Claim Interpretation

Claim Interpretation

Is the careful consideration of

each and every word

in a claim to determine what the claim covers.

Each application is considered on its own.

Our Best Resource

The MPEP

- Especially MPEP § 2111
- Refer to the relevant sections and the decisions cited therein for further guidance

Broadest Reasonable Interpretation

- The Patent and Trademark Office determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction in light of the specification as it would be interpreted by one of ordinary skill in the art.

See: MPEP §2111

Plain Meaning

- During examination, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification.

See: MPEP §2111.01

Some Guidance for Claim Interpretation

Consideration of the Specification:

- background description
- explicit definitions
- general description
- preferred embodiments
- working examples
- prophetic examples

Some Additional Guidance

Things to consider outside of the specification:

- prior art and technical disclosures
- declarations and experimental evidence
- technical and English language dictionaries

Claim Structure

- A claim can be broken into parts much like diagramming a sentence.
- The beginning or introductory phrase of the claim is the "preamble."
- The next "part" is a transitional phrase.
  - "comprising," "consisting of," or other like terms
  - See: MPEP §2111.03 for more information
- Finally, the remainder of the claim is referred to as the "body" of the claim.

Claim Interpretation
Example 1 – The Preamble

Guidance in Determining When a Preamble *Is Not Likely* to Limit a Claim

A couple points of consideration:

- When the body of the claim following the preamble is a self-contained description of the structure and does not depend on the preamble for completeness it may not be limiting.

  Kropa v. Robie, 88 UPSQ 478 (CCPA 1951); *IMS Technology Inc. v. Haas Automation Inc.*, 54 USPQ2d 1129, 1137 (Fed. Cir. 2000).

- When a preamble recites merely the use or purpose of the claimed invention it generally does not limit the claims.

  Catalina Mktg. Int'l v. Coolsavings.com, 62 USPQ2d at 1781 (Fed. Cir. 2002).

Sample Claim

A method ***for treating the cornea*** comprising:

administering to the eye a composition comprising vitamin A and a sterile buffer.

(Note: the specification teaches a preferred treatment following cornea surgery to enhance corneal healing by topical application via eye drops of the composition of vitamin A and sterile buffer to facilitate corneal healing)

Sample Prior Art

- Reference #1 discloses a solution of vitamin A and sterile buffer in the form of eye drops.
- Reference #1 teaches the use of the eye drops to improve comfort for wearing contacts.
- There is no mention of any post-surgical healing in the disclosure.

Does the Prior Art Support a Rejection?

- Compare the compositions used
- Compare the active steps of the method

Conclusion

- The prior art composition and the composition limitations in the claim are the same.
- Both the prior art method and the claimed method are topical administration to the eye.
- Therefore, the application of the prior art teaching to eye drops is a “treatment of the cornea.”
- The prior art teaching of a different benefit is moot.

Guidance in Determining When a Preamble *Will Likely* Limit a Claim

A couple points of consideration:

- When the preamble is essential to understand limitations or terms in the body of the claim it may limit the claim.

  Pitney Bowes, Inc. v. Hewlett-Packard Co., 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999).

- When the body of the claim depends on the preamble phrase for antecedent basis the preamble may be limiting.

  Bell Communications Research, Inc., v. Vitalink Communications Corp., 34 USPQ2d 1816, 1820 (Fed. Cir. 1995).

Sample Claim

A method ***for enhancing corneal healing in a patient in need thereof*** comprising:

administering to the eye of said patient a composition comprising vitamin A and a sterile buffer.

(Note: the specification teaches a preferred use for healing following cornea surgery, with no other embodiments listed for the types of "healing")

Sample Prior Art

- Reference #1 discloses a composition comprising vitamin A and a sterile buffer for improving comfort for wearing contacts.
- Reference #1 does not teach “corneal healing”.
- Reference #2 teaches that vitamin A in an ointment is useful for reducing allergy-related inflammation and irritation of the cornea.

Conclusion

- The Reference #1 composition and the composition limitations in the claim are the same.
- Reference #1 teaches a method for reducing irritation with vitamin A and Reference #2 teaches reducing allergy-related irritation and inflammation with vitamin A.
- A combination of Reference #1 and #2 would reasonably address the limitation of "enhancing corneal healing in a patient in need thereof."

Guidance in Determining When a Preamble *Will Likely* Limit a Claim (*cont.*)

One additional point of consideration:

- When the preamble recites additional structure disclosed by the specification it may limit the claim.

Corning Glass Works v. Sumitomo Elec. U.S.A., Inc, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989).

Sample Claim

A method for administering ***a pharmaceutically effective amount of vitamin A*** for enhancing corneal healing to a patient in need thereof comprising:

topically applying eye drops comprising vitamin A and a sterile buffer to the patient's eye.

(Note: the specification states that pharmaceutically effective amounts of the composition used to "enhance corneal healing" require "at least one 50 µl drop having a concentration of at least 20 mg/ml of vitamin A.")

Sample Prior Art

- Reference #1 teaches a sterile buffer and vitamin A as eye drops for reducing contact lens irritation.
- Reference #2 teaches that vitamin A is useful for reducing allergy-related inflammation in the eye.
- Reference #2 was studied on patients that had “no injuries to the eye”.
- The amount of vitamin A in Reference #1 and #2 are both shown to be about 1 mg/ml and can be administered with 1 to 3 eye drops of 50 µl.

Conclusion

- The limitation “pharmaceutically effective amount” used in conjunction “for enhancing corneal healing” limits the claims to specific amounts of vitamin A as defined by the specification.
- References #1 and #2 can not be used alone to address this limitation for art purposes.

Claim Interpretation
Example 2 – Term Definitions

Glaxo Wellcome Inc. v. Andrx Pharmaceuticals, Inc.
68 USPQ2d 1302(Fed. Cir. 2003)

Example 2 – Term Definitions
Claim 1 of U.S. Patent No. 5,427,798

1. A controlled sustained release tablet comprising 25 to 500 mg of bupropion hydrochloride and ***hydroxypropyl methylcellulose***,

the amount of ***hydroxypropyl methylcellulose*** to one part of bupropion hydrochloride being 0.19 to 1.1

and said tablet having a surface to volume ratio of 3:1 to 25:1 cm^{-1}

and said tablet having a shelf life of at least one year at 59° to 77° F and 35 to 60% relative humidity,

said tablet releasing between about 20 and 60 percent of bupropion hydrochloride in water in 1 hour, between about 50 and 90 percent in 4 hours and not less than about 75 percent in 8 hours.

Example 2 – Term Definitions (*cont.*)
The Words of the Claim: Identify the Claim Limitations

Is the claim term "hydroxypropyl methylcellulose" limited by the specification to a *specific* hydroxypropyl methylcellulose?

- Andrx: should be limited to the HPMC in the examples.
- Glaxo: should *not* be limited to a particular HMPC.

Example 2 – Term Definitions (*cont.*)
The Disclosure of the Specification

- "This invention is directed to control sustained release (SR) tablets containing bupropion hydrochloride (as the drug or active ingredient), preferably hydroxypropyl methylcellulose (Methocel™) for controlling drug release rate, and cysteine hydrochloride or glycine hydrochloride."
- "Methocel™ is the brand name for hydroxypropyl methylcellulose (HPMC) from Dow Chemical. Other companies also supply HPMC."
- "In order to prepare the controlled sustained release (SR) tablets of this invention, particles of bupropion hydrochloride are preferably blended with microcrystalline cellulose and hydroxypropyl methylcellulose Methocel™ to form an admixture of blended powders."
- "Hydroxypropyl Methylcellulose 2910, USP used in the examples, conforms to 28.0 to 30.00% methoxyl substitution and 7.0 to 12.0% hydroxypropyl substitution. The preferred nominal viscosity of 2% solution in water is not less than 3,000 centipoise and not more than 5,600 centipoise. It is supplied by Dow Chemical Company, Midland, Mich. as Methocel E4M Premium CR."

- From the Specification of U.S. Patent No. 5,427,798

Example 2 – Term Definitions (*cont.*)
The Examples are not Limiting

Conclusions

- When a claim term has an accepted scientific meaning, that meaning is generally not subject to restriction to the specific examples in the specification.

- The HPMC used in admixture with the bupropion hydrochloride is not limited to the grade and molecular weight of HPMC in the specific examples.

Improper to Import Claim Limitations from the Specification

Although "it is entirely proper to use the specification to interpret what the patentee meant by a word or phrase in the claim, …this is not to be confused with adding an extraneous limitation appearing in the specification, which is improper."

See *In re Paulsen*, 31 USPQ2d 1671 (Fed. Cir. 1994).

Claim Interpretation
Example 3 – Definitions and Intrinsic Evidence

Adams Respiratory Therapeutics v. Perrigo Co.,
96 USPQ2d 1041 (Fed. Cir. 2010)

Example 3 – Term Definitions
U.S. Patent No. 6,372,252

Claim 24. A modified release product having two portions, wherein a first portion comprises a first quantity of guaifenesin in an immediate release form which becomes ***fully bioavailable in the subject's stomach*** and a second portion comprises a second quantity of guaifenesin in a sustained release form wherein the ratio of said first quantity to said second quantity provides a C_{max} in a human subject equivalent to the C_{max} obtained when the first of three doses of a standard immediate release formulation having one third the amount of guaifenesin is dosed every four hours over a 12 hour period and wherein said product also provides therapeutically effective ***bioavailability*** for at least twelve hours after a single dose in a human subject according to serum analysis.

Example 3

The Words of the Claim: Identify the Claim Limitations

- What does the limitation "fully bioavailable in the subject's stomach" encompass?
  - Perrigo: means "absorption" – those of skill in the art would understand bioavailabe to mean absorption
  - Adams: means "released into the stomach, rather than into the body" – argues that specification repeatedly states that drug is released in the stomach, but never states where drug is absorbed

Example 3

The Words of the Claim: The Specification

- The court noted that the term "bioavailability" was not explicitly defined.

- However, the court did explain that the specification used the term "bioavailability" with context detailing how the drug becomes available or released from the formulation.

- Conclusion: "bioavailability refers to the availability of [the drug] for absorption, not the subsequent actual absorption itself."

Claim Interpretation
Example 4 –Definitions and Post-Filing Evidence

Adams Respiratory Therapeutics v. Perrigo Co.,
96 USPQ2d 1041 (Fed. Cir. 2010)

Example 4 – Term Definitions

Claim 24. A modified release product having two portions, wherein a first portion comprises a first quantity of guaifenesin in an immediate release form which becomes fully bioavailable in the subject's stomach and a second portion comprises a second quantity of guaifenesin in a sustained release form wherein the ratio of said first quantity to said second quantity provides a C_{max} in a human subject ***equivalent*** to the C_{max} obtained when the first of three doses of a standard immediate release formulation having one third the amount of guaifenesin is dosed every four hours over a 12 hour period and wherein said product also provides therapeutically effective bioavailability for at least twelve hours after a single dose in a human subject according to serum analysis.

Example 4

Interpretation Based on Post-Filing Evidence

- The court noted that the term “equivalent” was not explicitly defined in the specification.

- However, the court did explain that Adams had argued this limitation during prosecution, and that Adams presented evidence that defined “equivalent” to the examiner.

Example 4
Interpretation Based on Post-Filing Evidence

- Evidence submitted during rexamination: excerpt of the guidelines, *U.S. Department of Health and Human Services, Approved Drug Products with Therapeutic Equivalence Evaluation, p. ix-x (19th ed. 1999) (FDA Guidelines).*

- "Two formulations whose rate and extent of absorption differ by -20%/+25% or less are generally considered bioequivalent. The use of the -20%/+25% rule is based on a medical decision that, for most drugs, a -20%/+25% difference in the concentration of the active ingredient in blood will not be clinically significant."

Example 4
Interpretation Based on Post-Filing Evidence

- Evidence submitted during rexamination: excerpt of the guidelines, *U.S. Department of Health and Human Services, Approved Drug Products with Therapeutic Equivalence Evaluation, p. ix-x (19th ed. 1999) (FDA Guidelines)*:

- "For approval of ANDAs, in most cases, the generic manufacturer must show that a 90% confidence interval for the ratio of the mean response (usually AUC and C_{max}) of its product to that of the innovator is within the limits of 0.8 to 1.25, using the log transformed data."

Example 4
Interpretation Based on Post-Filing Evidence

- What does the limitation "equivalent" encompass?
  - Perrigo: means "within 80% to 125% of the value to which it is being compared, *at a 90% confidence interval*"
  - Adams: means "within 80% to 125% of the value to which it is being compared"

Example 4
Interpretation Based on Post-Filing Evidence

- Conclusion: the term "equivalent" in this particular case is construed to mean "a C_{max} that is 80% to 125% of the value to which it is being compared" because the limitation is about the blood concentration of a drug, not a concern that a generic drug formulation comply with any degree of a consistency to NDA performance.

Claim Interpretation
Product-by-Process

Product-by-Process Claims

- Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.
- When the art teaches a product appearing to be substantially identical to the claimed composition, a proper rejection under 35 USC §§ 102 and103 will shift the burden to the applicant to show an unobvious or untaught difference.

  See: MPEP §2113

What is the Basis for Patentability in a Product-by-Process Claim? (*cont.*)

- The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product.

See: MPEP §2113. See also *In re Garnero,* 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1969).

Example 5 – Product-by-Process

A crystalline composition of a salt of compound X made by a process comprising:

dissolving and refluxing a crude form of the salt of compound X in organic solvent Z;

precipitating a crystal form of the salt of compound X; and

treating the crystal form of the salt of compound X with solvent Y;

resulting in a moisture-stable crystal salt of compound X being essentially free of Z.

Example 5 – Product-by-Process (*cont.*)

What does this claim require?

- a salt of compound X;
- essentially free of Z; and
- a crystal form that is moisture-stable.

Example 5 – Product-by-Process (*cont.*)

The specification teaches that:

- Compound X and salts are very moisture sensitive and oxidize; more stable in crystal form than amorphous solid;
- Solvent Z is required in the preparation of X crystal forms;
- Challenge to prepare crystal forms that do not have Z solvates; solvent Y unexpectedly removes most of Z.
- Specification teaches that prior art salt compositions typically result in 50% breakdown within 1 year under atmospheric conditions due to a high percentage of Z solvates (e.g., 30%).
- The preferred embodiment teaches an HCl salt of compound X that results in only 10% breakdown under atmospheric conditions after one year, with about 5% Z solvate.

Example 5 – Product-by-Process (*cont.*)

- The prior art reference discloses a crystalline composition having a citrate salt of compound X with 10% of the crystals being a Z solvate.
- Solvent Y is never used by the prior art.
- The x-ray crystallography data suggest that the crystal composition of compound X citrate does not measurably change within the first six months (e.g., no evidence of the oxidized form).

Should the Examiner reject the claim over the reference?

Example 5 – Product-by-Process (*cont.*)

Yes.

First, the Examiner should explain that the claim is a product by process claim and that the product itself does not depend on the process of making it.

Then, the Examiner should apply the criteria for product by process claims.

Questions

Thank you!

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