STRANGLEHOLD!
Written Description & Functional Claiming in the Chemical & Biotech Arts

Thursday, January 7, 2016

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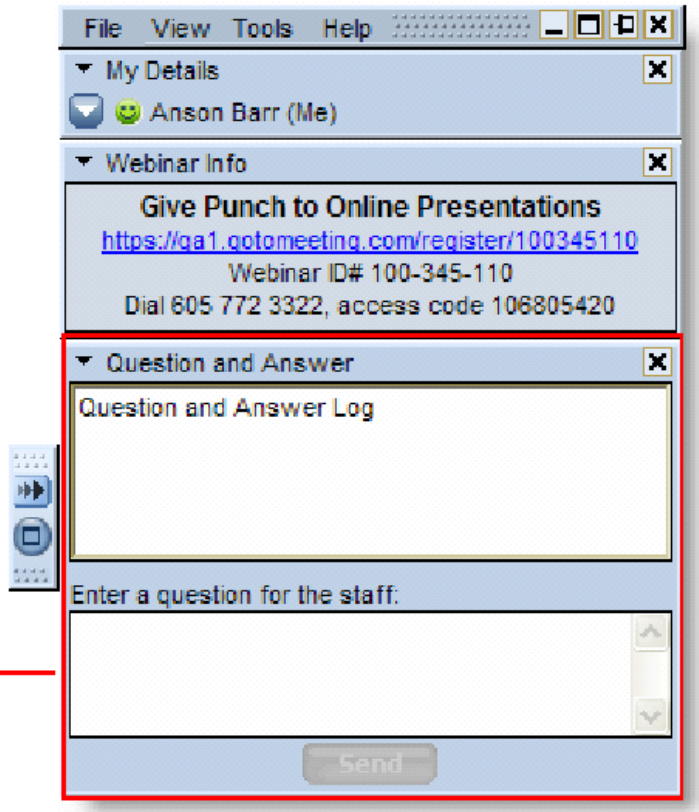

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Part 1 – Summary of Recent Case Law
Kenneth Jenkins, PhD, Member,
Mintz Levin Cohn Ferris Glovsky and Popeo, PC.

Part 2 – Chemical Arts
Robert D. Titus, Senior Director and Assistant General Patent Counsel,
Eli Lilly and Company

Part 3 – Biotech Arts
Suzannah K. Sundby, Partner
Canady + Lortz LLP

Part 1

Functional Claiming and Written Description – Summary of Recent Case Law

Kenneth Jenkins, PhD, Member,
Mintz Levin Cohn Ferris Glovsky and Popeo, PC

General Principles

- The written description requirement is met if the specification shows that the stated i**nventor had possession** of the claimed invention at the time of filing. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991).
- **Possession is shown by disclosure** in the patent from the perspective of PHOSITA. *Ariad Pharm., Inc. v. Eli Lilly & Co*., 598 F.3d 1336, 1355 (Fed. Cir. 2010) (en banc). at 1351

Functionally Claiming DNA

- A claim to "a DNA which codes for a human fibroblast interferon-beta polypeptide" failed to comport with the written description requirement because the specification failed to provide "a precise definition [of the DNA], such as by structure, formula, chemical name, or physical properties." *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993)

Functionally Claiming DNA

- "A definition by function . . . does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is." *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).
- "[No] bright-line rules govern[] the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention, and it changes with progress in a field."

Functionally Claiming a Compound

- Claim to administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to [or in] a human host in need of such treatment
- Federal Circuit affirmed the district court's finding of no WD because the patent "neither discloses any such compound nor provides any suggestion as to how such a compound could be made or otherwise obtained other than by trial-and-error research.'"

Functionally Claiming a Modulating Substance

- Claims drawn to "methods encompassing a genus of materials achieving a stated useful result, *i.e.*, reducing NF-κB binding to NF-κB recognition sites in response to external influences." *Ariad Pharma., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010)
- Specification failed to "disclose a variety of species that accomplish the result"
- "the specification fails to meet the written description requirement by describing only a generic invention that it purports to claim."

Summary

- The *Eli Lilly*, *Rochester*, and *Ariad* decisions suggest that a functionally defined genus claim might be valid if the patent application were to disclose either a representative number of species falling with the scope of the genus, or structural features common to the members of the genus.

Abbvie Deutchland v. Janssen Biotech

- Abbvie US 6,914,128 and 7,504,485: Anti IL-12 Human Ab that binds to human IL-12 and disassociates with a koff of 1x10(-2)s(-1) or less, as determine by SPR.
- Over 300 species disclosed covering range of claim k_{off}'s but all derived from single antibody (Joe-9) with minor CDR sequence changes.
- Stelera® Ab includes Vh5 heavy chains and Kappa light chains not present in Abbvie disclose species

Abbvie Deutchland v. Janssen Biotech

- Functional claims are "**inherently vulnerable** to invalidity challenge[s] for lack of written description support, especially in technology fields that are **highly unpredictable**."
- "[I]f the disclosed species **only abide in a corner of the genus**, one has not described the genus sufficiently to show that the inventor invented, or had possession of, the genus. He only described a portion of it. That is the case here." Slip. op. at 23.
- "the jury heard ample evidence that AbbVie's patents only describe **one type of structurally similar anti-bodies** and that those antibodies are not representative of the **full variety** or scope of the genus"

Abbvie Deutchland v. Janssen Biotech

- "the patents must at least describe **some species representative of** [the alleged infringing product]." Slip op. at 25.
- Must "establish **reasonable structure function correlation**."
- Summary of *Abbvie* Functional Claim Considerations:
  - Predictability of art (antibodies, small molecule modulators)
  - Overall structural diversity/variety of disclosed species (not just one corner of the genus)
  - Similarity of disclosed species to infringing product
  - Communication of structure function correlation

Par Pharm., Inc. v. TWi Pharms., Inc.

- Par Pharma patent claimed a method of increasing body mass by administering megestrol nanoparticles, **wherein no substantial Cmax difference between fed and fasting states**.
- Federal Circuit reversed the district court in finding that the functional wherein clause rendered the claims non-obvious; WD not at issue
- Indicates functional language in chemical **use** claims is an acceptable way to distinguish over the prior art.

Functional Language in Chemical Arts

- Necessary to:
  - Prevent easy design around
  - Cover optimization based on fundamental principles disclosed in specification
  - Deter competitors
- Case law has established chemical unpredictability as solid basis for non-obviousness of novel molecule patentability (*Eisai v. Dr. Reddy*)
- Same unpredictability undercuts WD requirement (*Ariad*, *Abbvie*)
  - *Reliance on PHOSITA knowledge may undercut non-obviousness (In re Kubin)*

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Part 2

Functional Claiming and the Chemical Arts

Robert D. Titus, Senior Director and Assistant General Patent Counsel
Eli Lilly and Company

General Comments

- The use of functional language in a peripheral claiming paradigm is an efficient technique for broadening claim scope commonly used in the chemical arts.

- The unpredictability of the chemical arts, however, creates a tension between functional claim scope and the written description requirement.

Context

- Experience with patent validity challenges and recent IPR proceedings demonstrate that not all patent claims granted by the USPTO will withstand post-grant review.

- It is through this lens that the following views of the application of the subject case law are offered for your consideration.

Problem Statement

- What degree of written description is required to support the desired claim scope breadth?
  - "The **level of detail** required to satisfy the written description requirement **varies depending on the nature and scope of the claims** and on the **complexity and predictability in the relevant technology**." (*Ariad Pharmaceuticals v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010))

Composition of matter

- Purely functional elements are commonly employed in claims directed to a composition of matter, expanding the structural space encompassed by the claims without structural limitation
  - Leaving group
  - Protecting group
  - Electron withdrawing group
  - Prodrug
  - Derivative

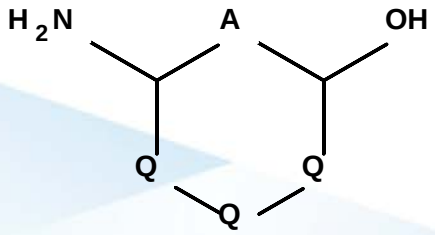
Composition of matter

- The function these terms describes is typically well-accepted, but the structural space encompassing moieties that possess these functions is vast.

- Furthermore, the skilled person would appreciate that not every moiety known to generally perform the desired function actually works in all instances.

Prodrug Hypothetical

A compound of formula I or a prodrug thereof.



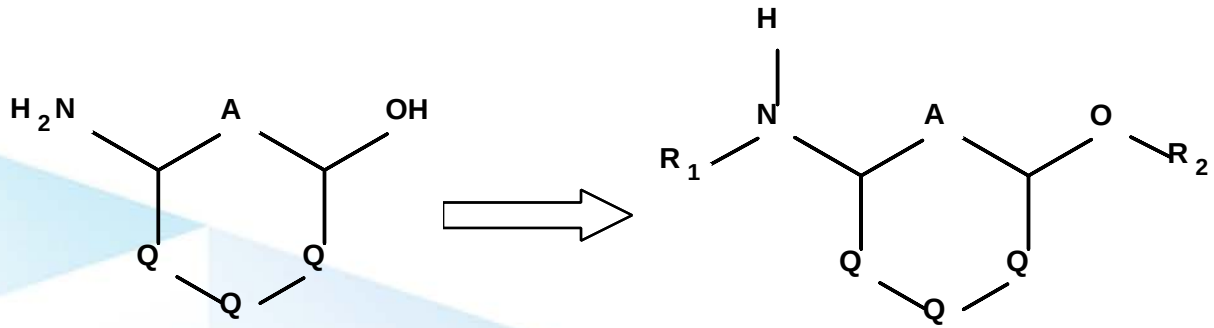
I

Prodrug Hypothetical

- The term "prodrug" is a functional element.

- A prodrug of the compound of formula I is a derivative or analog of any compound of formula I that undergoes an *in vivo* transformation to a compound of formula I.

Prodrug Hypo – Scope Expansion



Compound of formula **I** or a prodrug thereof

where R_1 and R_2 are independently selected from H or a prodrug moiety so long as no more than 1 of R_1 and R_2 are H.

Prodrug Hypo – State of the Art

- The prodrug function can be met by moieties within the ester, ether, carbonate, carbamate, amide, phosphate, oxime, thioether, thioester, imine, and Mannich base structural classes.
- Whether any particular R_1 or R_2 moiety will behave as a prodrug is empirical as are the absorption, distribution, metabolism, excretion and pharmacokinetic properties of the prodrug itself.

Claim Drafting Challenges

- What claim scope is supportable from the available written description?
  - Is the written description limited as a matter of strategy?
  - Is the written description limited as a matter of availability?

- How much written description will be required to support the desired claim scope?

Prodrug Hypo – Claim scope

All prodrugs of formula I

- There is no art-recognized unifying structural element associated with prodrug functionality, so encyclopedic structural definitions and/or specific exemplification will be necessary to meet written description.
- Recent case law suggests that satisfying written description for this functional scope would be extremely difficult if not impossible.

Prodrug Hypo – Claim scope

Functional element as Markush expression

- In addition to the "prodrug" definition, the specification includes a list of members alternatively useful as prodrug moieties for purposes of the invention that do not fall within a recognized generic class.

- Written description requirement satisfied for claim scope limited to the specific members identified in the specification.

Prodrug Hypo – Claim scope

Extrapolate from specific examples/definitions

- Very fact sensitive analysis.
- *AbbVie* suggests that in an unpredictable art even extensive exemplification will not satisfy the written description requirement where a claim encompasses diverse structural space unless the diversity of exemplification comports with the scope of the claim.

Prodrug Hypo – Claim scope

Extrapolate from specific examples/definitions

- The prodrug art is highly unpredictable and largely empirical.
- There is no unifying structural element for prodrug moieties.
- Functional claim scope beyond actual exemplification and definitions will likely not satisfy the written description requirement.

Functional Scope Considerations

- Is unpredictability in the relevant art central to the theory of patentability of the claims?
  - Extrapolation of scope beyond exemplification and definitions will be difficult.
- What advances have occurred in the relevant art that may impact predictability?
  - Has it changed since it was last evaluated?
  - Beware "bioisosterism" and computational methodology assertions.

Conclusions

- Functional claim language remains a useful tool, but expectations regarding preclusive reach must be re-evaluated in view of the prevailing case law.
  - Stating the function alone does not satisfy the written description requirement in the unpredictable arts.
  - The written description requirement serves as a barrier to scope expansion from specific exemplification and definitions of functional terms.

Part 3

Functional Claiming and the Biotech Arts

Suzannah K. Sundby, Partner
Canady + Lortz LLP

General Comments

- Functional language can *seemingly* broaden the scope of biotech claims.
  - Depends on if the glass is half full or half empty.
- Functional language can provide the requisite enablement for biotech claims by, e.g., narrowing the claim scope
- As the biotech arts are highly unpredictable, functional claiming often leads to invalidity for lack of written description support.

Written Description

- The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same…

Over a Decade Ago…

- When DNA was patent eligible…
- Claim 1 of US 4,900,659:
  - 1. A composition of matter that is specific for *Neisseria gonorrhoeae* comprising at least one nucleotide sequence *for which the ratio of the amount of said sequence which hybridizes to chromosomal DNA of Neisseria gonorrhoeae to the amount of said sequence which hybridizes to chromosomal DNA of Neisseria meningitidis is greater than about five*, said ratio being obtained by a method comprising the following steps…

Federal Circuit said:

- [A]dequate written description of genetic material "`requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention," and that none of those descriptions appeared in that patent.
- It is not correct, however, that all functional descriptions of genetic material fail to meet the written description requirement.

Referred to USPTO's Guidelines

- [T]he written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics... *i.e.*, complete or partial structure, other physical and/or chemical properties, *functional characteristics when coupled with a known or disclosed correlation between function and structure*, or some combination of such characteristics." *Guidelines*, 66 Fed. Reg. at 1106 (emphasis added).

No Actual Compounds

- Claim 1 of US 6,048,850:
  - 1. A method for *selectively inhibiting PGHS-2 activity* in a human host, comprising administering a non-steroidal compound *that selectively inhibits activity of the PGHS-2 gene product* to a human host in need of such treatment.

Federal Circuit said:

- Regardless whether a compound is claimed per se or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods.

Ditto…

- Claim 80 of US 6,410,516:
  - 80. [A method for modifying effects of external influences on a eukaryotic cell, which external influences induce NF-kB mediated intracellular signaling, the method comprising altering NF-kB activity in the cells such that NF-kB-mediated effects of external influences are modified, wherein NF-kB activity in the cell is reduced] wherein *reducing NF-kB activity comprises reducing binding of NF-kB to NF-kB recognition sites on genes which are transcriptionally regulated by NF-kB*.

Representative of Genus

- Claim 1 of US 4,767,708:
  - 1. A recombinant plasmid containing *a cloned complete structural gene coding region isolated from a bacterial source for the expression of DNA polymerase I*, under operable control of a *conditionally controllable foreign promoter functionally linked to said structural gene coding region*, said foreign promoter being functional to express said DNA polymerase I in a suitable bacterial or yeast host system.

Representative of Genus

- Claim 1 of US 6,017,745:
  - 1. A recombinant plasmid containing a DNA coding sequence for the expression of DNA polymerase activity, wherein said DNA coding sequence is derived from *a source that encodes a bacterial DNA Polymerase*, said source not containing an amber mutation affecting expression of said DNA polymerase activity, such that when said plasmid is transformed into a bacterial host system the host system can grow and divide thereby replicating said plasmid.

Representative of Genus

- Federal Circuit explained that adequate written description can be met by providing a "representative number of species". Eli Lilly (Fed. Cir. 1997).
  - Means that the *species which are adequately described are representative of the entire genus*.
  - When there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Federal Circuit said:

- To satisfy the written description requirement in the case of a chemical or biotechnological genus, more than a statement of the genus is normally required.
- [T]he narrow disclosure of the *E. coli polA* gene was not representative of and failed to adequately support the entire claimed genus under *Eli Lilly.*

No Example Having All Limitations

- Claim 1 of US 7,713,723:
- 1. An isolated variant of a parent alpha-amylase, wherein:

(a) the variant has at least 90% sequence identity to SEQ ID NO: 6 [BSG alpha-amylase],

(b) the variant comprises a substitution of serine at position 239 relative to the parent alpha-amylase, using the amino acid sequence of SEQ ID NO: 8 [BLA alpha-amylase] for determining position numbering, and

(c) the variant has *increased thermostability relative to the parent alpha-amylase, wherein thermostability is determined at pH 4.5, 90° C and 5 ppm calcium and has alpha-amylase activity*.

Examples of Only One Sub-Genus

- Claim 29 of US 6,914,128:
  - 29. A neutralizing isolated human antibody, or antigen-binding portion thereof that *binds to human IL–12 and dissociates from human IL–12 with a k_{off} rate constant of 1x10 $^{-2}$ s $^{-1}$ or less*, as determined by surface plasmon resonance.

Federal Circuit said:

- Instead, AbbVie used a trial and error approach to modify individual amino acids in order to improve the IL–12 binding affinity.
- [The] patents do not describe any common structural features of the claimed antibodies. The asserted claims attempt to claim every fully human IL–12 antibody that would achieve a desired result, i.e., high binding affinity and neutralizing activity…

Federal Circuit said:

- It is true that functionally defined claims can meet the written description requirement if a reasonable structure-function correlation is established, whether by the inventor as described in the specification or known in the art at the time of the filing date.
- [T]he record here does not indicate such an established correlation.

Practice Pointers

- Provide definitions for functional language
- Ensure the specification explicitly sets forth detailed protocols for determining whether something exhibits the recited functional characteristics
- Provide a representative number of species
  - Actual compounds
  - Variety of different sub-species
  - Set forth function/structure correlation
- Avoid functional limitations inherent to prior art and naturally occurring products

Thank You!

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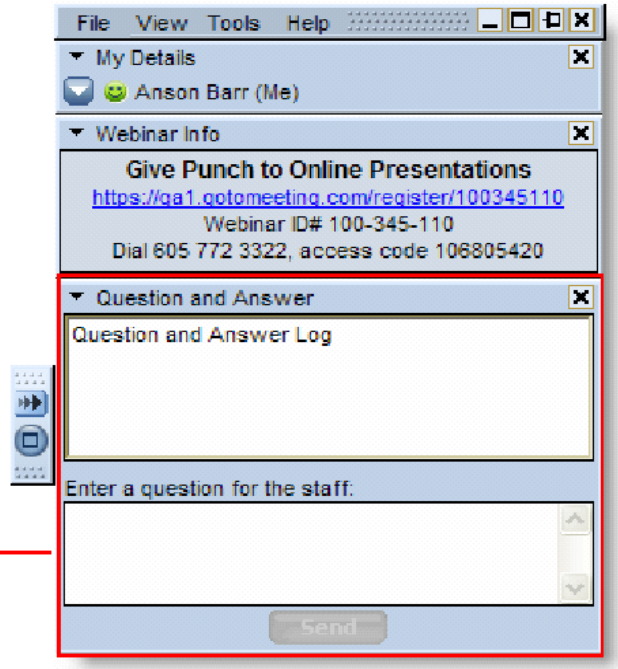

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