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# **Pharmaceutical PATENT LAW FUNDAMENTALS**

**Presenters:**

**Srikumaran Melethil, Ph.D., J.D.  
Raj Bawa, M.S., Ph.D.**

DECEMBER 2013

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## COURSE DIRECTORS

### Pharmaceutical Patent Law Fundamentals

December 12, 2013 at 11:00 a.m.–12:30 p.m. (ET)

90 Minute Accredited Online Training



**Srikumaran Melethil, Ph.D., J.D.**, is President and CEO, Law and Science Consulting (Springfield, OH), Professor Emeritus, University of Missouri-Kansas City (Schools of Pharmacy and Medicine) and Of Counsel, Fraser Clemens Martin & Miller, LLC, Perrysburg, OH, where his legal practice focuses on patent prosecution and infringement analysis in the area of Pharmaceutical sciences.

Dr. Melethil is both a pharmaceutical scientist and a registered patent attorney. His scientific expertise covers the areas of pharmacokinetics, drug delivery, clinical pharmacology and drug analysis; he has published extensively in these areas. In the legal arena, he has published on the regulation of dietary supplements, World Anti-Doping Agency inclusion criteria for prohibited substances, and drug patent litigation arising under the Hatch-Waxman Act. He has presented short courses in patent law to graduate students at several pharmacy schools in the United States and Canada.




**Raj Bawa, MS, PhD** is a Patent Agent, Bawa Biotech LLC (Ashburn, VA); Adjunct Professor, Biology Department, Rensselaer Polytechnic Institute (Troy, NY); Scientific Advisor, Teva Pharmaceuticals, Ltd. (Israel); Co-chair, Nanotechnology Subcommittee, American Bar Association (Chicago, IL).

Dr. Raj Bawa is President of Bawa Biotech LLC. He is a biochemist and microbiologist by training as well as a registered patent agent licensed to practice (since 2002) before the US Patent and Trademark Office (PTO). He specializes in all aspects of biotechnology, chemical, nanotechnology and pharmaceutical patent law, including prosecution, patent strategy, application drafting, prior art searching, freedom-to-operate searching and technology research opinions. Dr. Bawa is an Adjunct Professor of Biology at Rensselaer Polytechnic Institute in Troy, New York as well as an Adjunct Professor of Natural and Applied Sciences at Northern Virginia Community College. He has hands-on bench experience, in biochemistry, microbiology and nanomedicine. He is Scientific Advisor to Teva Pharmaceutical Industries, Ltd. (Israel). He was previously employed as Patent Legal Advisor at Sequoia.

# Pharmaceutical Patent Law Fundamentals

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*Raj Bawa, M.S., Ph.D.*



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## Pharmaceutical PATENT LAW FUNDAMENTALS

Presenters:

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**Raj Bawa, M.S., Ph.D.**

Moderator:  
LaTonya McRae

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**Pharmaceutical  
PATENT LAW FUNDAMENTALS**

**MODULE 1**

**Anatomy of a Patent Document**



**Dr. Raj Bawa**

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**FACE BEHIND THE MASK**

*"The only thing that keeps us alive is brilliance.  
The only way to protect our brilliance is patents."*

-- Edwin Land, founder of Polaroid

*"Ideas are to the Information Age what iron ore  
and other raw materials were to the Industrial  
Age - only you can't put a fence around ideas.  
The closest thing is a patent."*

-- Thomas Field Jr.

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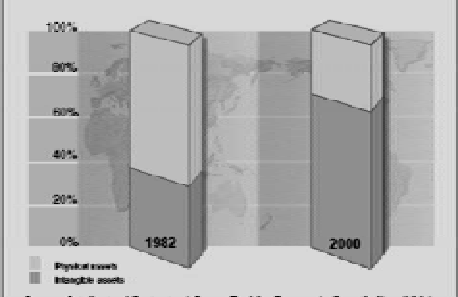
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**Rise of Intellectual Property - US**

**US Companies' Intangible Assets as a Percentage of Total Assets**



Year	Physical assets (%)	Intangible assets (%)
1982	~75	~25
2000	~45	~55

Source: Intellectual Property: A Power Tool for Economic Growth, Nassim Alirza

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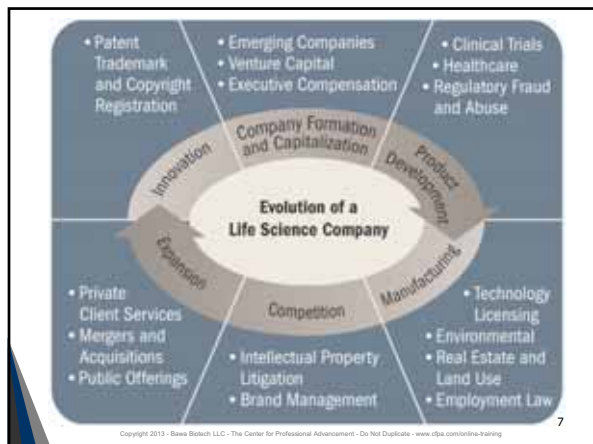
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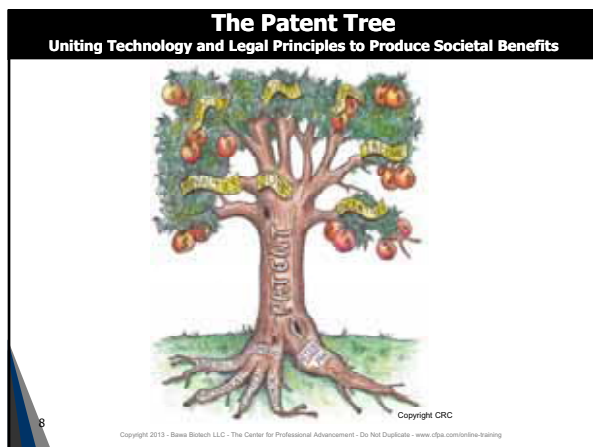
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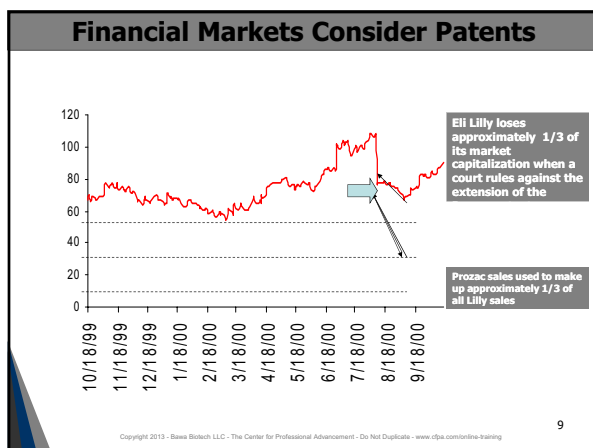
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*Raj Bawa, M.S., Ph.D.*

# Pharmaceutical Patent Law Fundamentals

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## Issues at the US Patent Office

High Attrition/ New Patent Examiners  
Funding Issues (Congress-PTO Issues)  
Limited Experience of Patent Examiners  
Patent Pendency  
Pending  
Limited Industry-PTO Interaction  
Training/Guidelines  
Access to Non-patent Prior Art (Problems?)  
Quality/Allowance Rate



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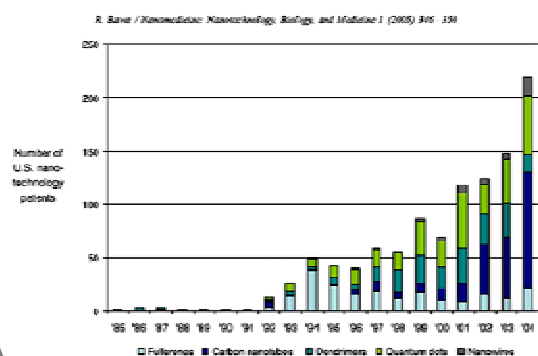
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## Patent Explosion at the US Patent Office - Nano



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## What is a Patent?

"If a man can...make a better mousetrap, though he builds his house in the woods, the world will make a beaten path to his door."  
-- Ralph Waldo Emerson in an 1871 lecture

- A US patent is a legal document granted by the federal government whereby the recipient (or "patentee") is conferred the temporary right (limited monopoly) to exclude others from:

**making,  
using,  
selling,  
offering for sale, or  
importing into the US the invention for  
up to 20 years from the filing date.**



- A US patent provides protection only in the US and its territories.
- Does not grant the owner/inventor the right to use his invention
- Monopoly is in return for full disclosure to the public
- Patent can be licensed, assigned or conveyed
- Basis of US patent system in the constitution - Thomas Jefferson

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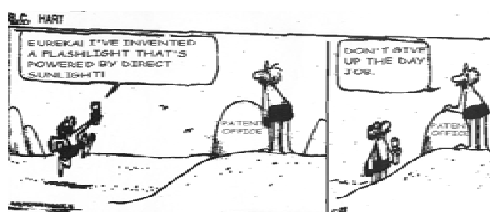
## The rationale behind patent law is simple.

- An inventor is encouraged to apply for a patent by a promise from the US government of a limited legal monopoly for the invention.
- This promise of limited monopoly rights justifies the development costs and assures a reasonable return on profit.
- In exchange, the inventor publicly discloses the new technology that might have otherwise remained secret and allows the public to freely use, make, sell or import the invention once the patent expires. Hence, the new technology that is brought to light encourages further innovation.
- In this way, society obtains a *quid pro quo* from inventors in exchange for the temporary grant of exclusive rights.
- Such an advantageous exchange spurs American industry and stimulates commerce.

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## INVENTORSHIP



Note that unlike the flash-of-genius moment in this BC comic strip, inventions often result from a long progression of experiments and results from the contributions of numerous co-inventors.

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*A country without a patent office and good patent laws is just a crab and can't travel any way but sideways and backwards.*

—Mark Twain, 1889

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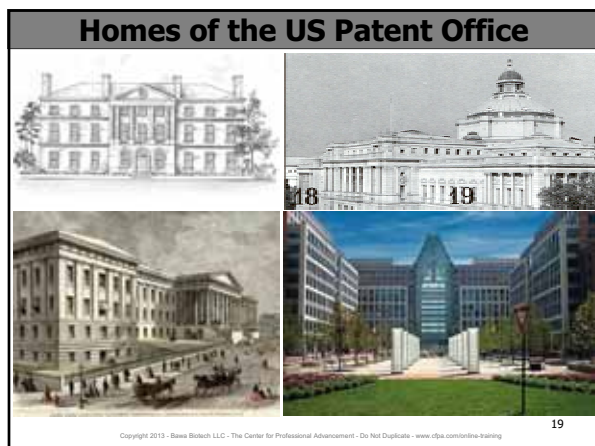
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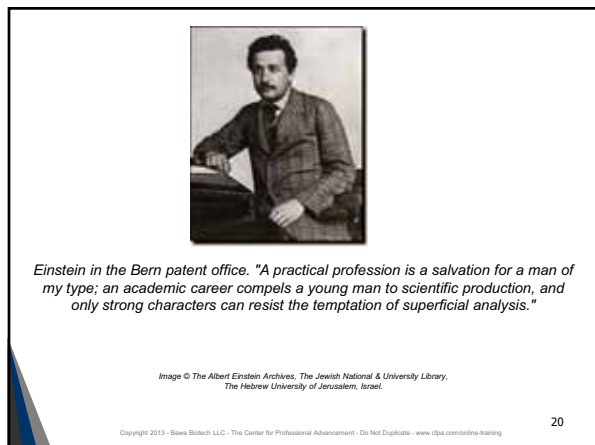
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## Patent Agents vs. Patent Attorneys

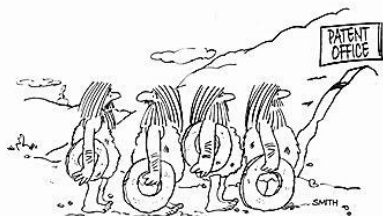
[Number of Patent Attorneys ("Beneshi") and Other Intellectual Property Specialists in Japan and the United States]

Japan March 31, 2005	Patent Attorneys ("Beneshi")	6,127
	Attorney specializing in intellectual property (Attorneys at law who have registered as patent attorneys)	339
United States May 5, 2005	Patent Agents	7,014
	Patent Attorneys	23,553

Japan: as of March 31, 2005, United States as of May 5, 2005

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Your invention might be brilliant, but odds are somebody else thought of it (and is patenting it) too



"WHAT HAVE YOU BROUGHT?"

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# Pharmaceutical Patent Law Fundamentals

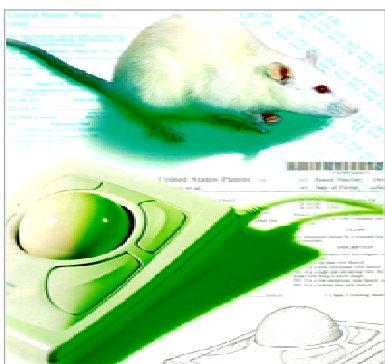
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## P.J. Federico

“[U]nder section 101 a person may have  
Invented a machine or manufacture, which  
may include **anything under the sun that is  
made by man.**”

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## Nanomedicines

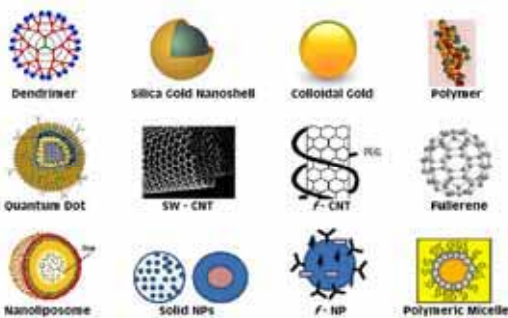


Figure Legend: SW-CNT: single-walled carbon nanotube; F-CNT: functionalized carbon nanotube; NP: nanoparticle; F-NP: functionalized nanoparticle  
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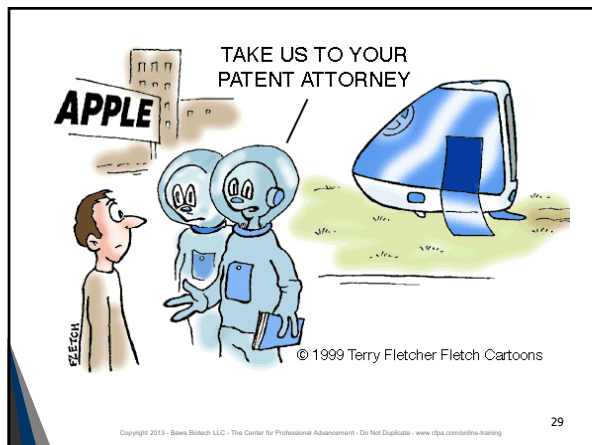
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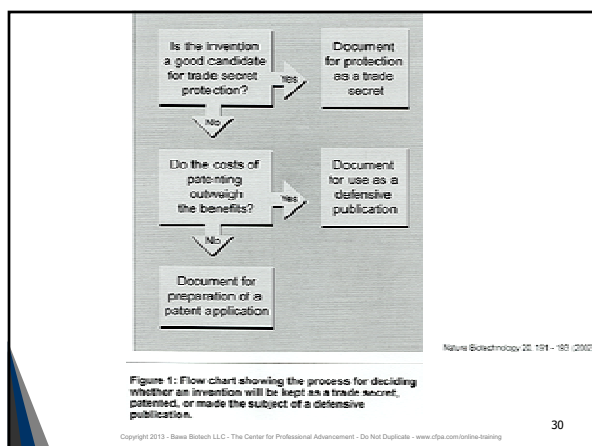
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Criterion For Patentability	
US Patent Statute	Brief Description of Statute
35 USC § 102 - Novelty Requirement	Invention must be novel (i.e., sufficiently new and unlike anything that has been previously patented, marketed, practiced, published, or published).
35 USC § 103 - Nonobviousness Requirement	Invention must be nonobvious to a person with knowledge in the field related to the invention, meaning that the person would not automatically arrive at the present invention from a review of existing ones (i.e., trivial variations that are readily apparent to a person with knowledge in the field related to the invention cannot be patented).
35 USC § 101 - Utility Requirement	Invention must have utility (i.e., the invention has some use and it actually works or accomplishes a useful task).
35 USC § 112(I) - Written Description Requirement	Invention must be adequately described to the public to demonstrate "possession" of the invention at the time of filing the patent application.
35 USC § 112(I) - Enablement Requirement, Part I	Invention must enable a person with knowledge in the field related to the invention to make or carry out the invention without "undue experimentation" (i.e., to make the claimed product or carry out the claimed process).
35 USC § 112(I) - Enablement Requirement, Part II	Invention must enable a person with knowledge in the field related to the invention to use the invention.
35 USC § 112(Q) - Clarity Requirement	Invention must be described in clear, unambiguous, and definite terms.
35 USC § 112(Q) - Best Mode Requirement	Invention must set forth the best mode of making or using the invention, contemplated by the inventor at the time of filing the patent application.
Note: USC stands for US Code.	
Bawa et al. <a href="#">TheSciTechLawyer</a> FALL 2008	
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## Obviousness – What Do You Think?

Your "Invention"

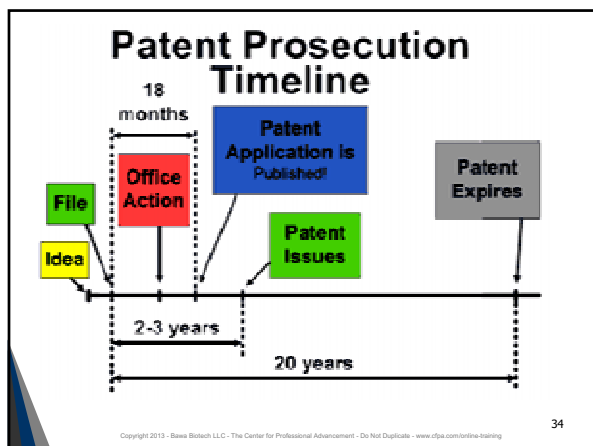
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## Using Intellectual Property

**As an patent owner, you ultimately have four choices regarding your rights:**

- You may choose to **do nothing** at all, which will have no effect on your rights (except that the IP owner must still "maintain" his/her patent).
- You may choose to **commercialize** or market the Intellectual property to the public – for example, manufacturing a product based on the patent
- You may **sell** the Intellectual property to somebody else (or transfer it for free). Legally, this is known as an **assignment**.
- You may permit someone else to use your Intellectual property for a limited time in exchange for payment (**license**).



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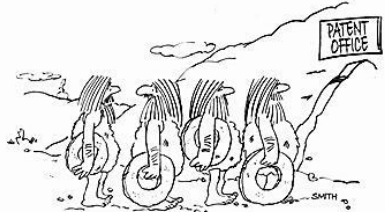
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Your invention might be brilliant, but odds are somebody else thought of it (and is patenting it) too



"WHAT HAVE YOU BROUGHT?"

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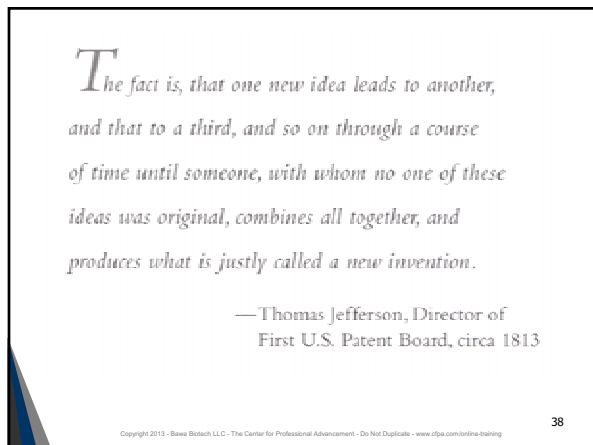
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## Arrangement and Contents of the Patent Specification

The following order of arrangement is preferable in framing the specification. See also MPEP § 608.01(a).

- (A) Title of the invention. (See MPEP § 606).
- (B) Cross-reference to related applications. (See MPEP § 201.11).
- (C) Statement regarding federally sponsored research or development. (See MPEP § 310).
- (D) The names of the parties to a joint research agreement (see 37 CFR 1.71(g)).
- (E) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc and an incorporation-by-reference of the material on the compact disc.
- (F) Background of the invention. (See MPEP § 608.01(c)).
  - (1) Field of the invention.
  - (2) Description of related art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98.
- (G) Brief summary of the invention. (See MPEP § 608.01(d)).
- (H) Brief description of the several views of the drawing. (See MPEP § 608.01(f)).
- (I) Detailed description of the invention. (See MPEP § 608.01(g)).
- (J) Claim(s). (See MPEP § 608.01(i)-(p)).
- (K) Abstract of the Disclosure. (See MPEP § 608.01(b)).
- (L) Sequence Listing, if on paper (see 37 CFR 1.821 through 1.825).

Source: US Patent & Trademark Office

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*Raj Bawa, M.S., Ph.D.*

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# Pharmaceutical Patent Law Fundamentals

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### The Specification and the Claims

- The specification is a written description of the invention and the manner and process of making and using it "in such full, clear, concise, and exact terms" as to enable any person skilled in the art to which it pertains to make and use the same," and setting forth the "best mode contemplated by the inventor" (at the time of the application) of carrying out the invention.
- The specification shall include one or more claims, each of which particularly points out and distinctly claims the subject matter which the applicant regards as his or her invention. The claims represent the metes and bounds of the property to be protected. As in real property, the claims stake out the patent holder's territory, and any encroachment on that territory constitutes patent infringement. [35 U.S.C. §112]
- "the claim is the name of the game." [Judge Giles S. Rich, 1990]
- The claims in a patent define the boundary of what the patentee owns
- A patent claim defines the invention and is what is legally enforceable.
- The claims in a patent describe the metes and bounds of an invention.
- All claims have three principal components: a preamble, a transitional phrase, and a body
- Start broad, get narrow
- Who is the potential infringer?
- Target 15-20 claims (three independent, rest dependent)
- PTO examiners determine claims' broadest reasonable construction to decide whether they are patentable.
- This standard is different from the one courts use to decide if the patent is invalid or infringing.



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### Background of Invention

- **Discuss the current technology**
- **"Problem/Solution"**
- **Cite references, if known**
- **You do not need to do extensive search and analysis**



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### The Written Description

Search, read and compare the "prior art"  
Who is "one-of ordinary skill" in the art?  
Explain the new idea as if you were telling someone about the technology.  
Point out the novel way you solved the "problem" of the existing technology.  
The right level of detail:  
- Be specific: describe the invention thoroughly  
- Be broad: provide examples and alternatives  
Chose language and words carefully  
-avoid contradictions and abbreviations  
- keep background section short  
- don't use limiting words  
- avoid slang, idioms, homographs  
-use technical language  
Minimize discussion of advantages and objects of invention



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### Patenting Life



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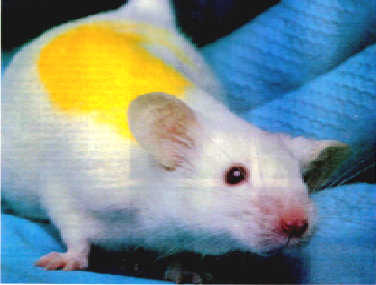
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### Patenting Animals - The Harvard Mouse



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### OF MEN IN MICE: BORN TO DIE!!

(THE WORLD'S FIRST PATENTED ANIMAL)

Some Specifications of the Harvard Transgenic Mouse are:

Trade Name	OncoMouse
U.S. Patent Number	4,736,866
Date of Issue	April 12, 1988
Purpose	Breast Cancer Research Model
Design	Contains a Variety of Genes
Average Cost	About \$50 each
Inventors	Philip Leder (Harvard) Timothy Stewart (Genentech)
Cancer Rate	Close to 100%
Life Expectancy	About One Year
Patent Assigned to	Harvard University
Licensed to	DuPont Company

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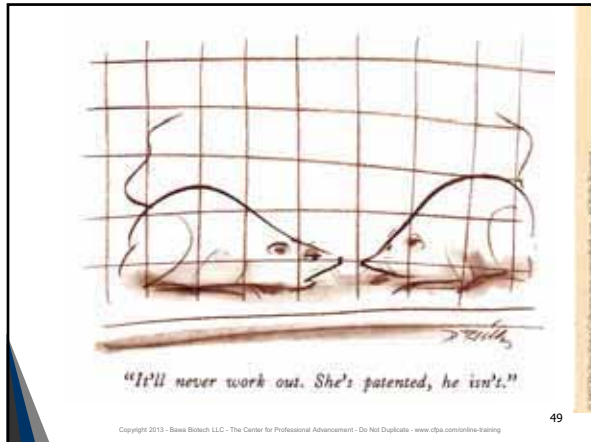
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# Pharmaceutical Patent Law Fundamentals

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I wish that the court to uphold my patent.



I also have, my invention.



Authorizing use of products



### What Constitutes Infringement of a Protein Patent?

ORIGINAL PATENTED GENE SEQUENCE → INVENTED PROTEIN

SLIGHTLY MODIFIED GENE SEQUENCE → SLIGHTLY DIFFERENT PROTEIN

Decisions about whether the modified protein infringes the original patent may depend on its properties.

**NO INFRINGEMENTS:**

If the proteins have different reactive properties, the modified form may be uniquely patentable itself.

**INFRINGEMENT:**

If both proteins have identical reactive properties, the modified version may be an infringement.

If the modified protein has both unique and previously patented features, its maker may not need to pay a licensing fee for some unique applications.

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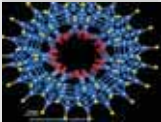
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## Expert Opinion

1. Introduction
2. Biomedical applications of carbon nanotubes
3. The carbon nanotube patent landscape
4. Conclusion



### Patenting Perspective

#### The carbon nanotube patent landscape in nanomedicine: an Expert opinion

[Dewu L. Harris<sup>1</sup> & Raj Bawa<sup>2</sup>  
<sup>1</sup>Grant, Douglas, Harris & Bawa, 407 Congress Avenue, Austin, Texas 78701, USA

Carbon nanotubes (CNTs) have extraordinary properties that make them promising candidates for a wide variety of potential biomedical applications, including nerve therapeutics, drug delivery systems and diagnostics. Because of their enormous commercial potential across industries, a classic patent landgrab is underway as competitors are busy locking up broad patents on CNTs. This is creating a chaotic, tangled patent thicket, where the validity and enforceability of numerous patents is unclear. In this article, the authors summarize the CNT patent landscape for nanomedicine, identifying key building block patents while raising legal questions regarding their validity.

**Keywords:** carbon nanotubes, drug delivery, multi-walled carbon nanotubes, nanomedicine, nanotechnology patent thicket, patents, single-walled carbon nanotubes, US Patent & Trademark Office

*Expert Opin. Ther. Targets (2007) 1(7)611-617*

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## The Nano Patent Thicket

- **Despite being an extremely active area for patent applications, nanotechnology development is being impaired by current intellectual property law.**
- **In contrast to other emerging fields at their times, nanotechnology was born as the Bayh-Dole Act enabled universities to lock down fundamental research effectively preventing open competition.**
- **Both technical complexity and bureaucratic mishandling of nanotechnology patent applications have created a dense patent thicket of overlapping claims and rights.**

Pierce, *Nano Today* (2013) 8, 339-341

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# Pharmaceutical Patent Law Fundamentals

Srikumaran Melethil, Ph.D., J.D.

Raj Bawa, M.S., Ph.D.

## Make nanotechnology research open-source

To drive innovation at the nanoscale, the patent thicket must be chopped down, argues **Joshua M. Pearce**.

**SUMMARY**

- Basic nanotechnology is widely patented.
- Many licences are needed to use 'building block' technologies.
- Downstream development of ideas may be stifled as a result.
- Publicly funded nanotechnology research should be open access.
- There should be a moratorium on patenting basic nanoscience.

22 NOVEMBER 2012 | VOL 491 | NATURE | 519

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## Is the US Patent System Broken?

The United States patent system is broken and desperately needs fixing... Why are so many bad patents being issued?... Under our current system, granting an application with little scrutiny takes less time than subjecting it to rigorous review... The examiners are unable to perform more than a cursory search of their own (due to time constraints)... Third parties—competitors and consumers—are generally excluded from the patent examination process, even though these parties have the greatest incentive to discover the prior art and disclose it to the Patent Office in order to prevent bad patents from being issued.

McDonald D: Fighting the modern patent war. Intellectual Property Today 18(1), 7 (2007).  
The Patent Register: <http://patft.uspto.gov/2007/05/subsource-us-patent-law-patent.html>

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## Due Diligence is Critical for commercialization

	Fullerenes	Carbon nanotubes	Dendrimers	Quantum dots	Nanowires
General	Highly embroiled	Highly embroiled	Highly embroiled	Highly embroiled	Highly embroiled
Structural materials	Highly embroiled	Highly embroiled	Highly embroiled	Highly embroiled	Highly embroiled
Energy	Highly embroiled	Highly embroiled	Highly embroiled	Highly embroiled	Highly embroiled
Optics	Highly embroiled	Highly embroiled	Highly embroiled	Highly embroiled	Highly embroiled
Electronics	Highly embroiled	Highly embroiled	Highly embroiled	Highly embroiled	Highly embroiled
Healthcare and cosmetics	Highly embroiled	Highly embroiled	Highly embroiled	Highly embroiled	Highly embroiled
Other	Highly embroiled	Highly embroiled	Highly embroiled	Highly embroiled	Highly embroiled
Platform approach	Highly embroiled	Highly embroiled	Highly embroiled	Highly embroiled	Highly embroiled

Low white space    High white space

Highly embroiled    Free from patent/embroiled

Fig 2 US patent thicket analysis by nanomaterial technology sector. (Courtesy of Lux Research, New York, NY, and Foley Lardner, Washington, DC).

R. Bawa. Nanomedicine: Nanotechnology, Biology and Medicine Volume 1, Issue 4 2005 346 - 350

# Pharmaceutical Patent Law Fundamentals

Srikumaran Melethil, Ph.D., J.D.

Raj Bawa, M.S., Ph.D.

TABLE 27.4

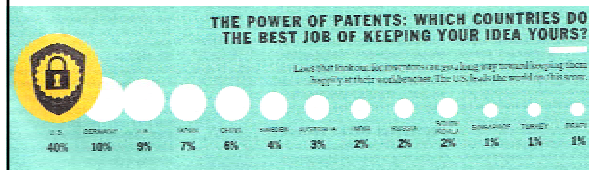
## Inventor's Reality Checklist and Complex Marketing Factors

- Does the invention offer a unique solution to a real problem?
- Does it offer a measurable improvement over previous attempts to solve the problem?
- Is it a stand-alone product or part of an existing product?
- Can it be easily manufactured or integrated into an existing product or system?
- How big is the potential market?
- Is the market growing or shrinking?
- Is the market global? Can the invention be expanded into new markets as they evolve?
- Will the invention become passé before a prototype is designed?
- Who are the prospective investors, partners, or licensing agents in the field?
- What price will consumers put on its value?
- What are the estimates for commercialization and marketing?
- What are the incentives for the consumer to buy the product?
- Is federal regulatory approval required?
- How long will it take to bring the product to market?

Source: Raj Bawa, 2013

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## Patent Strategy is Critical for Eventual Market Entry



Courtesy: Time, Nov 2013

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Laws and institutions must go hand in hand with the progress of the human mind. As that becomes more developed, more enlightened, as new discoveries are made, new truths disclosed, and manners and opinions change with the change of circumstances, institutions must advance also, and keep pace with the times.

—Thomas Jefferson, 1816



Should we revise intellectual property and statutes? The best answer will arise when the legal issue is focused by previous conversations among science, business, economics and law. Neither courts nor legislatures may find wise answers in the absence of such earlier interaction.

—Hon. Stephen Breyer, Supreme Court Justice, 2000

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# Pharmaceutical Patent Law Fundamentals

Srikumaran Melethil, Ph.D., J.D.

Raj Bawa, M.S., Ph.D.

Pharmaceutical Patent Law Fundamentals  
Anatomy of a Patent Document

QUIZ 1

1. Which of the following is true (select all that apply):

- a. The US Patent & Trademark Office is part of the US Department of Justice.
- b. Patents represent a form of intellectual property.
- c. A US patent provides protection both in the US and abroad.

2. Which of the following is true (select all that apply):

- a. Patent expiration on numerous blockbuster drugs in recent years is altering the drug R&D landscape.
- b. An invention on a drug formulation must be both *novel* and *nonobvious* to one of ordinary skill in the art.
- c. Depending on the invention, a patent application when filed at the US Patent Office may lack *utility* (usefulness).

3. Which of the following is true (select all that apply):

- a. Patent agents and patent lawyers are often referred to as patent practitioners.
- b. Examiners at the Patent Office determine claims' broadest reasonable construction to decide whether there is patentable subject matter submitted in a patent application.
- c. As in real property, the claims stake out the patent holder's territory, and any encroachment on that territory constitutes patent infringement.

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Pharmaceutical Patent Law Fundamentals  
Anatomy of a Patent Document

QUESTIONS

INSTRUCTOR - Dr. Bawa  
Email - [bawa@bawabiotech.com](mailto:bawa@bawabiotech.com)  
Download Articles - [www.bawabiotech.com](http://www.bawabiotech.com)

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Pharmaceutical  
PATENT LAW FUNDAMENTALS

MODULE 2

Hatch-Waxman Act  
DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984



Srikumaran Melethil, Ph.D., J.D.

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# Pharmaceutical Patent Law Fundamentals

Srikumaran Melethil, Ph.D., J.D.

Raj Bawa, M.S., Ph.D.

## INTRODUCTION

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**Scientists Invent**

**Lawyers Patent**

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**“Because there is a general lack of understanding of each culture, these interactions often lead to a cognitive friction that is both disturbing and costly to society.” (emphasis added)**

**A Convergence of Science and Law**  
(National Academy Press, 2001)

[http://books.nap.edu/html/science\\_law/report.pdf](http://books.nap.edu/html/science_law/report.pdf)

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## Patent Claims

**To coin a phrase, the name of  
the game is the claim**

- Giles Rich, then Chief Judge of the Federal  
Circuit (CAFC), *The Extent of the Protection and  
Interpretation of Claims-American Perspectives*, 21 Int'l  
Rev. Indus. Prop. & Copyright L., 497, 499 (1990)

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**Meaning of words  
often the grounds for patent  
infringement disputes**

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**Which word is open to  
interpretation?**

### **Claim 2.**

**A touch probe . . . the probe  
generating a trigger signal when said  
sensing tip contacts an object . . .**

**(Touch Probe, US Patent No. 5,491,904)**

[Renishaw PLC v. Marposs Societa' Per Azioni 158 F.3d. 1243 (Fed. Cir. 1998)]

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**Patent claims define  
boundaries of an invention  
("metes and bounds")**

**Infringement: Like Trespassing**

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**CLAIMING YOUR  
INVENTION  
AN EXAMPLE**

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**METHOD FOR TREATING PAIN BY  
ADMINISTERING 24 HOUR ORAL OPIOID  
FORMULATIONS**

- **US Patent No. 5,672, 360**
- **Issued : 9/30/1997**
- **Inventors: Richard S. Sackler, Robert F. Kalko and Paul Goldenhelm**
- **Assignee: Purdue Pharma L.P.**

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# Pharmaceutical Patent Law Fundamentals

Srikumaran Melethil, Ph.D., J.D.

Raj Bawa, M.S., Ph.D.

## Claims

What is claimed is:

1. A method of effectively treating pain in humans comprising orally administering to a human on a once-a-day basis an oral sustained release dosage form containing an opioid analgesic or salt thereof which upon administration provides a time to maximum plasma concentration (T<sub>max</sub>) of said opioid in about 2 to about 10 hours and a maximum plasma concentration (C<sub>max</sub>) which is more than twice the plasma level of said opioid at about 24 hours after administration of the dosage form, and which dosage form provides effective treatment of pain for about 24 hours or more after administration to the patient.  
(emphasis added)

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## Claims (cont'd)

2. The method of claim 1, wherein T<sub>max</sub> occurs in about 2 to about 8 hours after oral administration of said dosage form

3. The method of claim 1, wherein T<sub>max</sub> occurs in about 6 to about 8 hours after oral administration of said dosage form

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## Claims (cont'd)

4. The method of claim 1 wherein the said opioid analgesic is morphine sulfate

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## H-W POLICY ISSUES

**To Protect Intellectual Property**  
– *Encourage Innovation*

**To Foster Competition**  
– *Marketing Generics*  
*(Consumer Benefit)*

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## Patents and H-W Act (where drug and patent laws meet)

- NDAs (New Drug Applications) are required to include:
  - patent number and
  - expiration date of any patent that claims either
    - the drug (active ingredient and/or composition or formulation) or
    - method of use (i.e., indication)

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## Patents and H-W Act (cont'd)

**FDA required to list the submitted patent information in its “Orange” book**

**Approved Drug Products with Therapeutic Equivalence Evaluations**

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# Pharmaceutical Patent Law Fundamentals

Srikumaran Melethil, Ph.D., J.D.

Raj Bawa, M.S., Ph.D.

## H-W Certifications

A generic company (the ANDA/503(b)2 applicant) must certify that drug :

- I) has not been patented;
- II) patent has expired;
- III) patent will expire on a given date and that generic will not be marketed prior to that date; OR
- IV) patent is not infringed or invalid  
- (where the action is!)

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## Paragraph IV Certification

Generic company:

- must notify innovator about ANDA filing
- must explain:
  - why generic product will not infringe innovator patent OR
  - why innovator patent is invalid

Under the H-W Act, filing such an ANDA is open to infringement challenges by the patentee.

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## THE PROZAC® CASE INVALIDITY-DOUBLE PATENTING

### FACTS

- Fluoxetine (active ingredient of “blockbuster” Prozac®)
- Barr Labs submitted ANDA in December 1995 for generic fluoxetine with ¶ IV certification
- Lilly brought action alleging Barr’s ANDA application infringed its patents

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# Pharmaceutical Patent Law Fundamentals

Srikumaran Melethil, Ph.D., J.D.

Raj Bawa, M.S., Ph.D.

## Obviousness-type Double Patenting

“[T]he extension of exclusive rights through claims in a later patent that are not patentably distinct for claims in an earlier patent.”

(222 F.3d at 985)

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## Issue for CAFC

222 F.3d. 973 (2000) – Part I

To determine whether Claim 1 of the ‘895 patent covers subject matter claimed in claim 7 of the ‘549 patent (the later patent)

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A method of blocking the uptake of serotonin by brain neurons in animals comprising the administering to said animal of fluoxetine (claim 7, ‘549 patent) (emphasis added)

A method of treating human suffering from depression which comprises administering to said human of an effective antidepressant dose of fluoxetine (claim 1, ‘895 patent) (emphasis added)

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# Pharmaceutical Patent Law Fundamentals

Srikumaran Melethil, Ph.D., J.D.

Raj Bawa, M.S., Ph.D.

## Issue for CAFC 251 F.3d 955 (2001) – Part II

To determine whether Claim 1 of the '213 patent covers subject matter claimed in claim 7 of the '549 patent (the later patent)

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A method of blocking the uptake of serotonin by brain neurons in animals comprising the administering to said animal of fluoxetine (claim 7, '549 patent) (emphasis added)

A method for treating anxiety in a human subject in need of such treatment which comprises the administration to such human an effective amount of fluoxetine or norfluoxetine or pharmaceutically acceptable salts thereof (claim 1, '213 patent) (emphasis added)

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## Decision – Lilly Loses

The subject of claim 7 of the '549 patent is obvious because it is covered by the claims from the '895 and '213 patents. Therefore, the '549 patent is invalid for double patenting

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# Pharmaceutical Patent Law Fundamentals

Srikumaran Melethil, Ph.D., J.D.

Raj Bawa, M.S., Ph.D.

## The Prilosec® Case NON-INFRINGEMENT

### Facts

- Omeprazole – active ingredient of “blockbuster” Prilosec®
- Kremers Urban Development Co. (KUDCo.) submitted ANDA for generic omeprazole with ¶ IV certification
- Patent holder Astra Aktiebolag, owner of US Patents Nos. 4,786,505 (the ‘505 patent and 4,853,230 (the ‘230 patent) filed an infringement suit against KUDCo.

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## Prilosec® Case (cont'd) 222 F. Supp.2d 423 (S.D.N.Y. 2002)

### The main issue:

- Did the KUDCo formulation core contain an alkaline reacting compound (ARC)?

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## Prilosec® Case (cont'd)

Claim 1 of the ‘505 patent states (in part):

- An oral pharmaceutical preparation comprising:
- (a) a core region comprising an effective amount of a material selected from the group consisting of omeprazole plus an alkaline reacting compound, an alkaline omeprazole salt plus an alkaline reacting compound and an omeprazole salt alone; (emphasis added). . .

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# Pharmaceutical Patent Law Fundamentals

Srikumaran Melethil, Ph.D., J.D.

Raj Bawa, M.S., Ph.D.

## Prilosec® Case (cont'd)

- **Formulation Differences**
  - **Core Composition**
- **KUDCo microtablet has 3 parts:**
  - **a core, a subcoat and enteric coat**
  - **The court concluded that the subcoat and the enteric coat of the microtablet do not differ from the '505 patent**

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## Prilosec® Case (cont'd)

### DECISION (affirmed by CAFC in 2003)

**Astra loses: KUDCo can market generic omeprazole.**

The Court concluded that the KUDCo tablet did not have an ARC in its core. Therefore, the generic version of KUDCo did not infringe Astra's patent.

**Weakness of Formulation Patents: They can be DESIGNED AROUND.**

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## Prilosec® Case (cont'd)

- **There were 3 other generic companies that had also filed ANDAs**
  - **Andrx Pharmaceuticals, Cheminor Drugs, and Genpharm, Inc.**

**They all were found to infringe on several of the claims of the Astra patent(s)**

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# Pharmaceutical Patent Law Fundamentals

Srikumaran Melethil, Ph.D., J.D.

Raj Bawa, M.S., Ph.D.

## Summary

1. **Effective communication between research scientists and patent attorneys is essential for patent protection.**
2. **Multiple patents on based on a single chemical entity is vulnerable to double patenting.**
3. **Formulation patents can be defeated by designing around them.**

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Pharmaceutical Patent Law Fundamentals

## QUIZ 2

1. The Hatch-Waxman Act was enacted to:
  - a. Promote drug innovation
  - b. Foster competition through generics
  - c. Both (a) and (b) above
2. One weakness of a formulation patent is that it can be "defeated" by designing around it.
  - a. True
  - b. False
3. Under paragraph IV certification, a company must explain why:
  - a. Its generic version does not infringe the patent(s) listed for the brand name drug
  - b. The patent(s) listed for the brand name drug is/are invalid
  - c. Both (a) or (b) above

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## Pharmaceutical PATENT LAW FUNDAMENTALS

### MODULE 3

IMPACT OF CASE LAW ON DRUG DEVELOPMENT

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# Pharmaceutical Patent Law Fundamentals

Srikumaran Melethil, Ph.D., J.D.

Raj Bawa, M.S., Ph.D.

## TOPICS

1. **Safe Harbor Provisions**
2. Patentable Subject Matter (“101” issues)
3. Obviousness (Obvious to Try) (“103” issues)

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## Safe Harbor Provisions

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products. (emphasis added) (35 U.S.C. 271(e)(1))

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## Safe Harbor Provisions (cont'd)

Enacted by Congress primarily to overrule *Roche v. Bolar* (733 F.2d. 858) (Fed. Cir. 1984)

Applying patent law\*, *Bolar* was found by CAFC to have infringed Roche's patent on flurazepam because it initiated ANDA studies before the expiry of the patent.

\* . . . “whoever without authority . . . uses . . . any patented invention, within the United States during the term of the patent therefor, infringes the patent .” 35 U.S.C §271(a)

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# Pharmaceutical Patent Law Fundamentals

Srikumaran Melethil, Ph.D., J.D.

Raj Bawa, M.S., Ph.D.

## Merck v. Integra

### FACTS

1. Integra Life Sciences owns several (5) patents covering the “RGD” peptide.
2. Scripps researcher discovers that a cyclic RGD (EMD 66203) peptide provided by collaborator Merck can inhibit tumor growth in chickens (inhibition of angiogenesis)

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## Merck v. Integra (cont'd)

### FACTS (cont'd)

3. Scripps then focused on developing EMD peptides as a potential drug candidates.
4. Integra files patent infringement suit against Merck and Scripps.

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## Question for the Court

Were the drug discovery activities of Merck and Scripps protected from infringement of the Integra patents?

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# Pharmaceutical Patent Law Fundamentals

Srikumaran Melethil, Ph.D., J.D.

Raj Bawa, M.S., Ph.D.

## Merck v. Integra (cont'd)

**At the District Court:**

**Integra wins:**

- a. Merck activities infringed Integra's patents.
- b. Integra was awarded \$15 million in damages (1998), later reduced to \$6.375 million (2004)

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## Merck v. Integra (cont'd)

331 F.3d 860 (Fed. Cir., June 6, 2003)

**At the appeals court (CAFC), Integra is still the winner:**

1. Lower court's ruling on infringement is was affirmed
2. Remanded to lower court to reconsider infringement award because Integra purchased all the infringing patents and products from Telios for \$20,000,000.

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## Merck v. Integra

543 U.S.193 (2005)

**At the Supreme Court:**

**Integra Loses**

**It overturned patent infringement ruling of lower courts, stating:**

**"Congress did not limit § 271(e)(1)'s safe harbor to development of information for inclusion in a submission to the FDA; nor did it create an exemption applicable only to research relevant to filing an ANDA for approval for a generic drug ."**

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# Pharmaceutical Patent Law Fundamentals

Srikumaran Melethil, Ph.D., J.D.

Raj Bawa, M.S., Ph.D.

## Patentable Subject Matter ("101" issue)

**"[L]aws of nature, natural phenomena, and abstract ideas are not patentable"**

***Diamond v. Diehr***, 450, U.S. 175, 185, (1981)

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## Mayo v. Prometheus

### FACTS:

Mayo Clinic used diagnostic tests sold by Prometheus Laboratories based their two patents: U.S. No. 6,355,623 (the '623 patent), and 6,680,302 (the '302 patent).

Mayo stated in 2004 that it planned to market its own version of a similar diagnostic test.

Prometheus filed infringement suit against Mayo

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## Mayo v. Prometheus (cont'd)

The Court examined claim 1 of the '623 patent (considered "typical"), which states:

"A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

"(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder, and

(b) Determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

"wherein the level of 6-thioguanine less than about 230 pmol per  $8 \times 10^8$  cells indicates a need to increase the amount of said drug subsequently administered to said subject, and

"wherein the level of 6-thioguanine greater than about 400 pmol per  $8 \times 10^8$  indicates a need to decrease the amount of said drug subsequently administered to said subject."

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## Mayo v. Prometheus (cont'd)

### 1. District Court: Mayo Wins.

It concluded that claims of the '623 patent, which deal with concentration-effect relationships, belong to natural laws, and thus, were not patentable.

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## Mayo v. Prometheus (cont'd)

### CAFC: Prometheus Wins:

It reversed lower court ruling, using the “machine or transformation” test for process claims.

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## Mayo v. Prometheus (cont'd)

### The Machine or Transformation test:

A process can patented, only if

- (a) “it is tied to a particular machine or apparatus, or
- (b) it transforms a particular article into a different state or thing.”

In re Bilski, 545 F3d. 934,954 (Fed. Cir. 2008) (en banc)

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## Mayo v. Prometheus (cont'd)

**Supreme Court: Mayo Wins:**

**In reversing CAFC, it said:**

While “the ‘machine-or-transformation’ test is an ‘important and useful clue’ to patentability, we have neither said or implied that the test trumps the ‘law of nature’ exclusion” (566 U.S. \_\_\_\_ (2012))

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## Obviousness (Obvious to try)

“When there is a design need or market pressure to solve problem, and there are a finite number of identified, predictable solutions, a person of ordinary skill has a good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103.” (emphasis added)

**-KSR INT'L CO. v. TELEFAX INC. 550 U.S. 398, 421 (2007)**

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## Bayer Pharma v. Barr Laboratories

**FACTS:**

**Barr filed an ANDA to market a generic version of Yasmin®.**

**Bayer files suit under the Hatch-Waxman Act alleging that Barr's product will infringe its U.S. Patent No. 6,787,531 (the '531 patent)**

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## Bayer Pharma v. Barr Laboratories (575 F3d. 1341) (2009)

### Claim 1, representative of the '531 patent:

A pharmaceutical composition comprising from about 2 mg to 4 mg of micronized drospirenone particles, about 0.01 mg to about 0.05 of 17 $\alpha$ -ethynlestradiol, and one or more pharmaceutically acceptable carriers, the composition being in an oral dosage form exposed to the gastric environment upon dissolution and the composition being effective for oral contraception in a human female. (emphasis added)

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## Drospirenone Pharmacokinetic Properties

1. Poorly water soluble (hence, micronized)
2. Acid labile (isomerizes at pH 1, in vitro)
3. Absorbed equally well in-vivo (with or without enteric coating)
4. It properties similar to spirorenone (prior art)

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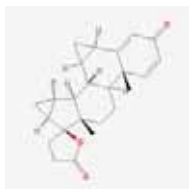
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**Drospirenone**  
Molecular Formula:  $C_{28}H_{30}O_3$   
Molecular Weight: 366.4932



**Spirorenone**  
Molecular Formula:  $C_{28}H_{30}O_3$   
Molecular Weight: 364.47732

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# Pharmaceutical Patent Law Fundamentals

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## Decision

Applying the “obvious to try” standard, the ‘531 patent was found to be invalid for obviousness by both the trial (district) court and CAFC.

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## QUIZ 3

Pharmaceutical Patent Law Fundamentals

- Which of the following are not patentable?
  - Laws of nature
  - Natural phenomena
  - Both (a) and (b) above
- A recent Supreme Court decision (Merck v. Integra) has \_\_\_\_\_ the scope of the safe harbor provisions.
  - Narrowed
  - Broadened
- The “obvious to try” standard for patentability (stated by the Supreme Court in the KSR decision) makes obtaining a patent \_\_\_\_\_ difficult.
  - More
  - Less

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## Summary

Supreme Court decisions have:

- broadened the scope of the safe harbor provisions, making it “easier” to avoid infringement when using patented information
- the “obvious to try” standard for obviousness can patenting an invention more difficult
- Patent eligibility of inventions is likely to receive stricter scrutiny

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# Pharmaceutical Patent Law Fundamentals

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Pharmaceutical Patent Law Fundamentals

## QUESTIONS

Presenters:

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**Raj Bawa, M.S., Ph.D.**

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**Raj Bawa, M.S., Ph.D.**

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