The Written Description Requirement of 35 U.S.C. 112, first paragraph: Chemical Practice

TC 1600 Training

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35 U.S.C. 112, first paragraph

- **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.**

Written Description: Applications

- **Utility patent applications:**
  - New claims and amended claims.
  - Claims asserting domestic benefit or foreign priority.
  - Original claims. *The Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398, (Fed. Cir. 1997).

Early Written Description (Domestic Benefit)

***In re Ruschig*, 379 F.2d 990, 154 USPQ 118 (CCPA 1967).**

- **Support required in originally-filed generic disclosure for later-presented or amended species claims.**
- **The *Ruschig* court employed the famous metaphor to indicate that a sufficient disclosure is one that marks a trail through the woods by supplying blaze marks on the trees. *Ruschig,* 154 USPQ at 122.**

See also: MPEP 2163 IA (Original Claims).

New or Amended Claims, or Claims Asserting Entitlement to Earlier Filing Date

- **Each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure.**

See also: MPEP 2163 IB (New or Amended Claims).

Inherent Support

Spero v. Reingold, **377 F.2d 652, 153 U.S.P.Q. 726 (CCPA 1967):**

- **Inherency provided an adequate written description of a specific 6-ß-methyl configuration of a compound, even in the absence of a specific naming of the compound or a disclosure of identifying characteristics, where:**

1. **It was known to chemists that there were only two possible configurations (6-ß-methyl and 6-α-methyl); and**
2. **The application procedure worked to produce only one steric configuration (the 6-ß-methyl).**

- **See also: *Kennecott v. Kyocera*, 835 F.2d 1419, 5 USPQ2d 1194 (Fed. Cir. 1987) (Disclosure in a subsequent patent application of an inherent property i.e., equiaxed microstructure of a ceramic product does not deprive that product of the benefit of an earlier filing date).**

USPTO Written Description Guidelines, Examples, and Notices

- **Written Description Guidelines (66 FR 1099 (Jan. 5, 2001); 1242 O.G. 168 (Jan. 30, 2001)**
  - **http://www.uspto.gov/web/menu/current.html#register**
  - **First posted December 27, 1999**
- **Training Materials**
  - **Revision I of the Written Description Training materials, posted 4/11/08 that supercede and replace the 1999 training materials at: http://www.uspto.gov/web/menu/written.pdf dated 3-25-08.**
  - **MPEP 2163**

Written Description - General Principles

- **Basic inquiry: Would one skilled in the art reasonably conclude that the inventor had possession of the claimed invention at the time the application was filed?**
  - ***Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566-67, 43 USPQ2d 1398, 1404-05 (Fed. Cir. 1997); *Hyatt v. Boone*, 146 F.3d 1348, 1354, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998); *MPEP 2106*.**

- **Written description requirement is separate and distinct from the enablement requirement.**
  - ***See, e.g., Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991). See also Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 920-23, 69 USPQ2d 1886, 1890-93 (Fed. Cir. 2004) (discussing history and purpose of the written description requirement); In re Curtis, 354 F.3d 1347, 1357, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004) ("conclusive evidence of a claim's enablement is not equally conclusive of that claim's satisfactory written description"); MPEP 2163.***

Written Description – Basics of Examiner's Analysis

- **Determine the scope of each claim as a whole**
  - **Broadest reasonable interpretation in light of and consistent with written description**
    - ***In re Morris*, 127 F.3d 1048, 44 USPQ2d 1023 (Fed. Cir. 1997); and MPEP 2163.**
  - **Consider the full scope of the claim**

Written Description –Basics of Examiner's Analysis (cont.)

- **Review entire application to understand how the applicant provides support for the claimed invention**
  - **Review includes consideration for each element and/or step claimed.**
  - **Review includes comparing the claim scope with the scope of the disclosure.**

Written Description – Basics of Examiner's Analysis (cont.)

- Factors to consider when analyzing claims for compliance with the written description requirement **:**
  a. **Actual reduction to practice**
  b. **Disclosure of drawings or structural chemical formulas**
  c. **Sufficient relevant identifying characteristics**
  d. **Method of making the claimed invention**
  e. **Level of skill and knowledge in the art**
  f. **Predictability in the art.**

See MPEP 2163 II. A. (a).

Written Description – Basics of Examiner's Analysis (cont.)

a. Actual reduction to practice

- Does the specification show any embodiments that meet all the limitations of the claim reduced to practice?
- *Actual Reduction to practice not required to meet written description cf.: Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).*
- *Actual Reduction to practice of a subset of embodiments may or may not be sufficient to show possession of a genus.*

b. Disclosure of drawings or structural chemical formulas

- An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole.
  - *See, e.g., Vas-Cath, 935 F.2d at 1565, 19 USPQ2d at 1118; In re Wolfensperger, 302 F.2d 950, 133 USPQ 537 (CCPA 1962); Autogiro Co. of America v. United States, 384 F.2d 391, 398, 155 USPQ 697, 703 (Ct. Cl. 1967); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; MPEP 2163.*

Written Description –Basics of Examiner's Analysis (cont.)

c. **Sufficient relevant identifying characteristics:**
   i. **Complete structure**
   ii. **Partial structure**
   iii. **Physical and/or chemical properties**
   iv. **Functional characteristics when coupled with correlation between structure and function**

***Enzo Biochem, Inc. v. Gen-Probe, Inc.,*, 323 F.3d 956, 964, 63 USPQ2d 1609, 1613;**

(Fed. Cir. 2002); MPEP 2163

Written Description – Basics of Examiner's Analysis (cont.)

d. **Method of making the claimed invention**

e. **Level of skill and knowledge in the art**

- **What is conventional or well known to one skilled in the art need not be disclosed in detail. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991).**
- **Prior art, IDS references and Applicant Declarations may be useful to establish the level of skill and knowledge in the art.**

f. **Predictability in the art**

Written Description – Basics of Examiner's Analysis for Genus Claims

- **WD for claimed genus may be satisfied through sufficient description of a representative number of species**
  - **inverse function of the skill and knowledge in the art.**
  - **depends on whether one of skill in the art would recognize necessary common attributes or features possessed by the members of the genus.**
  - **generally, in an unpredictable art, adequate WD of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.**
- ***See Enzo Biochem,* 323 F.3d 956,966, 63 USPQ2d 1609,1615*; Noelle v. Lederman,* 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004); *Regents of the University of California v.Eli Lilly,* 119 F.3d at 1568, 43 USPQ2d at 1406 (Fed. Cir. 1997) .**

Burden on the Examiner with Regard to the Written Description Requirement

- **Description as filed presumed adequate**
- **No *per se* rules**
- **Unsupported allegation of unpredictability in the art is insufficient**
- **Need reasonable basis to challenge**
  - **Evidence**
  - **Technical reasoning**

See MPEP 2163.04

Level of Skill and Knowledge in the Art: Predictability

- ***In re Herschler*, 591 F.2d 693 (CCPA 1979).**
- **Claim: A method of enhancing the penetration into and across an external membrane barrier of a human or animal subject of a physiologically active steroidal agent capable of eliciting a physiological effect upon topical application thereof, which comprises the concurrent topical administration to the external membrane of an amount of said steroidal agent effective to produce the desired physiological effect and an amount of DMSO sufficient to effectively enhance penetration of said steroidal agent to achieve the desired physiological effect (emphasis added).**

In re Herschler : Issue

- **Issue: For purposes of 35 U.S.C. 120 benefit, did the prior application provide sufficient WD for the claimed invention as a whole, including the limitation requiring "an amount of DMSO sufficient to effectively enhance penetration of said steroidal agent to achieve the desired physiological effect"?**

In re Herschler: Parent Disclosure

- **Claim: A method of enhancing the penetration into and across an external membrane barrier of a human or animal subject of a physiologically active steroidal agent capable of eliciting a physiological effect upon topical application thereof, which comprises the concurrent topical administration to the external membrane of an amount of said steroidal agent effective to produce the desired physiological effect and an amount of DMSO sufficient to effectively enhance penetration of said steroidal agent to achieve the desired physiological effect (emphasis added).**
- **Exemplified making topical compositions (ointment and lotion) of DMSO and a corticosteroid; and demonstrated penetration to relieve inflammation in a patient.**
- **Disclosed DMSO, Glucocorticosteroids(20-keto steroid structure) and a corticosteroid (dexamethasone 21-phosphate).**

In re Herschler: Analysis

- Claim: A method of enhancing the penetration into and across an external membrane barrier of a human or animal subject of a physiologically active steroidal agent capable of eliciting a physiological effect upon topical application thereof, which comprises the concurrent topical administration to the external membrane of an amount of said steroidal agent effective to produce the desired physiological effect and an amount of DMSO sufficient to effectively enhance penetration of said steroidal agent to achieve the desired physiological effect (emphasis added).
- **Exemplified making and using DMSO in steroid compositions to enhance topical delivery.**
- **No structure / function correlation need be shown since only DMSO is claimed for its functional properties.**
- **Cortico-steroids are a recognized subclass of "physiologically active steroidal agents" with predictable art-recognized functions.**

In re Herschler: Conclusion

- **Held: prior disclosure of a corticosteroid in DMSO was sufficient to support claims drawn to a method of using a mixture of a "physiologically active steroid" and DMSO because "use of known chemical compounds in a manner auxiliary to the invention must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds. … Occasionally, a functional recitation of those known compounds in the specification may be sufficient as that description.". MPEP 2163 IBII.A.**

In re Herschler: Conclusion (cont.)

- **Note however, that: "[C]ases … such as *In re Herschler*, 591 F.2d 693 (C.C.P.A. 1979) … indicate, as this Court has recognized, that it is not always necessary to set forth exact chemical formulas to satisfy § 112, ¶ 1, but they do not hold that a functional description of a chemical compound is necessarily sufficient. *University of Rochester v. G.D. Searle & Co., Inc*. 249 F. Supp.2d 216, 227 (W.D.N.Y., 2003).**
- **Adequate WD is determined on a case-by-case basis.**

Level of Skill and Knowledge in the Art: Unpredictability

- ***In re Curtis 354 F. 3d 1347; 69 USPQ 2d 1274 (Fed. Cir. 2004):***

Claim: A dental cleaning floss comprising at least one polytetrafluoroethylene (PTFE) strand that has been expanded by stretching under conditions to increase the tensile strength thereof, said floss having a coating of at least one material capable of increasing the coefficient of friction, wherein said dental floss has a denier of about 500 to 1500 and a coefficient of friction of about 0.08 to about 0.25.

- **Issue: Entitlement of above claim in child case to 35 U.S.C. 120 benefit of the filing date of the parent case when the disclosure in the parent was limited to floss coated with microcrystalline wax (MCW).**

In re Curtis: Parent Specification

Claim: A dental cleaning floss comprising at least one polytetrafluoroethylene (PTFE) strand that has been expanded by stretching under conditions to increase the tensile strength thereof, said floss having a coating of at least one material capable of increasing the coefficient of friction, wherein said dental floss has a denier of about 500 to 1500 and a coefficient of friction of about 0.08 to about 0.25.

- **Specification compared the coefficient of friction (COF) of MCW coated PTFE flosses to leading brands of commercially marketed dental floss and expanded PTFE floss having no coating.**
- **Found that from amongst different waxes, microcrystalline wax (MCW) adheres to Expanded PTFE and unexpectedly results in a COF sufficiently high enough to permit the user to securely grasp the floss, but generally not so high as that of the prior art which would not easily slide between the teeth without breaking.**

In re Curtis: Analysis

Claim: A dental cleaning floss comprising at least one polytetrafluoroethylene (PTFE) strand that has been expanded by stretching under conditions to increase the tensile strength thereof, said floss having a coating of at least one material capable of increasing the coefficient of friction, wherein said dental floss has a denier of about 500 to 1500 and a coefficient of friction of about 0.08 to about 0.25.

- **MCW was the only PTFE floss coating actually reduced to practice.**
- **Although other waxes were disclosed, there was no disclosure of drawings, partial or complete structure or chemical formulas of any other coating for PTFE floss.**
- **No known or disclosed correlation between non-wax compound structure and the ability to function as a friction enhancing coating.**
- **Lack of prior art friction coating materials capable of possessing COF of MCW resulted in unexpected property.**

In re Curtis: Conclusion

- **MCW was not representative of the genus of "friction enhancing coatings", especially when MCW properties were unexpected.**
- **Conclude: "parent" application does not provide WD for later-claimed genus of friction enhancing PTFE dental floss coatings since there was only one disclosed embodiment (MCW) that unpredictably adhered to PTFE.**

Level of Skill and Knowledge In the Art : Summary

- **Generally, a well-established subclass of compounds of similar structure with predictable properties should not be the basis of a WD rejection:**

- **Steroids (*In re Herschler*):**

  "[S]teroids, when considered as a class of compounds carried through a layer of skin by DMSO, appear on the record to be chemically quite similar. The diversity of exemplified materials "potentiated" by DMSO in the great-grandparent application, is much broader than the diversity of steroid compounds shown contemporaneously in the art. In this instance, we conclude that one having ordinary skill in the art would have found the use of the subgenus of steroids to be apparent in the written description of the great-grandparent application". *In re Herschler,* 591 F.2d 693, 701(CCPA 1979*).*

Level of Skill and Knowledge In the Art : Summary (Cont.)

- **However, a subclass of compounds whose members unpredictably vary in structure and/or properties may raise WD concerns:**

- **PTFE dental floss coatings (*In re Curtis):***

  "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when … the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." *In re Curtis, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004).*

- **See MPEP 2163 IBII.A.**

WD: Single Compound: Original Claim

- **Satisfies WD when the compound claim corresponds to an actual reduction to practice of the compound in the specification by, e.g., use of a structure or detailed drawing of a readily synthesized compound.**
- **However, compound claims may, in some instances, further satisfy WD by use of one or more disclosed "identifying characteristics":**

1. **Partial structure e.g., Partial Protein Structure: Example 5, Revised WD Training materials;**
2. **Physical and/or chemical properties**
3. **Functional Characteristics;**
4. **Structure/Function correlation**
5. **Method of Making.**

WD: Single Compound: Partial Protein Structure

- ***Partial Protein Structure: Example 5, Revision I of the Written Description Training materials.***
  - **Claim. An isolated protein comprising Protein A, wherein said Protein A**
    - **includes the amino acid sequence of SEQ ID NO: 1 in the N-terminal portion of the protein,**
    - **has the same ability to bind to and activate Protein X as Protein A from human urine,**
    - **and wherein said Protein A is purified by subjecting a crude protein recovered from a dialyzed concentrate of human urine to affinity chromatography on a column of immobilized Protein X, and elutes from a reversed-phase HPLC column as a single peak in a fraction corresponding to about 31% acetonitrile and shows a molecular weight of about 22 kDa when measured by SDS-PAGE under reducing conditions.**

Partial Protein Example: Disclosure

- The specification discloses partial structure, i.e., SEQ ID: 1.
- Other relevant identifying characteristics are disclosed
  - ability to bind and activate Protein X,
  - molecular weight and
  - concentration of acetonitrile at which Protein A will elute from a reverse phase HPLC column.
- The specification also discloses a method for isolating Protein A from human urine and a working example demonstrating successful isolation.

Partial Protein Example: Conclusion

- Those of skill in the art of isolating proteins would recognize the inventor to be in possession of the claimed protein at time of filing based on
  - the identifying characteristics and
  - disclosed method of isolating.

- The specification satisfies the WD requirement with respect to the full scope of claim 1.

Markush Original Claims (synthesizable, without a claimed function)

- **Original claims that define compounds by "structure or formula" such as:**

  X-Phenyl-CH2-CH-NH-C(O)-Y, wherein

  X is selected from the group consisting of ….; and

  Y is selected from the group consisting of … .

Markush Original Claims

***Generally*, for Markush Claims Defined by Structure or Formula:**

- **Possession may be shown by a clear depiction of the invention … in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. MPEP 2163.**
- **Original claims constitute their own description, *In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980); MPEP 2163.**

Genus Claims: WD

- **WD may exist for a genus whose members are generally known or are recognizable based:**

- **on a generic formula (*In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973)) or**

- **on a known or disclosed correlation between structure and function.**

- **WD for claimed genus may also be satisfied through sufficient description of a representative number of species.**

See MPEP 2163 IA.

- **Note: a claim may meet WD but not be enabled.**

WD: Example 1: Derivatives and Analogs (Claim)

- ***Based on the facts of Coolidge and Ehlers v. Efendic (BPAI: Patent Interference No. 105,457: May 16, 2008).***

- **Claim: A method of treating stroke, comprising administering an effective amount of a compound selected from the group consisting of GLP-1, GLP-1 analogs, GLP-1 derivatives, and pharmaceutically–acceptable salts thereof, to a patient in need thereof.**
- **GLP-1 (Glucagon-like Peptide-1).**

Ex.1: Derivatives and Analogs (Specification)

- **Claim: A method of treating stroke, comprising administering an effective amount of a compound selected from the group consisting of GLP-1, GLP-1 analogs, GLP-1 derivatives, and pharmaceutically–acceptable salts thereof, to a patient in need thereof.**
- **Specification discloses:**
  - **that the risk of stroke is elevated in diabetic and hyperglycemic patients; and that**
  - **GLP-1 (Glucagon-like Peptide-1) lowers blood glucose levels in people with elevated blood glucose levels.**
- **Specification exemplifies:**
  - **GLP-1(7-36) amide infusion in NIDDM patients was better than injected insulin at lowering blood glucose levels and controlling post-prandial glucose levels.**

Ex. 1: Derivatives and Analogs (Specification Cont.)

- **Claim: A method of treating stroke, comprising administering an effective amount of a compound selected from the group consisting of GLP-1, GLP-1 analogs, GLP-1 derivatives, and pharmaceutically–acceptable salts thereof, to a patient in need thereof.**

  - **"GLP- 1" means GLP- 1 (7-37) with well known sequence:**

NH_2-His^{7}-Ala-Glu-Gly^{10}-Thr-Phe-Thr-Ser-Asp^{15}-Val-Ser-Ser-Tyr-Leu^{20}-Glu-Gly-Gln-Ala-Ala^{25}-Lys-Glu-Phe-Ile-Ala^{30}-Trp-Leu-Val-Lys-Gly^{35}-Arg-Gly^{37}-COOH

  - **A "GLP-1 analog" is a molecule having a modification including one or more amino acid substitutions, deletions, inversions, or additions when compared with-GLP-1.**

  - **A "GLP-1 derivative" is a molecule having the amino acid sequence of GLP-1 or of a GLP-1 analog but additionally having at least one chemical modification of one or more of its amino acid side groups, alpha-carbon atoms, terminal amino group, or terminal carboxylic acid group. Chemical modification includes adding chemical moieties, creating new bonds, and removing chemical moieties.**

Ex. 1: Derivatives and Analogs (Specification Cont.)

- **Claim: A method of treating stroke, comprising administering an effective amount of a compound selected from the group consisting of GLP-1, GLP-1 analogs, GLP-1 derivatives, and pharmaceutically–acceptable salts thereof, to a patient in need thereof.**
- **GLP-1 analogs known in the art include, for example, GLP-1(7-34) and GLP-1 (7-35), GLP-1 (7-36), Val.sup.8-GLP-1(7-37), Gln.sup.9-LP-1 (7-37), D-Gln.sup.9-GLP-1(7-37), Thr.sup.16-Lys.sup.18-GLP-1(7-37), and Lys.sup.18-GLP-1(7-37). Preferred GLP-1 analogs are GLP-1(7-34) and GLP-1(7-35), which are disclosed in U.S. Pat. No. 5,118,666, and also GLP-1(7-36). Other GLP-1 analogs are disclosed in U.S. Pat. No. 5,545,618.**
- **GLP-1 analogs, derivatives, variants, precursors and homologues are all suitable for the practice of the invention as long as the active fragment that effects reduced mortality or morbidity after stroke is included.**

Ex. 1: Derivatives and Analogs (Analysis)

- **Claim: A method of treating stroke, comprising administering an effective amount of a compound selected from the group consisting of GLP-1, GLP-1 analogs, GLP-1 derivatives, and pharmaceutically–acceptable salts thereof, to a patient in need thereof.**
- **Exemplified metabolic control and reduced blood glucose levels with GLP-1(7-36) amide in NIDDM patients (Actual Reduction To Practice of a GLP-1 analog / derivative species in a stroke susceptible patient).**
- **Although specification discloses structural formulas for specific GLP-1 analogs and derivatives, the claim is not so limited, but encompasses millions of compounds.**
- **The active fragment definition (i.e., that effects reduced mortality or morbidity after stroke) is functional in nature and there is no art-recognized correlation between a defined active fragment function with a particular chemical structure.**

Ex. 1: Derivatives and Analogs (Analysis)

- **Claim: A method of treating stroke, comprising administering an effective amount of a compound selected from the group consisting of GLP-1, GLP-1 analogs, GLP-1 derivatives, and pharmaceutically–acceptable salts thereof, to a patient in need thereof.**
- **Although there may be more than one active GLP-1 fragment, neither the specification, nor the prior art have identified any active fragments.**
- **Although one could test potential active fragments for insulinotropic activity, the correlation between insulinotropic activity and reducing mortality and morbidity after stroke would need to be determined.**

Ex. 1: Derivatives and Analogs: Conclusion

- **The achievement of reduced blood glucose levels in patients using one GLP-1 analog/derivative compound would not be deemed by one of skill in the art to be representative of the claimed scope of GLP-1 analogs/derivative useful for treating stroke.**
- **Claimed treatment of stroke administering GLP-1 analogs and derivatives lacked sufficient written description under 35 U.S.C. § 112, 1st paragraph.**

WD: Example 2: Drug Release Tablet (Claim)

- ***Based on the facts of Ex parte Oberegger et al. (BPAI: Appeal 2008-0304: July 31, 2008)*.**
- **Claim: A modified release tablet suitable for use in once-daily oral administration of Drug X wherein said modified release tablet provides a blood C_{max} for Drug X of about 60ng/ml at between 3 and 8 hours post administration and an area under the plasma drug concentration-time curve ($AUC_{0\text{-}infinity}$) of about 800ng-hr/ml to about 2850ng-hr/ml.**

Ex. 2: Drug Release Tablet (Specification)

- **Claim: A modified release tablet suitable for use in once-daily oral administration of Drug X wherein said modified release tablet provides a blood C_{max} for Drug X of about 60ng/ml at between 3 and 8 hours post administration and an area under the plasma drug concentration-time curve ($AUC_{0\text{-}infinity}$) of about 800ng-hr/ml to about 2850ng-hr/ml.**

- **6 modified release tablets are exemplified in the specification, each characterized by:**
  - **a core containing Drug X plus a binder and excipient**
  - **a semi-permeable coating comprising water-permeable film-forming polymer A, a plasticizer and water-soluble polymer B**
  - **a surrounding moisture barrier coat comprising acrylic polymer C plus permeation enhancer A.**

Ex.2: Drug Release Tablet (Specification Cont.)

- **Claim: A modified release tablet suitable for use in once-daily oral administration of Drug X wherein said modified release tablet provides a blood C_{max} for Drug X of about 60ng/ml at between 3 and 8 hours post administration and an area under the plasma drug concentration-time curve ($AUC_{0\text{-}infinity}$) of about 800ng-hr/ml to about 2850ng-hr/ml.**
- **All six exemplified tablets contain the same ingredients, in the same layers, differing only in the amount of polymer present.**
- **The specification contemplates that an extensive number of alternative ingredients may be used in varying amounts to form the modified release tablet, with instructions for testing for bioavailability metrics.**

Ex. 2: Drug Release Tablet (Analysis)

- **Claim: A modified release tablet suitable for use in once-daily oral administration of Drug X wherein said modified release tablet provides a blood C_{max} for Drug X of about 60ng/ml at between 3 and 8 hours post administration and an area under the plasma drug concentration-time curve ($AUC_{0\text{-}infinity}$) of about 800ng-hr/ml to about 2850ng-hr/ml.**
- **The claim is drawn to a genus of tablets capable of achieving the recited C_{max}, and AUC metrics.**
- **The claim is not limited to any specific tablet structure.**
- **There may be substantial variability among the species of tablets encompassed including variability in tablet design structure and ingredients.**
- **Actual reduction to practice and the complete structure of 6 species of tablets are disclosed.**
- **No other tablet structures or designs are disclosed.**

Ex. 2: Drug Release Tablet (Analysis Cont.)

- **Claim: A modified release tablet suitable for use in once-daily oral administration of Drug X wherein said modified release tablet provides a blood C_{max} for Drug X of about 60ng/ml at between 3 and 8 hours post administration and an area under the plasma drug concentration-time curve ($AUC_{0\text{-infinity}}$) of about 800ng-hr/ml to about 2850ng-hr/ml.**
- **The only disclosed structures meeting the functional requirements have defined features in common, i.e., a core and two layers of specific polymers and ingredients.**
- **There is no correlation between any other tablet structure and the required bioavailability metrics.**
- **The specification describes a method of testing tablets for the required bioavailability metrics.**
- **No information regarding what other structures would likely result in the required bioavailability metrics.**

Ex. 2: Drug Release Tablet (Analysis Cont.)

- **Claim: A modified release tablet suitable for use in once-daily oral administration of Drug X wherein said modified release tablet provides a blood C_{max} for Drug X of about 60ng/ml at between 3 and 8 hours post administration and an area under the plasma drug concentration-time curve ($AUC_{0\text{-}infinity}$) of about 800ng-hr/ml to about 2850ng-hr/ml.**
- **There are no tablets known in the art with the required bioavailability metrics.**
- **It is known in the art that polymer selection greatly affects release of drugs from drug delivery vehicles, including core tablets.**
- **There is no guidance in the art directed to which tablet structures/ingredients combination predictably correlate with the required bioavailability metrics for Drug X.**

Ex. 2: Drug Release Tablet (Conclusion)

- **One of skill in the art would have concluded that applicant was in possession of once per day modified release tablets with the common structural features of**
  - **a core containing Drug X plus a binder and excipient**
  - **a semi-permeable coating comprising water-permeable film-forming polymer A, a plasticizer and water-soluble polymer B**
  - **a moisture barrier comprising acrylic polymer C plus permeation enhancer A.**
- **One of skill in the art would have concluded that applicant was <u>not in possession</u> of the claimed genus of any tablet having the specified bioavailability metrics.**

Ex. 2: Drug Release Tablet (Conclusion cont.)

- **If the specification in this fact pattern had a diversity of examples showing different polymers or polymer combinations which give rise to the same release profile, written description might be satisfied.**
- **Written description for a claimed genus may be satisfied through sufficient description of a representative number of species.**

Questions

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