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# Synthetic Biology and Intellectual Property

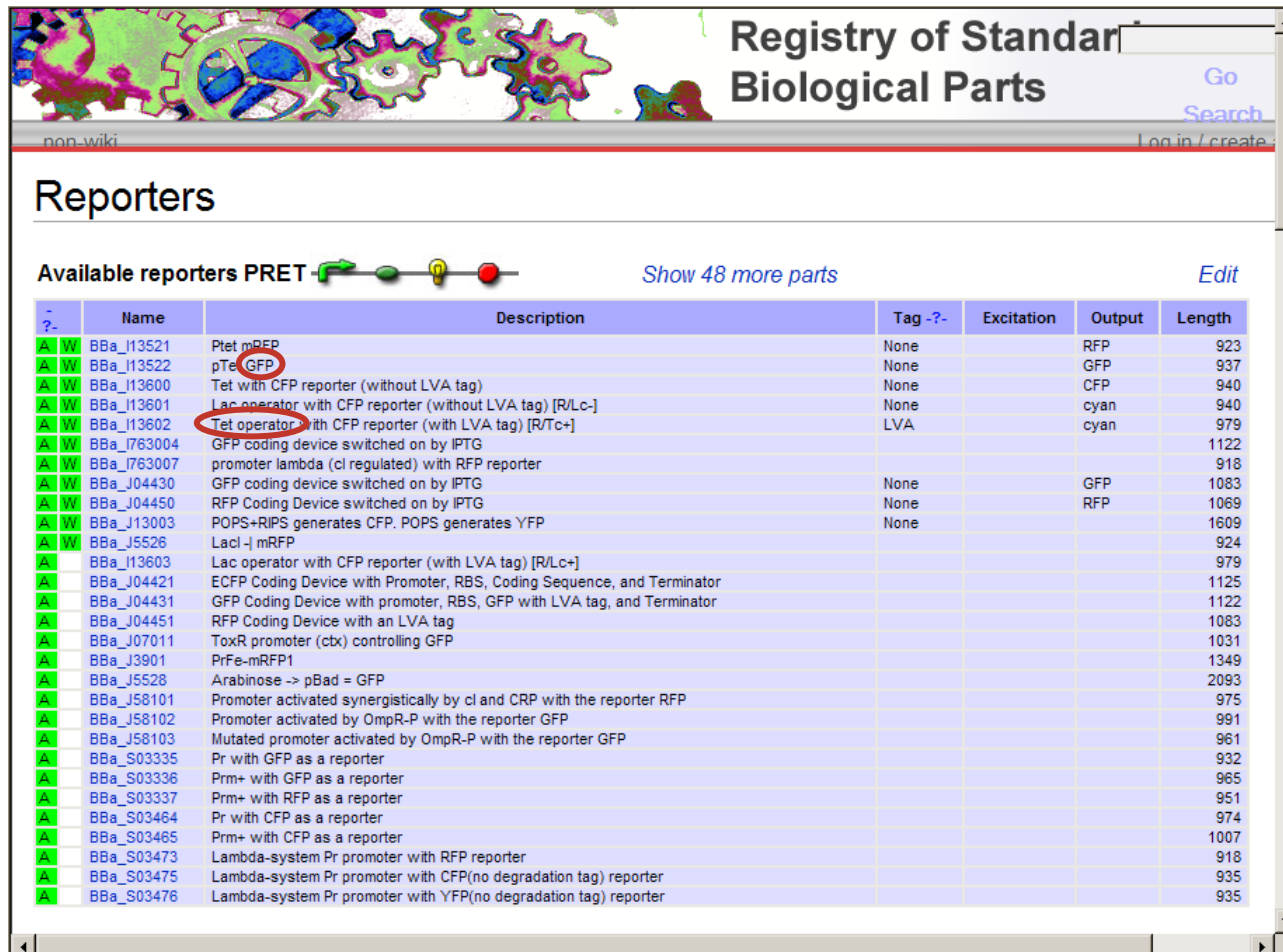
Dr. Berthold Rutz,  
Directorate 2.4.01 Biotechnology  
European Patent Office Munich

ECSB II: Design, Programming and  
Optimisation of Biological Systems  
Sant Feliu de Guixols, Spain  
29 March - 03 April 2009



# BioBricks: free to share and reuse?


The BioBricks Foundation, Inc. (BBF), is a not-for-profit organization founded to promote and protect the development, *sharing, and reuse* of BioBrick™ standard biological parts. The BBF's goals are to provide stewardship in developing and promoting technical standards, in *building and protecting a public commons* of synthetic biological parts, and in supporting a vibrant community of biological engineers.



Registry of Standard Biological Parts

non-wiki

## Reporters

Available reporters PRET  [Show 48 more parts](#) [Edit](#)

?	Name	Description	Tag -?-	Excitation	Output	Length
	BBa_113521	Ptet mRFP	None		RFP	923
	BBa_113522	pTet <b>GFP</b>	None		GFP	937
	BBa_113600	Tet with CFP reporter (without LVA tag)	None		CFP	940
	BBa_113601	Lac operator with CFP reporter (without LVA tag) [R/Lc-]	None		cyan	940
	BBa_113602	<b>Tet operator</b> with CFP reporter (with LVA tag) [R/Tc+]	LVA		cyan	979
	BBa_1763004	GFP coding device switched on by IPTG				1122
	BBa_1763007	promoter lambda (cl regulated) with RFP reporter				918
	BBa_104430	GFP coding device switched on by IPTG	None		GFP	1083
	BBa_104450	RFP Coding Device switched on by IPTG	None		RFP	1069
	BBa_113003	POPS+RIPS generates CFP. POPS generates YFP	None			1609
	BBa_15526	LacI -I mRFP				924
	BBa_113603	Lac operator with CFP reporter (with LVA tag) [R/Lc+]				979
	BBa_104421	ECFP Coding Device with Promoter, RBS, Coding Sequence, and Terminator				1125
	BBa_104431	GFP Coding Device with promoter, RBS, GFP with LVA tag, and Terminator				1122
	BBa_104451	RFP Coding Device with an LVA tag				1083
	BBa_107011	ToxR promoter (cbx) controlling GFP				1031
	BBa_13901	PrFe-mRFP1				1349
	BBa_15528	Arabinose -> pBad = GFP				2093
	BBa_158101	Promoter activated synergistically by cl and CRP with the reporter RFP				975
	BBa_158102	Promoter activated by OmpR-P with the reporter GFP				991
	BBa_158103	Mutated promoter activated by OmpR-P with the reporter GFP				961
	BBa_S03335	Pr with GFP as a reporter				932
	BBa_S03336	Prm+ with GFP as a reporter				965
	BBa_S03337	Prm+ with RFP as a reporter				951
	BBa_S03464	Pr with CFP as a reporter				974
	BBa_S03465	Prm+ with CFP as a reporter				1007
	BBa_S03473	Lambda-system Pr promoter with RFP reporter				918
	BBa_S03475	Lambda-system Pr promoter with CFP(no degradation tag) reporter				935
	BBa_S03476	Lambda-system Pr promoter with YFP(no degradation tag) reporter				935

Examples (illustrative, no legal opinion):

### GFP:

32 EP patents with "Green fluorescent protein" in title

### Tet operator:

56 patent applications worldwide with "Tet operator" in title or abstract

### T7 promoter:

4 EP patents with "T7 promoter" in title

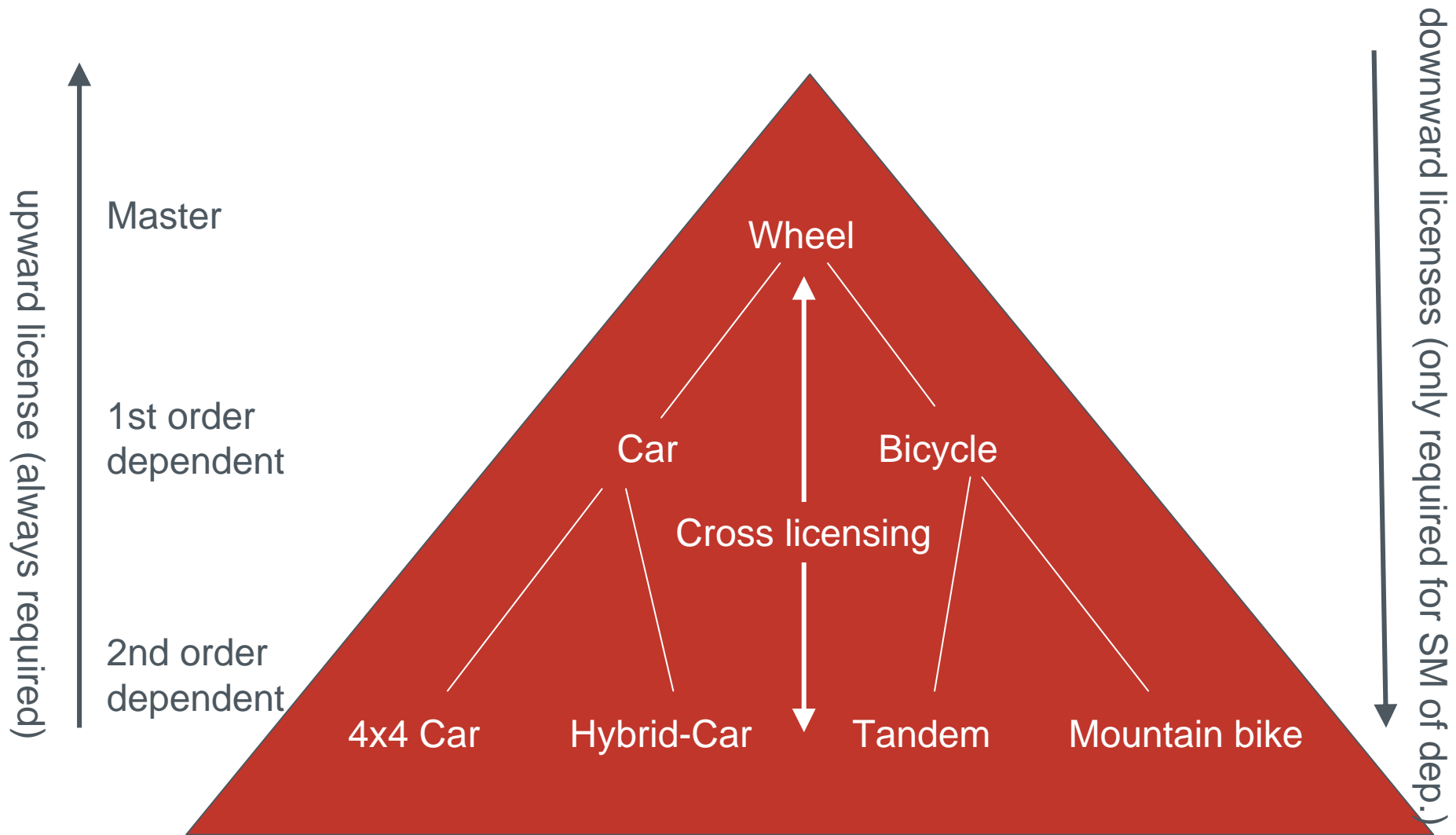
**A thorough search, i.e. using sequence alignment tools is likely to generate even more hits!**

# What is a patent?

- temporally (20 years) and geographically (EPC, US, Japan etc.) limited right to **prevent others from making, using, offering for sale, selling, or importing the invention**
- **not a right to perform the invention!**
  - other regulatory provisions, e.g. drug approval, animal protection
  - already existing patents or other IP rights on particular aspects of the invention



# Master and dependent patents



## Why patents?

- **incentive** for investment into R&D
- prevent secrecy (obligatory **disclosure** after 18 months)
- avoid duplication of R&D
- **tradable right** in knowledge goods (intangible assets)
- ...



## Legal background for patents in Synthetic Biology (1)

- European Patent Convention (EPC, 35 member states)

### *Article 53*

### **Exceptions to patentability**

European patents shall not be granted in respect of:

- (a) inventions the commercial exploitation of which would be **contrary to "ordre public" or morality**; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
- (b) **plant or animal varieties or essentially biological processes** for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

*Rules 26 to 34 (implementation of Directive 98/44/EC)*

### **Biotechnological inventions**

- European Directive 98/44/EC on the legal protection of biotechnological inventions (to be used for interpretation of Rules 26 to 34 EPC)

## Legal background for patents in Synthetic Biology (2)

### EPC

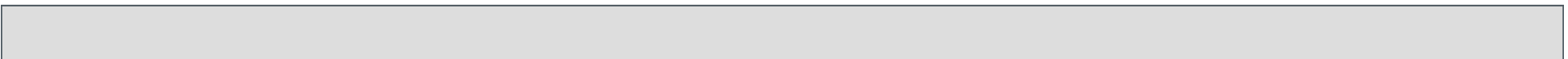
#### Rule 26

##### *General and definitions*

- (2) "Biotechnological inventions" are inventions which concern a **product consisting of or containing biological material** or a process by means of which biological material is produced, processed or used.
- (3) "Biological material" means any **material containing genetic information and capable of reproducing itself** or being reproduced in a biological system.

What about Synthetic biology, e.g.  
artificial codons, non-natural amino acids,  
protocells etc.?

Closer to chemistry?



## Legal background for patents in Synthetic Biology (3)

### EPC

#### Rule 27

##### *Patentable biotechnological inventions*

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;
- (b) **plants or animals** if the technical feasibility of the invention is not confined to a particular plant or animal variety;
- (c) a **microbiological or other technical process**, or a product obtained by means of such a process other than a plant or animal variety.

#### Rule 28

##### *Exceptions to patentability*

e.g. human cloning, human germ line modification, industrial or commercial use of human embryos,



## Legal background for patents in Synthetic Biology (4)

- Relevant national law after patent grant
  - research exemption
  - compulsory licenses (e.g. for public health, Belgium)
  - research tool licenses (e.g. for biotechnology, Switzerland)
- Licensing practice, registration and regulation (private contract law)



## Research exemption in Europe

No provision regarding defences to infringement in the EPC

→ subject to national law

Most countries in Europe have adopted legal provisions using the wording of Art. 31(b) of the 1975 Luxembourg Convention on the Community Patent (Community Patent Convention, not in force):

**"Patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention".**

**Interpretation** by national courts can differ, in many European countries:

research on is exempted, research with is not exempted

e.g. improvement of Taq polymerase by mutagenesis: yes

use of Taq polymerase to amplify gene of interest: no

**Special case:** clinical trials (Bolar exemption)

# What is Synthetic biology?

## Classical biotechnology

focus on one or few genes

scientific approach

non-standardised

biological synthesis of DNA

"modified" life

...

## Synthetic biology

focus on many genes

engineering approach

standardised (methods and "parts")

chemical synthesis of DNA

"artificial" life?

...

an incremental change?

## Anything new from a patent point of view?

- Product claims: nucleic acids (genes, regulatory elements, mRNA), proteins, vectors, cells, micro-organisms
- Method claims: "Method for synthesis of compound X ..."
- Use claims: "Use of micro-organism Y for synthesis of ..."
- Apparatus claims: "Apparatus for synthesising ..."

Probably not, at first sight!

## Possible differences to classical Biotech

- Complexity: Claims for micro-organisms or processes with tens to hundreds of defined parts (comparable to micro-arrays, molecular diagnostic?)
- Interconnectedness, interoperability, standardisation: parts have to interact to achieve functionality which resides in the combination
- Interdisciplinarity: interlinked with informatics (software, hardware), chemistry, electronics, nanotechnology, mechanical engineering

## Possible problems arising (1)

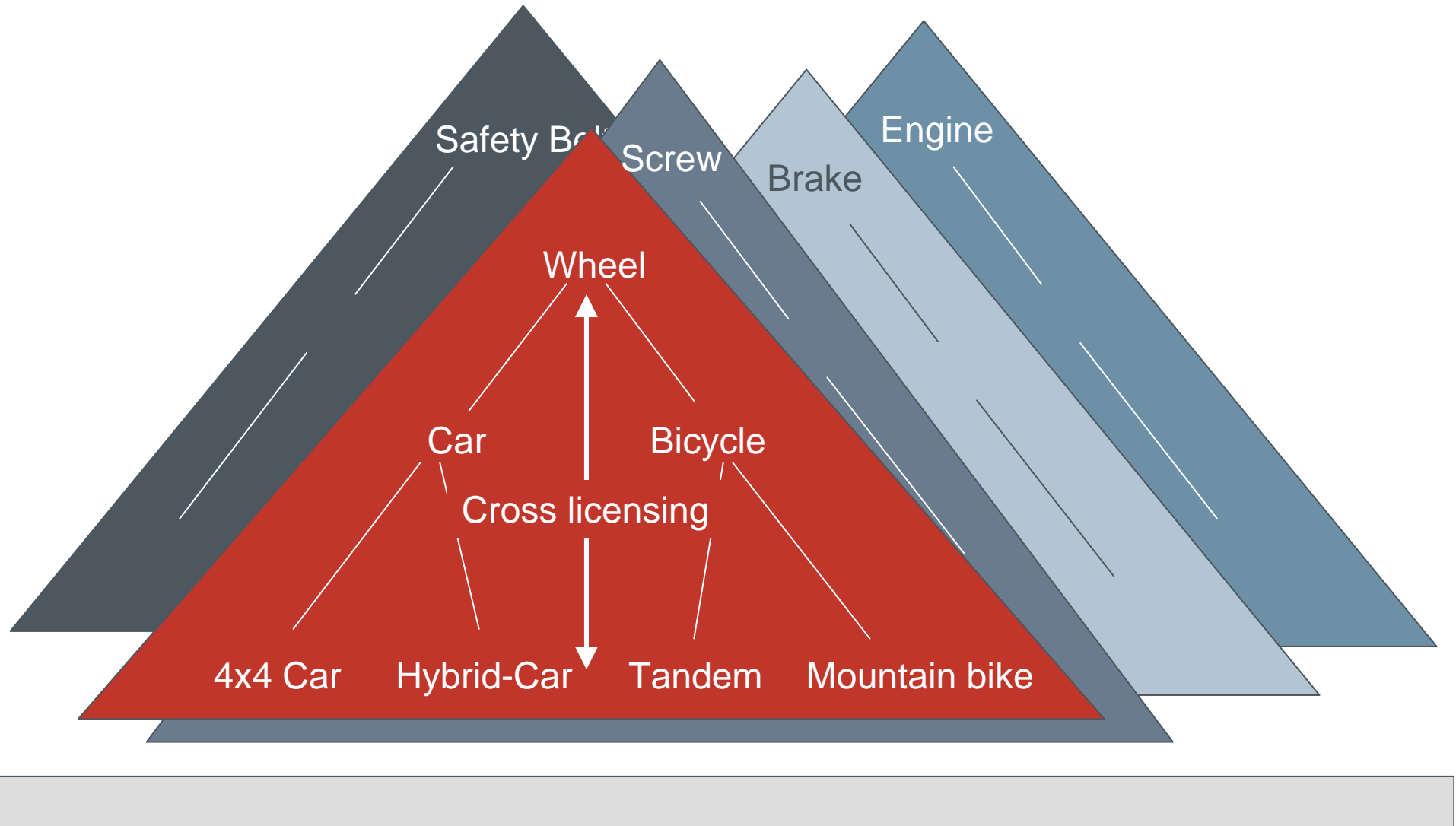
Complexity → patent thickets



Picture by Ilia Polian

# Patent Thickets and Royalty Stacking

Complex products may involve many patent dependencies



## Possible problems arising (2)

Interoperability and Standards → patent blockage





## Possible problems arising (3)

- Interdisciplinarity → difficulties in patent search and examination:  
Who's the expert?
- Ethics/morality:
  - safety concerns (e.g .environmental release)
  - creation of new life forms ("playing god")
  - bio-terrorism (disclosure of sensitive information)
  - access to technology/knowledge/medicine for developing countries

# Patent information is crucial

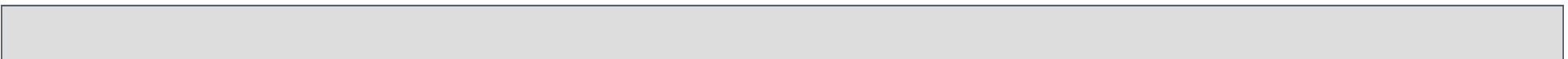
- Determining existing patent rights:
  - Search for relevant patents/patent applications
    - Keyword search (*esp@cenet*)
    - EPLA classification search (*esp@cenet*)
    - Sequence search (European Bioinformatics Institute, EBI)
  - Legal status (for EPO: *epoline/Register Plus*)
  - Geographical status (national patent offices, WIPO)
  - Claim scope (*esp@cenet*, *epoline/Register Plus*)
  - Possible overlap with own activities, risk of infringement
- "Freedom to operate" without infringing others' patent rights
- "Freedom to cooperate" while knowing each other's rights
- "Freedom to put into public domain", e.g. BioBricks
- "Freedom to protect/patent", prior art of all kinds (oral, written, prior use) worldwide has to be considered

## Towards open "standard biological parts"

- Identify possible patent holders of parts
  - by patent search
  - through public call (internet, print-media)
- Negotiate non-assertion for research purposes
- Indicate parts covered by patents and status (asserted/non-asserted, unknown) in database
- Develop license conditions for newly generated parts based on patent rights (e.g. "Science Commons" or "BiOS" type)
- Create patent pool(s) for Synthetic Biology (comparable to *Open Invention Network* for Linux)
- Alternatively/complementary: put new parts directly into public domain ("no strings attached", but also no way to control dissemination/commercialisation)

Thank you for your attention!

Contact: [brutz@epo.org](mailto:brutz@epo.org)



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So many of you wrote in response to our editorial on the biometric application which would interrupt your esp@cenet searches with soothing images and calming sounds if it thought that you were too stressed, anxious or tired.

It seems that most of you thought that such an intervention would lead to an *increased* level of tension and indeed anger.....

We agree totally and we will NOT be implementing that biometric application after all.

And - and for those of you with strong negative opinions on the matter- we refer you to the *date* of the publication of the announcement :-)

Sorry to disappoint those of you who thought that restful images and [relaxing sound effects](#) would be a good idea.

We'll be back soon with the winners of esp@cenet quiz no2 and the correct answers and with the questions for esp@cenet quiz no3.

European Patent Office

epo@line

\*Electronic communication and transaction during the patent granting procedure

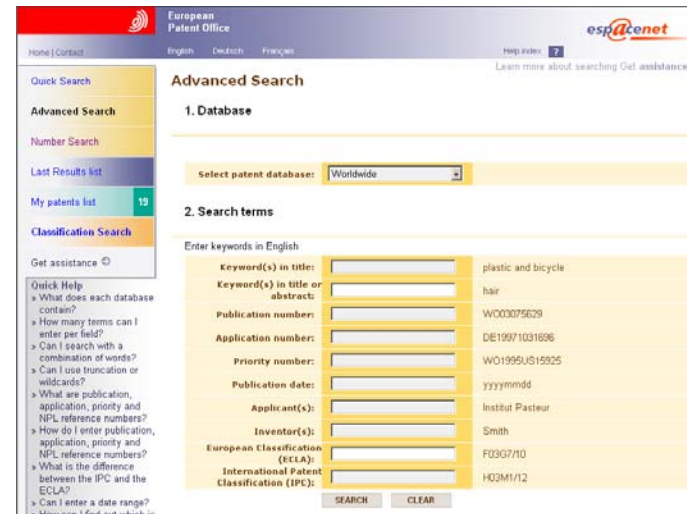
- access to more than 60 million patent documents from all over the world (more than 80 patent-granting authorities)
- data from 1836 to today
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# esp@cenet

Four search options, e.g.

## Advanced search

- to combine various search terms and fields. For example, you can search for patent documents from a particular year and country that have specific words in their title or abstract



The screenshot shows the 'Advanced Search' page on the esp@cenet website. It features a sidebar with navigation options like 'Quick Search', 'Advanced Search', 'Number Search', 'Last Results list', 'My patents list', and 'Classification Search'. The main content area is titled 'Advanced Search' and includes sections for '1. Database' (with a dropdown menu set to 'Worldwide') and '2. Search terms'. Under '2. Search terms', there are several input fields for keywords in English, with pre-filled examples: 'Keyword(s) in title: plastic and bicycle', 'Keyword(s) in title or abstract: hair', 'Publication number: W000075629', 'Application number: DE19971031806', 'Priority number: WO1995US15925', 'Publication date: yyyyymmdd', 'Applicant(s): Institut Pasteur', 'Inventor(s): Smith', 'European Classification (ECLA): F03G7/10', and 'International Patent Classification (IPC): H03M1/12'. There are 'SEARCH' and 'CLEAR' buttons at the bottom.

## Classification search

- to find all the patent publications in a particular technical area.



The screenshot shows the 'Search the European classification' page on the esp@cenet website. It features a sidebar with navigation options like 'Quick Search', 'Advanced Search', 'Number Search', 'Last result list', 'My patents list', 'Classification Search', and 'Get assistance'. The main content area is titled 'Search the European classification' and includes a 'View Section' dropdown menu set to 'Index A B C D E F G H Y'. There are two search input fields: 'Find classification(s) for keywords' (with the example 'e.g. mast sail') and 'Find description for a symbol' (with the example 'e.g. A23C'). There are 'Go' buttons for both. Below the search fields, there is a list of classification categories with checkboxes: 'HUMAN NECESSITIES' (A), 'PERFORMING OPERATIONS; TRANSPORTING' (B), 'CHEMISTRY; METALLURGY' (C), 'TEXTILES; PAPER' (D), 'FIXED CONSTRUCTIONS' (E), 'MECHANICAL ENGINEERING; LIGHTING; HEATING; WEAPONS; BLASTING ENGINES OR PUMPS' (F), 'PHYSICS' (G), 'ELECTRICITY' (H), and 'GENERAL TAGGING OF NEW TECHNOLOGICAL DEVELOPMENTS [N0403]' (Y). There are 'show notes', 'Expand groups', 'Copy to searchform', 'Copy', and 'Clear' buttons at the bottom.

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none	-14	-4	6	10.0	default

DNA STRAND	HISTOGRAM	MOLECULE TYPE
both	no	DNA

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● No opposition filed within time limit  
*Database last updated on: 22/03/2007*

**Most Recent Event:** 17/02/2006 Lapse of the patent in a contracting state published on 05/04/2006 [2006/14]

**Applicant(s):** For all designated states  
Beheermaatschappij De Boer Nijmegen B.V.  
Koopvaardijweg 2  
6541 BS Nijmegen / NL

# Evaluation of patents and patent portfolios

## IPscore:

- developed by the Danish Patent Office
- available free of charge from [www.epo.org](http://www.epo.org)

## IPscore is...

- a tool for the evaluation and management of patents
- a catalyst for dialogue within the company about patents
- a guide for locating potential gains and opportunities for saving costs

## IPscore can be used to evaluate...

- individual patents
- patented technologies (1...x patents)
- R&D projects, even if no patent exists yet
- ideas and project proposals

