Advanced Patent Law Institute:

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§ 112 Implications for Genus Claims

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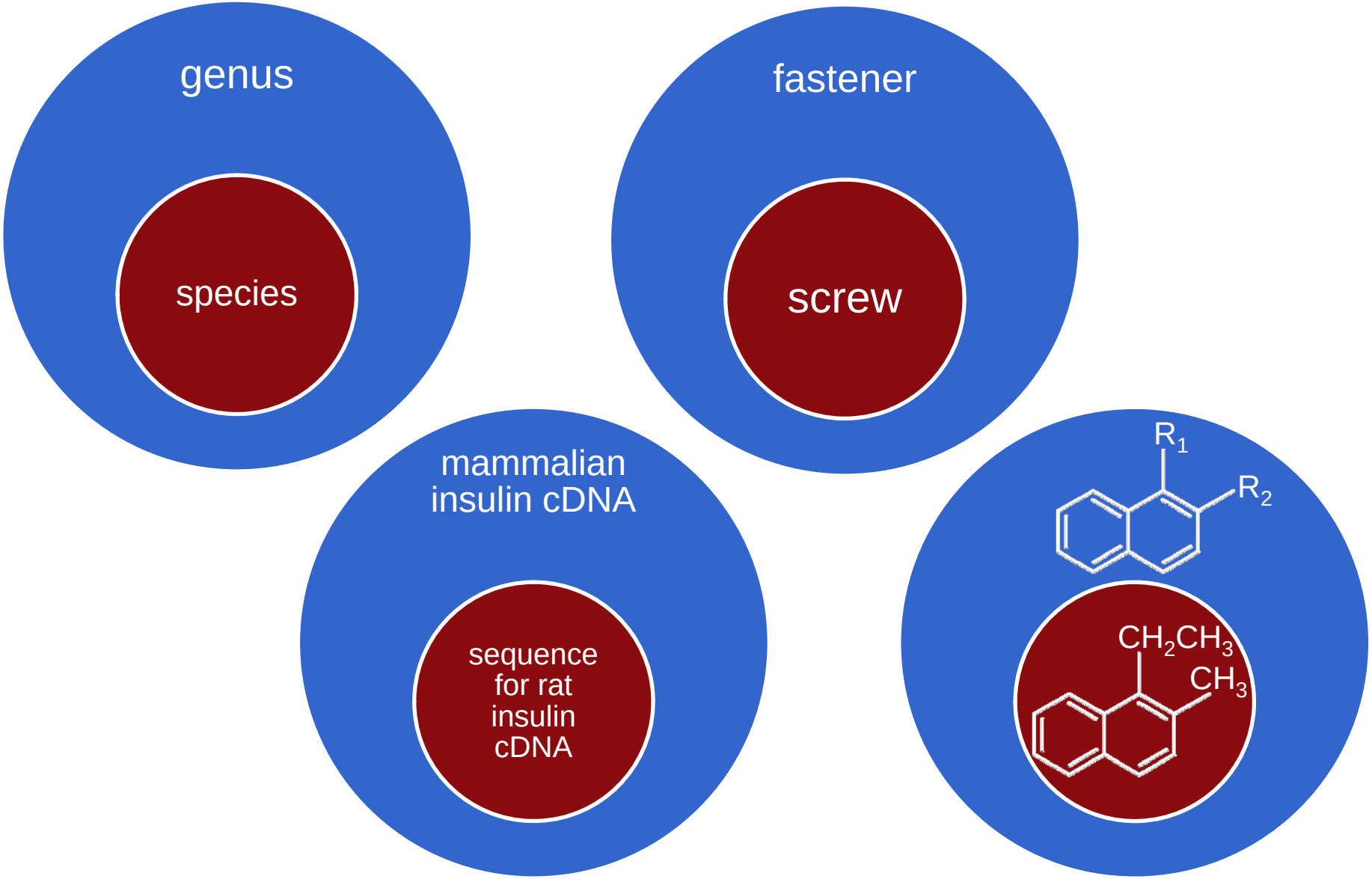
Genus and Species Claims



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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…

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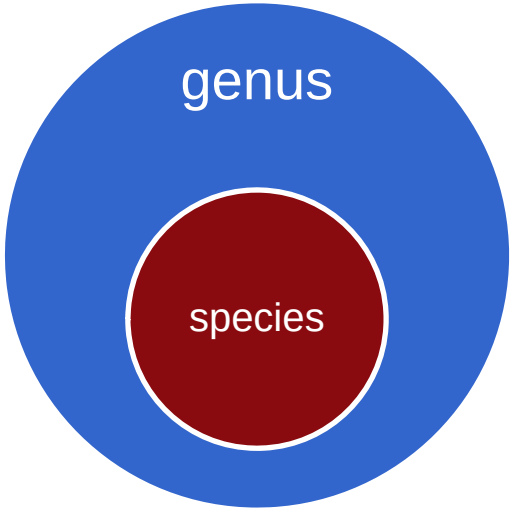
Genus and Species Claims: Section 112

- 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.

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Genus and Species Claims: Section 112

- 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?

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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?

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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 'structural[ly] 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**

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Functional Genus Claims: *AbbVie v. Janssen* (2014)

- 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?)

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Functional Genus Claims: *GlaxoSmithKline v. Banner* (2014)

- 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."

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Not "Merely Unrecited Elements": *Promega v. LifeTech* (2014)

- 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."

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Mechanical Predictability: *Synthes v. Spinal Kinetics* (2013)

- 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*.

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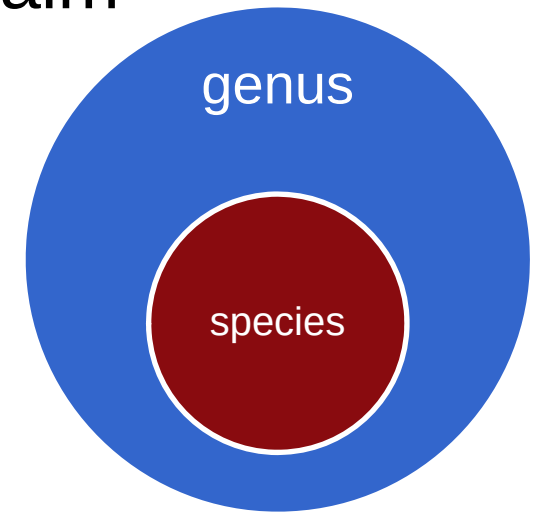
Genus and Species Claims: Section 112

- How can a patentee adequately describe and enable a genus?
- When does a generic disclosure describe and enable a species?
  - Usually arises in the context of claim amendments.



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Species Described by Genus: *Union Oil v. Atlantic Richfield* (2000)

- 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…

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Species NOT Described by Genus: *Novozymes v. DuPont* (2013)

- 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.

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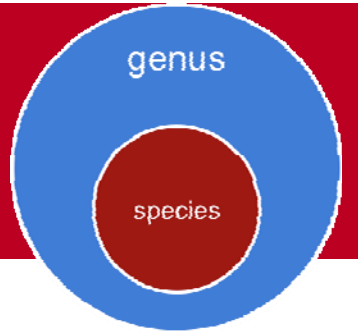
Conclusions



- 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*).