



RECENT DEVELOPMENTS IN PATENT LAW AND THEIR EFFECT ON THE VALUE OF IP

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Dedication

“Whenever I figure out where it’s at,
they move it.”

Anonymous, circa 1975.



Disclosure Requirements

- 35 USC § 112:
 - Written description
 - Enablement (making and using)

- 35 USC § 101
 - Utility



Written Description

University of California v. Eli Lilly

Prior art: Human insulin protein

Invention: Isolation of the rat insulin gene

Disclosure in patent:

the actual isolation of the rat insulin gene,
the DNA sequence of the rat insulin gene,
a speculative method for isolating the human gene, and
the sequence of the (known) human insulin protein

Held: Insufficient to satisfy the written description requirement for the human insulin gene.

Reason: No disclosure of the sequence of the DNA encoding human insulin

University of California v. Eli Lilly, 119 F.3d 1559, 43 USPQ2d 1389, (Fed. Cir. 1997), cert. denied 523 U.S. 1089 (1998).



The *Eli Lilly* Rule

Written description requirement is separate from enablement requirement.

A structure cannot be described solely by its function.

An adequate written description of a chemical/biological compound “. . . 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.”

University of California v. Eli Lilly, above, 43 USPQ2d 1389, 1404.



The Eli Lilly Rule Is Alive and Well for Nucleic Acids

Invention: a novel protein.

Disclosure:

a partial (5%) amino acid sequence,
molecular weight,
function, and
method of isolating corresponding DNA

In re Wallach, 378 F.3d 1330, 71 USPQ2d 1939 (Fed.
Cir. 2004).



The Eli Lilly Rule Is Alive and Well

Written description requirement satisfied:

Protein - yes

DNA - no

“Appellants have provided no evidence that there is any known ... correlation between the partial structure of a protein, ... and the structure of the DNA encoding the protein.”



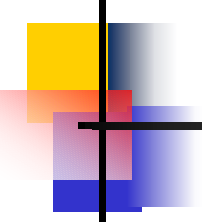
The Lilly Rule Is Inconsistent for Biological Molecules

THE LILLY RULE IS ABSOLUTE FOR NUCLEIC ACID MOLECULES:

The Federal Circuit has never accepted anything other than complete nucleic acid sequence.

THE LILLY RULE IS MORE REASONABLE FOR PROTEINS:

Need a sufficient number of structural “distinguishing characteristics.”



The Lilly Rule Is Especially Reasonable for Antibodies

Antibodies that bind specifically to a “fully characterized” mouse antigen satisfy the written description requirement.

The corresponding human antigen was not “fully characterized.”

Antibodies that bind specifically to the human antigen do not satisfy the written description requirement.

Noelle v. Lederman, 69 USPQ2d 1508 (Fed. Cir. 2004).



The Lilly Rule Is Less Strict for Nucleic Acids at PTO BPAI

A polynucleotide comprising a naturally occurring polynucleotide sequence at least 95% identical to a specific polynucleotide sequence was allowed.

Dicta: "Adequate written description may be present for a genus of nucleic acids based on their hybridization properties, 'if they hybridize under highly stringent condition to known sequences because such conditions dictate that all species within the genus will be structurally similar.' "

Ex parte Bandman, Appeal No. 2004-2319 (BPAI 2004)



Written Description for Small Molecules

“We see no reason for the (*Eli Lilly*) rule to be any different when non-genetic materials are at issue ...”

Known: NSAIDS inhibit cyclooxygenase (COX) to reduce inflammation (Aspirin, Ibuprofen, Acetaminophen, etc.)

Discovery: Good COX-1 and bad COX-2

Invention: Screening method for selective COX-2 inhibitors

Claim: Method for reducing inflammation by selectively inhibiting COX-2 with a compound that does not inhibit COX-1 (Celebrex, Vioxx, Bextra, etc.)

Held: Insufficient written description

Cannot describe structure of molecule solely by its function

No “reach through” claims

University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (Fed. Cir. 2004)



Written Description in a Mechanical Case

Parent application discloses dental floss made of expanded PTFE filaments coated with microcrystalline wax having a coefficient of friction between 0.08 and 0.25.

CIP claims dental floss made of PTFE having any coating capable of increasing the coefficient of friction to between 0.08 and 0.25.

CIP denied priority date of parent for lack of written description of genus.

In re Curtis, 69 USPQ2d 1276, (Fed. Cir. 2004).



Claim Construction

Federal Circuit reached broad consensus *en banc* to resolve split on court regarding claim interpretation:

Order of importance of sources for interpreting claim terms:

- (1) definitions in the specification
- (2) statements made during prosecution
- (3) dictionary definitions

Phillips v. AWH, 75 USPQ2d 1321 (Fed. Cir. 2005)
(*en banc*)



Claim Construction

Definitions in specification are interpreted strictly and literally.

Limitations will not be imported from the specification into the claims unless the limitation is clearly and explicitly stated to be part of the definition of a claim term.

Claim scope can only be disclaimed by a clear and explicit statement in the specification.

Phillips v. AWH, 75 USPQ2d 1321 (Fed. Cir. 2005)
(*en banc*)



Effect of Disclosure Requirements and Claim Construction on Value of IP

1. Patent application must be carefully written to describe and to enable.
2. Beware the trap of the cheap provisional application.
3. Expect claims that issue, and are upheld as valid, to be narrower than before;
biotech > chemical > mechanical.



Research Tool Patents and Research Exemption

Statutory Infringement:

“... whoever without authority ... uses ...
any patented invention during the term
of the patent therefor, infringes the
patent.”

35 U.S.C. § 271(a)



Research Tool Patents and Research Exemption

Common Law Research Exemption:

Patent infringement requires “the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification.”

Justice Story in *Sawin v. Guild*, 21 F. Cas. 554, 555
(C.C.D. Mass. 1813)



The Common Law Research Exemption Is Narrow

Roche v. Bolar was a test case in 1984 for the purpose of resolving a debate that inhibited progress during negotiations between proprietary and generic drug industries that led to Hatch-Waxman Act.

Roche Products v. Bolar Pharmaceutical Co.,
733 F.2d 858 (Fed. Cir. 1984)



The Common Law Research Exemption Is Narrow

Issue in *Roche v. Bolar*: Whether conducting clinical trials is exempt from patent infringement.

District court: No Infringement. "Bolar's use was *de minimis* and experimental."

Roche Products v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 1984)



The Common Law Research Exemption Is Narrow

On appeal, the Federal Circuit reversed

“... unlicensed experiments conducted with a view to the adaption of the patented invention to the experimenter’s business is a violation of the rights of the patentee to exclude others from using his patented invention.”
(Emphasis added.)

“We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of ‘scientific inquiry,’ when that inquiry has definite, cognizable, and not insubstantial commercial purposes.” (Emphasis added.)

Roche Products v. Bolar Pharmaceutical Co.,
733 F.2d 858 (Fed. Cir. 1984)



“The Experimenter's Business” Is Construed Broadly

Facts: Duke University was conducting graduate research with lasers patented by Madey.

Held: Duke infringed patent. Common law research exception did not apply.

“Duke’s acts appear to be in accordance with any reasonable interpretation of Duke’s legitimate business objectives.”

Madey v. Duke University, 307 F.3d 1351, 64 USPQ2d 1737 (Fed. Cir. 2002)



American Intellectual Property Law Association Resolution (2004)

“... the Association supports legislation providing, *inter alia*, that acts of infringement shall not extend to making or using patented subject matter to discern or discover

- (1) the **validity** of the patent and the **scope of protection** afforded under the patent;
- (2) **features**, properties, inherent characteristics or **advantages** of the patented subject matter;
- (3) **methods of making or using** the patented subject matter; and
- (4) **alternatives** to the patented subject matter, **improvements** thereto or substitutes therefor.”



Safe Harbor Provision of the Hatch-Waxman Act

Congress overruled *Roche v. Bolar* in part later in 1984 by passing the Hatch-Waxman Act.

The safe harbor provision of the Hatch-Waxman act exempts from patent infringement the use of a patented invention “solely for uses reasonably related to the development and submission of information (to the FDA) . . .”

35 U.S.C. §271(e)(1)



The Safe Harbor Is Deep and Wide

Supreme Court Decision (June 13, 2005).

Scripps Institute, under a research agreement with Merck, discovered a new use for peptides patented by Integra, and determined the best one for clinical trials.

The Federal Circuit had held the safe harbor exemption to be limited to clinical tests leading to NDA, and maybe even to ANDA.

Therefore, the Federal Circuit held Scripps' research to constitute infringement, and not covered by the safe harbor provision.

Merck KGaA v. Integra Lifesciences I, Ltd., 125 S.Ct. 2372, 74 U.S.P.Q.2d 1801 (2005)



The Safe Harbor Is Deep and Wide

Supreme Court Decision (June 13, 2005)

The Supreme Court reversed the narrow scope of protection accorded the safe harbor provision by the Federal Circuit. Justice Scalia stated the standard most definitively in *Merck v. Integra* as follows:

At least where a drug maker ... uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is “reasonably related” to the “development and submission of information under...Federal law. §271(e)(1).

Merck KGaA v. Integra Lifesciences I, Ltd., 125 S.Ct. 2372, 74 U.S.P.Q.2d 1801 (2005)



Value of Research Tool Patents and the Effect of Research Exemption Issues on Value of IP

Research not reasonably related to clinical trials: Currently, most, if not all, research is subject to patent infringement. Possible future legislation.

Pre-clinical and clinical trials: Research is exempt.



Business Method Patents in the United States

A claimed invention that involves only manipulating numbers constitutes patentable subject matter. Software patents are broadly permitted in the U.S.

The software can be directed to a business method.

State Street Bank v. Signature Financial Group, 47
USPQ2d 1596 (Fed. Cir. 1998)



Partnership Meeting of PTO TC

3600 on May 4, 2005

- Backlog

36 months for first office action

Policy of “second level review”

Solution: Streamlined review procedure and more examiners



Partnership Meeting of PTO TC

3600 on May 4, 2005

- Is the PTO too liberal or too conservative?
- Low allowance rate
 - 55% for 00; 45% for 01; 26% for 02;
16% for 03; and 11% for 04
 - Higher rate predicted for '05



Value of Software/Business

Method Patents

- Time consuming, difficult (expensive) prosecution
- High uncertainty of outcome in U.S.
- More difficult and higher uncertainty of outcome in Europe and most other countries



Doctrine of Equivalents (RIP)

Even if a product does not literally infringe a patent claim, the product may still infringe under the doctrine of equivalents, if the differences between the product and the claimed invention are “insubstantial.”



Doctrine of Equivalents (RIP)

The Festo Rule

A narrowing amendment to an element of a patent claim during prosecution creates a very strong presumption of surrender of all “foreseeable” equivalents of that element.

Equivalents are usually foreseeable if they are known at the time of the amendment.

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,
344F.3d 1359 (Fed. Cir. 2003) (*en banc*)



Festo Rule Extends to Incorporating Limitation from a Dependent Claim into an Independent Claim

Original claims:

1. A rock weighing up to 50 pounds.
2. The rock of claim 1 weighing up to 40 pounds.

Prosecution:

Claim 1 rejected because rocks weighing 45 pounds were known at the time of the invention.

Cancel claim 1 and substitute with: A rock weighing up to 40 pounds.

Honeywell International v. Hamilton Sundstrand,
370 F.3d 1131, 71 USPQ2d 1065 (Fed. Cir. 2004)



Festo Rule Extends to Incorporating Limitation from a Dependent Claim into an Independent Claim

Competition product: A rock weighing 40.1 pounds.

Arguments:

Scope of claim 2 unchanged. *Festo* rule does not apply.

Scope of claim 1 narrowed. *Festo* rule applies.

Held: *Festo* rule applies. No infringement.

Honeywell International v. Hamilton Sundstrand,
370 F.3d 1131, 71 USPQ2d 1065 (Fed. Cir. 2004)



Effect of Festo Rule on Value of Patents

- If a claim in an application is amended by adding a limitation in order to obtain a patent, the limitation cannot normally be expanded under the doctrine of equivalents.
- The Federal Circuit wanted to revoke the doctrine of equivalents. The Supreme Court wouldn't let the Federal Circuit do it.
- 99.9% of cases are argued before the Federal Circuit.



Trends

What you see (or at least write in your specification and claims) is what you get.

- Stricter written description requirement (*Lilly* rule)
- Stricter claim construction approach (*Phillips*)
- Reduced doctrine of equivalents (*Festo*)



Trends

Under the patent act, all technologies are created equal, but

Some technologies are less equal than others:

Nucleic acid molecules, gene therapy, and software patents are difficult to protect.



Trends

Research as infringing activity (as a practical matter):

pre-clinical and clinical activity is not subject to infringement (*Merck*); but

if unrelated to clinical trials:

currently – subject to infringement (*Roche, Duke*)

watch for possible legislation (AIPLA resolution)



Recommendations

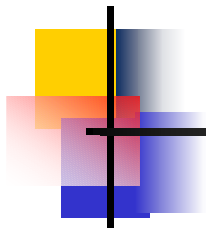
- Study prior art.
- Claim carefully and realistically.
- Prepare well written patent applications.
- Be selective.

Cost of investment in patent application

Probability patent will issue

Market value of exclusivity

- Have a good time at LES 2005.



Thank You.



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