Patent Strategies for Nanotechnology: Unique Challenges of the Written Description Requirement

FOR:
SULLIVAN UNIVERSITY
COLLEGE OF PHARMACY
NANOTECHNOLOGY SYMPOSIUM

September 25, 2010

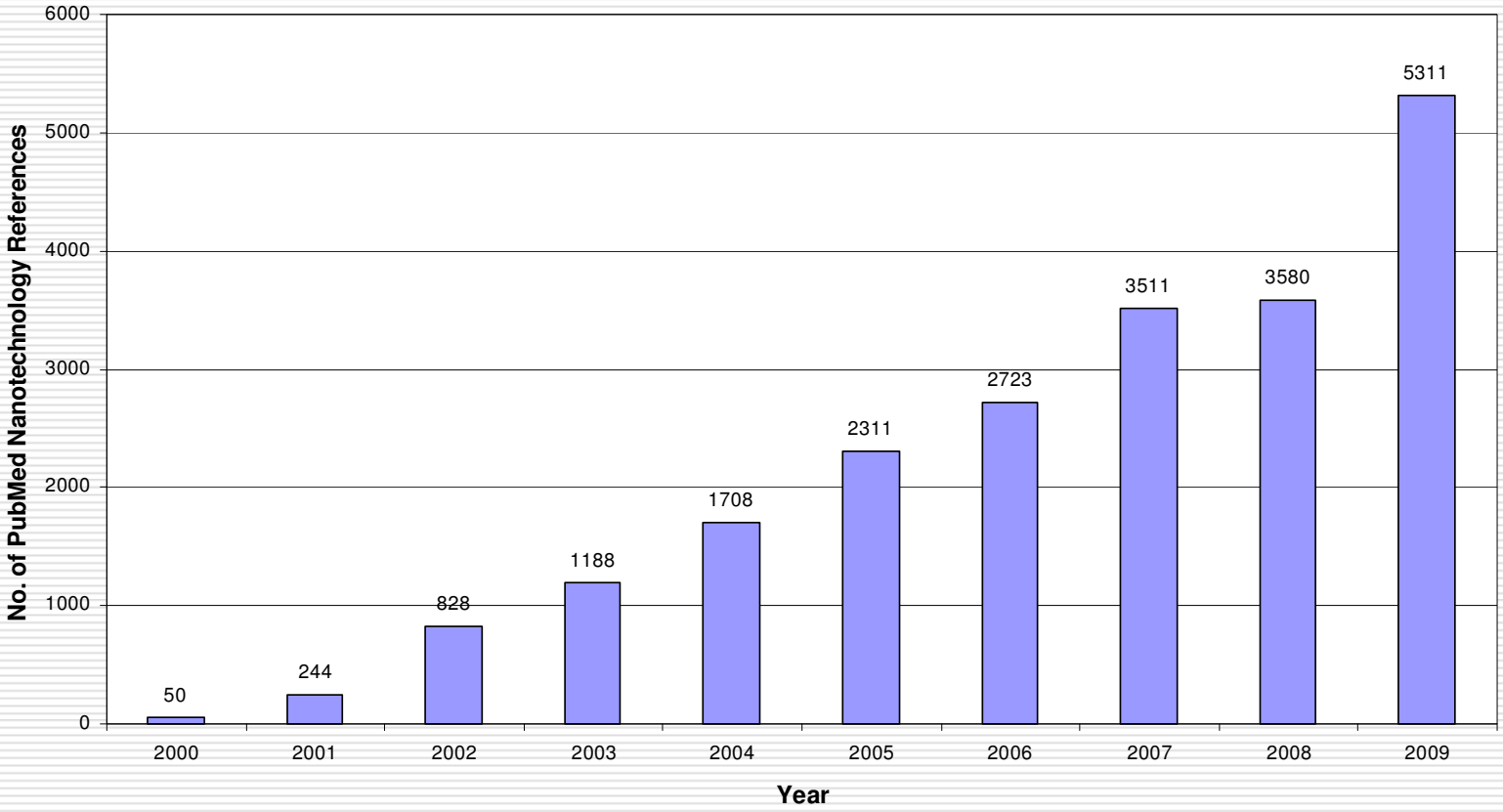
Stephen C. Hall, Esq.
Stoll Keenon Ogden PLLC
2000 PNC Plaza
Louisville, KY 40202
(502) 333-6000
steve.hall@skofirm.com

STOLL·KEENON·OGDEN

Outline of Presentation

- Attention on nanotechnology
- Overview of U.S. patent law
- Ariad Pharmaceuticals v. Eli Lilly, Federal Circuit Court of Appeals (Opinion, March 22, 2010)
- Specific examples related to nanotechnology

Nanotechnology Trends



Patentability: 3 Key Requirements

- The invention must be patent eligible subject matter
  - § 101 of U.S. Patent Act (35 United States Code)
  - Key phrase: cannot patent law of nature or natural phenomena, e.g., “gene patents”
- The invention must be novel
  - § 102 of U.S. Patent Act
  - Key word: must not be identical to invention found in prior art

Patentability Requirements – Cont'd

- The invention must be nonobvious
  - § 103 of the U.S. Patent Act
  - Key phrase: "combination" of prior art references can be used to reject or invalidate the patentPatentability: 3 Key Requirements

THE INVENTOR MUST ALSO PROVIDE, TO THE PUBLIC:

- Adequate Written Description
  - This requirement was the subject of the case study, Ariad Pharmaceuticals v. Eli Lilly, see *infra*
- Enablement
  - The patent must enable a person of "ordinary skill in the art" to make and use the invention
- Best Mode (aka preferred embodiment)
  - The inventor must disclose what he or she believes to be the best mode for practicing the invention

THE INVENTOR MUST ALSO CLAIM THE INVENTION

- Claims must particularly point out and distinctly claim the subject matter which the inventor regards as the invention.
- The requirements of written description, enablement, best mode, and claims are found in § 112 of the U.S. Patent Act.

Ariad Pharmaceuticals v. Eli Lilly (**March 22, 2010**)

U.S. Pat. No.: 6,410,516

Title: *Nuclear Factors Associated with Transcriptional Regulation*

Date of Application: 4-21-89

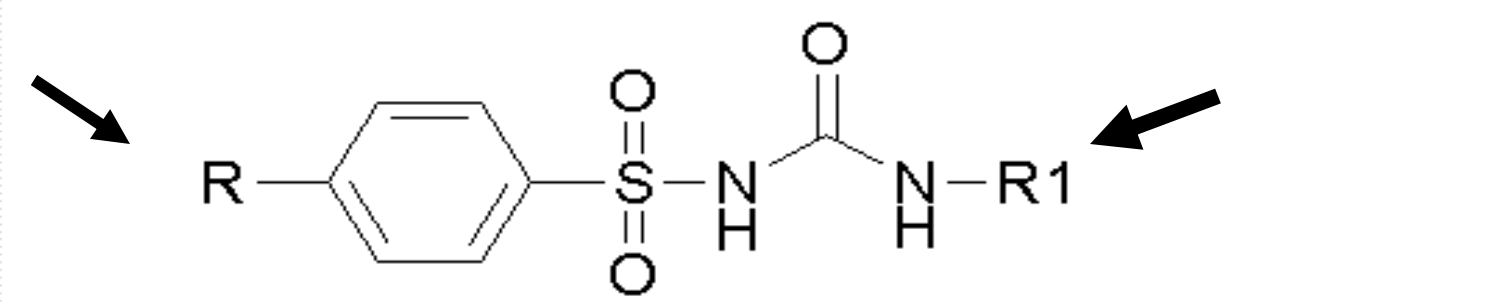
Date Patent Issued: 6-25-02

Lawsuit filed: 6-25-02

The patent claimed methods for controlling cytokines by reducing activity of transcription factor, NF-kB.

Generic Inventions

A generic invention means a single claim broad enough to encompass more than one embodiment (species). The use of chemical formulae is a classic way to write generic (genus) claims, e.g.



Ariad Pharmaceuticals v. Eli Lilly– cont'd

Ariad's patent claimed methods for controlling cytokines by reducing activity of transcription factor, NF-kB.

Lawsuit filed: 6-25-02

Jury trial (***Mass.***): April 2006

Result: Lilly infringed 4 patent claims

Jury awarded ~ $65,000,000

PATENT CASES IN THE COURTS

U.S. SUPREME COURT
(Very few cases)

FEDERAL CIRCUIT COURT OF APPEALS
(1 automatic appeal)

DISTRICT COURTS IN 50 STATES
(Trial judges and juries)

Ariad Pharmaceuticals v. Eli Lilly– cont'd

Title: *Nuclear Factors Associated with Transcriptional Regulation*

Jury trial (***Mass.***): April 2006

Result: Lilly = **Infringer**; Damages = $65M

First appeal in 2009 = 3-Judge panel

Rehearing in 2010 = 12 Judges

The result of the appeal in Ariad v. Eli Lilly

The level of detail required to satisfy the written description requirement varies depending on

- Nature, scope of claims
- complexity of technology and
- predictability of technology.

The result of the appeal in Ariad v. Eli Lilly – Cont'd

The written description requirement ensures that claims do not overreach the inventor's contribution to the field of art.

The result of the appeal in Ariad v. Eli Lilly - Cont'd

Claims that merely recite a description of the problem – and a result to be achieved – while claiming all solutions to it, including later-invented compounds, are not valid.

The Written Description Requirement and Basic Research

Basic research was taken to the patent system ***before*** its practical application was demonstrated.

Basic research is not the subject of patents… The role of the patent system is to encourage the practical application of scientific advances, through investment and commerce.

Take-aways about written description

1. Claims should contain a balance of broad (generic) claims and narrow (species) claims.
2. Teachings should adequately support claims.
3. Merely pointing out a desirable result does not suffice.
4. Basic research produces important discoveries, but not all important discoveries are patentable ***when*** the application is filed.

Remainder of Talk = Specific Examples

How the Written Description Requirement applies to nanotechnology patents.

3 examples:

- Apparatus claims (coated stents)
- Method claims (carbon nanotubes)
- Composition claims (magnetic particles)

Example # 1 – Drug delivery systems to blood vessel lumens (paclitaxel)

Assignee = Abbott Laboratories
Claim to an "Apparatus" = coated stents

(12) **United States Patent**
Burke et al.

(10) **Patent No.: US 7,378,105 B2**
(45) **Date of Patent: *May 27, 2008**

(54) **DRUG DELIVERY SYSTEMS, KITS, AND METHODS FOR ADMINISTERING ZOTAROLIMUS AND PACLITAXEL TO BLOOD VESSEL LUMENS**

60/664,328, filed on Mar. 23, 2005, provisional application No. 60/727,080, filed on Oct. 14, 2005, provisional application No. 60/726,878, filed on Oct. 14, 2005, provisional application No. 60/732,577, filed on Oct. 17, 2005, provisional application No. 60/554,

Example # 1 – Cont'd

- Problem: restenosis
- Strategy: paclitaxel-containing nanoparticles on a coated stent
- Claimed apparatus (excerpt):
  - a stent + a therapeutic composition +
  - wherein neointimal hyperplasia is reduced when the system is implanted in a lumen of a blood vessel …

↓

Broadly stated in terms of a result to achieve

Example # 1 – Cont'd

How the WD* supported the (functional) genus

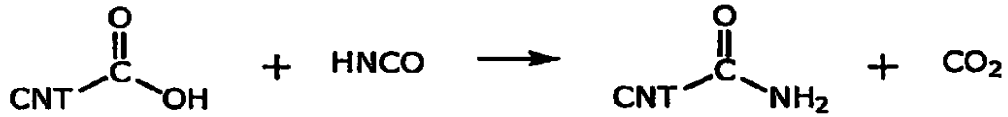
- Chemical names, ratios, and ranges
  - wherein the ratio of zotarolimus : paclitaxel is by weight $10:7 \leq r \leq 10:0.01$
- Comparative properties
  - a stent + coating + therapeutic composition wherein neointimal hyperplasia is reduced by $\geq 10\%$ when compared to a control like the experimental stent except no therapeutic substance

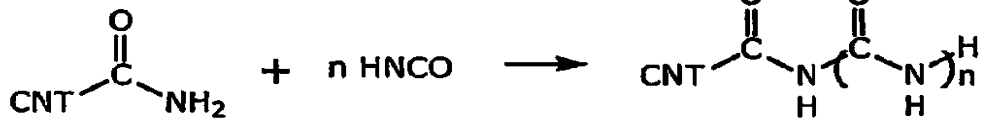
* = Written Description

Example # 2 – Carbon Nanotubes

U.S. Pat. No. 7,531,157
Originated in Germany
Claims a "Method" of solubilizing CNT's using chemical reactions, e.g.

Reactions involving carboxylic acid groups





From Fig. 3

Example # 2 – Cont'd

- Problem: poorly soluble drugs
- Strategy: Soluble CNT's as carrier
- Claimed "method" (excerpt)
  - Mix CNT's with urea → precursor to isocyanic acid
  - Initiate polymerization of isocyanic acid
  - Add ***at least one aldehyde*** to mixture and heat

↓

Broad genus claim

Example 2 – Cont'd

How the WD supported the genus

- Chemical names:
  - aldehyde is selected from the group comprising acetaldehyde, benzaldehyde, carboxybenzaldehyde …
- Structural features:
  - the benzaldehyde is substituted with at least one electron-donating group …in the paraposition

Example 2 – Cont'd

How the WD supported the genus – cont'd

- Properties
  - the aldehyde … should have a boiling point greater than approximately 100°C.
  - The criterion for the boiling point of the aldehyde … is that the aldehyde can be present during the polymerization long enough to react without evaporating completely

Example # 3 – Thermotherapy via targeted delivery of nanoscale magnetic particles

US Pat. No. 7,074,175

Inventors = from Massachusetts

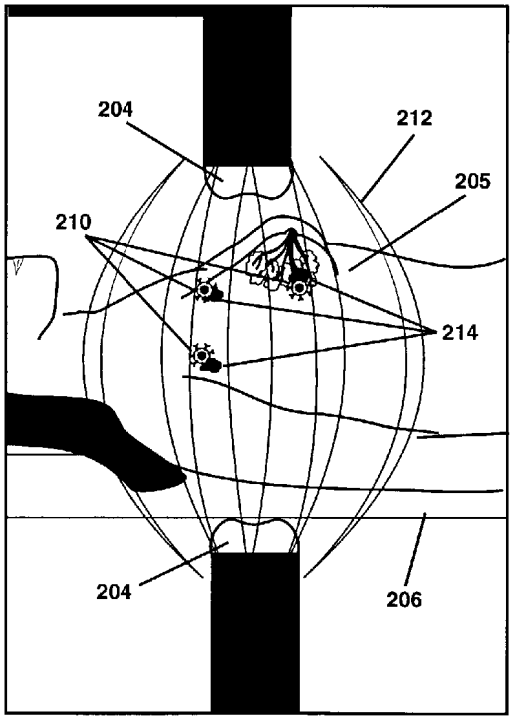


Figure 2.

Claims a "Composition"

Fig. 2 illustrates bioprobes (210) bound to cancer cells (214) in a magnetic field

Example # 3 – Cont'd

- Problem: cancer treatment destroys healthy tissues, too
- Strategy: targeted cancer hyperthermia therapy
- Claimed composition: nanoscale magnetic bioprobe w/ ligand selective to cancer cell marker

Broad genus claim in 2 respects
(ligand and cancer marker)

Example # 3 – Cont'd

How the WD supported the ligand genus

- Definition:
  - Ligand means compound which targets biological markers, e.g. proteins, peptides, antibodies, antibody fragments, saccharides, carbohydrates ...
- Structural features:
  - ligand = antibody stabilized by a disulfide bond between the variable regions

Example # 3 – Cont'd

How the WD supported the marker genus

- Members of the genus
  - e.g., cell surface markers such as EGFR receptor, melanoma antigen (MAGE) gene, tumor suppressor gene, oncogene receptor, apoptosis related factor
- Specific examples from *in vitro* testing:
  - Her2 antibody bioprobes → Her2 receptor
  - MUC-1 antibody bioprobes→ MUC-1 marker

Thank You for Your Attention, Insights, and Questions!

STOLL·KEENON·OGDEN