



Vepachedu Professional Corporation

(Intellectual Property Consultants)

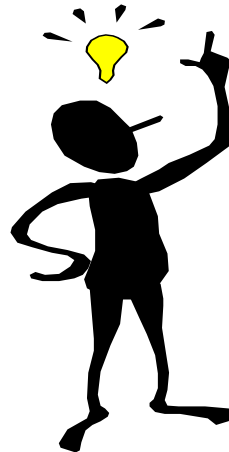
Intellectual Property Rights

by

Sreenivasarao Vepachedu, PhD, JD, LLM

“No army can withstand the strength of an idea whose time has come.”

Victor Hugo





Depatched Professional Corporation

(Intellectual Property Consultants)

Intellectual Property

Without IP, the Future of Your Business May be Owned by Someone Else!

“If ever there were a field with financial opportunity written all over it, it would have to be the fusty musty world of patent,” Forbes, February 1998

IPC

Deparchedn Professional Corporation

(Intellectual Property Consultants)

Trade Secrets

A Secret

Is a Piece of Information

That the Possessor

Has Entrusted Nobody



Depatched Professional Corporation

(Intellectual Property Consultants)

Sharing Ideas

Thomas Jefferson:

“...He who receives an idea from me, receives instructions himself without lessening mine; as he who lights his taper at mine, receives light without darkening me. That ideas should freely spread from one to another over the globe, for moral and mutual instruction of man, and improvement of his condition, seems to be peculiarly and benevolently designed by nature.”

IPC

Deparchedn Professional Corporation

(Intellectual Property Consultants)

Open System

Patents

Copyrights

Trademarks



Deparchedn Professional Corporation

(Intellectual Property Consultants)

US Patent's Purpose

- **For the Patentee:** Reward the patentee with the Property Right to *Exclude Others* from benefiting from the patented invention for the Statutory Term. 35 USC 271, i.e., exclude others from making, using, selling, offering to sell in the US or importing into the US, the patented invention.
- **For Society:** Knowledge of the Invention Disclosed



Deparchedn Professional Corporation

(Intellectual Property Consultants)

History of IP

- Sybaris, a Greek Colony, 500 BC
 - If a confectioner developed a new and unusual dish he was granted monopoly for one year on that dish
- Italian City-States
 - 20- year patent was granted to Galileo (1564-1642) by Doge of Venice on a mechanism of raising irrigation water to the fields.
- British Parliament
 - Statute of Monopolies 1624: the Basis for All the Patent Systems in the World



Deparchedn Professional Corporation

(Intellectual Property Consultants)

American Constitution

Article 1, Section 8:

“The Congress shall have the power... to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”

In India, No Such Constitutional Mandate



Deparchedn Professional Corporation

(Intellectual Property Consultants)

USPTO

Creation:

- In 1790, Patent of Act of 1790 Created a Commission to Examine the Patent Applications
- In 1793, A Registration System was Adopted
- In 1836, Patent Act of 1836 Created the Position of Commissioner of Patents

Main Functions:

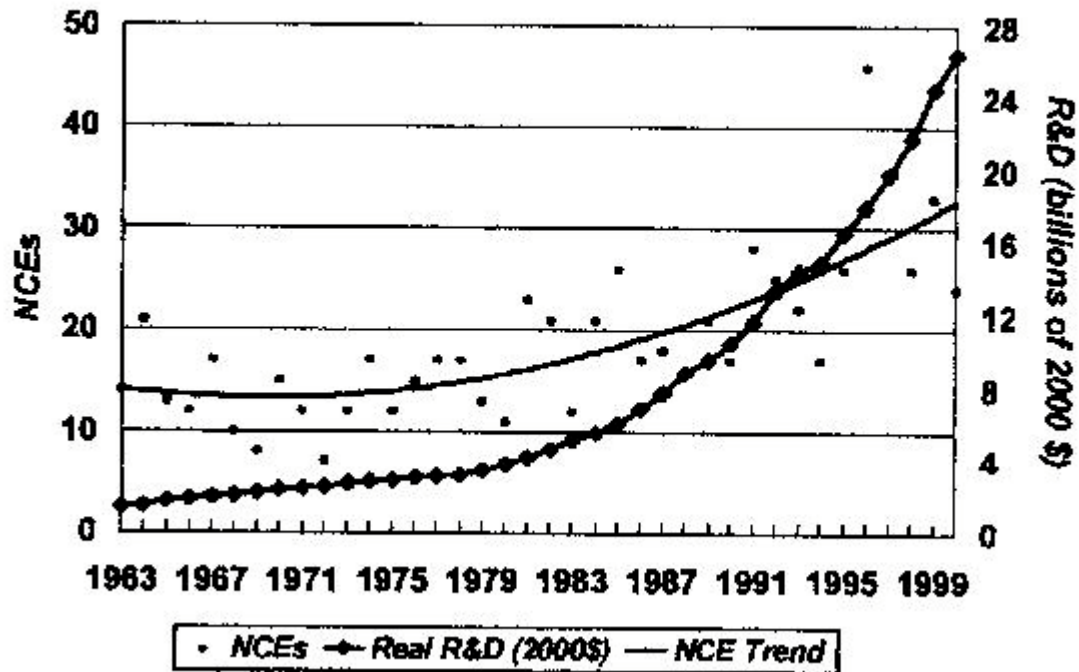
- Protect known and obvious knowledge from being unfairly usurped by an applicant who has not made really any contribution
- Encourage disclosure of inventions to stimulate the development of technology



Deparchedn Professional Corporation

(Intellectual Property Consultants)

J.A. DiMasi et al. / Journal of Health Economics 22 (2003) 151-185



Inflation-adjusted Industry R&D expenditures (2000 dollars) and US new chemical entity (NCE) approvals



Deparchedn Professional Corporation

(Intellectual Property Consultants)

R&D Costs of Drug Development Per Drug

- Average cost in 1987 = \$ 231 m
- Pre-approval out of pocket cost in 2000 = \$ 403 m
- Pre-approval capitalized cost in 2000 = \$ 802 m
- Pre-approval out of pocket cost in 2001 = \$ 540 m
- Pre-approval capitalized cost in 2001 = \$ 1.1 b
- Pre-approval out of pocket cost in 2013 = \$ 970 m
- Pre-approval capitalized cost in 2013 = \$ 1.9 b

DiMasi et al, *Journal of Health Economics* 22(2003) 151-185

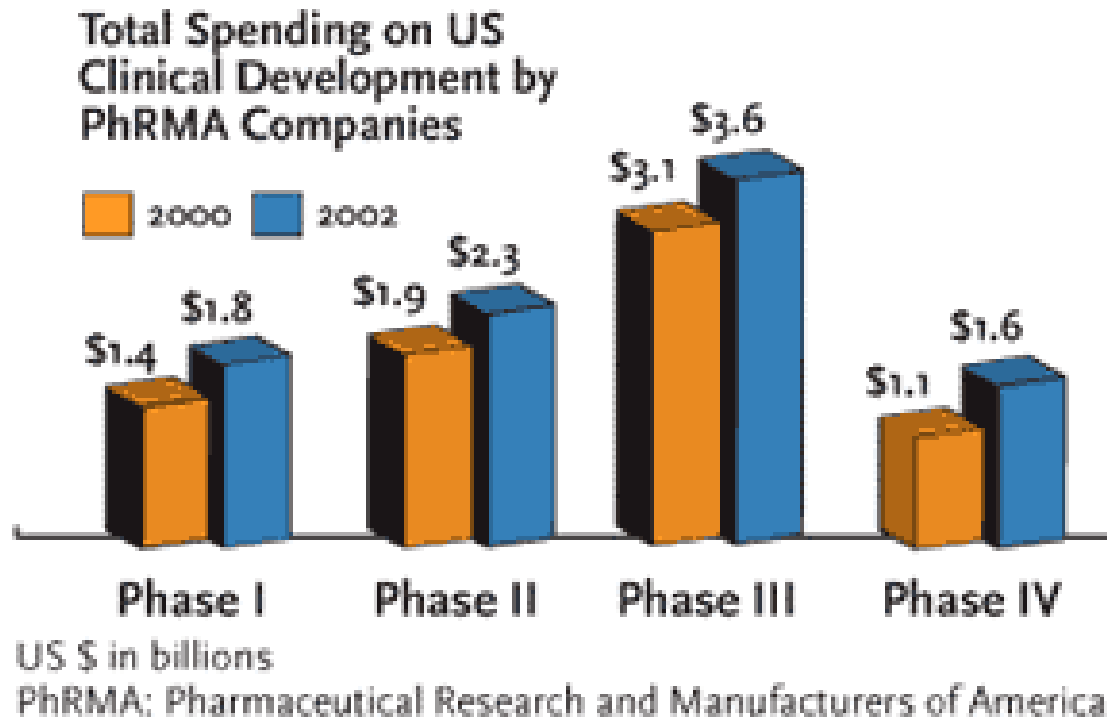
(<http://www.cptech.org/ip/health/econ/dimasi2003.pdf>)

12 years to 15 years



Depatched Professional Corporation

(Intellectual Property Consultants)



Source: Centerwatch, PhRMA



Deparchedn Professional Corporation

(Intellectual Property Consultants)

Kinds of Patents

Utility Patents

Machines

Articles of Manufacture

Compositions of matter

Processes or methods

Improvements

Plant Patents

Design Patent



Deparchedn Professional Corporation

(Intellectual Property Consultants)

Chemical/Biotech Patents

- 1) A Composition**
- 2) A Method of Use**
- 3) A Process or A Method of Manufacture**
- 4) Miscellaneous: recombinant DNA,
monoclonal antibodies, etc.**



Deparchedn Professional Corporation

(Intellectual Property Consultants)

Basics of a Utility Patent

- In the US, an Inventor Will be Granted a Patent, If it's:
 - 1) Useful (35 USC 101 and 112)
 - 2) Novel (35 USC 102)
 - 3) Non-obvious (35 USC 103)
 - 4) Best Mode (35 USC 112)
 - 5) Enabling Disclosure (35 USC 112)
- Parts of A Patent
 - Specification
 - Drawing
 - At least One Claim



Deparchedn Professional Corporation

(Intellectual Property Consultants)

Patent Cooperation Treaty (PCT)

- PCT came into existence on January 24, 1978
- The PCT keeps foreign patent rights alive for a while
- The PCT provides for the filing of a single application
- A patentee must file a PCT application within twelve months of US filing date.
- Chapter I: The applicant must file in the designated countries within 20 months of the earliest priority date.
- Chapter II: The applicant has an opportunity to extend the actual filing date in most of the countries (or EPO) to 30 months. Must file the request before the end of 19th month.



Deparchedn Professional Corporation

(Intellectual Property Consultants)

Applications

- Provisional-35 USC 111b, 119 (e) and 112
- Non-Provisional/Original or Parent- 35 USC 111 and 112
- Continuing- 35 USC 120-121
 - Continuation
 - Continuation-in-Part
 - Divisional
- Reissue -35 USC 251
- Refiled
- Substitute



Deparchedn Professional Corporation

(Intellectual Property Consultants)

Advantages of Provisional Application

Considered Constructive Reduction to Practice

Establishes a priority date

Can be relied upon for a PCT application

It will not be reviewed

It can be abandoned without disclosing it to public

Dies automatically after 12 months if a non-provisional is not filed

Provides a level playing field with Europeans

Requirements are not as strict as for non-provisional

No need for any claims

Filing fee is only \$ 80 (Small Business)



Vepachedu Professional Corporation

(Intellectual Property Consultants)

When to File a Provisional

When you are in a hurry

If you want to test the market with your invention

Constructive reduction to practice

To get venture capital

To learn more about provisional application visit:

<http://www.vepachedu.org/AJIN/September2004.html>



Deparchedn Professional Corporation

(Intellectual Property Consultants)

Filing and Issue

- **File the Application**
- **Review process by PTO**
to ensure that it meets all the criteria:
Novelty, Non-obviousness, Utility, Best mode etc.
- **Approximately 18 months for the process**
- **Biotech patents may take more**
- **The Allowance Notice**
- **Pay the Fee**
- **Patent Issues**



Deparchedn Professional Corporation

(Intellectual Property Consultants)

Life of a Patent

- Fixed twenty years from the date of the application
- Total life of patent = 20 – process time
- FDA approval time cuts into the total life of a patent
- FDA approval is about 12 months
- American Inventors Protection Act of 1999 extends the life.



Deparchedn Professional Corporation

(Intellectual Property Consultants)

Proof of Priority and Diligence: Notebooks

- Experiments should be noted in chronological order and dated
- Cross reference to journal, notebook pages, lot numbers, serial numbers, etc.
- Detailed ideas, experimental
- Structures
- Starting material
- Methodology
- Results, data, conclusions etc.
- Future Plans, Ideas, Results of Brainstorming etc.
- Hand Written, Legible, Permanent Ink, Title on Pages, Index, Key for Abbreviations etc. Electronic records are as valid as written records.

Notebooks should be signed and countersigned in a timely fashion by a colleague who is not a co-inventor.



Deparchedn Professional Corporation

(Intellectual Property Consultants)

Authorship, Inventorship and Ownership

Authorship in scientific publications: Any one can be an author.

Inventorship in a Patent: It is very strict.

Conception is the touchstone to determine the inventorship.

One must contribute to the conception to be an inventor.

It is irrelevant who reduced it to practice.

Usually technicians, who didn't contribute to the conception, are not inventors.

Ownership:

Inventorship cannot be purchased, but ownership can be.



Deparchedn Professional Corporation

(Intellectual Property Consultants)

Indian Context

Historical Roots:

The Patent and Designs Protection Act of 1872

The Protection of Inventions Act of 1883

The Indian Patents and Designs Act of 1911

The Patent Act of 1970

The Drug Price Control Order of 1970



Deparchedn Professional Corporation

(Intellectual Property Consultants)

Indian Interest in Patents

India Paid a Stiff Price for Having a Protectionist Patent Regime for 35 years:

- R&D Spending is a Pathetic 1.8% of the Total Turnover
- In 1995, 235,440 patent applications were filed in America whereas the number in India (with a population four times larger) was only 6,566, approximately 1/36th.
- Kenya, 32 times smaller than India with a population of only 32 million, saw four times more patent applications in 1995.

While 350,000 Engineers are Produced Every Year in India!

Where Are Their Inventions?



Deparchedn Professional Corporation

(Intellectual Property Consultants)

New Patent Regime

The Patent (Amendment) Act of 1999

The Patent (Amendment) Act of 2002

The Patent Rules of 2003

The Patent (Amendment) Act of 2004



Deparchedm Professional Corporation

(Intellectual Property Consultants)

Implications of the New Patent Regime

- Most of the essential drugs are not under patent protection.
- Less than 10% of India's list of essential drugs are covered by patents worldwide.
- Only one drug in 250 in the WTO's list of essential drugs is currently under patent.
- A large number of off-patent substitutes are available to patients for patented drugs.
- Between 2005-2010, patents of many widely used drugs will expire.
- India is blessed with more than 5000-years-old well-tested **Ayurveda**.
- Unani and Homeopathy Medicine are bestowed upon India.



Deparchedn Professional Corporation

(Intellectual Property Consultants)

Opportunities

- Reduction of Total Cost of Drug Development
- Clinical Trials in India
- Global Collaborations and Alliances
- Jobs Will be Displaced from America and Europe to India

This is Possible Only if India Becomes TRIPS Compliant



Depatched Professional Corporation

(Intellectual Property Consultants)

Challenges

- Promulgation of New Pieces of Legislation
 - Challenges in the Court to New Laws
 - Enforcement of New Laws
 - Patent Office Staff
 - Corruption



Deparchedn Professional Corporation

(Intellectual Property Consultants)

CONCLUSION

America's preeminence in science and technology is, without a doubt, due to its patent regime.

Today, India stands poised to capitalize on the global and domestic opportunities the new patent regime can provide.

Indian realization of the potential of individual citizens by unleashing their creativity through their products and inventions is inevitable!

WPC

Vepachedu Professional Corporation

(Intellectual Property Consultants)

Read science and cultural journals at: www.vepachedu.org

Subscribe: OneWorld_OneFamily-subscribe@yahoo.com

My company website: www.vepachedu.com

Thanks!