

Protection of Medical Device Innovation Through Patenting:
An Overview
and
Critical Considerations: Part 1

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Fundamentals Every Professional Should Know About Intellectual Property in General And Patents In Particular

- Intellectual property

Is property initiated/generated by mental thought
process

(Turning **concepts** into intellectual property)

Abstract Ideas? NO

Enabling Concepts? YES

Keyword: **CONCEPTION** (Vanderbilt v. ICOS)

Types of Intellectual Property

Trademarks and Service Marks

(Identifying the Source of Goods/Services)

Copyright

(Form of Expression)

Trade Secrets

(Business Advantage)

Trade Dress

(Source of Goods/Service)

Brown. What Can Brown Do for You?

Secondary Meaning

Non-Functional

Patents

Enabling Concepts

Useful (Utility Patents) or Ornamental (Design Patents)

Novel

Non-obvious

Right to Exclude Others

(Not the Right to Practice !!!!)

Focus on Patents

Intellectual property rights are constitutionally-rooted and contractually-based. (The rule of good faith and fair dealing is implied in every filing/filed application and transaction with the U.S. Patent Office).

- A Filing as an offer
- An allowance as an acceptance
- An issuance as a memorialization of the contract, as indicated on the front cover of each issued patent

The
United
States
of
America



**The Director of the United States
Patent and Trademark Office**

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of annuity fees as provided by law.

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the U.S. filing date, subject to any statutory extension. If the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121 or 365(c), the term of the patent is twenty years from the date on which the earliest application was filed, subject to any statutory extensions.

Director of the United States Patent and Trademark Office

A Patent May Be Regarded As a Business Advantage

Right to exclude others (Lawful Monopoly)

Even Experimental Use (*Embrex v. Service Engineering*)

Licensing

Securing a company's future (Obsolete your own products before someone else obsoletes them for you)

Patent Term (Duration of Lawful Monopoly)

Transitional Rules (June 8, 1995)

Patentable subject matter:

What may be patented? 35 U.S.C. 101

- a. Chemical composition/Ingredients of matter
(Ingredients, Weights %, Ranges, . . .)
- b. Articles of manufacture. (Products)
(Naturally Occurring Things? **NO**. Myriad Genetics)
- c. Apparatus/device/machine
(Components, their functions and relationships)
- d. Method/Process, Including;
Business Methods and
New Use of an Existing Process
(Action Verbs/Steps)

Crunchy Cookies (a, b, c and d) All in One.

Inventor's Understanding of How an Invention Works? Not a Requirement!!!!

Enabling Disclosure. A Requirement.

Definite Terms: (Crunchy?, Chewy?)

Claim Construction, Markman Hearing

Types of Patents

Design Patents (The Ornamental Appearance/Design)

Plant Patents

Utility Patents (Usefulness is a Requirement)

Requirements an Invention Must Meet in Order to be Patentable

- a. Subject matter (35 U.S.C. 101)

b. Novelty (35 U.S.C. 102)

Is the Invention New?

Prior Use/Experimental Use

Prior Publications (By the Inventor, By Others)

Invented by Another, but Suppressed

Not Invented by the Applicant

c. Non-obviousness 35 U.S.C. 103

More than 1 Reference, Combined to Yield the Elements of the Invention.

(CAFC): Teaching/Suggestion/Motivation. **(OUT)**

(Supreme Court, 2007): KSR v. Teleflex **(IN)**

d. Enablement of Disclosure. Document, standing on its own, must be enabling, i.e., making a person of ordinary skill in the relevant art, in possession of the invention and capable of implementing the invention.

e. Disclosure of a Preferred Embodiment.

What is an Embodiment?

Some Critical Considerations

Inventorship:

Sole Inventor

Who is a Co-inventor?

Vanderbilt Univ. (Corbin, Francis, Konjeti)

v.

ICOS (Daugan) (USP# 5,859,006 & 6,140,329)

CAFC: “Daugan discovered Tadalafil, the claimed compound at issue”

Others; No conceptual contribution to the claimed invention.

Definiteness of Terms, Ranges, Relationship of Components, etc.:

EXAMPLES:

less than 70%: (Includes 0.0%)

a kit vs. an airplane

Relative Location of Components
(Ask Jack !!)

at vs. to (Heating the dough TO a
temperature in the range of 400 F to 800 F)



Cooked at 850°
How cool is that?



Enjoy the taste of tradition: our legendary Margherita pizza, just one of Bertucci's award-winning Neapolitan pizzas and truly one of the world's best. Try it with an ice-cold Michelob Ultra.

Anticipate An Obviousness Rejection in a First Office Action; Prepare for It.

Teaching, Suggestion Motivation? **OUT**

KSR v. Teleflex? **IN**

Alleged Infringement of Claims, by others:

Look Before You Leap

Examine the claims

Examine the allegedly infringing product, method, device, composition, ...

The mirror image matching process, A MUST.

Literal Infringement

Infringement under the Doctrine of
Equivalents (Function, Way, Result)

Thank You