§ 112 Implications for Genus Claims

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Genus and Species Claims

- genus
- species
- mammalian insulin cDNA
- fastener
- screw
- sequence for rat insulin cDNA
- chemical structure with R1, R2, CH2CH3, and CH3 groups
Genus and Species Claims: Anticipation

- Single species *always* anticipates genus.
- Genus anticipates species *only if* species can be “at once envisaged” from genus.
  - Generic chemical formula that represents limited number of compounds that PHOSITA can easily draw or name anticipates each compound.
  - Generic chemical formula for vast number of compounds doesn’t anticipate each—and such a claim likely has § 112 problems…
Genus and Species Claims: Section 112

- How can a patentee adequately describe and enable a genus?
- When does a generic disclosure describe and enable a species?

Disclosures required by § 112 serve not just teaching function but also evidentiary function—showing what inventor actually possessed. Key policy lever for limiting claim scope to inventive contribution.
How can a patentee adequately describe and enable a genus?

- *Ariad v. Eli Lilly*
- What is a representative number of species?
- When is functional claiming ok?
- When do you have to enable and describe unrecited elements?
- Are § 112 genus claims only problematic in biotech?
Ariad v. Eli Lilly (en banc 2010)

- Genus claims for all methods of reducing binding of a certain transcription factor. → inadequate description
- Need “disclosure of either a representative number of species ... or structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus.”
- No “bright-line rules”: “changes with each invention, and it changes with progress in a field.”
  - E.g., 1977 claim to DNA sequence not described by amino acid sequence it coded for (Regents v. Eli Lilly); by 2002 conversion was “routine matter” (In re Wallach).
- What’s happened more recently?
How many species are required? At least some…

- **Boston Scientific v. Johnson & Johnson** (2011):
  - Claimed use of rapamycin analogs in stents but with “no examples” of analogs and “no guidance … besides vaguely indicating they must be ‘structurally similar.’”
  - Only a few analogs were known in art; structural changes have “unpredictable effects.” → **inadequate description**
  - Gajarsa concurrence: Problem is non-enablement. (Similar claims found non-enabled in **Wyeth v. Abbott** (2013).)

- **Streck v. Research & Diagnostic** (2012):
  - Claimed use of reticulocytes (true & analog) as component for blood analysis; “not a case where a patentee attempts to claim a broad genus without defining specific species” b/c “listed several specific true reticulocytes in its specifications.”
  - True reticulocytes are well known in art and “virtually indistinguishable” for this purpose. → **adequate description**
Patent claimed antibodies by function: binding protein IL-12 (causes psoriasis & arthritis).
- Disclosed amino acid sequence of all known species.
- Competitor developed structurally different but functionally equivalent antibody.

CAFC affirms jury invalidation for inadequate description.
- “Functionally defined genus claims can be inherently vulnerable to invalidity challenge for lack of written description support, especially in technology fields that are highly unpredictable…”
- “[M]erely drawing a fence around a perceived genus is not a description of the genus”; rather, it is “only a research plan.”
- BUT “functionally defined claims can meet the written description requirement if a reasonable structure-function correlation is established.” (What meets this standard?)

- CAFC affirms bench trial: “solvate” genus is adequately described.
- “Describing a complex of dutasteride and solvent molecules is an identification of structural features commonly possessed by members of the genus … further narrowed by requiring that the structure result from (one or any of three) identified processes.”
- “The claims in this case, not involving functional claim language, do not present the fundamental difficulty presented by the claims in virtually all of the precedents on which Defendants rely.”
Claim to “a set of short tandem repeat [STR] loci … comprising [specific STR loci]” covers any combination that includes those specific loci.
- Amplification of STR loci used for DNA fingerprinting; co-amplification requires that primers not overlap.

CAFC reverses SJ denial, says claims are invalid for lack of enablement. (International inducement of other claims being challenged in S.Ct. petition.)
- Claims “cover potentially thousands of undisclosed embodiments in an unpredictable field” and the specification has “no disclosure that would have allowed a skilled artisan, absent laborious testing, to add new loci to these recited STR loci combinations that would still successfully co-amplify.”
Spec disclosed “grooves” in spinal implants; patentee later added broader genus claim to all “openings.”

CAFC affirmed jury invalidation for inadequate description.

“[W]hile we did state in Bilstad [2004] that the mechanical field was ‘fairly predictable,’ we did not hold that all inventions that may be characterized as ‘mechanical’ allow claiming a genus based on disclosure of a single species.”

“[J]ury was free to conclude, based on the evidence, that the use of internal slots for these devices was not predictable.”

Note: at least for now, written description, unlike enablement, is a question of fact.
How can a patentee adequately describe and enable a genus?

When does a generic disclosure describe and enable a species?

- Usually arises in the context of claim amendments.
• Specification has general description of variables affecting emission-reducing gasoline; amendments claim specific compositions.

• Jury finds not invalid; CAFC affirms JMOL denial.
  • **Rader opinion:** Patent “informs skilled refiners … to arrive at preferred combinations.” Written description is “fact-sensitive,” jury heard “many days of testimony” and verdict is supported by substantial evidence.
  • **Lourie dissent:** Majority uses “enablement reasoning”; there are “no distinct embodiments corresponding to any claim at issue” or “blaze marks” pointing the way.

• Somewhat of an outlier…

- Broad early disclosure “listing several variables that might, in some combination, lead to a useful result” + 2 examples with data → later claims to specific enzyme (based on competitor’s development).
- CAFC affirmed JMOL of invalidity for lack of WD (overturning jury verdict on question of fact).
  - Species elements are each “literally described,” but no “blaze marks” toward “integrated whole.” Application is at best a “roadmap,” but patent “is not a reward for the search.”
  - Issue is not whether PHOSITA would test all variables; it is whether early application shows patentee “actually invented” later-claimed invention.
- CJ Rader (Union Oil author) dissents.
Conclusions

- Federal Circuit isn’t afraid to use § 112 to limit scope:
  - Patentees who only possess a few specific examples can’t claim something much broader.
  - Patentees who only possess a general idea can’t claim later-developed specific implementations.
- Describing a genus requires (1) representative species or (2) structure, or perhaps (3) function if correlated with structure (but “inherently vulnerable”). No bright-line rules, but predictability is key.
- Beware broad, open constructions that draw unrecited, unpredictable elements into the claim scope (as in Promega).