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Claim Interpretation

"In the Examination Process"

Brenda Brumback
Supervisory Patent Examiner Art Unit 1647
U.S. Patent & Trademark Office
(571) 272-0961; brenda.brumbach@uspto.gov



What are patent claims?

- Patent claims are the inventor's attempt to delineate by way of a single sentence in the English language the technology which applicant regards as his or her invention.
- Claim language defines property boundaries. Patent claims provide notice to the public as to the technology which is “fenced off” or protected from trespass.



Keep your eye on the claims, not on the “invention”.

- Since the claims define the invention, focus must begin and remain on the claims during the examination process.
- “The invention disclosed in Hiniker’s written description may be outstanding in its field, but **the name of the game is the claim.**”

In re Hiniker Co., 47 USPQ 1523, 1529 (Fed. Cir. 1998)



Claim Interpretation

Is the careful consideration of
each and every word
in a claim to determine what the claim
covers.



Ordinary and Customary Meaning

- “[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a **person of ordinary skill** in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.”

Phillips v. AWH Corp., 75 USPQ2d 1321, 326 (Fed. Cir. 2005)



Ordinary and Customary Meaning

- “The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation...Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the **context** of the particular **claim** in which the disputed term appears, but in the context of the **entire patent** including the specification.”



Ordinary and Customary Meaning

- “Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the **claims** themselves, the remainder of the **specification**, the **prosecution** history, and **extrinsic** evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art”.
- *Phillips*, 75 USPQ2d at 1327 (internal citations omitted)



Ordinary and Customary Meaning

- “Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims. Differences among claims can also be a useful guide in understanding the meaning of particular claim terms. For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.”
- *Phillips*, 75 USPQ2d at 1327 (internal citations omitted).



Ordinary and Customary Meaning

- The claims, of course, do not stand alone. Rather, they are part of ‘a fully integrated written instrument’, consisting principally of a specification that concludes with the claims. For that reason, claims ‘must be read in view of the **specification**, of which they are a part.’ As we [have] stated [], the specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’”
- *Phillips*, 75 USPQ2d at 1327 (internal citation omitted).



Claim Interpretation

MPEP 2111

Claims must be given their **broadest reasonable** interpretation consistent with the supporting description.

In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000)



Claim Interpretation

MPEP 2111

A claim must be interpreted in light of the specification **without** reading limitations into the claim.



Tips

- Provide claim breadth commensurate in scope with the disclosure.
- Provide claims directed to the inventive concept.
- Avoid reach-through claims.



Red Flag Terms

- Fragments thereof
- Analogues thereof
- Derivatives thereof
 - “A compound of formula II...and its pharmaceutically acceptable salts *or derivatives* thereof.”



Claim Interpretation

Effect of the Preamble on Claim Scope



What is a Preamble?

A preamble is an introductory phrase of a claim. A preamble *might*:

- (1) summarize the invention;
- (2) summarize its relation to the prior art;
- (3) summarize its intended use or properties; or
- (4) constitute a limitation of the claimed device or process.



Guidance in determining when a preamble **will likely** limit a claim

- 1) Preambles of claims in Jepson form generally are structural or step limitations being claimed in combination with the subject matter that follows “wherein the improvement comprises”.

Rowe v. Dror, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997); 37 C.F.R. 1.75(e).

- 2) If the preamble recites essential structure or steps or is “necessary to give life, meaning and vitality to a claim,” it is likely to limit the claim.

Pitney Bowes, 51 USPQ2d at 1165-66; *Kropa v. Robie*, 88 UPSQ 478,480-481 (CCPA 1951).



Guidance in determining when a preamble is **not likely** to limit a claim

- (1) 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, the preamble does not usually limit the claim.

Kropa v. Robie, 88 UPSQ at 480-481; *Rowe*, 42 USPQ2d at 1553; and *IMS Technology Inc. v. Haas Automation Inc.*, 54 USPQ2d 1129, 1137 (Fed. Cir. 2000).

- (2) A preamble that recites the use or purpose of the claimed invention generally does not limit the claim.

Catalina, 62 USPQ2d at 1785.



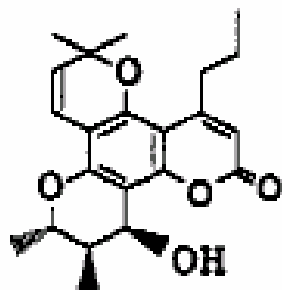
Claim Interpretation

Example 1



The Claim

1. A cancer therapeutic composition comprising a compound of structure A



and a pharmaceutically acceptable carrier.



The Prior Art

- Reference A discloses a composition comprising a compound of structure A in a pharmaceutically acceptable carrier.
- Reference A teaches that the composition is used as an antiviral therapeutic for treating human immunodeficiency virus type 1 (HIV-1) infections.



Does the prior art support a
rejection?



Conclusion

- The compound and composition found in the prior art and in the instant composition are identical.
- Therefore, the prior art anticipates the claimed composition.
- The preamble of the claim merely recites an intended use of the composition and as such does not limit the claims.
- *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801,808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002)



Intended Use Limitation

- When a compound or composition is limited by a particular use, enablement of that claim should be evaluated based on that limitation. MPEP 2164.01(c)
- Prior art evaluation may or may not turn based upon an intended use. The language used and where it occurs in the claim must be considered.

See *Eaton Corp. v. Rockwell International Corp.*, 66 USPQ2d 1271 (CA FC 2003).



Claim Interpretation

Example 2



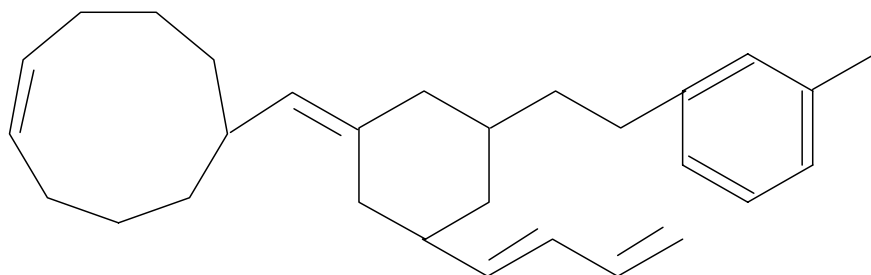
The Claim

1. A martianase compound.



The Specification

Martianase compounds are useful for the release of water from ancient Martian soil. A martianase compound is a compound having the following structure, or derivatives or metabolites thereof.

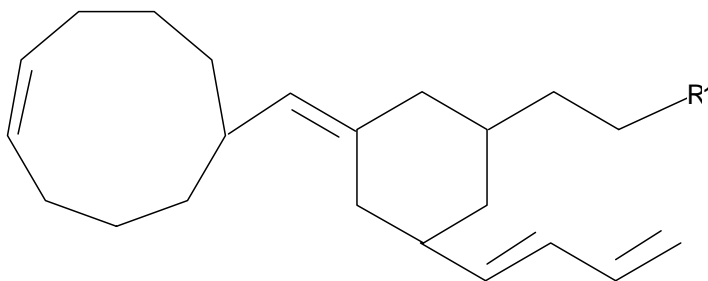




The Prior Art

(U.S. Patent No. 9,876,543)

The prior art discloses a series of compounds that are useful for treating hair loss (alopecia). The compounds of the prior art have the following structure:



wherein R1 is a substituted aryl group. The prior art patent does not disclose a specific embodiment wherein R1 is a methylphenyl group. There are, however, a number of synthetic schema disclosed and, if one were to select among the various substituents disclosed in the prior art patent, one could arrive at the same compound as that claimed in the application under examination.



Conclusion

- Therefore, U.S. Patent No. 9,876,543 would anticipate the invention of claim 1.
- When writing this rejection, the examiner should explain how the term ‘martianase’ is being used.



Claim Interpretation

Example 3



Sample Claim

1. A method of *enhancing corneal healing* comprising:
administering to the eye a composition comprising vitamin A and a sterile buffer.



Sample Prior Art

- Reference A discloses a solution of vitamin A and sterile buffer in the form of eye drops.
- Reference A teaches the use of the eyedrops to rewet contact lenses.



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 instantly claimed invention are identical, as are the methods of administration.
- There is no difference between the patient populations in the instant method and the prior art method.
- Therefore, the application of the prior art-taught eye drops would inherently result in the enhancement of any corneal healing.



Consideration of Intended Use Limitations for Purposes of Applying Prior Art

If the prior art fails to discuss the intended use and the examiner has a basis for asserting that prior art product is capable of performing in the claimed manner, the claims should be rejected.

“(T)he recitation of a new intended use for an old product does not make a claim to that old product patentable.”

In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

In the rejection, the examiner should set forth the basis for stating that the prior art is capable of performing the intended use.



Claim Interpretation

Example 4



The Claim

1. A vaccine comprising an isolated protein comprising SEQ ID NO:1 or a portion thereof which is antigenic.



Vaccine

Dorland's Medical Dictionary (25th ed. 1974)

- a suspension of attenuated or killed microorganisms administered for the prevention, amelioration, or treatment of infectious diseases



Patentability Determination- Vaccine

Prior Art

- A reference which discloses the composition comprising the recited protein in a pharmaceutically acceptable carrier would anticipate the claimed invention.
- Composition comprising a deleterious substance (sodium azide) would not usually be considered a vaccine



Claim Interpretation

Product-by-Process Claims



What is a Product-by-Process Claim?

A product-by-process claim is a **product** claim.

A product-by-process claim is one in which a product is defined at least in part in terms of the **method or process** by which it is made.



Product-by-Process Claims

MPEP 2113

- Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.
- Once a product appearing to be substantially identical is found and a 35 U.S.C. 102 /103 rejection made, the burden shifts to the applicant to show an unobvious difference.
- The use of 35 U.S.C. 102 /103 rejections for product-by-process claims has been approved by the courts.



Examining Product-by-Process Language (cont'd)

How can the examiner examine the claim if the claimed structure is unknown?

If the claimed product appears to be the same or similar to that of the prior art, the claim should be rejected under 102/103.

Advise the applicant that the claim is being construed as a product-by-process claim.

See MPEP 2113.



Examining Product-by-Process Language (cont'd)

Once the examiner provides a **rationale** which supports the conclusion that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the **burden shifts** to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product.

In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

A statement or argument by the attorney is not factual evidence. MPEP 716.01



Claim Interpretation

Example 5



The Claims

1. An isolated and purified polynucleotide that encodes a protein that binds a black hole growth factor.

2. The polynucleotide of claim 1 comprising SEQ ID NO: 1.



The Specification

- The specification discloses the isolation of a black hole **protein** (BHP) from big bang cell line Explodin1 using a subtraction hybridization methodology. This protein was used to generate **antibodies** against BHP and these antibodies were used in expression cloning experiments to isolate a **cDNA** molecule (SEQ ID NO: 1) from the Explodin1 cell line that encodes BHP.



The Specification (cont.)

- The specification also discloses results from a Southern blot using Explodin1 DNA that reveals that this cell line has a **single** Explodin1 allele. The Southern blot also shows a **single** 1700 base pair *EcoR1* genomic DNA fragment that hybridizes with SEQ ID NO: 1. Results of Northern blot experiments reveal a **single** band when SEQ ID NO: 1 is used as a probe.



The Specification (cont.)

- BHP is a **207 kd** protein and has **seven** transmembrane domains. Gene mapping experiments indicate that the BHP gene is present on chromosome 7 at position p4 (**7p4**).



Prior Art

(Hawkings et al.)

- Hawkings *et al.* disclose the isolation of a nucleic acid from the Explodin1 cell line. This nucleic acid encodes a **207 kd** protein having **seven** transmembrane domains.
- This protein includes a catalytic domain that is homologous to other cation channels and, when activated using heat, results in the massive expansion of cell size due to an increase in water uptake by a cell. Southern blot experiments reveal that this protein is encoded by a DNA sequence present on a 1700 base pair *EcoR1* genomic DNA fragment and gene mapping experiments indicate that this fragment of genomic DNA is present on chromosome 7 at position p4 (**7p4**).
- Hawkings *et al.* disclose the isolation of a cDNA molecule that encodes the 207kd protein described, but do **not** present any sequence information.



Rejection

- Claims 1 and 2 are rejected under 35 USC 102(x) as being anticipated by Hawkings *et al.*
 - The instantly claimed invention is drawn to a polynucleotide that encodes a protein that binds to the black hole growth factor (BHGF). Claim 2 recites that this polynucleotide has the sequence set forth in SEQ ID NO: 1.
 - Hawkings *et al.* disclose the isolation of a cDNA molecule that appears to be identical to that instantly claimed. In particular, they disclose the isolation of a cDNA molecule that maps to chromosome **7p4** and encodes a **207kd** protein.
 - It is noted that Hawkings *et al.* do not disclose the sequence of the cDNA or protein or its ability to encode a protein that binds BHGF. However, because their cDNA was obtained from the **same cell line**, has the **same genomic DNA Southern blot** pattern, and maps to the **same genomic locus**, it appears to be the same polynucleotide as that instantly claimed.



Prosecution Issues

1. Applicant may provide a showing that the cDNA of Hawkins *et al.* does not encode a protein that binds BHGF.
2. Applicant may provide a showing that indicates that the cDNA of Hawkins *et al.* has a sequence other than SEQ ID NO: 1.

This showing might overcome a rejection of claim 2, but would not necessarily overcome a rejection of claim 1 in the absence of the showing in (1) above.



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Thank you for attending!

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