IGE | IPI

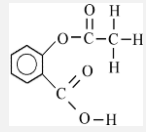
Biotech/Pharma Patents

IGE | IPI

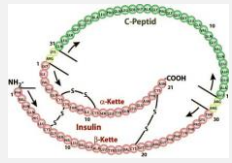
Protection of a biological or chemical compound

- compound

(Aspirin)
acetylsalicylic acid



Human recombinant
insulin



- Additional charcteristics

melting point 135,0°C, boiling point 140,0°C
Mechanism of function, potency

- Industrial Application (intended purpose)

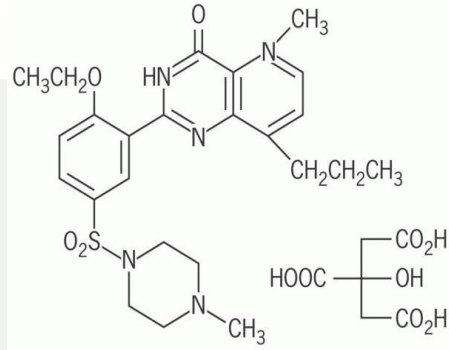
acetylsalicylic acid can be used as an analgesic
insulin can be used to treat diabetes

IGE | IPI

Absolut compound protection

Chemical compounds

The chemical compound is protected for all uses, including the uses not known at the application date.



Böhm M et al. Blickpunkt der Mann 2004; 2 (1): 21-23 ©

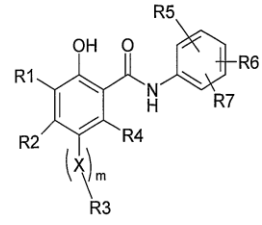
Sidenafil

IGE | IPI

Markush Structures

- **However: Selection inventions**

1. A compound according to formula I



wherein X represent  or  , and m is 0, 1 or 2;

R1 represents branched C_{1-6}alkyl or phenyl;

R2 and R4 independently represent, hydrogen, C_{1-6}alkyl, C_{1-6}alkenyl, C_{1-6}alkynyl or C_{1-6}alkoxy;

R5, R6 and R7 independently represent hydrogen, nitro, cyano, halogen, -OR8, C_{1-6}haloalkoxy, C_{1-6}haloalkyl, C_{1-6}alkyl, -C(O)OR8, -COR8, -C(O)NR8R8, -SH, -S(O)2OR8, $-S(O)_2N(R8)_2$, $-S(O)_nR9$, aryl, heteroaryl, wherein said aryl and heteroaryl may optionally be substituted with one or more C_{1-6}alkyl, oxo or phenyl wherein said phenyl is substituted with one or more halogen or C_{1-6} alkyl; n is 0,1,2 and each R8 independently represents hydrogen or C_{1-6}alkyl, and R9 represents C_{1-6}alkyl;

R3 represents C_{1-6}alkyl, C_{1-6}alkenyl, C_{1-6}alkynyl, C_{1-6}haloalkyl, arylC_{1-6}alkyl, arylC_{1-6}alkenyl,

IGE | IPI

..and biological compounds?

- **Proteins:** Absolute compound protection
- **Nucleotide sequences:** Absolute compound protection
  But: the protection is limited to the sequence segments that perform the function specifically described in the patent (CH).

IGE | IPI

2nd Medical Indication

Known Indication

reduction of inflammation, analgesia (relief of pain)

New Indication

irreversible inactivation of cyclooxygenase (COX), prevention of blood clotting

Patenting of a Dosage Regime

A medicament comprising an effective antihyperlipidemic amount of nicotinic acid taken once a day and instructions for administration, said administration to take place in the evening or at night prior to a periodic physiological loss of consciousness.

New is: once a day in the evening or at night

Product by Process claims

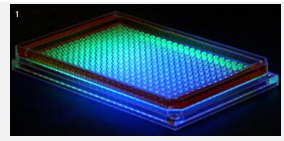
A product-by-process claim defines a product in terms of the method (manipulative steps) used to manufacture the same.

The problem: often there is no possibility to determine with which process the product has been manufactured. There is no sign of the process on the product.

Only if there is no other way to characterize the product than by the manufacturing process, such claims are allowed. However, the product needs to be novel since the product and not the process is claimed.

IGE | IPI

Reach-through claims



Specifically, a *reach-through claim* is one in which "claims for products or uses for products when experimental data is provided for screening methods or tools for the identification of such products.

-
- **a) A compound identified by a specific screen, that inhibits target protein X**
- **b) A method for selectively inhibiting protein X comprising administering a compound that selectively inhibits protein X, wherein said compound is found using a specific screen."**
- **c) A method of inhibiting the interaction of protein X and protein Y by binding an inhibitory compound.**
- **→ (not) allowed?**

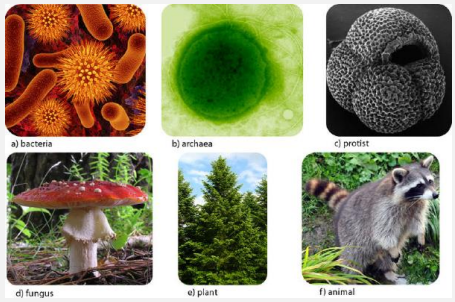
IGE | IPI

Can biological material be an invention and novel?

- **According to Article 54 of the EPC, an invention shall be considered novel if it does not form part of the state of the art.**
- **Biotechnological inventions shall also be patentable if they concern:**
  - **a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature. (EPC Rule 27a)**
  - **b) plants and animals if the technical feasability of the invention is not confined to a particular plant or animal. (EPC Rule 27b)**

Biological material in its natural state is not available to the public and thus not part of the prior art. It is a new product, because it was not previously available to the public.

IGE | IPI



Patenting of Organisms

Microorganisms
Plants
Animals
Humans

IGE | IPI

Patenting of Microorganisms (MO)

Definition of MO:

In general single cell organisms not visible by the naked eye that can be proliferated and manipulated in the lab.

- bacteria, yeast, funghi, algea, and protozoa
- plasmids and viruses
- human, animal or plant cells

A sample of the biological material has to be depositedin a recognized institution (Budapest Treaty) and a reference for the accession number for this material has to be inlcudedinto the application

IGE | IPI

Plant and animal varieties

1. The following shall not be patentable:
(a) plant and animal varieties;
(b) essentially biological processes for the production of plants or animals (breeding, crossing).

2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

However: patenting of (unaltered) microorganisms is possible but patenting of only transgenic plants or animals is possible

IGE | IPI

Patenting of plants

Prerequisites for the patenting

- Novelty
- Not obvious
- Industrial application

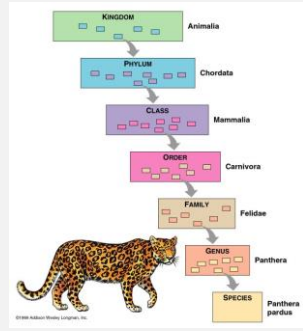
- Disclousure
- Reproducability

Exclusions from patentability

- inventions contrary to morality
- biological methods (breeding)
- plant varieties

IGE | IPI

Patenting of animals



Prerequisites for the patenting

- Novelty
- Not obvious
- Industrial application

- Disclousure
- Reproducability

Exclusions from patentability

- inventions contrary to morality
- biological methods (breeding)
- anmial varieties
- processes of surgery, therapy and diagnostics on the animal body

IGE | IPI

16

Transgenic Animals

Animal

Removal from the animal body

genetic alteration with

Isolated cell

Altered cell (including dauther cells)

Back into the animal body

IGE | IPI

The patentability of human beings

IGE | IPI

Exclusions from Patentability

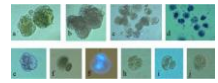
Art. 1a

II. The human body and its elements

1 **The human body as such in all stages of its formation and development, including the embryo, is not patentable.**

2 Elements of the human body in their natural environment are not patentable. An element of the human body is however patentable as an invention if it is produced by means of a technical process, a beneficial technical effect is indicated and the further requirements of Article 1 are fulfilled; Article 2 is reserved.

IGE | IPI



Art. 2

B. Exclusion from patentability

1 Inventions whose exploitation is **contrary to human dignity** or that disregard the dignity of the creature or that are in any other way contrary to public convention or morality are excluded from patentability. In particular, no patent may be granted for:

a. processes for **cloning human beings** and the clones obtained thereby;

b. processes for forming **hybrid organisms by using human germ cells**, human totipotent cells or human embryonic stem cells and the entities obtained thereby;

c. processes of **parthenogenesis using human germ cells** and the parthenotes produced thereby;

d. processes for **modifying the germline identity of human beings** and the germline cells obtained thereby;

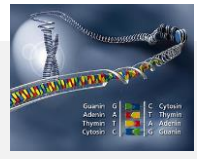
e. unmodified **human embryonic stem cells** and stem cell lines;

f. the **use of human embryos** for non-medical purposes;

g. processes for **modifying the genetic identity of animals that are likely to cause suffering** without being justified by reason of overriding interests that are worthy of protection, as well as the animals resulting from such processes.

IGE | IPI

Genes



Rule 27

Patentable biotechnological inventions

Art. 52

Biotechnological inventions shall also be patentable if they concern:

(a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;

Art. 1b

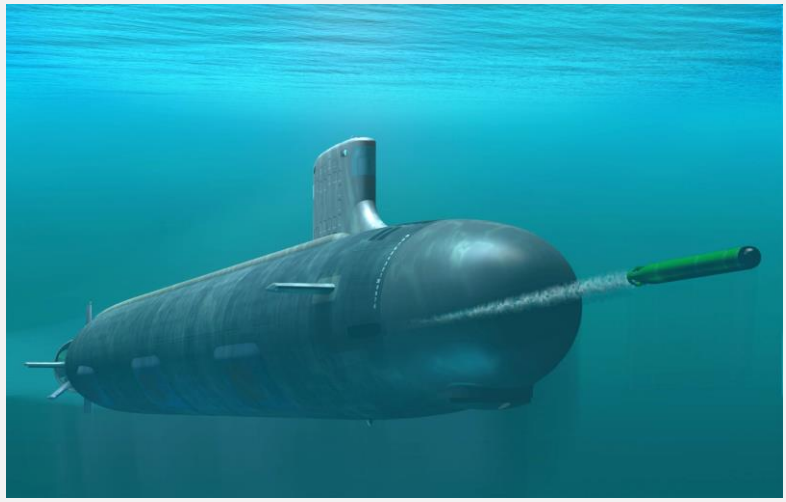
III. Genetic sequences

1 A naturally occurring sequence or partial sequence of a gene is not patentable as such.

2 Sequences that are derived from a naturally occurring sequence or partial sequence of a gene, may however be patented as an invention, if they are produced by a technical process, their function is specifically indicated.

03.10.2019

of submarines, torpedos …



Submarines

Analogous to a submarine, submarine patents could stay "under water" for long periods until they "emerge" and surprise the relevant market.

- In the United States, patent applications filed before November 2000 were not published and remained secret until they were granted.
- Today: the applicant can explicitly certify that they do not intend to file a corresponding patent outside the U.S. at the time they file the patent, and keep the application secret.

Torpedos

- Torpedo action is a court action for declaration of non-infringement of a patent (or patent invalidation)
- → Belgium torpedos, Italien torpedos

- The legal background:

Article 21 of the Brussels Convention (now Article 27(1) of European Council Regulation 44/2001

"*Where proceedings involving the same cause of action and between the same parties are brought in the courts of different member states, any court other than the court first seized shall of its own motion stay its proceedings until such time as the jurisdiction of the first court seized is established*."

Solution → Unified European Patent Court?

… and trolls

Non-practicing entities (NPE)

- A **non-practicing entity** (NPE) is someone who holds a patent for a product or process but has no intentions of developing it.
- **Patent trolling** or **patent hoarding** is a categorical or pejorative term applied to a person or company that attempts to enforce patent rights against accused infringers far beyond the patent's actual value or contribution to the prior art, often through hardball legal tactics.

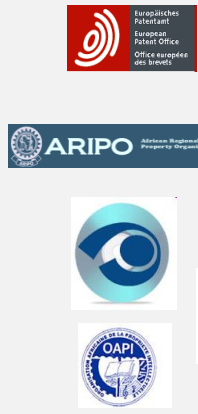
...

Patent Filing Procedures
Strategies for Patent Filings

IGE | IPI

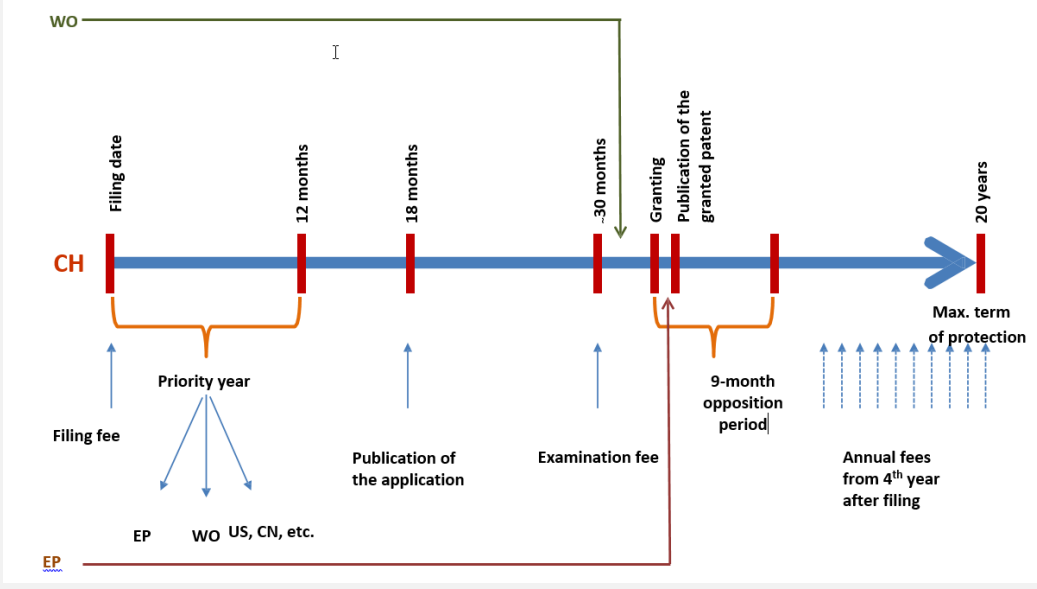
3 application routes

National Regional Worldwide



IGE | IPI

National route



IGE | IPI

National:

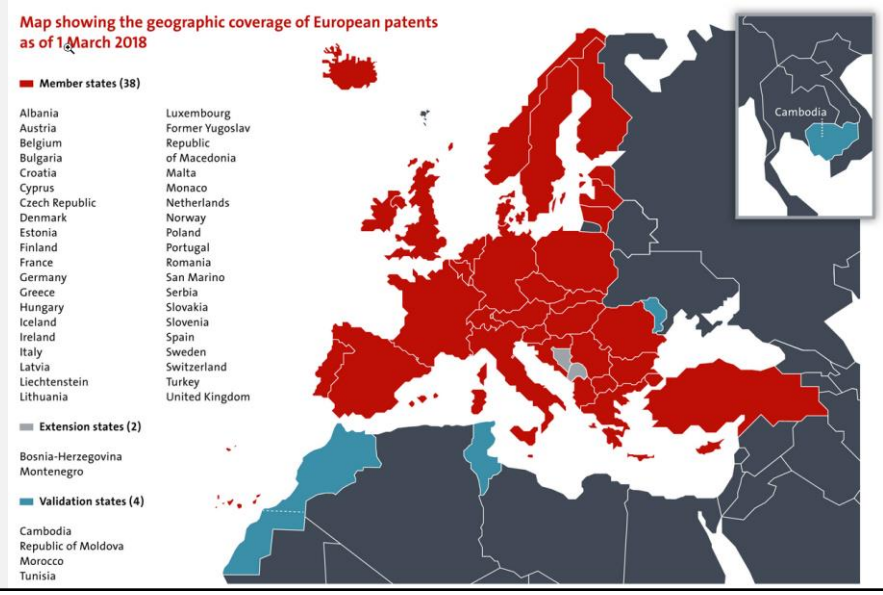
Patent granting procedure

- Applications are examined after 2-5 years
- Granting of a patent or rejection
- Applications are published after 18 months (according to TRIPS)
- Issued patent published weeks or days after granting
- Opposition period within **9 months after granting (in many countries)**

IGE | IPI

38 contracting states of the European Patent Convention (March 2014)

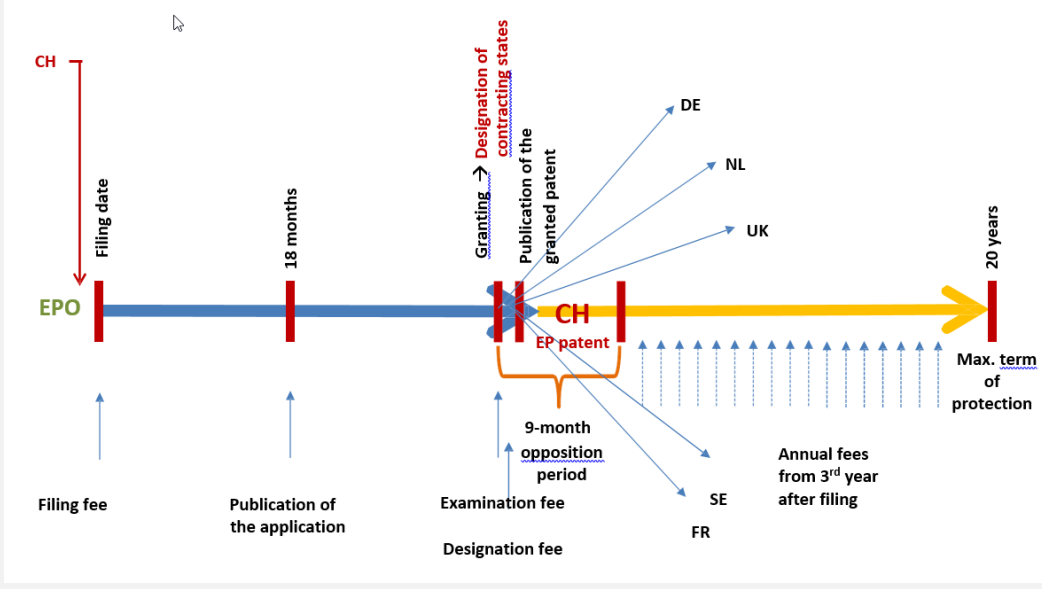
≠



European Patent Convention

- Centralized application and prosecution procedure
- After grant, patent essentially disintegrates into bundle of national patent rights in the designated countries
- Procedure administered by European Patent Office (EPO)
- 16 countries signed the EPC in 1973
- Implemented in 1977 by: Belgium, Germany, France, Luxembourg, Netherlands, Switzerland and Sweden.
- Territory covered by EPC as of today does not coincide with territory of European Union
- Today: 38 contracting states and offices in Munich, The Hague, Berlin, Vienna, Brussels

Regional route



EPO:

Patent granting procedure

- Opposition procedure within 9 months after granting; everybody has the right to object against the granting.
- Against all decisions of the EPO an appeal can be deposited at the EPO

and an EU patent?

Unitary patent in the making:

The European Council of Ministers and the European Parliament agreed on 11 December 2012 to a new regulation which provides for the granting of a patent with direct legal effect in almost all EU Member States (Italy and Spain are not participating

Agreements on languages, unitary patent court, and procedures (handeld by the EPO)

Still not solved: fees, money distribution among the member states.

IGE | IPI

WIPO

The Patent Cooperation Treaty (PCT)
152 member states (November 2018)

IGE | IPI

WIPO

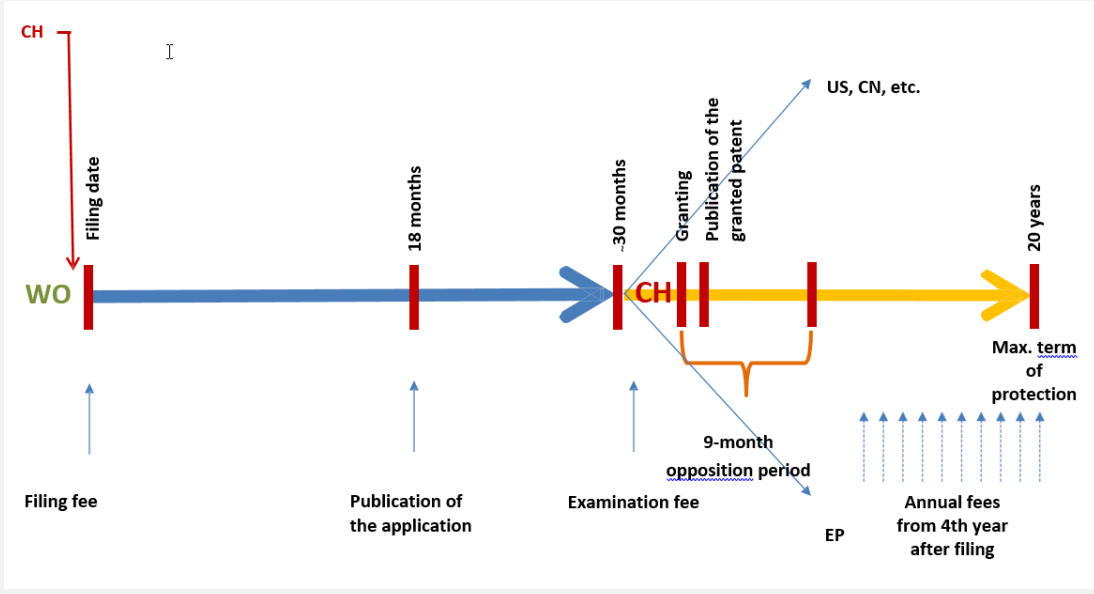
Patent Cooperation Treaty (PCT):

–Main goal: providing unified *application* procedure for filing patent applications in member states
–*No* granting procedure
→ 'international (worldwide) patent' does not exist
–concluded in 1970
–Administered by WIPO
–All patent offices of member states and WIPO are receiving offices for PCT applications

IGE | IPI

International route

WIPO



IGE | IPI

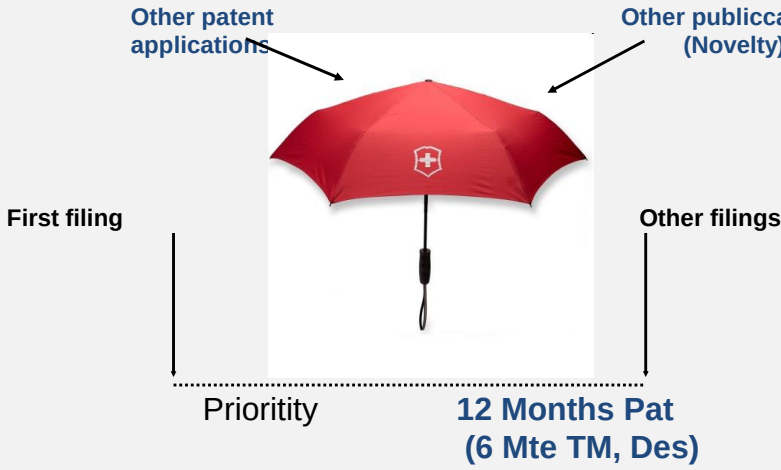
WIPO

PCT:

Patent granting procedure

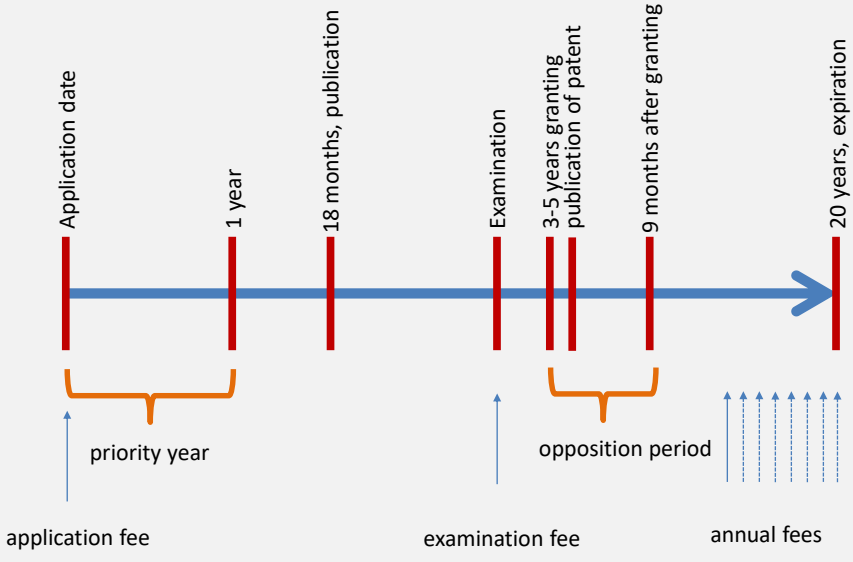
- Search report
- Publication of the unexamined application together with the search report
- Examination of novelty and inventiveness on request
- Forwarding of application to the desiganted states for examination and granting according to the national laws

Priority period



Within the priority period, the applicant can file the patent in any other country of the WTO and obtain a preliminary protection with the first filing date.

The life of a patent



IGE | IPI

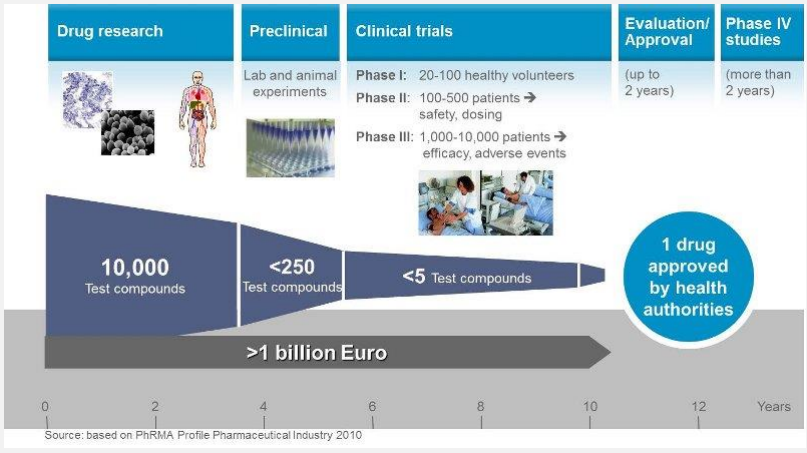
Supplementary Protection Certificates (SPC) for biologically active agents

namely human or veterinary medicaments and plant protection products (e.g. insecticides, and herbicides)

- Protection
  - **Up to + 5 years (5.5 years)**
- Prerequisits
  - Patent must be in effect
  - Substance must be registered

IGE | IPI

Why SPCs?



Source: based on PhRMA Profile Pharmaceutical Industry 2010

Patent strategy of BMW

BMW Z4

Which countries?

DE
FR
IT
GB

cost / benefit analysis

Costs ?
Countries ?
Enforcement ?
Distribution ?

Enforcement problems

- Countries with bad enforcement possibilities:
  - India
  - Argentina
  - Spain
  - Italy
  - Japan
- Countries with good enforcement possiblities:
  - Canada
  - Netherlands
  - Great Britain
  - Germany
  - France

[aus „The World Patent Survey“, Jan 2000, S.16]

Patent strategy of BMW

BMW Z4

Which countries?

PEUGEOT sport

Audi

DE
FR
IT
GB

cost / benefit analysis

Costs ?
Countries ?
Enforcement ?
Distribution ?

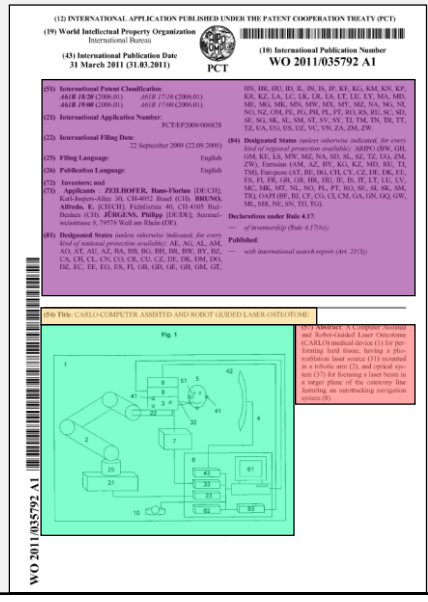
Enforcement problems

- Countries with bad enforcement possibilities:
  - India
  - Argentina
  - Spain
  - Italy
  - Japan
- Countries with good enforcement possiblities:
  - Canada
  - Netherlands
  - Great Britain
  - Germany
  - France

[aus „The World Patent Survey“, Jan 2000, S.16]

Content and Structur of Patents

The content of Patents: first page



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
31 March 2011 (31.03.2011)

PCT

(10) International Publication Number
WO 2011/035792 A1

(54) Title: CARLO-COMPUTER ASSISTED AND ROBOT GUIDED LASER-OSTEOTOME

Fig. 1

WO 2011/035792 A1

Bibliographic data

Title

Abstract

Drawing

IGE | IPI

Publication Levels (kind code)

- A1
- A2
- A3
- …
- B1
- B2
- …
- C1
- …
- T1

„Disclosure“
„Application“
„…“

„Patent“
„Granted“
„…“

„Translation“
„Validation“
„…“

WIPO Standard ST. 16

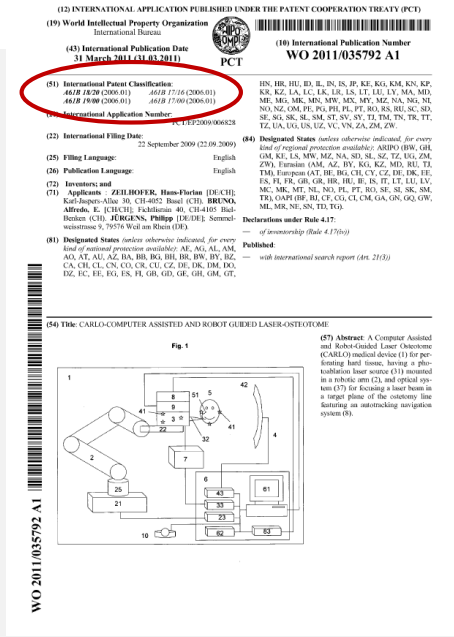
First publication level

Second publication level

Third publication level

IGE | IPI

Patent Classifications



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
31 March 2011 (31.03.2011)

PCT

(10) International Publication Number
WO 2011/035792 A1

(51) International Patent Classification:
A61B 18/20 (2006.01) *A61B 17/16* (2006.01)
A61B 19/00 (2006.01) *A61B 17/00* (2006.01)

(21) International Application Number:
PCT/EP2009/006828

(22) International Filing Date:
22 September 2009 (22.09.2009)

(25) Filing Language: English

(26) Publication Language: English

(72) Inventors; and
(71) Applicants : **ZEILHOFER, Hans-Florian** [DE/CH]; Karl-Jaspers-Allee 30, CH-4052 Basel (CH). **BRUNO, Alfredo, E.** [CH/CH]; Fichtlistein 40, CH-4105 Biel-Benken (CH). **JÜRGENS, Philipp** [DE/DE]; Semmelweisstrasse 9, 79576 Weil am Rhein (DE).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:
— *of inventorship (Rule 4.17(iv))*

Published:
— *with international search report (Art. 21(3))*

(54) Title: CARLO-COMPUTER ASSISTED AND ROBOT GUIDED LASER-OSTEOTOME

Fig. 1

(57) Abstract: A Computer Assisted and Robot-Guided Laser Osteotome (CARLO) medical device (1) for perforating hard tissue, having a photoablation laser source (31) mounted in a robotic arm (2), and optical system (37) for focusing a laser beam in a target plane of the osteotomy line featuring an autotracking navigation system (8).

WO 2011/035792 A1

Patent data:
Patent classifications

- Advantages:
  - patent classes are assigned by independent experts (mostly patent examiners)
  - hierarchical structure
  - multiple classification systems available → complementary searches possible
- Most important classification systems:
  - International Patent Classification (IPC): global coverage
  - Cooperative Patent Classification (CPC): jointly developed by European Patent Office and the United States Patent and Trademark Office

Classification sytems

„ Device and method for examination and/or treatment of the eye „

- **IPC** **A61B3/16**
- **ECLA** **A61B3/125**
- **ICO** **K61F9/00B4**
- **UCLA** **351/219**

→ **CPC**

- **Derwent** **P31 P32**
- **F-Terms** **2H087/KA11**
- **Alte Dt. Klassifikation** **...**
- **I.d.T.** **...**
- **UKC**

IGE | IPI

Description:

– Problem, State-of-the-art

– Solution = Invention

– examples (with drawings

➔ Disclosure for the person skilled in the art

Draft
CARLO Patent Application 040809
AEB, HFZ & PHJ

CARLO - Computer Assisted and Robot Guided Laser- Osteotome

Technical Field

The present invention relates to an automated Computer Assisted and Robot-Guided laser osteotome (CARLO) according to the preamble of independent claim 1. Such medical device can be used for cutting, drilling and milling bone and cartilage tissues to perform all forms of osteotomies in the field of craniomaxillofacial (CMF), orthopaedic, skullbase and dentoalveolar surgeries including dental implantology.

Background Art

Osteotomies are currently performed with mechanical tools such as oscillating saws, chisels or drills. The precision in the cut, drilling or milling in the bones and cartilages obtained with these tools is limited by the size of the instrument used and only simple cutting geometries can be performed with these tools. An inherent drawback of using mechanical tools for osteotomy is that they are in direct contact with the hard tissue transmitting unwanted vibrations to the patient and, the heat generated by frictions, degrades the otherwise obtainable precision in the osteotomy.

Taking advantage of laser ablation methods of wide use in the micromachining of non-biological materials such as metals and plastics for replication and fast prototyping a new method to perform contact-free osteotomies is emerging offering distinct advantages over mechanical methods (see e.g. Kuttenberger JJ., Stübinger S., Waibel A., Werner M., Klasing M., Ivanenko M., Hering P., Von Rechenberg B., Sader R., and Zeilhofer HF., *Photomed Laser surg.*, 2008 Apr; 26(2):129-36 and references herein). However, an important difference is encountered when micromachining biological tissues of patients by photoablation, as compared with e.g. metals or plastics, which contributed to delays in its development for osteotomic purposes, is the difficulty to properly fix the anatomical target of the patient to be operated. This difficulty precludes that the precision of the intervention be dominated by the size of the beam waist (the size of the laser beam at its focal point) but by the movements and vibrations of the

IGE | IPI

Claims:

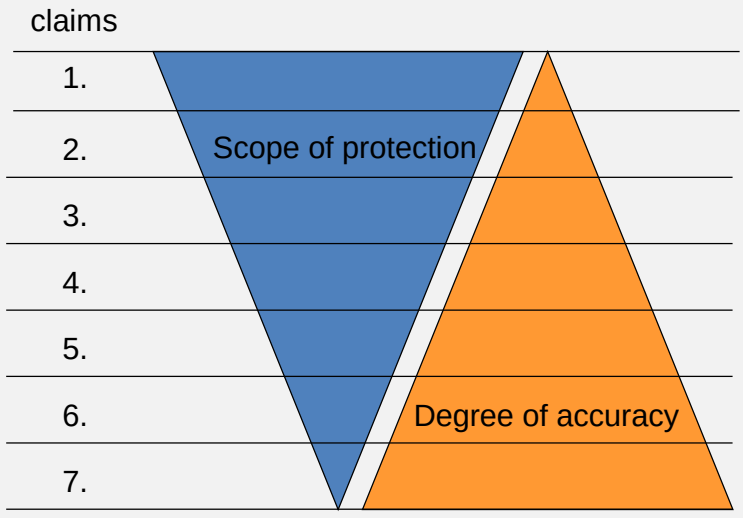
– Definition of the Invention

➔ Extent of Protection

Claims

1. An automated CARLO medical device (1) to photoablate human hard tissues to facilitate surgical interventions comprising:
   a) A photoablation laser source (31);
   b) a robotic arm (2) for precisely positioning the photoablation laser beam (32) into a target osteotomic line (51);
   c) an autotracking system (4) to correct for position of the target with respect to the photoablation source;
   d) a disposable particle filter (35) connected to an aspirating nozzle (34) and a aspirating pump (71) to capture photoablation generated odorous molecules and debris;
   e) a central operating console (6) to drive the robotic arm (2) over the osteotomic line and, control the photoablation laser source (31) and perform other controlling tasks.
2. A CARLO medical device (1) of claim 1, wherein the photoablation laser source (31) is a pulsed Erbium solid state laser.
3. A CARLO medical device (1) of claims 1 and 2, wherein the laser beam is a laser diode pulsed Erbium solid state laser.
4. A CARLO medical device (1) of claim 1 to 3, wherein the pulses have temporal width between 10 femtoseconds to 300 μseconds.
5. A CARLO medical device (1) according to any one of the preceding claims, comprising a closed loop drilling system (80) to control the depth of the individual holes and able to stop the laser photoablation in the neighborhood of the ventral hard-to-soft tissue interface.

Schematic structure of patent claims



Patents: the most fantastic scientific library in the world

~ 80% of the technical kowledge is only in patent documents!!!

IGE | IPI

Assisted Patent Searches for Public Research Institutions and Inosuisse-Projects

- The customer (researcher) must be personally present at the Institute for the search.
- The time limit for the Assisted Patent Search is one day, including the informational part.
- The search is done in all accessible patent databases including EPODOC, the European Patent Office database.
- Price: CHF 300.- (Euro 280.-) for one full day

IGE | IPI

60

Free internet tools for patent searches

Google Patents — Full text US, 17 other countries
Machine translated abstracts
http://patents.google.com

WIPO PATENTSCOPE Search International and — PCT and national patents (if available)
65 million documents
http://www.wipo.int/patentscope/en/

FPO DRIVING IP FORWARD — US, EP, JP abstracts and PCT documents
http://www.freepatentsonline.com/search.html

UNITED STATES PATENT AND TRADEMARK OFFICE uspto — US documents only (but also full text)
http://www.uspto.gov/patents/process/search/
http://patft.uspto.gov/

LENS.ORG Solving The Problem Of Problem Solving™ — https://www.lens.org
Includes Biosequence search
currently featuring over 90 million patent documents
- many of them full-text

IGE | IPI

Database of the European Patent Office
100+ million patents from 80+ countries
(Search language: English only,
All titles and abstracts translated into English)
http://http://worldwide.espacenet.com

Database of the German Patent Office
90+ million patent documents
(Search languages: german, English etc.)
http:// http://depatisnet.dpma.de