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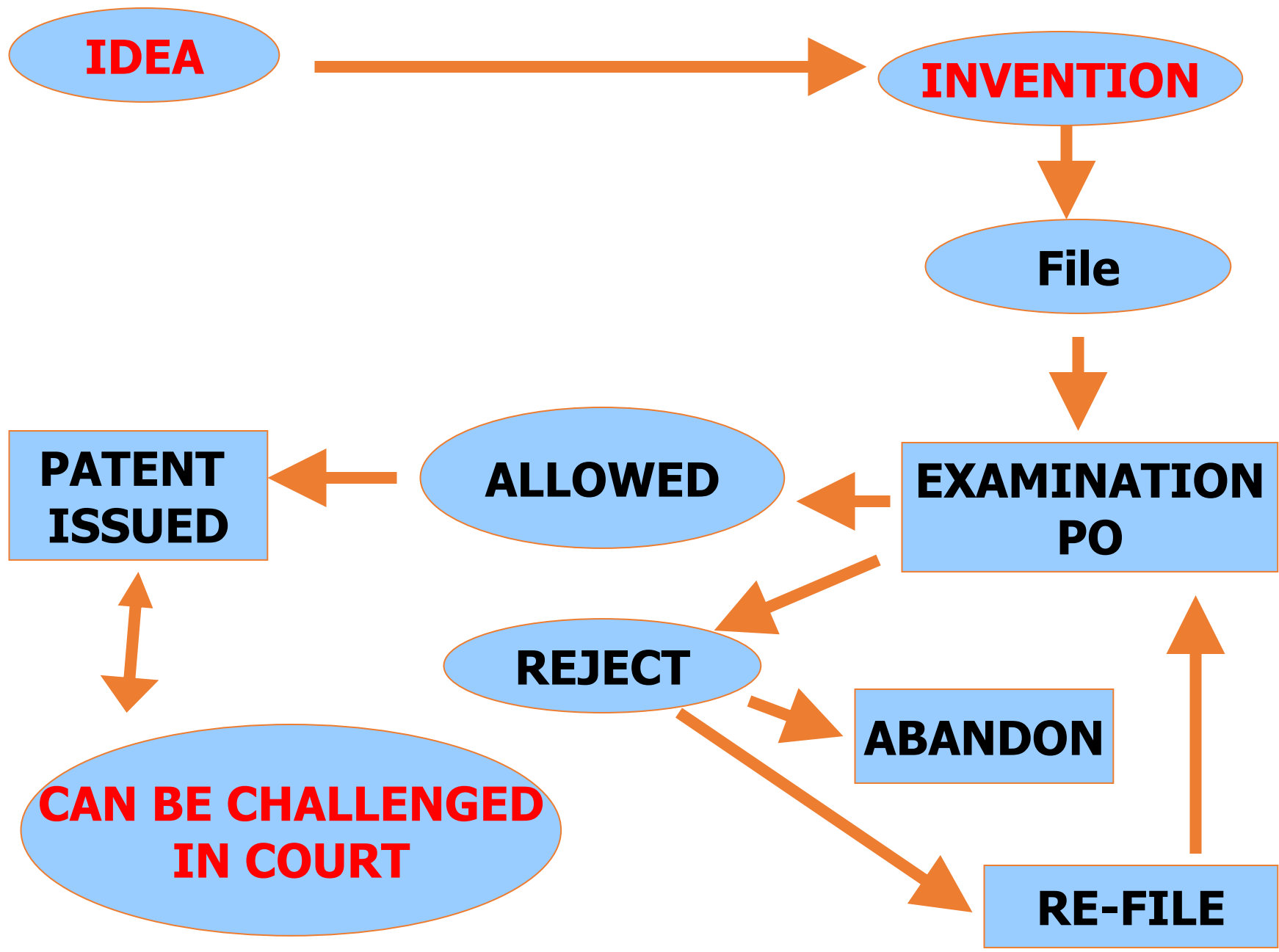
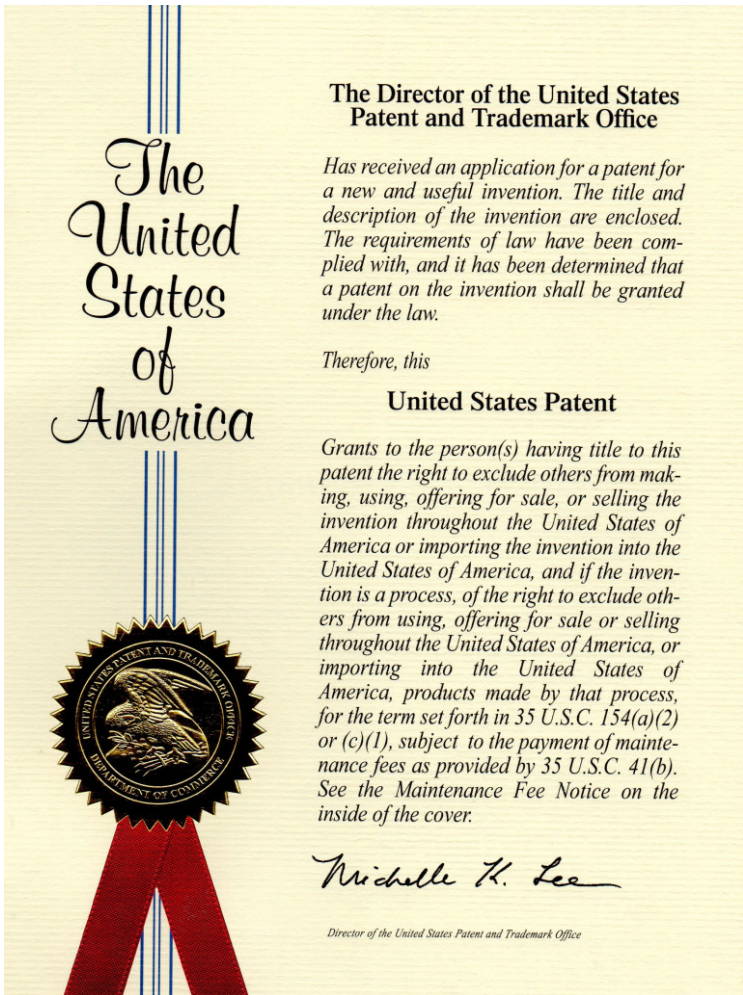


# *Basics of Patent Drafting*

Advanced Diploma In Patent Law  
NALSAR University of Law, Hyderabad  
Contact Class; November 2022.

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ANINDYA SIRCAR



# Must be New and Useful

## Novelty

- The invention, as claimed, was not known prior to your invention.
  - All elements of your claimed invention are disclosed in one “prior art” reference
  - 1-year grace period in several PTOs after publishing your invention.
- Newly discovered properties of known compounds do not render these compounds novel !!
  - Often an issue for biotechnology inventions and inventions arising out of University research



# Must be Non-obvious

## Prima Facie Obviousness

- All elements of the claimed invention are taught in the prior art, albeit in different references,
- There is a motivation, in the prior art, to combine the relevant disclosures, and
- One would have had a reasonable expectation of success



## Objective Evidence of Non Obviousness

- Unexpected properties as compared to the closest prior art
- Long-felt need
- Failure of others
- Commercial success

# Industrial Application - Principles

- The patent must disclose *“a practical application”* and *“some profitable use”* for the claimed substance, so that the ensuing monopoly *“can be expected [to lead to] some ... commercial benefit”*;
- A *“concrete benefit”*, namely the invention’s *“use ... in industrial practice”* must be *“derivable directly from the description”*, coupled with common general knowledge;
- A merely *“speculative”* use will not suffice, so *“a vague and speculative indication of possible objectives that might or might not be achievable”* will not do;
- The patent and common general knowledge must enable the skilled person *“to reproduce”* or *“exploit”* the claimed invention without *“undue burden”*, or having to carry out *“a research programme”*;



# Unity of Invention

- In most patent laws, unity of invention is a formal administrative requirement that must be met by a patent application to become a granted patent.
- A patent application can relate only to one invention or a group of closely related inventions.
- The purpose of this requirement is administrative, as well as financial.
- It makes the classification of patent documents easier.

The requirement serves to preclude the option of filing one patent application for several inventions, while paying only one set of fees (filing fee, search fee, examination fee, renewal fees, and so on).



# Method of claim construction

- Define the invention and are what are legally enforceable.
- *The claim or claims shall define the matter for which protection is sought. Claims shall be clear and concise. They shall be fully supported by the description.*



# Role of Specification and Claims

- The **claims** define the legal boundaries of the invention.
  - Must claim the invention with reasonable precision
- The **specification** describes the invention, and how to make and use it.
  - Written description requirement (demonstrate possession)
  - Enablement requirement
  - Best Mode



# A Simple Approach

- Write claims to the intended audience
- Use plain English – fully and clearly supported and defined in the specification
- Every term in a claim means something



# Scope of the Patent

- The prohibition against new matter will prevent you from introducing further description after filing
- New claims may be added, and claims amended during prosecution, but must be supported by the specification as filed.
  - ***Sub-genus and particular embodiments must have support!***
- Continuation-in-Part application may contain added matter
  - Claims may not be entitled to earlier filing date

# How to Start Drafting

- Draft a set of claims first, to define the invention.
  - Requires an understanding of the content of the prior art, and an understanding of what makes the invention patentable.
  - Do a prior art search!
- The specification is then drafted in view of the necessary content.



First drafts  
don't have to be  
perfect.  
They just have to  
be written.

# Parts of the Claim

## ➤ Preamble

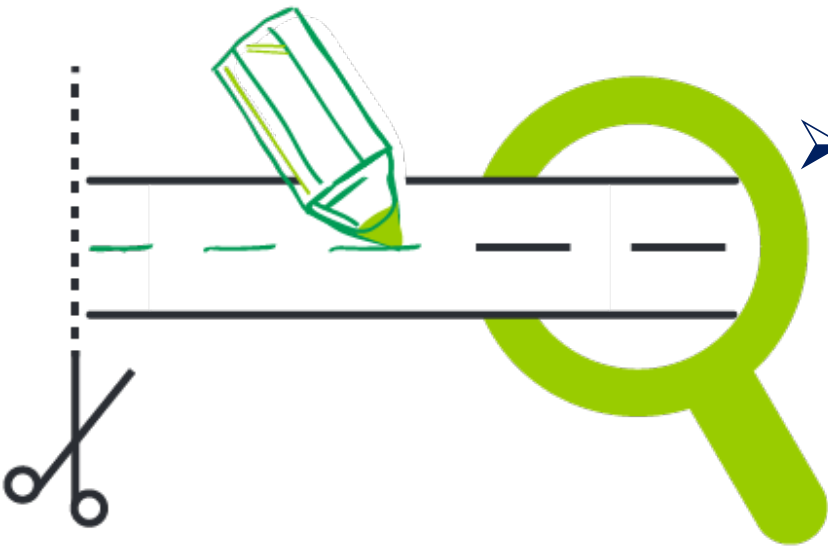
- Should be short, and should not imply any unnecessary limitations.

## ➤ Transition term

- “comprising” – encompasses additional elements
- “consisting essentially of” – encompasses additional elements that do not affect the essential features of the invention
- “consisting of” - does not encompass additional elements

## ➤ Body

- Recite all essential elements (components or steps), and their limitations
- Relate the elements to each other



# Drafting Claims

- Draft at least one “**independent**” claim for each type of patentable invention (i.e. product, process, apparatus etc...)
  - Consider potential infringers and products. The claims should be drafted so as to maximize enforcement on a direct infringement theory.
  
- Draft “**dependent**” claims to...
  - Help define broad terms in the independent claim
  - Create “*fall-back*” positions
  - Commercial or preferred embodiments
  - Expedite prosecution





1. A method of lowering cholesterol in a subject, comprising, administering to said subject compound X, or a pharmaceutically acceptable salt thereof.
2. The method of claim 1, wherein said subject is a human.
3. The method of claim 2, wherein said pharmaceutically acceptable salt is a sodium salt.

just  
another  
example

1. A nanoparticle comprising, an antibody bound to a polymeric nanoparticle core.
2. The nanoparticle of claim 1, wherein said antibody is indirectly bound to the polymeric nanoparticle core.
3. The nanoparticle of claim 2, wherein said antibody is bound directly to the polymeric nanoparticle core.

just  
another  
example

1. A method of diagnosing Disease X, comprising,
  - (a) taking a body fluid sample from a patient suspected of having disease X,
  - (b) contacting said sample with a probe capable of hybridizing with abnormal gene A, and
  - (c) detecting abnormal gene A in said sample.

just  
another  
example

1. A polypeptide comprising an amino acid sequence having at least 80% homology to SEQ ID NO: 1.
2. The polypeptide of claim 1 comprising the amino acid sequence of SEQ ID NO: 1.

just  
another  
example

1. A compound of the following formula 1, or a pharmaceutically acceptable salt thereof....

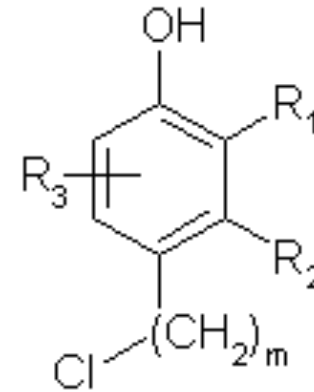
just  
another  
example

1. A method comprising:
  - identifying at a server,  
a plurality of processing services, each service  
provided over a network;
  - describing each processing service as a formulaic  
structure;
  - federating those formulaic structures to create a  
virtual data center.
2. The method of claim 1 wherein the network is the Internet.

# Other Types of Claims

## ➤ Markush Group

- “wherein R1 is selected from the group consisting of alkyl, alkene, and aryl.”
- “wherein said stabilizer comprises at least one member selected from the group consisting of albumin, mannitol, and glycine.”



## ➤ Product-by-Process

- Patentability is based upon the product

Substituent variation: R<sub>1</sub> is methyl or ethyl  
Homology variation: R<sub>2</sub> is alkyl  
Position variation: R<sub>3</sub> is amino  
Frequency variation: m is 1-3

# Multiple Dependency

- Requires a multiple dependent claim fee.
- Useful for filling “*gaps*” in the claim scope.
- No multiple dependent claim may depend from another multiple dependent claim.



**TITLE**

**Preamble / Technical Field**

**BACKGROUND OF INVENTION**

**SUMMARY OF INVENTION**

**DETAILED DESCRIPTION OF INVENTION**

**Examples**

***Best Mode / Preferred Embodiments***

**CLAIMS**

**FIGURES**

**OTHER ATTACHMENTS** (Sequences, Deposits)

**ABSTRACT**



# Background

- The Background describes the field of an invention, and may describe limitations of the closest prior art.
- Some statements can be interpreted as admissions that a certain feature is prior art.

# Summary of the Invention

- May describe objectives of the invention. How does the invention meet the objective.
- Brief description of the independent claims, often paralleling the claim language itself.
- Statement of utility



# Detailed Description of the Invention

- Describe independent and all dependent claims.
- Describe elements of the claims in different ways if possible, and in varying scopes
  - i.e. describe polynucleotide by sequence, by encoded polypeptide, by homology, by hybridization stringency
- Describe ranges and sub-ranges - ***Important for compound formulas***
- Describe how to make and use the invention, and provide as much guidance as possible
- Describe invention through reference to drawings
- May incorporate non-essential matter & essential matter by reference to other documents
  - Use words “incorporate by reference” and to US Patents where possible
  - Negative limitations



**Description**

# The Language

➤ Use language such as:

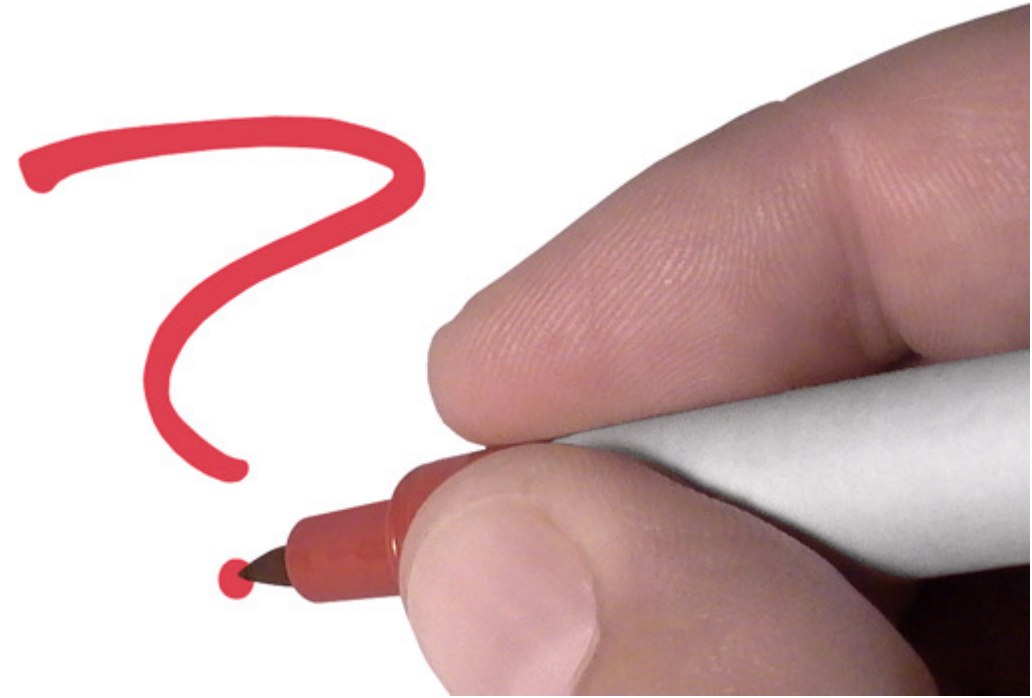
- “An aspect of the invention is...”
- “A preferred embodiment of the invention is...”
- “An exemplary embodiment of the invention is...”

➤ Do not use terms such as:

- “necessary”
- “critical”



# Should You Define Terms?



- Only define terms where necessary.
- Use conventional terms in the claims in the conventional context.
  - Do not provide definitions, so that the actual boundaries of term are left for argument.

# Examples in Description

- This is where you provide all relevant experimental results
- Examples are not mandatory, but ***are vital*** for biotechnology and pharma
- May be working examples or prophetic
  - Prophetic examples must be in the present tense.

# Polypeptides and Polynucleotides

## Polynucleotides

- ✓ By gene name and/or source
- ✓ Homology
- ✓ Hybridization stringency
- ✓ Encoding polypeptide
- ✓ By sequence
- ✓ Sequence alignments

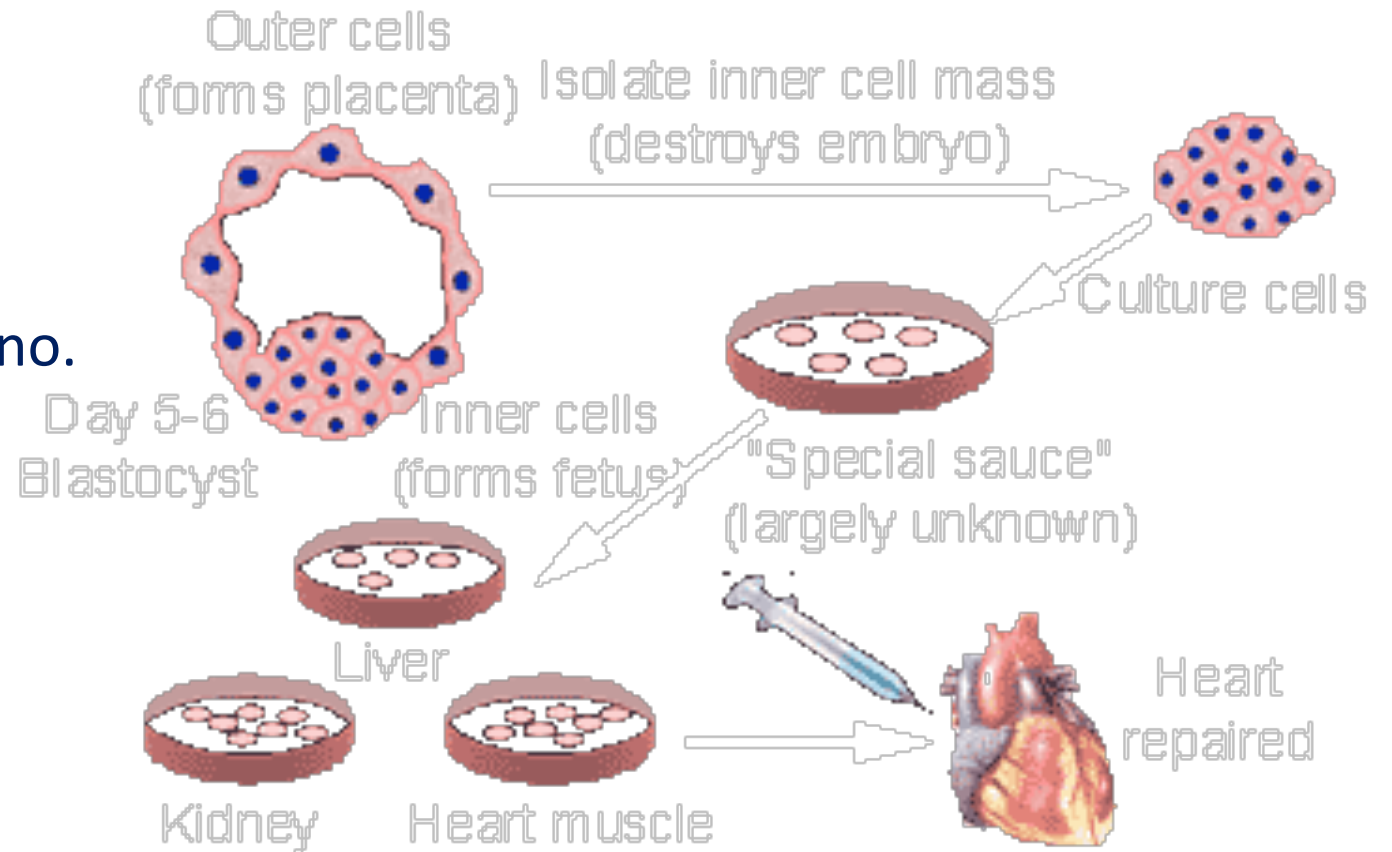
## Polypeptides

- ✓ By polypeptide name and/or source
- ✓ By sequence
- ✓ By function
- ✓ By number of substitutions, deletions, insertions etc....
- ✓ Sequence alignments



# Cell Lines

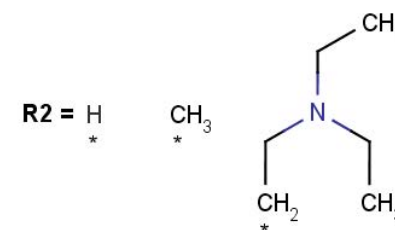
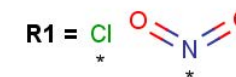
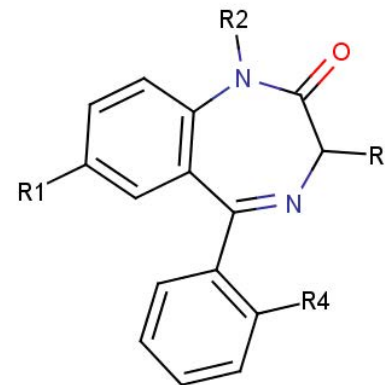
- ✓ Genus species
- ✓ Source
- ✓ Strain name and/or accession no.
- ✓ Deposit
- ✓ Genetic manipulations
- ✓ Product-by-process



# Chemical Compounds

## ✓ Chemical structures

- Varying ranges for each substituent
- For example
  - “R may be a C<sub>1-8</sub> alkyl, and is preferably a C<sub>3-5</sub> alkyl

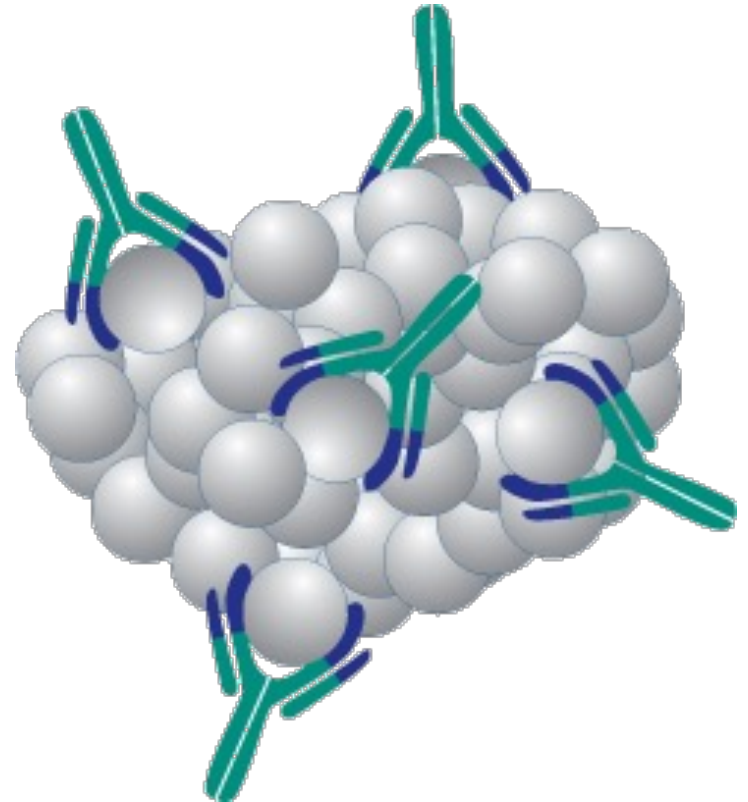


## ✓ Chemical names

- “R may be a phenylalkyl, and is preferably phenylmethyl.”

# Antibodies

- ✓ May be described by their antigen!
- ✓ Amino acid sequence of an antibody is unnecessary.



# Computer Related/Implemented Inventions



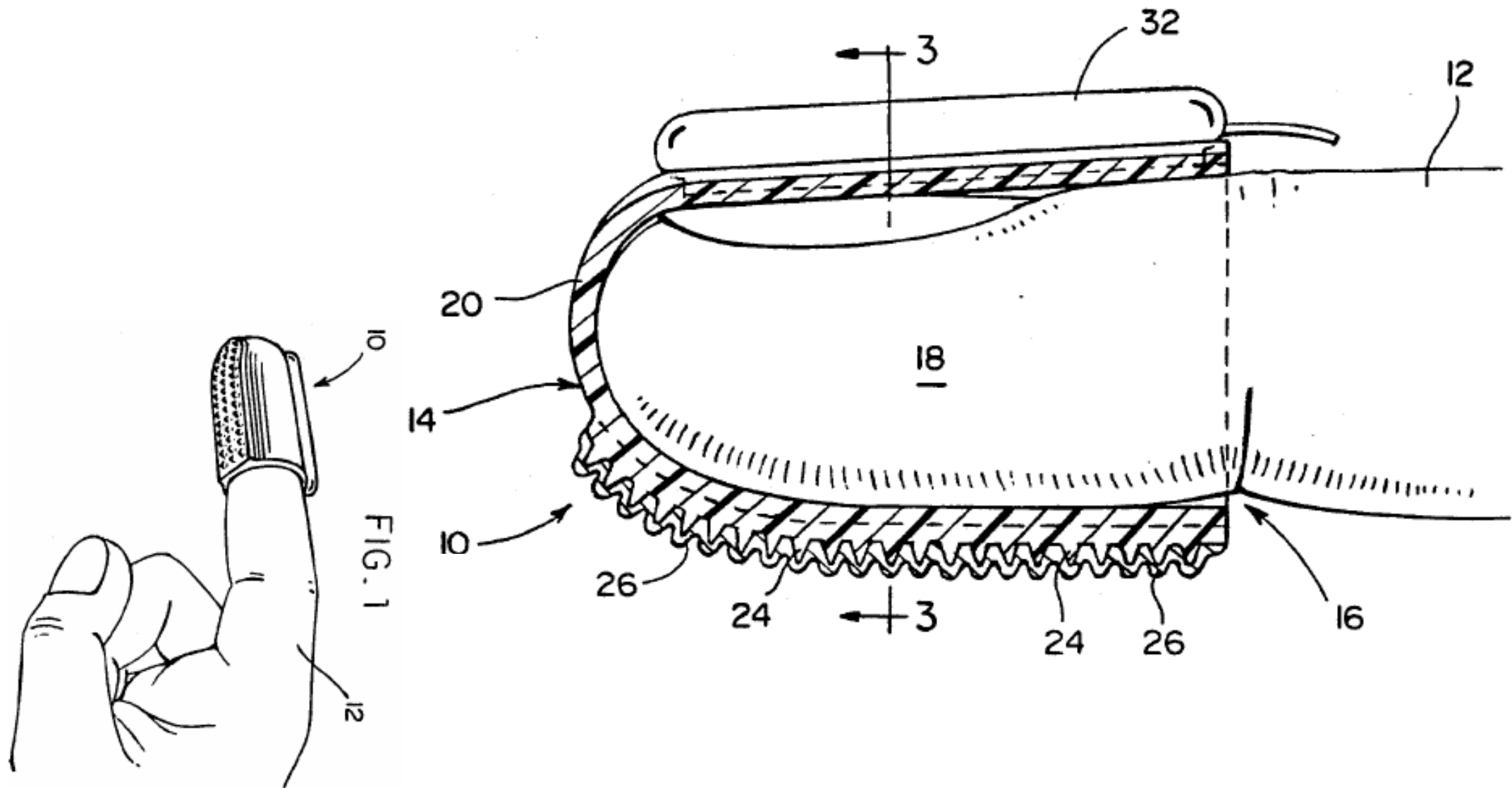
- ✓ Yes it is patentable - if the program has the potential to bring about, when running on a computer, a technical effect which goes beyond the normal interactions between the program and the computer.
- ✓ The normal interactions like flow of electrical current are not sufficient to establish the technical effect.

# Computer Related/Implemented Inventions

- Highlight technical problem being solved
- Highlight the technical effect or technical advance of a specified program (whether by means of hardware or software)
- Try to avoid look and feel of algorithm, mathematical method, business method as even technical advance cannot save it due to absolute bar
- Avoid certain terms in claims, like program, instructions, calculating, etc.
- Link the invention to one or more end application/use
- Keep method as primary claims
- Clearly state what device/ component performs the method
- Avoid multi-party system claims – client and server, server and database
- Separate claim for each device, such as transmitter and receiver, source and destination device



# Discussion Problem



# Claims

I claim:

1. A disposable toothbrush comprising:  
a cap including an opening for receipt of a fingertip,  
a flat surface located on one side of said cap having  
bristles projecting therefrom for brushing of teeth,  
a layer of dehydrated toothpaste being located on  
said bristles, and  
at least one dental hygiene accessory located on a side  
of said cap opposite to said one side,  
said at least one dental hygiene accessory being lo-  
cated within a capsule slidably mounted on said  
cap.
2. A disposable toothbrush as claimed in claim 1,  
wherein said capsule surrounds said at least one dental  
hygiene accessory.
3. A disposable toothbrush as claimed in claim 1,  
wherein said cap is biodegradable.
4. A disposable toothbrush as claimed in claim 1,  
wherein said bristles are integral with said cap.
5. A disposable toothbrush as claimed in claim 1,  
wherein said cap includes a groove for receipt of a  
projection extending from said capsule.
6. A disposable toothbrush as claimed in claim 1,  
wherein said capsule includes a void for storing of said  
dental hygiene accessory.
7. A disposable toothbrush comprising:  
a cap including an opening for receipt of a fingertip,  
a flat surface defined by one side of said cap and  
having bristles projecting therefrom for brushing  
of teeth,  
a layer of dehydrated toothpaste embedded on said  
bristles, and  
a dental hygiene accessory located on said cap,  
said dental hygiene accessory being located on a side  
of said cap opposite to said one side and within a  
capsule slidably mounted on said cap.
8. A disposable toothbrush as claimed in claim 7,  
wherein said dental hygiene accessory is a liquid lo-  
cated in said capsule housed within said cap.
9. A disposable toothbrush as claimed in claim 8,  
wherein said liquid is released upon opening of a cap-  
sule having stored said liquid.
10. A disposable toothbrush as claimed in claim 9,  
wherein said cap includes a groove for receipt of a  
projection extending from said capsule.
11. A disposable toothbrush as claimed in claim 7,  
wherein said cap is biodegradable.



US005213428A

**United States Patent** [19]**Salman**[11] **Patent Number:** **5,213,428**[45] **Date of Patent:** **May 25, 1993**[54] **BIODEGRADABLE TOOTHBRUSH**[75] **Inventor:** **Naser Salman, Gaithersburg, Md.**[73] **Assignee:** **Elisabetta Molari, Cesena, Italy**[21] **Appl. No.:** **878,550**[22] **Filed:** **May 5, 1992**[51] **Int. Cl.<sup>5</sup>** ..... **A46B 5/04**[52] **U.S. Cl.** ..... **401/7; 15/227;**  
15/167.1[58] **Field of Search** ..... **401/6-8;**  
132/308, 309; 15/227, 167.1[56] **References Cited****U.S. PATENT DOCUMENTS**

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*Primary Examiner*—Danton D. DeMille*Attorney, Agent, or Firm*—Jacobson, Price, Holman &  
Stern[57] **ABSTRACT**

A disposable toothbrush formed of a biodegradable material such as biodegradable plastic. The toothbrush would fit, preferably, over the index finger of a user. By using the index finger, it is easy to reach any part of the teeth by locating the toothbrush so as to apply a brushing action to the upper and lower teeth, with the toothbrush located on the outside or inside of the index finger. A toothbrush cap provides an opening for receipt of an index finger of a user. On a flattened portion of the toothbrush cap, are defined two to four rows of short bristles, preferably 3/16 inches in height. These bristles may be formed integrally with the toothbrush cap or include bristles imbedded in the cap. These bristles are impregnated with dehydrated toothpaste which bonds with the bristles to form a defined layer on top of the bristles. Upon contact with water, the impregnated toothpaste would hydrolyze to aid in brushing of the teeth for a single use. Upon completion of brushing, the toothbrush would be disposed of in its entirety.

**11 Claims, 1 Drawing Sheet**

thank  
you



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