Drafting Biotechnology Patents

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Why do patents exist at all?

- "to promote the progress of science"
  - Artifact of English law
- Teach competitors how to replicate / copy your innovation
  - Teaching is the price to pay to obtain a limited government monopoly
  - Patent must be an "enabling disclosure" of best mode

- 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, and shall set forth the best mode contemplated by the inventor of carrying out his invention. 35 U.S.C. § 112, ¶ 1 (1994)

- functional descriptions of genetic material
- In its Guidelines, the PTO has determined that the 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."
- For example, the PTO would find compliance with § 112, ¶ 1, for a claim to an "isolated antibody capable of binding to antigen X," notwithstanding the functional definition of the antibody, in light of "the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature."

- material defined only by a statement of function or result, ... did not adequately describe the claimed invention.
- a claim to a microorganism containing a human insulin cDNA was not adequately described by a statement that “the invention includes human insulin cDNA.” The recitation of the term “human insulin cDNA” conveyed no information about the identity of the claimed DNA sequence.
- adequate 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”

- What of inventions which are impossible to describe in writing?

In re Argoudelis:

- the patent application claimed antibiotic compounds produced by a microorganism.
- By making the microorganism accessible to the public, applicant enabled the public to make and use the claimed antibiotics.
- Held: Non-written deposit suffices where it is impossible to enable in writing alone
- The practice of depositing biological material arose to satisfy the enablement requirement of § 112, ¶ 1.

Enzo simply repeats this

- capable of detecting N. gonorrhoeae may also show a positive result when only N. meningitidis is present. Enzo derived three sequences that preferentially hybridized to N. gonorrhoeae over N. meningitidis.
- Enzo deposited recombinant DNA within E. coli bacterial host at the American Type Culture Collection.

Enzo simply repeats this

- the exact nucleotide base pairs not set forth in Specification
- they were not reasonably obtainable
- it would take 3,000 scientists one month to sequence the genome of one strain of N. gonorrhoeae and one strain of N. meningitidis. ’659 patent, col. 3, ll. 40-46

Enzo #1

- the claimed composition of matter was defined only by its biological activity or function, viz., the ability to hybridize to N. gonorrhoeae in a ratio of better than about five with respect to N. meningitidis, which it was held was insufficient to satisfy the § 112, ¶ 1 requirement set forth in this court's holdings in Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997),

"Written" description

- In Enzo #1, the inventor of DNA probes deposited three polypeptides at the American Type Culture Collection.
- Even for claims limited in scope to the deposited material, the court invalidated the patent for insufficient ***written*** description of the invention.
  - (concluding that "a deposit is not a substitute for a written description of the claimed invention" (quotation omitted)).
  - The 1997 Eli Lilly doctrine requires a ***written*** description (e.g., a nucleotide-by-nucleotide recitation of the structure.

- Enzo’s deposits were correctly incorporated by reference in the specification.
- ? What if this were not done correctly ?

Tempest in a 96-well plate

- reference in the specification to a deposit accessible to the public "when ***it is not [] available in written form***," constitutes compliance with the written description requirement. Enzo Biochem.
- "Where the invention involves a biological material and words alone ***cannot*** sufficiently describe how to make and use the invention in a reproducible manner." MPEP § 2402 (8th ed. Aug. 2001).

PTO Guidelines

- The PTO has rules addressing the procedural requirements relating to bio deposits.
- PTO has declined to correlate procedural rules with particular statutory requirements. See Deposit of Biological Materials for Patent Purposes, 53 Fed. Reg. 39,420, 39,425 (Oct. 6, 1988) (notice of proposed rules) (codified at 37 C.F.R. Part 1) ("The rules are not intended to address which requirements of 35 U.S.C. 112 may be met by the making of deposits.").
- Full compliance with PTO Guidelines is not itself sufficient.

- Thus, under the Guidelines, the written description requirement would be met for all of the claims of the ’659 patent if the functional characteristic of preferential binding to N. gonorrhoeae over N. meningitidis were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed. We are persuaded by the Guidelines on this point and adopt the PTO’s applicable standard for determining compliance with the written description requirement.

Why do patents exist at all?

- Promote science by providing enabling disclosures
- Patents Act of 1793:
  - a "written description" sufficient to distinguish invention from prior art
  - no claims
- After enablement, "[t]he other object of *the specification* is to put the public in possession of what the party claims as his own invention." U.S. Supreme Court (1822)

- Patents exist to promote science
- Patent coverage without claims is vague
  - Vagueness hinders designing-around activities
  - Vagueness hinders scientific progress
  - Further the intent of patents by clarifying boundaries of patent.
- Patent Act revised to require applicant "particularly point out and distinctly claim"

Specification ? Claim

- Specification = enable scientists
- Claim = public notice of lawsuit
  - Do not impute specification limitations into claims
- Relation: Can't claim what is not enabled

Example

- Specification teaches plasmids
- I claim: 1. An electrical receiver comprising 3 m of #14 copper wire wrapped around a cardboard tube, said wire having a first end connected to a positive pole of a 9.2 volt battery, ...
  - A claim detailed enough to enable
- ? Is patent valid ?
  - Does patent enable?
  - Does patent “distinctly claim” ?

- “The question is, ‘Does the written description describe the invention recited and described in the claims--themselves part of the specification--in terms that are sufficient to enable one of skill in the art to make and use the claimed invention?’ That is the mandate of the statute and is all our precedent, prior to Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and the present case, demand.” Judge Rader.

- Claims make patent coverage precise
- Designing-around is easier
- Patentees' response...

- retroactively change patent application to encompass the design-around technology.
- Prohibited in 1953 Patent Act, Section 132
- § 132 literally embraces both new matter rejections of claims and new matter objections to amended specifications. Both claims and the rest of the specification are part of the patent "disclosure" within the terms of § 132. See, e.g., In re Frey, 166 F.2d 572, 575, 77 USPQ 116, 119 (CCPA 1948) ("Certainly the [claim] is a disclosure of itself.").

- Under PTO practice, new matter in the claims would draw a § 132 rejection of the claims; new matter in the specification would draw a § 132 objection to the addition.
- The Court distinguished between adding new matter to the specification and to the claims.
  - The specification is a § 132 matter.
  - To deal with new matter in the claims, the court made a new doctrine based on the enablement requirement.

- Combined § 132/ § 112 rejections
- To avoid confusion between new matter rejections and objections, the court chose to eliminate the § 132/ § 112 rejections and to use § 112 for new matter rejections of claims

Written Description ?

- Noone knows how to satisfy this
- Claims per se may not meet the written description requirement even if they appear in ipsis verbis in the written description.
- written description requirement for genetic material may apply even if it is deposited, thereby demonstrating “possession” of the invention

Example : Enzo Claim 4

- 4. The composition of claim 1 wherein said nucleotide sequences are selected from the group consisting of:
  a. the Neisseria gonorroheae [sic] DNA insert of ATCC 53409, ATCC 53410 and ATCC 53411, and discrete nucleotide subsequences thereof, [and]
  b. mutated discrete nucleotide sequences of any of the foregoing inserts that are within said hybridization ratio and subsequences thereof.

An Example

- An inventor invents an “electrical receiver.”
  - I claim: 1. An electrical receiver comprising 3 m of #14 copper wire wrapped around a cardboard tube, said wire having a first end connected to a positive pole of a 9.2 volt battery, ...

An Example

- His patent disclosure only describes a radio receiver. The Patent, however, enables those of skill to make and use both a radio and a TV.
- His patent claims an “electrical receiver”:

An Example

- A claim detailed enough to enable
- Thus, his claim seems to encompass TV literally
- Specification does not describe TV, but does enable TV
- ? Is patent valid ?
  - Inventor *might* fully disclose TV and claim it – IF Inventor recognizes value of TV in time.

- What happens if the inventor asserts the “electrical receiver” claim against a TV maker?

Various outcomes

- Textbook : limitations from Specification not read into claims.
  - Does patent enable claim 1?
  - Does claim 1 "distinctly claim"?
- Judge Rader: "properly interpret the claim as limited to the radio. The TV maker would not infringe [the] claim."
- Judge Lourie: the Eli Lilly doctrine would invalidate the "electrical receiver" patent.
  - Is that the best result? After all, the inventor did invent "electrical receiver" and the radio. Should he lose everything because he did not disclose TV?

- "Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed."
  - ? Do not the claims do this ?
- "One may consider examples from the chemical arts. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its function of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function."
  - ? If all AIS are equivalent, then why not allow the claim to cover them ?
- "The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described."
  - But the purpose of patents is enablement, not "visualizing"

- “ One must first state what one’s invention is. That is quite different from telling how to make and use it.” Judge Lourie
  - Correct: this is why there are claims (state what one’s invention is) and specifications (telling how to make and use it)

- An example of how the written description and enablement provisions differ:

  a propyl or butyl compound may be made by a process analogous to a disclosed methyl compound. In the absence of a statement that the propyl and butyl compounds are part of the invention, they have not been described and they are not entitled to a patent. Judge Lourie

- This appears to directly contradict doctrine of equivalents law

Patents are less predictable

- Juries face the “cumbersome task” of deciding if the Specification could enable a skilled artisan to make and practice the entire invention, but still not inform that same artisan that the inventor possessed the claimed invention. Moba v. Diamond

Drafting Strategies

- The U.S. Patent and Trademark Office says: "Although [the Federal Circuit] has addressed the 'written description' requirement of section 112 on a number of occasions, its decisions have not taken a clear and uniform position regarding the purpose and meaning of the requirement."
- In both Eli Lilly and Rochester, the invention (human insulin in Eli Lilly; a Cox 2 inhibitor in Rochester) was not *enabled*.

- "Lilly and [Enzo] are panel cases and cannot override the statute that makes enablement the general disclosure doctrine and the vast body of prior case law limiting [Written Description] to its original purpose." Judge Rader, dissenting.

- The inventor in Enzo amended the original claims in response to the examiner's request to place the selective hybridization steps in the claims. Thus, the amendments were all narrowing – meaning the applicant added no new matter to the claims by amendment. Instead, the applicant copied material from the original specification into the original claims. By definition, this case presents no new matter or priority issues requiring application of the original WD doctrine. The original specification contained all of the subject matter included in the inventor's claims.

Obvious variants

- Eli Lilly imposes illogical requirements on patent drafters. Must a software patent disclose every potential coding variation that performs a claimed function? Must a biotechnological invention list every amino acid variation for a particular protein or protein function?

Antibody

- Applicant should disclose a fully characterized antigen if the applicant wants written description support for a claim to an antibody defined by its binding affinity to that antigen.
- Broader antibody coverage : demonstrating the claimed antibody's ability to recognize isoforms of the antigen from different species
- Broader antibody coverage : mapping the epitope recognized by the antibody.
- Will this work for chemical cpds (e.g., “Cox-2 inhibitor”)

Include Broad Claim?

- Include a claim of extreme breadth as a first filed claim even at the risk of presenting a claim that is highly likely to be rejected, to negate inference that "written description" will bar any broader claim later. Gentry Gallery
- Contra: waiver of equivalents between first filed claim and issued claim. Festo

Recite species *ad nauseum*?

- Specification preferably omits that which is well known in the art. MPEP.
- Genus claim in predictable art may be limited to the species disclosed in Specification. Gentry Gallery , Utter v. Hiraga

Precise description of best mode

- Omitting best mode -> patent is invalid.
- Giving precise description of preferred embodiment may make "crystal clear" that a narrow claim interpretation is intended. Gentry Gallery; Johnson Worldwide
- Is description in writing really not possible?
  - Vulnerable to rely on biological deposits

What is minimum standard?

- Description of the invention in functional terms may be inadequate.
- There are no “bright line” rules prescribing what is or is not an adequate written description. Instead, satisfaction of written description is a fact-specific inquiry, decided on a case-by-case basis.

Offensive use

- If the prior art patent fails to describe an embodiment for the purposes of § 112, first paragraph, then it is difficult to believe that the same patent describes the same embodiment for the purposes of § 102.

Opportunity to invalidate existing patents

- "This new 1997 rule changes the established rules of claiming and disclosing inventions. Many biotechnological inventions predate Eli Lilly. Before the 1997 change, no inventor could have foreseen that the Federal Circuit would make a new disclosure rule. Without any way to redraft issued patents to accommodate the new rule, many patents in the field of biotechnology face serious and unavoidable validity challenges simply because the patent drafter may not have included the lengthy nucleotide sequences. After all, the sequences are often routinely available (albeit at some cost) to those of ordinary skill in this art." Judge Rader

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