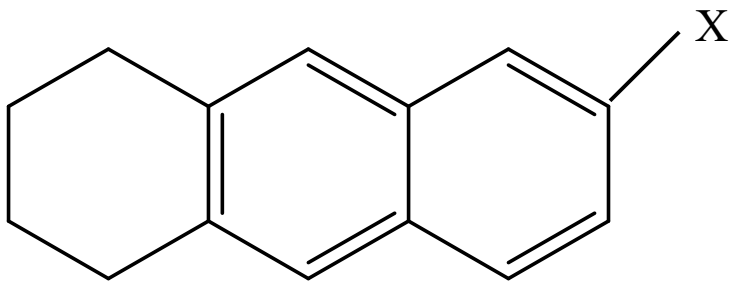
A non-statutory double patenting rejection should be made because the issued claim teaches a structure with a methyl at position 2, and

In this case, the substitution of a hydrogen for a methyl group is obvious.

Example 6A

Claim under examination:

A compound of formula (I):

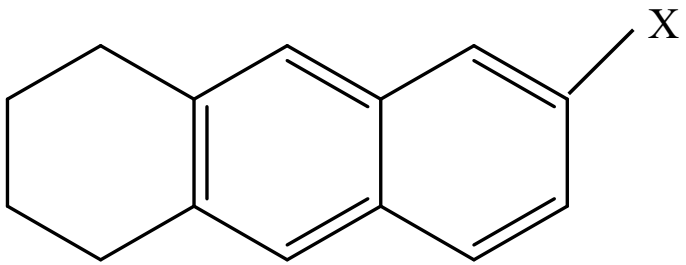


wherein X is CH_3.

Example 6A

Issued Patent X, same inventorship, not prior art to the application being examined:

Claim 1: A compound of Formula (I):



wherein X is selected from the group consisting of methyl or methoxy groups.

Example 6A Analysis and Conclusion

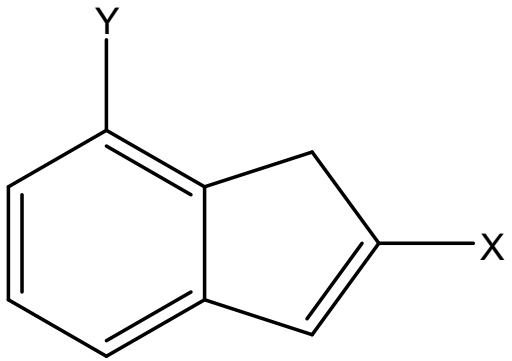
An non-statutory double patenting rejection should be made because the issued claim recites a structure with a methyl at position 2.

Note, the difference in scope of groups encompassed by X precludes a statutory double patenting rejection.

Example 7

Claim under examination:

Claim 1: A compound of Formula (I):

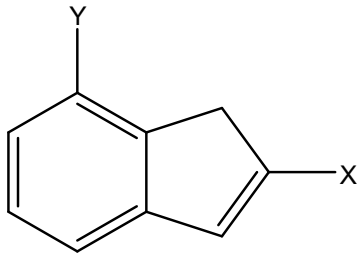


wherein X is selected from C1- C4 alkoxy and Y is selected from 6 membered heterocyclic rings containing 2 nitrogen atoms .

Example 7

Issued Patent X, same inventors, not prior art to the application being examined:

Claim 1: A compound of Formula (I):



wherein X is selected from the group consisting of methyl, ethyl, butyl, methoxy, ethoxy and butoxy, and Y is selected from pyridine, piperdine, pyrimidine and piperazine groups.

Example 7 Analysis

The currently claimed compound requires X to be selected from C_1-C_4 alkoxy which is met when the variable X of the issued claim is methoxy, ethoxy, or butoxy.

The currently claimed compound requires Y to be a 6 membered heterocyclic ring with 2 nitrogen atoms which is met when variable Y of the issued claim is pyrimidine or piperazine.

Example 7 Conclusion

A non-statutory double patenting rejection should be made.

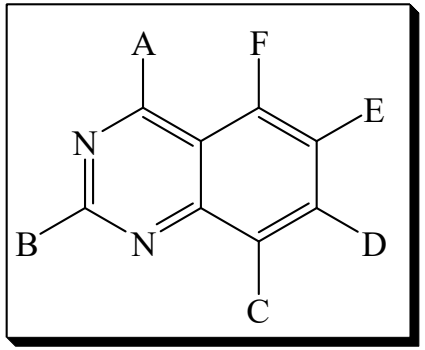
The issued claim includes a core structure corresponding to the structure of the claim under examination

The issued claim already provides patent protection for species which are within the scope of the claim under examination.

Example 8

Claims under consideration:

Claim 1. A compound having the formula:



wherein

A is C_8-C_{12} alkyl or tetrahydropyran or pyran ;
B is haloalkyl ;
C is substituted phenyl ;
D is azocine or azecine ;
E is CN or SO_3 ;
F is C_6-C_7 alkoxy .

Example 8

Claims under examination cont…

Claim 2. A compound of claim 1 wherein

A is pyran ;
B is CCl_3 ; difluoromethyl or 2-bromoethyl ;
C is 3,4,5-trimethoxy-phenyl or 2-chloro-phenyl ; and
F is C_7 alkoxy.

Example 8

Claims under examination cont…

Claim 3. A compound of claim 1 wherein

A is tetrahydropyran ;

B is pentafluoroethyl, dichloromethyl or 1-chloro-2-propyl

C is 3,4,5-trimethoxy-phenyl or 2,4-dichloro-phenyl ;

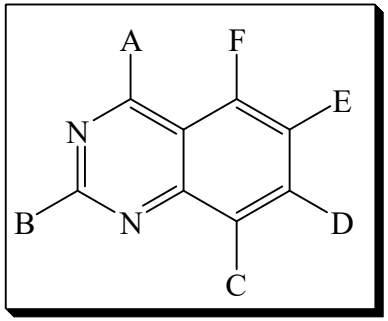
D is azocine; and

E is CN.

Example 8

Issued Patent X claims:

Claim 1. A compound of Formula 1:



wherein variable
A is C_{1-12} alkyl, C_1-C_{10} alkenyl, C_1-C_8 alkynyl, C_3-C_{12} aryl or C_5-C_8 heteroaryl ;
B is CN, CF_3 , NO, SO_2 or OH;
C is C_{1-12} alkyl, C_1-C_{10} alkenyl, C_1-C_8 alkynyl or C_3-C_{12} aryl;
D is substituted or unsubstituted C_5-C_7 heterocyclic,substituted or unsubstituted C_5-C_7 aryl or substituted C_4-C_7 carbocyclic ;
E is CN, CF_3 , NO, SO_2 or OH; and
F is methoxy , ethoxy, propoxy, butoxy, or pentoxy.

Example 8

Issued patent X, cont…

Claim 2. The compound of claim 1 wherein

A is methyl;
B is CN or OH
C is C_1-C_5 alkyl
D is imidazole or pyrrole
E is NO or OH; and
F is methoxy.

Example 8

Issued Patent X cont..

Claim 3. The compound of claim 1, wherein

A is propyl, butyl, or pentyl;
B is CN
C is C_4-C_{10} alkyl
D is 1,2-oxazole or 1,2-oxathiolane
E is NO; and
F is methoxy or ethoxy.

Example 8

Issued Patent X:

Disclosure limited in scope to the preparation of compounds of Formula I wherein:

- Variable A= alkyl moieties that range from C_1 to C_5
- Variable B= CN or OH
- Variable C= C_1-C_{10} alkyl
- Variable D= C_5 containing nitrogen containing heterocyclic rings
- Variable E= NO or OH
- Variable F= methoxy or ethoxy moieties.

No disclosure of how to prepare compound beyond scope of species set forth above or encompassed by dependent claims.

Example 8

Substantial overlap between the core of claims under examination and issued patent.

Overlap does not necessarily result in an improper extension of patent rights.

The number of possible combinations is very large.

The embodiments encompassed by the current claim are within the scope of the issued claims but there is no direction to select the moieties to make the currently claimed compounds.

A non-statutory double patenting rejection cannot be made.

Thank You

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