Europäisches Patentamt
European Patent Office
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Patent issues in SynBio applications

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European Patent Office Munich

Synthetic Biology Workshop:
From Science to Governance
Brussels, Sofitel Hotel
18-19 March 2010

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What is a patent?

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Urkunde Certificate Certificat

Es wird hiermit bescheinigt, daß für die ihr der beigefügten Patentschrift beschriebene Erfindung ein europäisches Patent für die in der Patentschrift bezeichneten Vertragsstaaten erteilt worden ist.

It is hereby certified that a European patent has been granted in respect of the invention described in the annexed patent specification for the Contracting States designated in the specification.

Il est certifié qu'un brevet européen a été délivré pour l'invention décrite dans le fascicule de brevet ci-joint, pour les Etats contractants désignés dans le fascicule de brevet.

Europäisches Patent Nr. / European Patent No. / Brevet européen n°
1166528

Patentinhaber / Proprietor of the Patent / Titulaire du brevet
Hensiek, Jobst
Roseneck 2
38640 Goslar/DE

München, den / Munich, / Fait à Munich, le 19.05.04

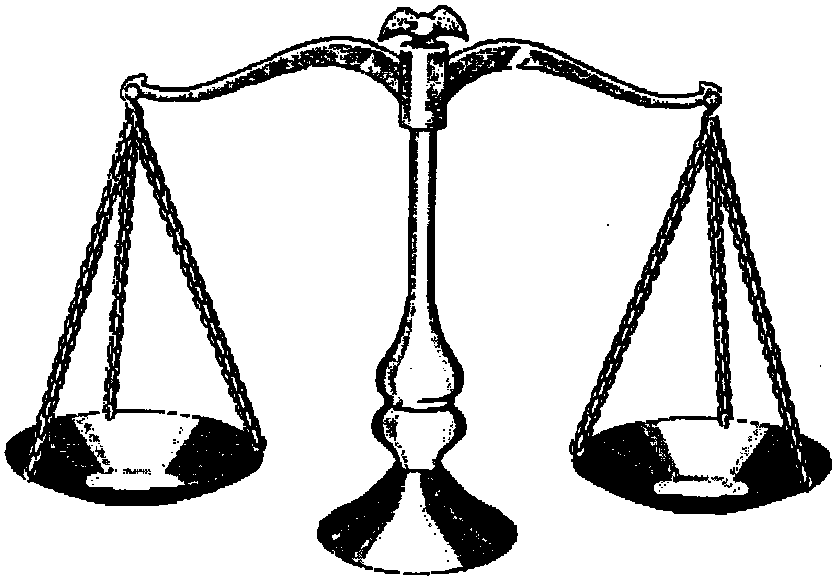
Ingo Kober
Président des Europäischen Patentamts
President of the European Patent Office
Président de l'Office européen des brevets

EPA/EPO/OEB Form 2031 02.03

- A patent is a legal title granting its holder the right to prevent third parties from using an invention without authorisation.
- It is not a right to perform the invention!
- Protection is granted:
  - for a limited period, generally 20 years
  - for a specific geographic area

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)
- ...

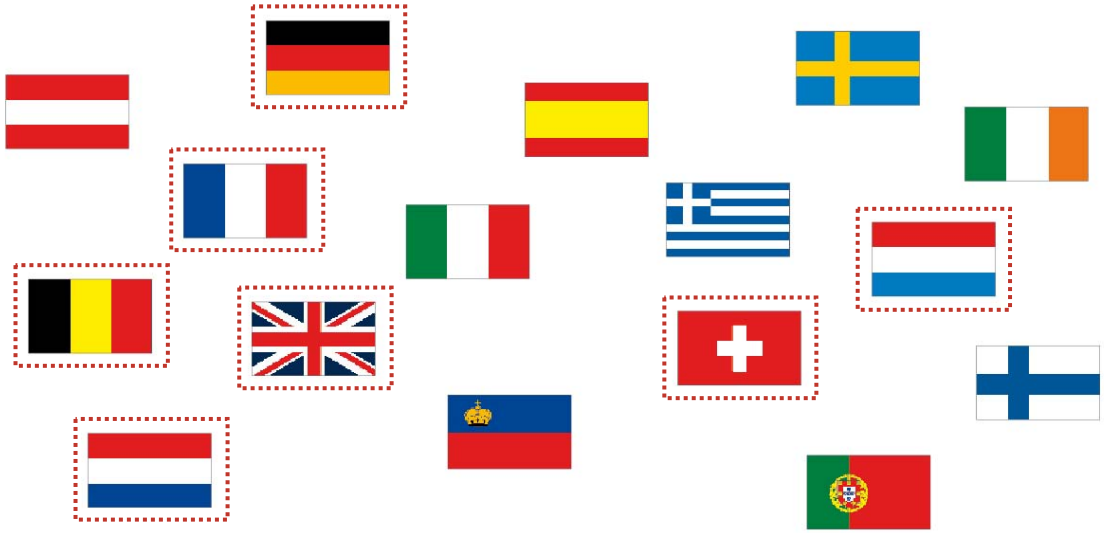


The European Patent Convention

- The European Patent Convention (EPC)
  - provides the legal framework for the granting of European patents via a centralised procedure
  - establishes the European Patent Organisation

- 1973 – Diplomatic Conference in Munich ► signature of the EPC by 16 countries

- 1977 – Entry into force of the EPC in 7 countries - marked as follows



36 member states

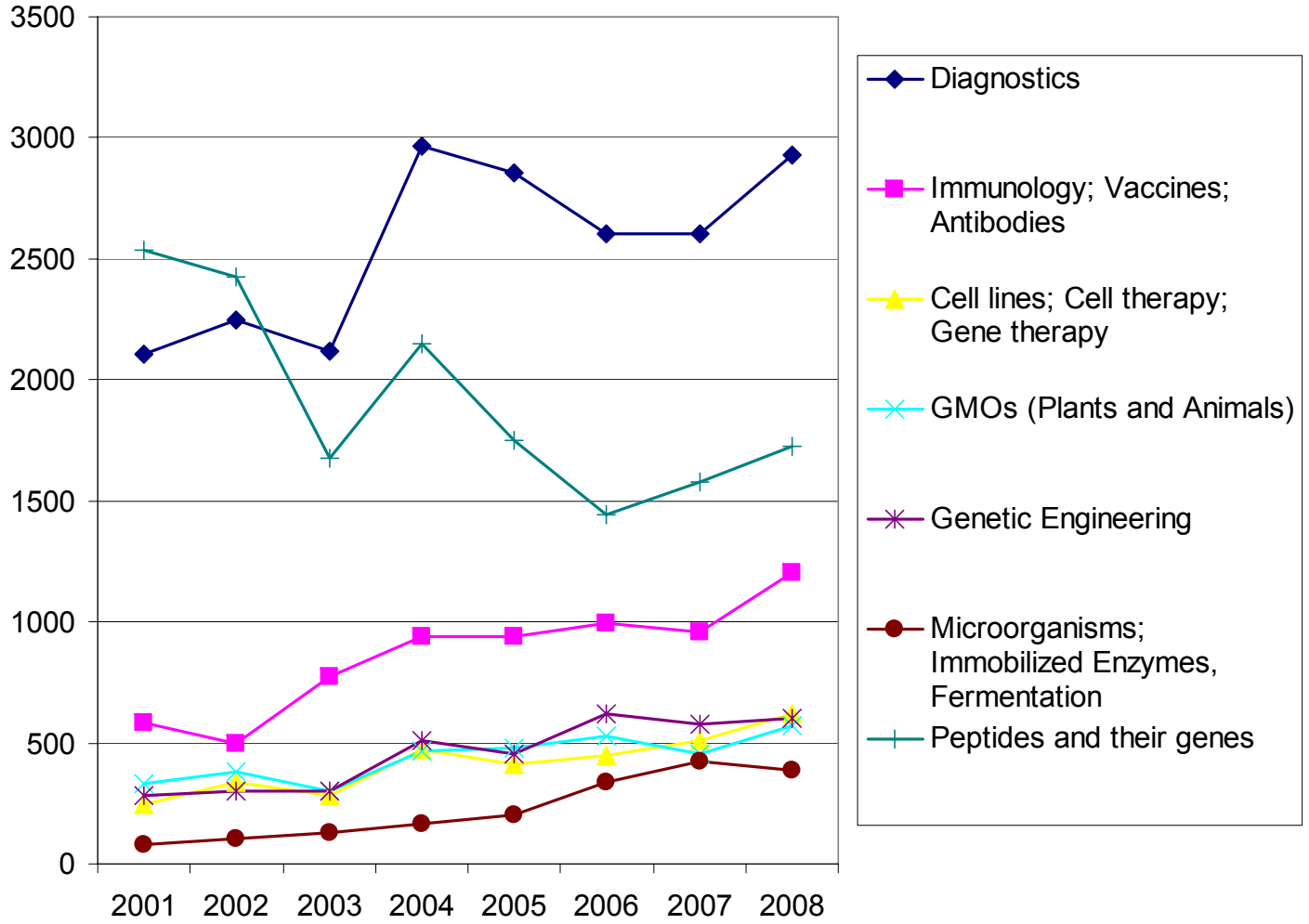
Austria • Belgium • Bulgaria • Croatia • Cyprus • Czech Republic • Denmark • Estonia • Finland • France • Germany • Greece • Hungary • Iceland • Ireland • Italy • Latvia • Liechtenstein • Lithuania • Luxembourg • Former Yugoslav Republic of Macedonia • Malta • Monaco • Netherlands • Norway • Poland • Portugal • Romania • San Marino • Slovakia • Slovenia • Spain • Sweden • Switzerland • Turkey • United Kingdom

European patent applications and patents can also be extended at the applicant's request to the following states:

Albania • Bosnia-Herzegovina • Serbia

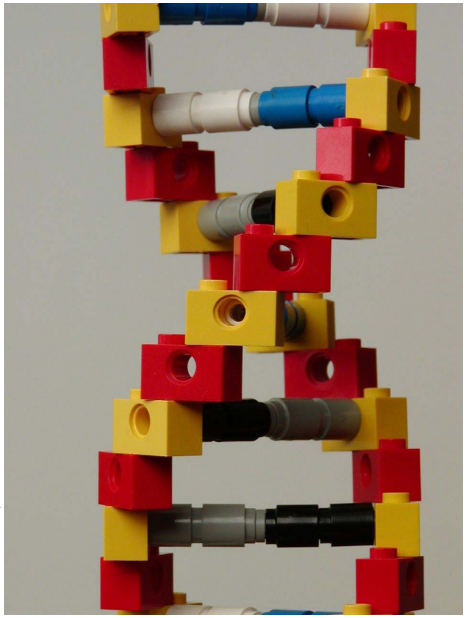
Status: July 2009

Patent filings Biotechnology EPO



Classical Biotechnology vs. Synthetic biology

Classical biotechnology	Synthetic biology
focus on one or few genes	focus on many genes
scientific approach	engineering approach
non-standardised	standardised "parts"
biological synthesis of DNA	chemical synthesis of DNA
"modified" life	"artificial" life?
...	...

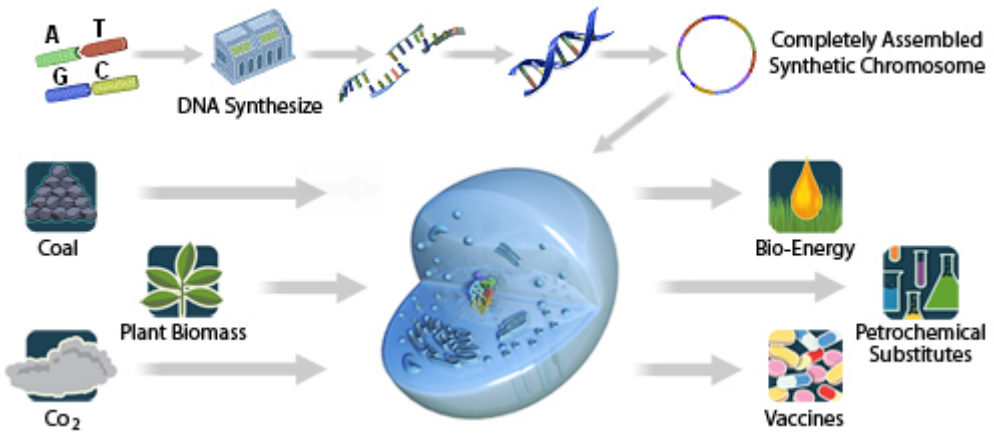


www.flickr.com/photos/mknowles/47457221/

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 ..."



Source: Synthetic Genomics Inc.

What is patentable?

Article 52 EPC

Patentable inventions

(1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

(a) discoveries, scientific theories and mathematical methods;

(b) aesthetic creations;

(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;

(d) presentations of information.

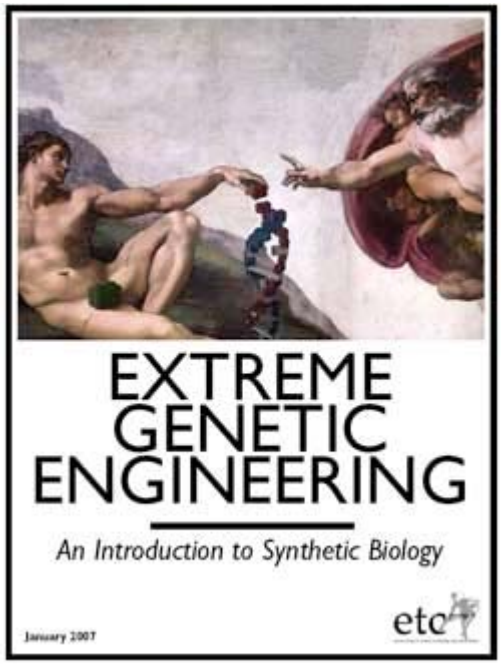
"Ordre Public" or morality?

Article 53 EPC

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



Specific requirements for biotechnological inventions: Rules 26-29 EPC

- Entered into force September 01, 1999

General and definitions

Patentable biotechnological inventions

Exceptions to patentability

The human body and its elements

- EU-Biotech-Directive 98/44/EC of 6 July 1998
  supplementary means of interpretation of Rules 26-29 EPC

Biological or synthetic?

Rule 26 EPC

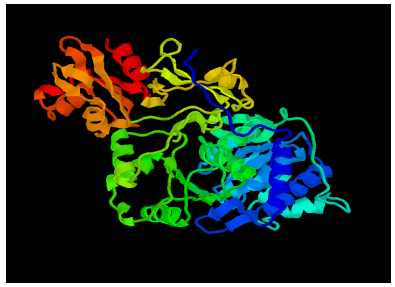
General and definitions

(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 artificial codons, non-natural amino acids, protocells etc.?

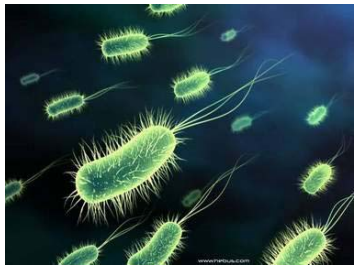
Discovery or invention?



Rule 27 EPC

Patentable biotechnological inventions

- Biological material which is isolated from its natural environment or technically produced even if present in nature (nucleic acid molecules, proteins, cells etc.)
- Plants or animals if not confined to a particular variety, e.g. transgenic plants or animals (G1/98)
- Microbiological processes and products (e.g. microorganisms)



European Group on Ethics

Opinion n°25 - 17/11/2009 - Ethics of synthetic biology

Recommendation N°16: The EGE proposes that debates on the most appropriate ways to ensure the public access to the results of synthetic biology is launched. These debates should include also what can be object of patent and what should be available through open access.

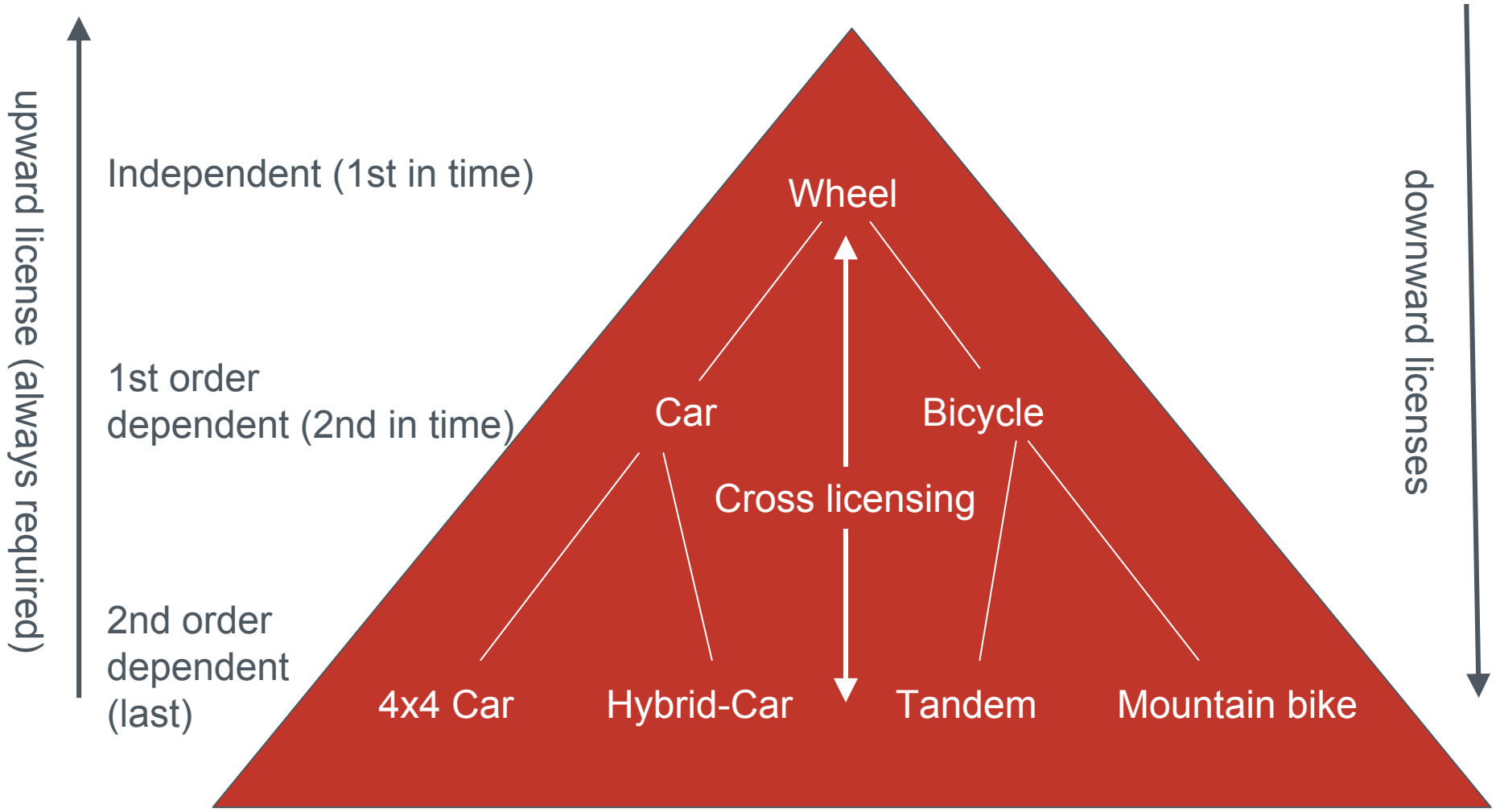
Recommendation N°17: The EU Patent Directive (98/44/EC) defines the EGE as the Body to assess ethics implications related to patents. The Group urges the European Patent Office and the National Patent Offices to take account of Article 7 of the Patent Directive and refer contentious ethical issues of a general relevance to the EGE for consideration. This is particularly important if a class of inventions that ought not to be directly exploited commercially[222] has to be defined.

What happens after the grant of a patent?

- EPC ends with grant (including opposition/appeal)
- EP patents converted into bundle of national patents after grant
- National law post-grant not harmonised
  - validation
  - revocation
  - infringement
  - research exemption
  - Ethics and governance
  - compulsory licenses (e.g. for public health, Belgium)
  - research tool licenses (e.g. for biotechnology, Switzerland)
  - ...

- Licensing practice, registration and regulation (private contract law)

Dependent patents



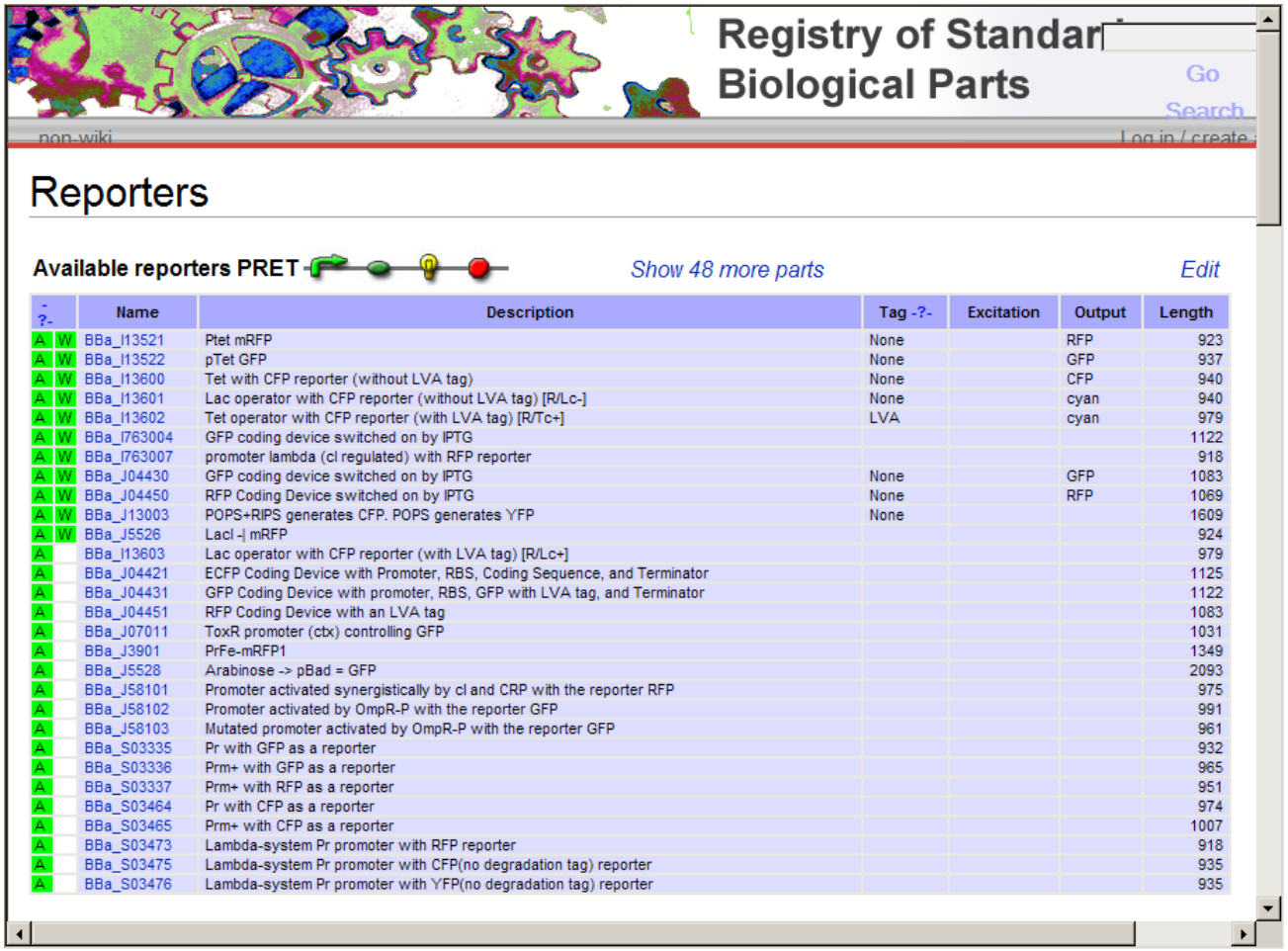
Interview for "EPO Scenarios for the Future"

"In synthetic biology, building blocks such as genes that have a certain function are synthesized and put into a cell so that a cell starts to produce a certain substance. To arrive at this result, you need sometimes hundreds of these building blocks. Now if each of these building blocks is protected by a patent, any innovation which is based on any of them is blocked. [...] In view of this situation, it might be advisable to exclude biological building blocks from being patentable, while the complex biological structures that result from these building blocks should be patentable."

Professor J. Henkel, Schöller Chair in Technology and Innovation Management, Technische Universität München

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 Standar
Biological Parts

Go
Search

parts wiki
Log in / create

Reporters

Available reporters PRET

Show 48 more parts

Edit

-?-	Name	Description	Tag -?-	Excitation	Output	Length
A W	BBa_I13521	Ptet mRFP	None		RFP	923
A W	BBa_I13522	pTet GFP	None		GFP	937
A W	BBa_I13600	Tet with CFP reporter (without LVA tag)	None		CFP	940
A W	BBa_I13601	Lac operator with CFP reporter (without LVA tag) [R/Lc-]	None		cyan	940
A W	BBa_I13602	Tet operator with CFP reporter (with LVA tag) [R/Tc+]	LVA		cyan	979
A W	BBa_I763004	GFP coding device switched on by IPTG				1122
A W	BBa_I763007	promoter lambda (cI regulated) with RFP reporter				918
A W	BBa_J04430	GFP coding device switched on by IPTG	None		GFP	1083
A W	BBa_J04450	RFP Coding Device switched on by IPTG	None		RFP	1069
A W	BBa_J13003	POPS+RIPS generates CFP. POPS generates YFP	None			1609
A W	BBa_J5526	LacI -| mRFP				924
A	BBa_I13603	Lac operator with CFP reporter (with LVA tag) [R/Lc+]				979
A	BBa_J04421	ECFP Coding Device with Promoter, RBS, Coding Sequence, and Terminator				1125
A	BBa_J04431	GFP Coding Device with promoter, RBS, GFP with LVA tag, and Terminator				1122
A	BBa_J04451	RFP Coding Device with an LVA tag				1083
A	BBa_J07011	ToxR promoter (ctx) controlling GFP				1031
A	BBa_J3901	PrFe-mRFP1				1349
A	BBa_J5528	Arabinose -> pBad = GFP				2093
A	BBa_J58101	Promoter activated synergistically by cI and CRP with the reporter RFP				975
A	BBa_J58102	Promoter activated by OmpR-P with the reporter GFP				991
A	BBa_J58103	Mutated promoter activated by OmpR-P with the reporter GFP				961
A	BBa_S03335	Pr with GFP as a reporter				932
A	BBa_S03336	Prm+ with GFP as a reporter				965
A	BBa_S03337	Prm+ with RFP as a reporter				951
A	BBa_S03464	Pr with CFP as a reporter				974
A	BBa_S03465	Prm+ with CFP as a reporter				1007
A	BBa_S03473	Lambda-system Pr promoter with RFP reporter				918
A	BBa_S03475	Lambda-system Pr promoter with CFP(no degradation tag) reporter				935
A	BBa_S03476	Lambda-system Pr promoter with YFP(no degradation tag) reporter				935

BioBricks Public License

The BioBrick™ Public Agreement

DRAFT Version 1

October 2009

Rights and Non-Assertion. If any portion of the Materials (including but not limited to a nucleic acid sequence within the Materials), or any compositions containing the Materials, and/or any uses of the Materials are covered by any patents, patent applications, or other proprietary rights belonging to the Contributor, the Contributor agrees not to assert or threaten to assert such patents; not to threaten assertion of any rights that may be granted through issuance of a patent application; not to invite to license; and not to enforce any other proprietary rights in the Materials as provided in any manner against or otherwise adverse to either the Foundation or any person or entity who uses the Materials under a BioBrick™ User Agreement (a “User”).

BiOS: open source build on patents

BiOS (Biological Open Source) is a legally enforceable framework to enable the sharing of the capability to use patented and non-patented technology, which may include materials and methods, within a dynamically expanding group of those who all agree to the same principles of responsible sharing, a “protected commons”. Those who join a BiOS "concordance" agree not to assert IP rights against each others's use of the technology to do research, or to develop products either for profit or for public good. BiOS-compatible agreements can support both freedom to operate, and freedom to cooperate.

http://www.bios.net

Outlook

- EPO initiative: "Raising the bar"

"Grant patents only for innovations with sufficient inventive merit meeting the needs of society"

  - rigorous application of search and examination standards
  - closing procedural loopholes
  - reducing pendency times (e.g. divisionals)

- European Harmonisation
  - European Union Patent (EUPat)
  - European and EU Patents Court system (EEUPC)

- Patent insight and knowledge
  - patent training and support for SMEs, universities (e.g. European Patent Academy, European Patent Network)
  - easy-to-use patent information (e.g. maps for worldwide patent landscapes)

Thank you for your attention!

Contact: brutz@epo.org