Functional Claiming

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Functional Claiming

- Common in the early 20th century
- Forbidden by the Supreme Court in the 1940s
- Congress passed a compromise in section 112(f):
  - **(f)ELEMENT IN CLAIM FOR A COMBINATION.**—An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Why Should I Care?

- If you know you write means-plus-function claims
- If you write M+F claims but don't know it
- If you write genus claims in the life sciences
- If you write functional claims that aren't currently treated as M+F, but might be in the future
- If the law changes and M+F claims turn out to be a good idea
  - *Amgen v. Sanofi*

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The death of genus claims

- Genus claims in the biopharma space have almost all been invalidated on enablement and written description grounds in the last 20 years
- The Federal Circuit's adoption of a "full scope" enablement test is essentially impossible to meet for a genus claim in an uncertain art
  - Unless you are in a happy corner of the world where structure predictably dictates function. But that is very little chemistry and essentially no biotechnology
- The Supreme Court affirmed that test in *Amgen v. Sanofi*, 598 U.S. ___ (2023)
  - Antibody claims are functionally written (an antibody that binds to a particular region on a particular antigen with certain affinity and specificity). This was originally because that was the only way we knew how to characterize the antibody. Now we can characterize it by structure, but it turns out that there is no relationship between structure and function for antibodies
  - Court holds that several hundred working examples wasn't enough where claims might cover millions of possibilities
  - Methods for finding more examples were "research assignments" requiring trial and error
- *Baxalta v. Genentech*, 81 F.4th 1362 (Fed. Cir. Sept. 20, 2023) (disclosing process for screening for successful candidates not enough under *Amgen*)

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Responding to *Amgen*

- Most existing genus claims in the life sciences are dead
  - Exceptions will be very small, known genuses of a few groups. Even then, you will likely have to prove efficacy for the full scope of the claimed genus. *United Therapeutics v. Liquidia Techs.*, 74 F.4th 1360 (Fed. Cir. July 24, 2023)
- Possible strategies:
  - Claim a genus without claiming efficacy or function (if possible)
    - Ironically, while such a claim is broader, it will be much easier to enable under *Amgen*
  - Claim a species and use the doctrine of equivalents
  - Write the claims in means plus function format
    - If the PTO allows it. *In re Xencor*, appeal pending, held that M+F claims fail written description because they cover equivalents of the disclosed structure, and the equivalents (by definition) haven't been disclosed. This just misunderstands section 112(f)

Is It a Means-Plus-Function Claim?

- "strong" presumption based on use of the word "means" or "mechanism." *Lighting World v. Birdhwood Lighting, Inc.*, 382 F.3d 1354, 1358 (Fed. Cir. 2004)
- Federal Circuit en banc weakens that presumption. *Williamson v. Citrix*, 732 F.3d 1339 (Fed Cir. 2015) (en banc)
  - "nonce words" won't trigger the presumption (here, "module")
- Presumption is overcome if non-means language has no structure associated with it
- Structure can be explicit or can be functional term the PHOSITA understands to be structure (i.e. "analog to digital converter", "detent mechanism"). *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583 (Fed. Cir. 1996)

Title search: Functional Claiming

Also available as part of the eCourse
[Functional Claiming]

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