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# Introduction to Patents


## Key Information for Researchers

Alacrita LLC  
303 Wyman Street  
Waltham  
Cambridge, MA 02451

Alacrita Consulting Limited  
London BioScience Innovation Centre  
2 Royal College Street  
London NW1 0NH

Alacrita AG  
Artherstrasse 7  
6300 Zug  
Switzerland

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What is a  
patent

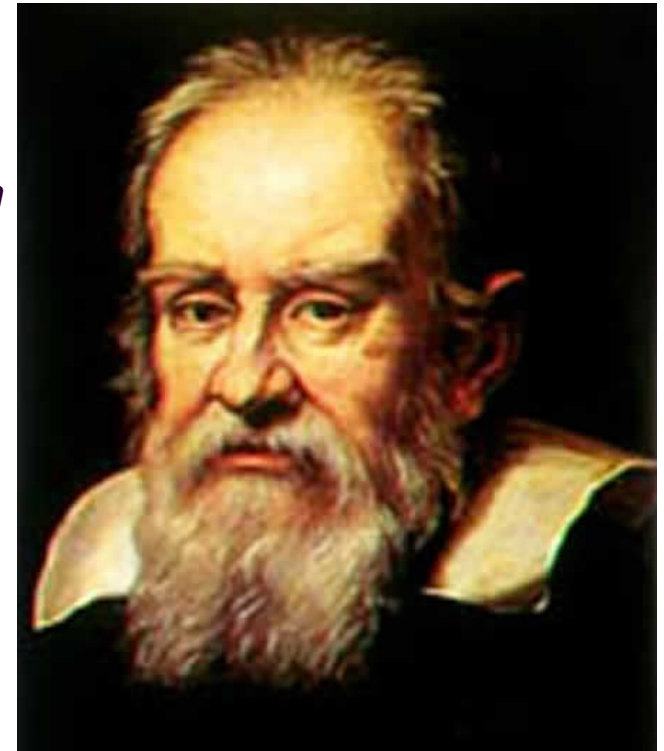
The patent  
process

Good practice  
and pitfalls

## Patent history: 1. Galileo

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- In 1593, Galileo Galilei invented a device for raising water and irrigating land
- Being commercially savvy, he wanted protection for his invention. He petitioned the Senate of Venice:  
*"I desire at present to reduce the invention to practice. But, it not being fit that this invention, which is my own, discovered by me with great labour and much expense, be made the common property of everybody..."*
- The Senate appreciated that this device would provide significant benefits for Venice as a whole and was motivated to grant Galileo a temporary monopoly
- The monopoly was granted in recognition of *"the compensation for the advantages derived by the Commonwealth"*



## Patent history: 2. King Edward II



- In the 14<sup>th</sup> century, Edward II wanted to import technologies to bring England up to the level of more advanced countries:
  - In 1324, he granted letters of protection to skilled German miners to entice them to bring new technologies to England, teach their skills to native craftsmen, and help establish new industries
  - In 1331, John Kemp of Flanders and his company, Flemish weavers, received a royal grant for introducing cloth making into England
- The letters protecting the technology owners and providing them with a monopoly were open to general inspection ("*letters patent*") rather than sealed or closed – hence the name
- Centuries later, Jeremy Bentham explained the rationale for granting patents: "*protection against imitators is necessary because he who has no hope that he shall reap will not take the trouble to sow*"





# Patents 101: What is a patent today?

- An exclusive right granted by the State for an **invention** that is **new**, **involves an inventive step** and is **capable of industrial application**
- It gives its owner the **exclusive right** to prevent or stop others from making, using, offering for sale, selling or importing a product or a process, based on the patented invention, without the owner's prior permission (e.g. through a **licence**)
- It is valid for a limited period of time, generally for **20 years** from the date of filing the patent application
  - For drugs, patent terms may be extended (in recognition of time spent at FDA/other regulators)
- A patent is a **territorial right**, limited to the geographical boundary of the relevant country or region

(19)	 Europäisches Patentamt European Patent Office Office européen des brevets	 (11) EP 1 218 508 B1
(12)	EUROPEAN PATENT SPECIFICATION	
(45) Date of publication and entry into force of the grant of the patent 28.08.2008 Bulletin 2008/26	(51) Int. Cl.: C12N 15/16(2006.01) A61K 46/00(2006.01)	(86) International application number: PCT/IB2006/001317
(21) Application number: 0058920.1	(87) International publication number: WO 2001/021801 (29.03.2001 Gazette 2001/13)	
(22) Date of filing: 18.09.2000		
(54) DNA sequences for the enhancement of feed efficiency and growth rate of pigs DNA Sequenzen zur Erhöhung der Futterausbeute und der Wachstumsrate bei Schweinen Séquences d'ADN pour accroître l'efficacité de l'alimentation et la vitesse de croissance des porcs		
(84) Designated Contracting States: AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE	(56) References cited: WO-A-98/05300	
(30) Priority: 17.09.1999 US 358473	• DRAGHIA-AKLI RUXANDRA ET AL.: "Enhanced growth by ectopic expression of growth hormone releasing hormone using an injectable myogenic vector," NATURE BIOTECHNOLOGY, vol. 15, no. 12, 1997, pages 1285-1289, XP002159709 ISSN: 1087-0156 cited in the application	
(43) Date of publication of application: 03.07.2002 Bulletin 2002/27	• REECY J M ET AL.: "Multiple regions of the porcine alpha-skeletal actin gene modulate muscle-specific expression in cell culture and directly injected skeletal muscle," ANIMAL BIOTECHNOLOGY, vol. 9, no. 2, July 1998 (1998-07), pages 101-120, XP00079429 ISSN: 1049-6398 cited in the application	
(73) Proprietor: Leadergene Limited New Territories, Hong Kong (CN)	• REECY JAMES M ET AL.: "Structure and regulation of the porcine skeletal alpha-actin-encoding gene," GENE (AMSTERDAM), vol. 180, no. 1-2, 1996, pages 23-28, XP002159710 ISSN: 0378-1118 cited in the application	
(72) Inventor: • LEE, Fuk Ki HKIB Shatin, New Territories, Hong Kong (CN) • TAM, Kai Tong HKIB Shatin, New Territories, Hong Kong (CN) • WAI, Sing Fai HKIB Shatin, New Territories, Hong Kong (CN)	• DRAGHIA-AKLI RUXANDRA ET AL.: "Myogenic expression of an injectable protease-resistant growth hormone releasing hormone augments long-term growth in pigs," NATURE BIOTECHNOLOGY, vol. 17, no. 12, December 1999 (1999-12), pages 1179-1183, XP002159711 ISSN: 1087-0156	
(74) Representative: Jones, Elizabeth Louise Frank B. Jones & Co. St Bride's House 10 Salisbury Square London EC4Y 3JD (GB)	Notes: "The following technical information is included in the specification"	
Note: With nine months from the publication of the grant of the European patent, any person may give notice to the proprietor that he or she opposes the grant of the European patent. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 89(1) European Patent Convention).		


- A patentable invention **must never have been publicly disclosed\*** – by the inventor or anyone else – prior to filing

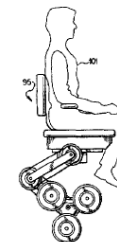
- \* Public disclosure = paper, abstract, poster, oral presentation, seminary, discussion with mates over a beer in the conference bar, etc.

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# Patents 101: Key concepts (2)

- Does not give the inventor the right to make, use or sell the patented invention: may need access to a 'dominating patent'
  - It does, however, block anyone else from these activities
- Patents provide:
  - Source of recognition for the inventor(s)
  - Incentives to develop a commercial product e.g.
    - License to an existing company
    - Start up a new company
  - Once published, a deterrent to competitors due to the threat of future granted rights

		 US005701965A	
<b>United States Patent</b> [19]		[11] <b>Patent Number:</b>	<b>5,701,965</b>
<b>Kamen et al.</b>		[45] <b>Date of Patent:</b>	<b>Dec. 30, 1997</b>
[54] <b>HUMAN TRANSPORTER</b>		<b>FOREIGN PATENT DOCUMENTS</b>	
[75] <b>Inventors:</b> Dean L. Kamen, Bedford; Robert R. Ambrogi, Manchester; Robert J. Duggan, Northwood; Richard K. Heinemann, Francetown; Brian R. Key, Pelham; Andrzej Skoskiewicz, Manchester; Phyllis K. Kristal, Sunapee, all of N.H.		098027 5/1951 France ..... 280/DIG. 10 3411489 10/1984 Germany ..... 180/907	
[73] <b>Assignee:</b> Deka Products Limited Partnership, Manchester, N.H.		(List continued on next page.)	
[21] <b>Appl. No.:</b> 250,693		<b>OTHER PUBLICATIONS</b>	
[22] <b>Filed:</b> May 27, 1994		Vos, D. "Dynamics and Nonlinear Adaptive Control of An Autonomous Unicycle". Massachusetts Institute of Technology, (1989). Vos, D. "Nonlinear Control of An Autonomous Unicycle Robot: Practical Issues", Massachusetts Institute of Technology, (1992).	
<b>Related U.S. Application Data</b>		(List continued on next page.)	
[63] Continuation-in-part of Ser. No. 21,789, Feb. 24, 1993, abandoned.		<i>Primary Examiner</i> —Anne Marie Boehler <i>Attorney, Agent, or Firm</i> —Bronberg & Sunstein LLP	
[51] <b>Int. Cl.<sup>6</sup></b> ..... B63D 61/12		[57] <b>ABSTRACT</b>	
[52] <b>U.S. Cl.</b> ..... 180/7.1; 180/6.5; 180/8.2; 180/21; 180/65.8; 180/907; 280/5.26; 364/176; 364/463		There is provided, in a preferred embodiment, a device for transporting a human subject over ground having a surface that may be irregular and may include stairs. This embodiment has a support for supporting the subject. A ground-contacting module, movably attached to the support, serves to suspend the subject in the support over the surface. The orientation of the ground-contacting module defines fore-aft and lateral planes intersecting one another at a vertical. The support and the ground-contacting module are components of an assembly. A motorized drive, mounted to the assembly and coupled to the ground-contacting module, causes locomotion of the assembly and the subject therewith over the surface. Finally, the embodiment has a control loop, in which the motorized drive is included, for dynamically enhancing stability in the fore-aft plane by operation of the motorized drive in connection with the ground-contacting module. The ground contacting module may be realized as a pair of ground-contacting members, laterally disposed with respect to one another. The ground-contacting members may be wheels. Alternatively, each ground-contacting member may include a cluster of wheels. In another embodiment, each ground-contacting member includes a pair of axially adjacent and rotatably mounted arcuate element pairs.	
[58] <b>Field of Search</b> ..... 180/7.1, 8.2, 8.3, 180/8.5, 8.6, 65.1, 65.8, 907, 118, 6.48, 6.5, 6.54, 41, 21; 901/1; 364/176, 463, 424.05, 424.06, 434; 280/5.2, 5.26, 5.28, 5.32, 6.1, 205, DIG. 10			
[56] <b>References Cited</b>		<b>54 Claims, 34 Drawing Sheets</b>	
<b>U.S. PATENT DOCUMENTS</b> 849,270 4/1907 Schafer et al. .... 280/5.26 2,742,973 4/1956 Johannesen ..... 280/DIG. 10 X 3,260,324 7/1966 Sauerz ..... 180/10 3,399,742 9/1968 Malick ..... 180/21 3,515,401 6/1970 Gross ..... 280/5.26 3,596,298 8/1971 Durst, Jr. .... 581 3,860,264 1/1975 Douglas et al. .... 280/266 3,872,945 3/1975 Hickman et al. .... 180/65 R 3,952,822 4/1976 Udden et al. .... 180/907 4,018,440 4/1977 Deutsch ..... 272/70.3 4,062,558 12/1977 Wasserman ..... 280/205		(List continued on next page.)	



# Patents 101: What is patentable?

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## **An invention: a new and inventive solution to a technical problem**

### **Must be:**

- Novel: not previously known, used or disclosed by anyone
- Useful: have a known use or produce a concrete and tangible result
- Non-obvious:
  - Is it obvious to a person having “ordinary skill in the art”?
  - Can not be found in a single or reasonable combination of publications that would yield a predictable result

### **Can not be:**

- Idea
- Law of Nature
- Scientific principle
- ‘Immoral’ inventions
- Human life and its parts





# Patents 101: Not all patents are commercially useful (1)

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(12) **United States Design Patent** (10) **Patent No.:** **US D498,801 S**  
**Cochrane** (45) **Date of Patent:** **\*\* Nov. 23, 2004**

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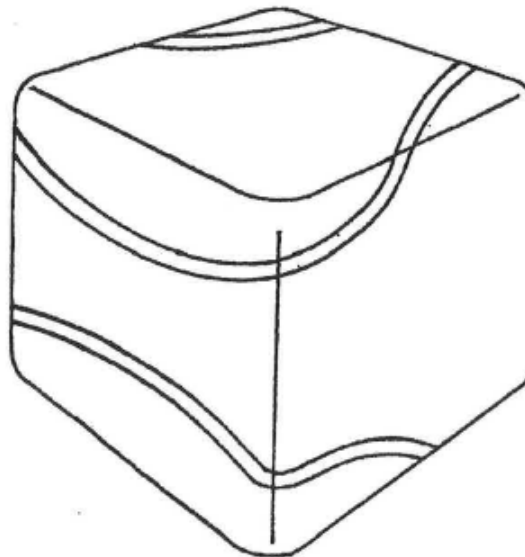
(54) **CUBE-SHAPED TENNIS BALL**

(76) **Inventor:** **Joseph P. Cochrane, 596 Carré**  
**Mathieu, Ste-Thérèse (CA), J7E 4B7**

(\*\*) **Term:** **14 Years**

(21) **Appl. No.:** **29/192,292**

(22) **Filed:** **Oct. 23, 2003**



# Patents 101: Not all patents are commercially useful (2)

## UNITED STATES PATENT OFFICE.

AUGUSTE BARTHOLDI, OF PARIS, FRANCE.

### DESIGN FOR A STATUE.

Specification forming part of Design No. **11,023**, dated February 18, 1879; application filed January 2, 1879.  
[Term of patent 14 years.]

#### *To all whom it may concern:*

Be it known that I, AUGUSTE BARTHOLDI, of Paris, in the Republic of France, have originated and produced a Design of a Monumental Statue, representing "Liberty enlightening the world," being intended as a commemorative monument of the independence of the United States; and I hereby declare the following to be a full, clear, and exact description of the same, reference being had to the accompanying illustration, which I submit as part of this specification.

The statue is that of a female figure standing erect upon a pedestal or block, the body being thrown slightly over to the left, so as to gravitate upon the left leg, the whole figure being thus in equilibrium, and symmetrically arranged with respect to a perpendicular line or axis passing through the head and left foot. The right leg, with its lower limb thrown back, is bent, resting upon the bent toe, thus giving grace to the general attitude of the figure. The body is clothed in the classical drapery, being a stola, or mantle gathered in upon the left shoulder and thrown over the skirt or tunic or under-garment, which drops in voluminous folds upon the feet. The right arm is thrown up and stretched out, with a flamboyant torch grasped in the hand. The flame of the torch is thus held high up above the figure. The arm is nude; the drapery of the sleeve is dropping down upon the shoulder in voluminous folds. In the left arm, which is falling against the body, is held a tablet, upon which is inscribed "4th July, 1776." This tab-

let is made to rest against the side of the body, above the hip, and so as to occupy an inclined position with relation thereto, exhibiting the inscription. The left hand clasps the tablet so as to bring the four fingers onto the face thereof. The head, with its classical, yet severe and calm, features, is surmounted by a crown or diadem, from which radiate divergently seven rays, tapering from the crown, and representing a halo. The feet are bare and sandal-strapped.

This design may be carried out in any manner known to the glyptic art in the form of a statue or statuette, or in alto-relievo or bas-relief, in metal, stone, terra-cotta, plaster-of-paris, or other plastic composition. It may also be carried out pictorially in print from engravings on metal, wood, or stone, or by photographing or otherwise.

What I claim as my invention is—

The herein-described design of a statue representing Liberty enlightening the world, the same consisting, essentially, of the draped female figure, with one arm upraised, bearing a torch, while the other holds an inscribed tablet, and having upon the head a diadem, substantially as set forth.

In testimony whereof I have signed this specification in the presence of two subscribing witnesses.

A. BARTHOLDI.

Witnesses:  
C. TERNIER,  
COTTIN.

DESIGN.

A. BARTHOLDI.

Statue.

No. 11,023.

Patented Feb. 18, 1879.



LIBERTY ENLIGHTENING THE WORLD.

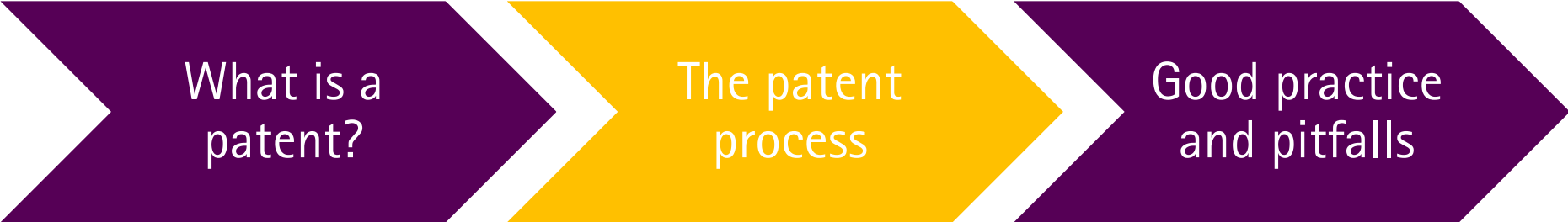
*Est. Dick*  
*J. H. Carpenter*

*Auguste Bartholdi*  
*by*  
*W. H. Wood*  
*engr.*

# Patents 101: What are the Parts of a Patent?

- Abstract
- Background of the Invention
- Summary of the Invention
- Figures with brief descriptions
- Detailed description or “specification”
  - Fully discloses what the invention is
  - How it is made
  - How it can be used
- Claim(s): sets the legal boundaries of protection
  - Independent
  - Dependent (subsidiary claims relying on a higher level independent claim)





What is a  
patent?

The patent  
process

Good practice  
and pitfalls

## Patents 101: Simplified outline of the patent process

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- Formal examination: are administrative details in order?
- The application is published 18 months after the first filing date
- Search/substantive examination: The aim of the substantive examination is to ensure that the application satisfies the patentability requirements
- The results of the examination are sent in writing to the applicant to provide an opportunity to respond to and/or remove any objections raised during the examination. This iterative process often results in the narrowing of the scope of the claims
- Many patent offices provide a period during which third parties may oppose the grant of a patent, for example, on the basis that the claimed invention is not new



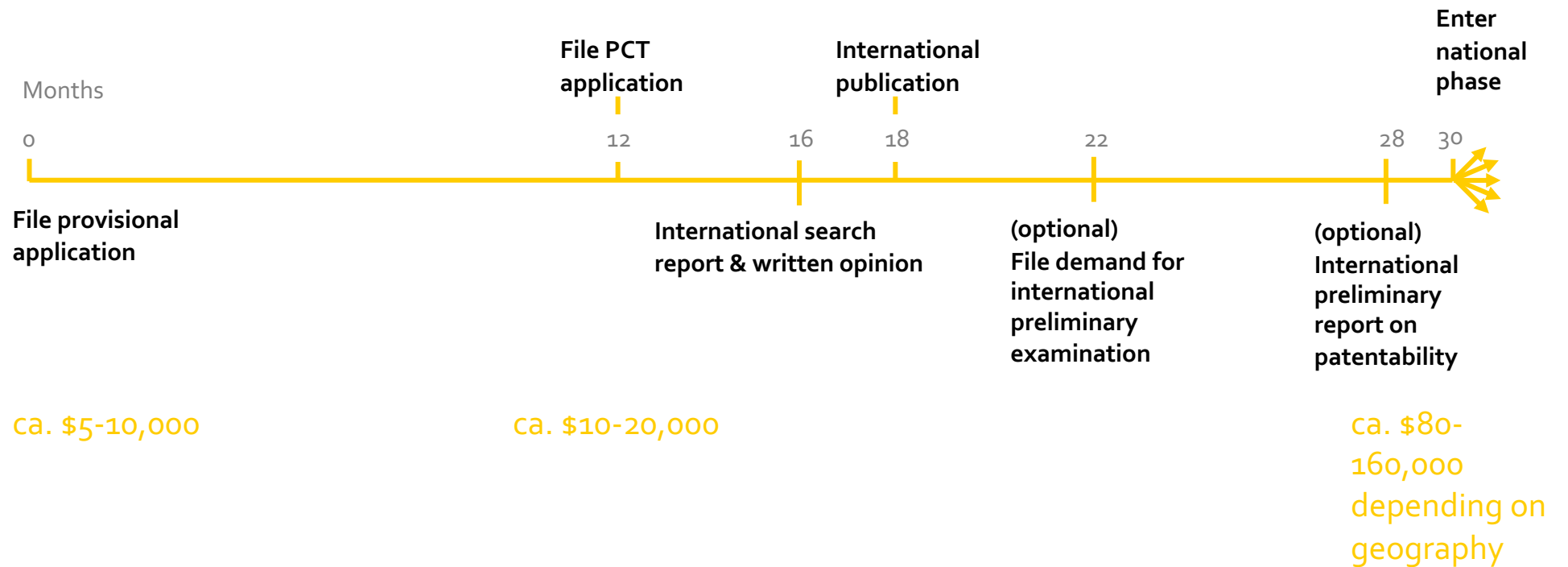


## Patents 101: Filing starts with a provisional application, followed by a PCT

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- A **provisional application** does not need to include specific claims but must be clear on what has been invented (and the limits thereof).  
Defines the **Priority Date**
- No more than 12 months later, a full application must be filed including the full set of claims
  - Claims are carefully worded statements that stake out the boundaries of the invention
  - This is known as the PCT application (Patent Cooperation Treaty) – it provides the opportunity for, at a later stage, seeking patents in up to 152 countries worldwide
  - After this filing, no additional subject matter can be added to the patent
  - The PCT application is published 18 months after the Priority Date
- A search or international search is then made by an authorized International Searching Authority (ISA) to find the most relevant prior art documents, resulting in an International Search Report (ISR), together with a non-binding written opinion regarding patentability
- If the ISR appears negative, there is an option to request an International Preliminary Examination (can save the costs of examination at national and regional stages if the application is deemed too uncertain to proceed by the applicant)
- Finally, at 30 months from the priority date, the application enters the national & regional phase (substantive examination)

# Patents 101: Overview of timeline and costs



# Pharmaceutical companies: beyond the 20 years

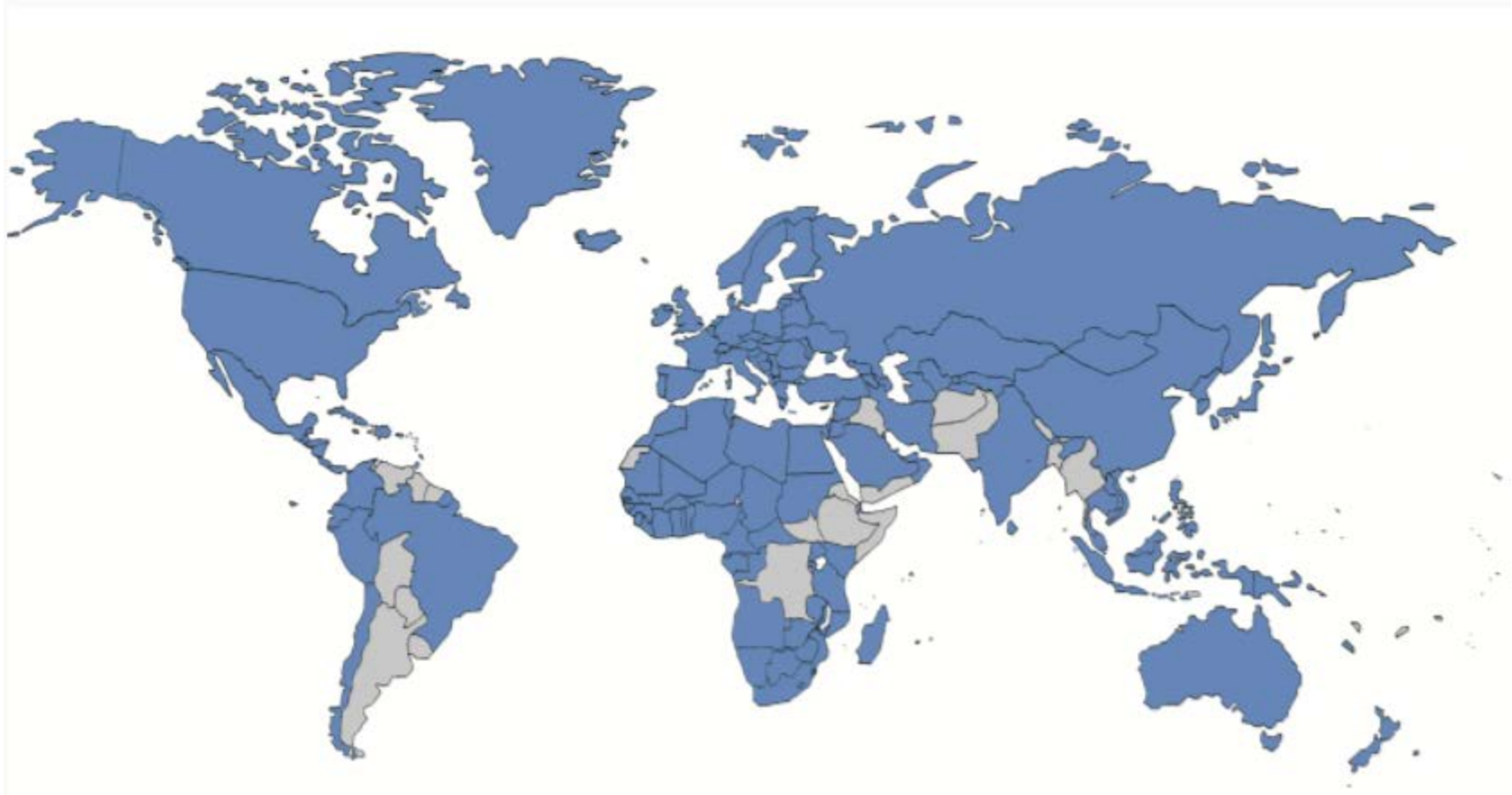
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As the time needed for a therapeutic, from discovery stages to the market can take 10 or more years, sometimes patent duration can be extended, and pharmaceutical companies, which make about 80% of their overall revenue because of their patents, often try to extend patent terms for as long as they can. Once drug patents fully expire, the way is paved for generic competitors to undercut prices significantly.

- New chemical entities – The Hatch-Waxman Act, passed in 1984 to allow patent extensions of **five years** to make up for the lengthy FDA approval process (irrespective of how long the actual FDA approval takes) (NCE exclusivity). Under EMA, supplementary protection certificates (SPC) allow an extension for up to **five years** the patent for certain medicinal products marketed in the EU. In 2005, the EU Data Exclusivity Directive was brought into force under which, sponsors may receive up to **11 years of exclusivity for new drugs** (may include **eight years of data exclusivity, two years of marketing exclusivity, and a potential one-year extension**). During this eight-year time, the innovator's data is treated as a trade secret and new entrants cannot reference the data until the expiration of the data exclusivity period.
- New methods of use – drug reformulation– by promoting patient compliance through reduced dosing or ease of use or improved therapeutic outcomes or more favorable side-effect profiles. Extended-release versions of drugs are common ways companies reformulate products. When a new use is discovered for a drug, it can earn an additional **three years** of protection under FDA rule 505(2)(b) (CI exclusivity), and **ten years** under EMA rule Art. 10 Directive 2001/83/EC.
- Orphan designation -The Orphan Drug Act (1983) promotes the development of drugs to treat rare diseases (those that affect 200,000 or fewer people in the US). Under this law, drugs developed for rare diseases gain **seven years** of additional exclusivity on drug sales, to recoup the considerable costs of developing and marketing drugs which are never expected to have wide markets. EMA grants **ten extra years** upon Regulation(EC) No 141/2000 (with a more inclusive remit). The designation may be extended to 12 years for pediatric products, or may be reduced to six years if, the drug no longer satisfies the original orphan designation criteria.
- Paediatric exclusivity – Since children may metabolize and respond differently to drug products, the lack of pediatric data raised concerns among regulators, legislators and practitioners. In order to address this concern and encourage pediatric drug development and testing, Congress enacted the Best Pharmaceuticals for Children Act in 2002, granting **six additional months of exclusivity** under FDA. Regulation (EC) No 1901/2006 (Paediatric Regulation). Similarly, the EMA grants a **six-month extension** to the product's SPC in return for conducting pediatric studies on the product (since 2007).

## Patents 101: PCT contracting states cover 152 states

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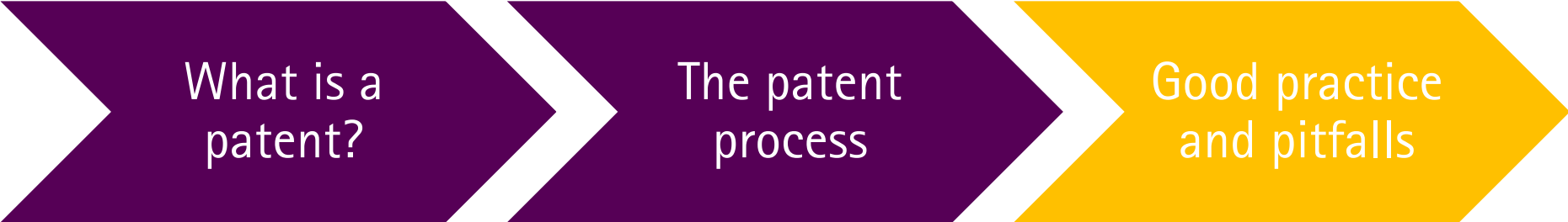


## Patents 101: Patent grants are made on a national or regional basis

- The national and regional phase is the most expensive – dealing with individual Patent Offices and Examiners requires local patent attorneys and multiple languages
- National e.g. USPTO, CIPO, etc
- Regional e.g. EPO
  - At Decision to Grant, must select which countries to proceed with
  - Each country has patent office fees and potentially translation costs
  - Strategic business decision – the applicant decides which countries to pursue
- The time taken for a patent office to grant a patent varies significantly from office to office and may range from a few months to a few years, generally 2 to 5 years







What is a  
patent?

The patent  
process

Good practice  
and pitfalls

# First question: do you really want to apply for a patent?

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## Advantages:

- May provide significant commercial rewards
- May block competition during the patent term
- Attractive to corporate partners/acquirers
- Reputational benefits; establishes credentials

## Risks:

- May result in a significant waste of money
- Informs competitors:
  - > Starting point for independent rival invention
  - > Guide on how to avoid the scope of your patent
  - > In any event, enables competition after expiry
- No certainty even if a patent is granted!

## Alternatives:

- Trade secret
- Industrial design
- Copyright – brand protection
- Do nothing – not everything needs to be patent protected!
  - Consider 'defensive publication' to prevent others from filing a blocking patent themselves

## Items to consider before embarking on a patent application

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- Is there a market for the invention?
- What are the alternatives to your invention, and how do they compare?
- Is the invention useful for improving an existing product or developing a new product? Does it fit with the business strategy?
- Do others own patents that dominate yours (i.e. do you have freedom to operate) requiring you to take a license (if available)?
- Are there potential licensees or investors who will be interested?
- Is it easy to “reverse engineer” your invention from your product or “design around” it?
- How likely are others, especially competitors, to invent and patent what you have invented?
- Do the expected profits from an exclusive position in the market justify the costs of patenting?
- What aspects of the invention can be protected by one or more patents, how broad can this coverage be and will this provide commercially useful protection?
- Will it be easy to identify violation of the patent rights and are you ready to invest time and financial resources for enforcing your patent(s)?
- Is it the right time to file an application?

## Timing – it's always too early until it's too late!

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- Early filing can be crucial if the field is competitive. Note: first-to-file (earliest priority date) is dominant
- Premature filing can be detrimental: if the invention is incomplete at the time of PCT filing it becomes impossible to add subject matter
- Can decide to withdraw a provisional application within the 12 month period and re-file with new subject matter (but you lose the priority date)
- Keep it confidential! Public disclosure of your invention prior to filing the application would destroy the novelty of your invention, rendering it unpatentable



# A patent application is NOT a grant application of scientific paper!

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## Grant/Scientific paper

- Need to show:
  - Logical train of thought
  - Building from evidence
  - Rationally developing hypotheses
  - Preliminary data
  - Systematic plan to conduct experiments based on known methodologies
- Author list often includes the Prof. and others who did little
- Often ends with speculation about future potential, applications or experiments



## Patent application

- Need to show inventiveness and novelty:
  - Nothing that would be obvious to a person skilled in the art
  - Nothing logical or incremental
  - Nothing that has ever been described by anyone, anywhere
- Inventor list must not include anyone supernumerary
- Must never, ever speculate about future potential, applications or experiments (as these would then be unpatentable)



## A special mention of “comprising” language

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- The word ‘comprising’ in a patent claim has a very special meaning. Consider the following two claims:
  1. A CAR **consisting** of an antigen recognition domain of a specific antibody and an intracellular domain of the CD3-zeta chain
  2. A CAR **comprising** an antigen recognition domain of a specific antibody and an intracellular domain of the CD3-zeta chain
- In #1 (‘consisting’), all that is patented is a first generation CAR
- In #2, the ‘comprising’ language means that additional components can be added, e.g. a costimulatory molecule (or two) to cover a second (or third) generation CAR as well

# When is it safe to publish?

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- NEVER! i.e. there is always a risk
  - Between provisional application and PCT: may need to withdraw and re-file. Can't do this if a publication has been made
  - After PCT: may provide Examiner with ammunition as to why you lack inventive step (the clarity of the scientific method is at odds with the 'surprise' element)
  - After grant: (a) you may be thinking of additional patent filings and you may not want to prejudice those and (b) you don't want to give aid to parties who may wish to oppose your patent in court
- Note that the most common source of novelty-destroying disclosures are made by the inventors themselves!
- Publication is a strategic issue, balancing patent issues vs. the need for businesses to establish credentials through high impact publications



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## Expertise-based consulting

Alacrita LLC  
303 Wyman Street  
Waltham  
Cambridge, MA 02451

Alacrita Consulting Limited  
London BioScience Innovation Centre  
2 Royal College Street  
London NW1 0NH

Alacrita AG  
Artherstrasse 7  
6300 Zug  
Switzerland

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