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# Claim Interpretation

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# Claim Interpretation

## *(What it is and Why we do it)*

- The careful consideration of each and every word and/or phrase in a claim to determine what the claim covers
- In order for the proper consideration of the claims under 35 U.S.C §§ 101, 102, 103 or 112, the scope of the claims must be properly determined

# Claim Interpretation

## Broadest Reasonable Interpretation

- During examination, the words of the claims are given their broadest reasonable interpretation in light of the specification as interpreted by one of ordinary skill in the art.

see MPEP § 2111.01

# Claim Interpretation

## Consideration of the Plain Meaning

- The claim terms must be interpreted as broadly as reasonably allowed.
- This means that the claims must be given their plain meaning unless the plain meaning is inconsistent with the specification or the specification provides reason to interpret differently.

see MPEP § 2111.01

# Some Guidance for Claim Interpretation

## Consideration of the Specification

- background description
- detailed description
- explicit definitions
- preferred embodiments
- working examples
- prophetic examples
- drawings
- citations from the specification to public disclosures

# Some Additional Guidance

## Things to consider outside of the specification

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

# Cautionary Considerations

- Claims must not be unnecessarily limited by reading limitations into the claims from the specification
- Claims are to be interpreted in view of the specification

# Claim Issues that May Require Extra Care

- Unique claim terms
- Functional language
- Optional language
- Alternative/multiple definitions of a term
- Intended use
- Non-functional descriptive material
- Means-plus-function claim language

# Patent Prosecution and First Considerations following Claim Interpretation

“The examiner’s focus during examination of claims for compliance with the requirement for definiteness of [35 U.S.C. 112\(b\)](#) or [pre-AIA 35 U.S.C. 112](#), second paragraph, is whether the claim meets the threshold requirements of clarity and precision set forth in the statute, not whether more suitable language or modes of expression are available.”

MPEP § 2173.02 II



# 35 U.S.C. 112(b) Definiteness Requirement

- Claims must define the boundaries of the invention by particularly pointing out and distinctly claiming the subject matter applicant regards as his or her invention
  - A claim that clearly identifies the boundaries of the claim scope is “definite”, *i.e.*, it complies with § 112(b)
  - A claim with unclear boundaries is “indefinite”, *i.e.*, it does not comply with § 112(b), and it must be rejected
- Definiteness is measured from the viewpoint of a person of ordinary skill in the relevant art at the time the application was filed

*MPEP 2173 et seq.*

# Purpose of 35 U.S.C. 112(b)

- Ensures understanding of the claimed invention throughout a patent's lifecycle:
  - During examination, an examiner's understanding of what is claimed is critical for determining whether all criteria for patentability of the claims and corresponding requirements for the specification are met
  - After issuance of a patent, the public will have a better understanding of the patent protection granted and what constitutes infringement
  - The PTAB and courts will be informed when construing the claims as to what the examiner and the applicant understood the claims to mean

# Sufficient Explanation on the Record

- An Office Action should communicate a complete and accurate picture of the Office's consideration of the patentability of the claims.
- If an examiner rejects a claim because a term is indefinite, the examiner must explain why a person of ordinary skill in the art could not reasonably determine the metes and bounds.

see MPEP § 2173.02 III A and B

# In Determining Whether or not Claim Terms are Definite

- In order to determine if a claim is definite, the examiner must not look at the limitations in a vacuum, but in light of:
  - the content of the application disclosure
  - the teachings of prior art
  - the claim interpretation given by PHOSITA at the time of the invention

see MPEP § 2173.02 II

# ***Example 1***

*In re Cortright*, 165 F.3d 1353,  
(Fed. Cir. 1999)

# The Claimed Invention

## Example: *In re Cortright*

Claim 1 from U.S. Pat. No. 6,033,676

“The method of treating scalp baldness with an antimicrobial to **restore hair growth**, which comprises rubbing into the scalp the ointment wherein the active ingredient 8-hydroxy.quinoline [*sic*] sulfate 0.3% is carried in a petrolatum and lanolin base.”

U.S. Patent No. 6,033,676



# Guidance from the Specification

## Example: *In re Cortright*

- The specification did not contain an explicit definition of the term “restore hair growth.”
- However, there were three distinct examples of using the claimed composition on the scalp that resulted in noticeable changes that related to hair growth.

# Claim Interpretation

## Example: *In re Cortright*

- It was determined that the claim limitation "**restore hair growth**" as requiring the hair to be returned to its original state was held to be an incorrect interpretation by the Office.
- The Court instead determined that one of ordinary skill in the art would instead construe "restore hair growth" to mean that the claimed method increases the amount of hair grown on the scalp as evidenced by the disclosure and related prior art patents using similar language.

see *In re Cortright*, 165 F.3d 1353, 1359 (Fed. Cir. 1999)

see also MPEP § 2111

## ***Example 2***

*Allergan, Inc. v. Apotex, Inc.*, 754 F.3d 952  
(Fed. Cir. 2014)

# The Claimed Invention

## Example: *Allergan v. Apotex*

- U.S. Patent No. 7,388,029 – claims directed towards methods of “***treating hair loss***” with the use of a certain prostaglandin compound.

# Apotex argues the Claim Meaning

## Example: *Allergan v. Apotex*

- Apotex argued that the “treating hair loss” limitation was narrowed by a specific description in the specification that served as an explicit definition requirement to avoid infringement.
- The specification of the '029 patent contained an explicit definition that stated:
  - “‘Treating hair loss’ includes arresting hair loss or reversing hair loss, or both, and promoting hair growth”

# Claim Interpretation

## Example: *Allergan v. Apotex*

- According to Apotex, the claimed treatment of hair loss was required to: 1) arrest or reverse hair loss; **and** 2) promote hair growth.
- Apotex's generic version using the same compound was alleged to treat hair loss by "lengthening, thickening and darkening existing healthy hair" which relates only to the promotion of hair growth *but not* the arresting or reversal of hair loss.

# The Proper Claim Interpretation

## Example: *Allergan v. Apotex*

- The Court disagreed finding that the Apotex improperly construed the claims more narrowly than warranted based on the definition term “and.”
- The Court instead found that the definition used the word “includes” and that the patentee plainly meant to define hair loss to be any one or more of arresting hair loss, reversing hair loss, or promoting hair growth.
- Also noted by the Court were the numerous examples of the claimed composition that “induced hair growth,” “darkened and thicken eyelashes,” “promote hair growth” or “promote eyelash growth.”

## ***Example 3***

*Teva Pharmaceuticals USA, Inc. v Sandoz, Inc., 789 F.3d 1335*  
(Fed. Cir. 2014)

# The Claimed Invention

## Example: *Teva v. Sandoz*

- Claim 1 of U.S. Patent No. 5,800,808:

“A method of manufacturing copolymer-1, comprising reacting... [certain specified reaction conditions] to result in copolymer-1 having ***a molecular weight of about 5 to 9 kilodaltons.***”

Copolymer-1: consists of four different randomly combined amino acids (*i.e.*, glutamic acid, lysine, alanine, and tyrosine)

# Claim Interpretation

## *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*

- Sandoz argues that the term “molecular weight” or even “average molecular weight” are indefinite since there are three different art-related molecular weights, each of the three yielding different numerical molecular weights:
  - Peak average molecular weight ( $M_p$ )
  - Number average molecular weight ( $M_n$ )
  - Weight average molecular weight ( $M_w$ )

# The District Court's findings

## *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*

- The district court found the expert testimony that the claimed “molecular weight” limitation be interpreted as the peak average molecular weight ( $M_p$ ) based on the chromatography data (Example 1 and Figure 1) and thus the claim is definite.
- The district court found that while  $M_n$  and  $M_w$  can sometimes be determined from chromatography data,  $M_n$  and  $M_w$  would require additional data manipulation and calculations not available in the specification.

# The Federal Circuit's findings

## *Teva Pharmaceuticals USA, Inc v. Sandoz, Inc.*

- No dispute between the parties that the specific molecular weight terms  $M_p$ ,  $M_n$  or  $M_w$  are not mentioned in the specification.
- Both parties also agreed that each of  $M_p$ ,  $M_n$  or  $M_w$  are all art-accepted species of "average molecular weights".
- The Federal Circuit concluded that there was no error in the findings of fact that  $M_p$  could be determined based on the data where  $M_n$  or  $M_w$  could not.

# Findings of Fact cannot replace Legal Analysis

## *Teva Pharmaceuticals USA, Inc v. Sandoz, Inc.*

- The court found the claim indefinite because one of ordinary skill in the art would not be reasonably certain in light of the record as to which measure of molecular weight to use
  - As understood in the art, “molecular weight” can refer to any of the three weight measures  $M_p$ ,  $M_n$ , or  $M_w$
  - The claim on its face offers no guidance on which measure of “molecular weight” the claims cover
- While one of ordinary skill in the art may have been able to infer it was  $M_p$  (and there was testimony that one of ordinary skill in the art could determine which method was most appropriate), that inference was not found to be sufficient to meet the precision required by § 112(b)

# ***Example 4***

*Subject Matter Eligibility*  
*Vaccines*

# Vaccines

## Which are Subject Matter Eligible?

- A vaccine comprising:
  - (a) a live attenuated pigeon flu virus
  - (b) peptide F and a pharmaceutical carrier
  - (c) peptide F, and a emulsion or cream carrier

# Vaccines

## A vaccine comprising (a) a live attenuated pigeon flu virus

- BRI: the vaccine is a “live attenuated pigeon flu virus” and has at least one nucleotide difference from its naturally occurring counterpart
- Step 1: virus are compositions of matter, therefore, the claim is directed to a statutory category
- Step 2: since the virus is a nature based product, it is then compared to determine if it has markedly different characteristics than its counterpart
  - the instant virus is has a different nucleotide sequence which results in a different function from the naturally occurring virus and is not a product of nature
- Conclusion: eligible

# Vaccines

## A vaccine comprising (a) peptide F and a pharmaceutically acceptable carrier

- BRI: the claim is directed to: (i) peptide F and (ii) carriers that include water
- Step 1: the combination is a composition of matter
- Step 2A: peptide F and water together is a nature-based product
  - Since the combination doesn't occur in nature together and there is no naturally occurring counterpart to compare, the mixture is compared by its components
  - Neither peptide F nor the water is subject matter eligible on its own
  - Neither peptide F nor the water affects each other in such a way that changes the structure, function or other properties of the peptide or water
- Step 2B: the combination is well-understood, routine and conventional
- Conclusion: ineligible

# Vaccines

## A vaccine comprising (a) peptide F, and an emulsion or cream carrier

- BRI: one embodiment of the the claim is directed to: (i) peptide F; (ii) oil (e.g., cotton seed oil) and (iii) water
- Step 1: the combination is a composition of matter
- Step 2A: peptide F, oil and water is a nature-based product
  - since the combination doesn't occur in nature together and there is no naturally occurring counterpart to compare, the mixture is compared to its closest naturally occurring counterpart
  - the combination imparts properties that would not occur in nature or the closest counterpart
- Conclusion: eligible

# Questions?

Thank you!

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