



Europäisches
Patentamt
European
Patent Office
Office européen
des brevets

Synthetic Biology and Patents

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Directorate 2.4.01 Biotechnology
European Patent Office Munich

"Patenting Synthetic Biology?
A Transatlantic Perspective"
WWICS, Washington D.C.
30.11.2009



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



SCENARIOS FOR THE FUTURE

How might IP regimes evolve by 2025?
What global legitimacy might such regimes have?



What is a patent?

Europäisches Patentamt European Patent Office Office européen des brevets

Urkunde Certificate Certificat

Es wird hiermit bescheinigt, daß für die in 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 États 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 |
|--|--------------------------|---------------------|
| Hensek, Jobst Roseneck 2 38640 Goslar/DE | | |

München, den 19.05.04
Munich, le 19.05.04

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

EP/EO/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!
- In return for this protection, the holder has to disclose the invention to the public.
- Protection is granted:
 - for a limited period, generally 20 years
 - for a specific geographic area

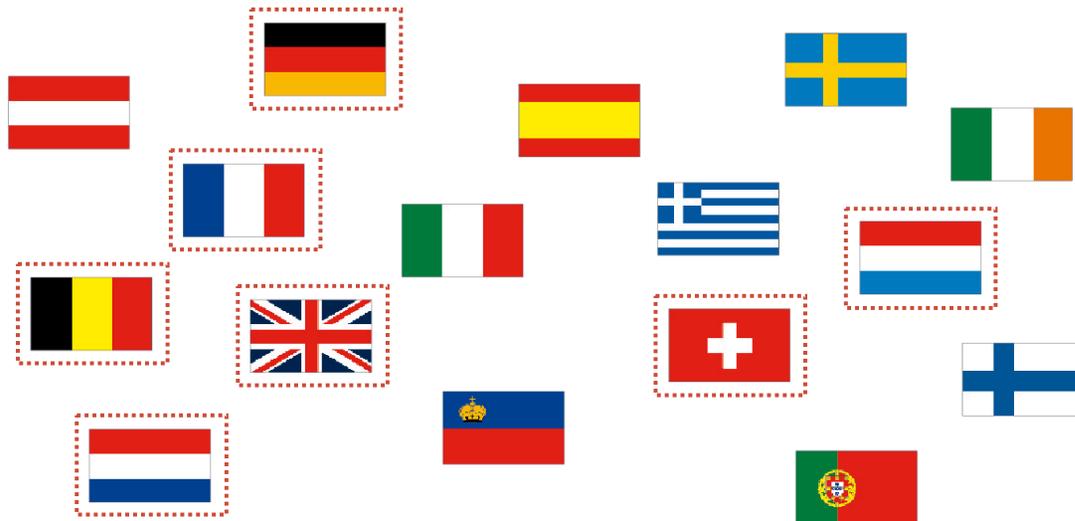
Why patents?

- **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 

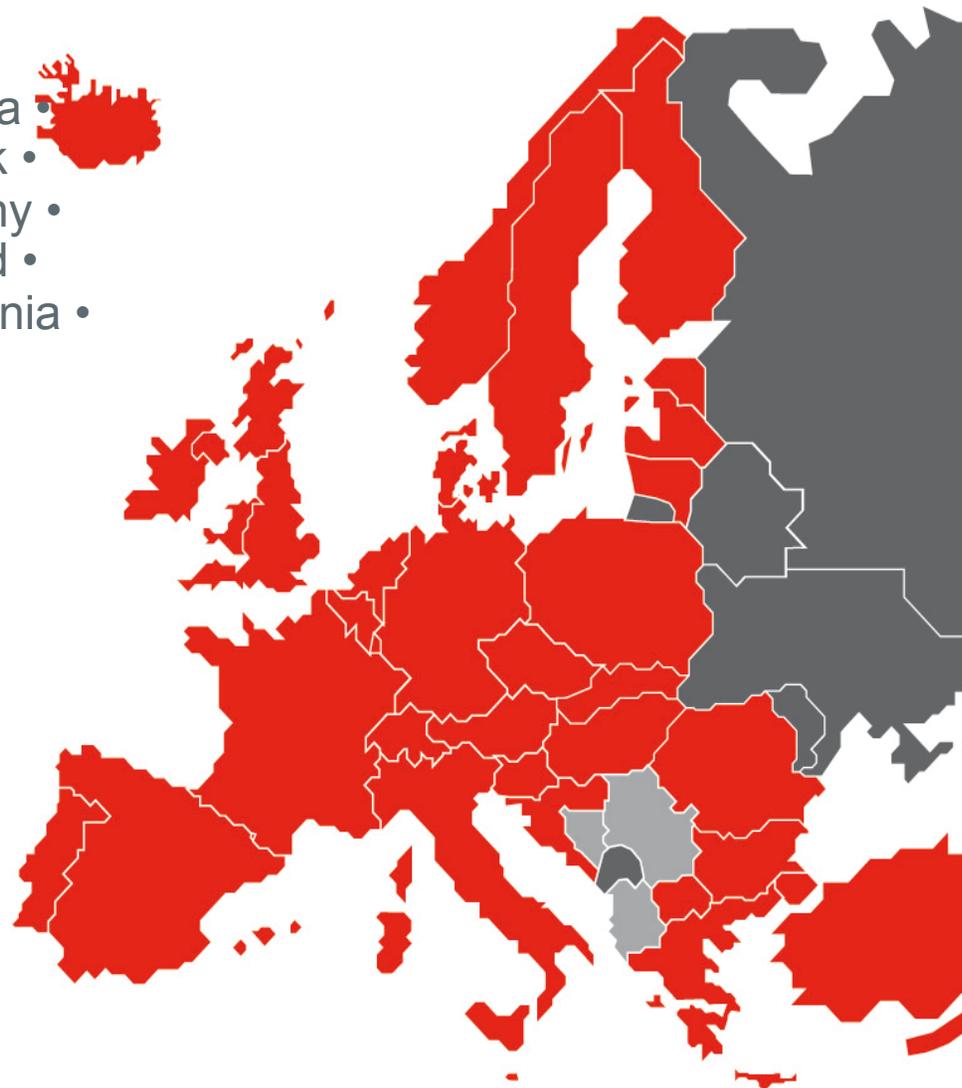


36 member states

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

"Ordre Public" or morality?

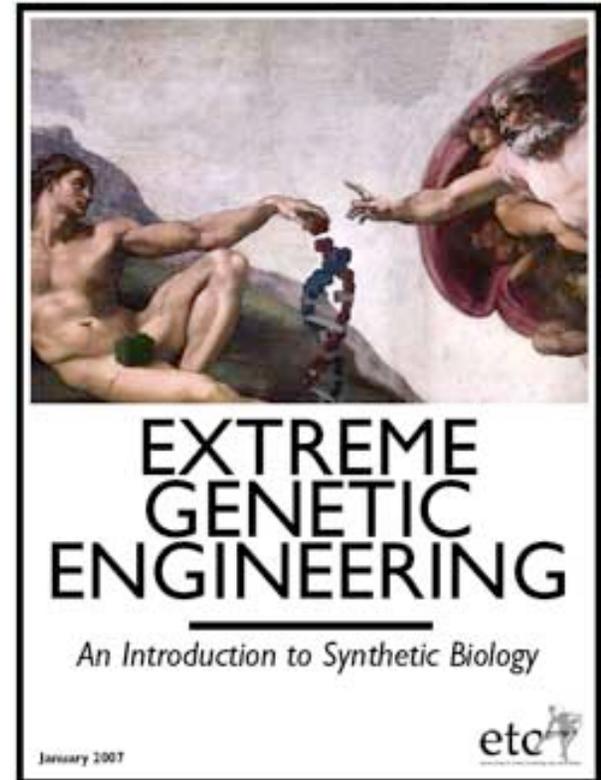
European Patent Convention

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



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

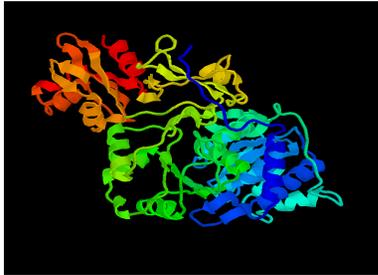
General and definitions

- (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



Biotechnological inventions shall be patentable if they concern:

- 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

Article 7 Directive 98/44/EC (not implemented into EPC):

The Commission's **European Group on Ethics** in Science and New Technologies evaluates all ethical aspects of biotechnology.

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 commercially²²² has to be defined.

Classical Biotechnology vs 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

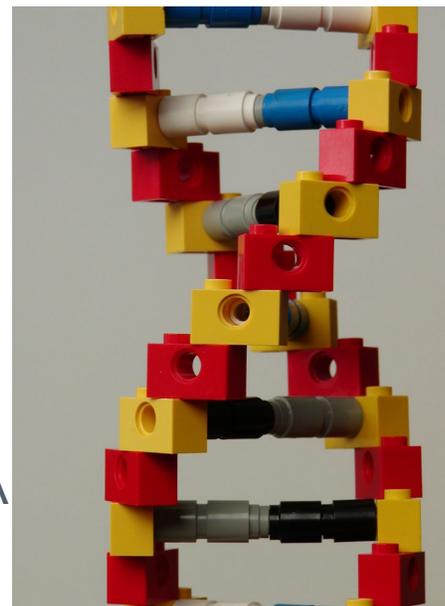
engineering approach

standardised "parts"

chemical synthesis of DNA

"artificial" life?

...



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

an incremental change?

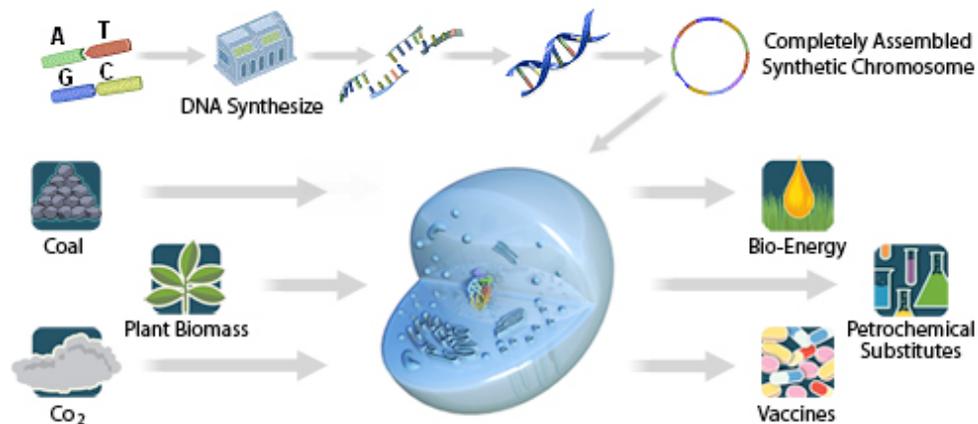
Anything new from a patent point of view?

- 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 ..."

Synthetic biology patents?

Examples of companies active in Synthetic Biology (non-exhaustive list):

Ambrex
Amyris Biotechnologies
Blue Heron
Egea Biosciences
Codon Devices
Diversa
DNA 2.0
EngeneOS
EraGen Biosciences
Firebird Biomolecular
Geneart
Genomatica
Ls9
Mascoma
Protolife
Sangamo
Synthetic Genomics

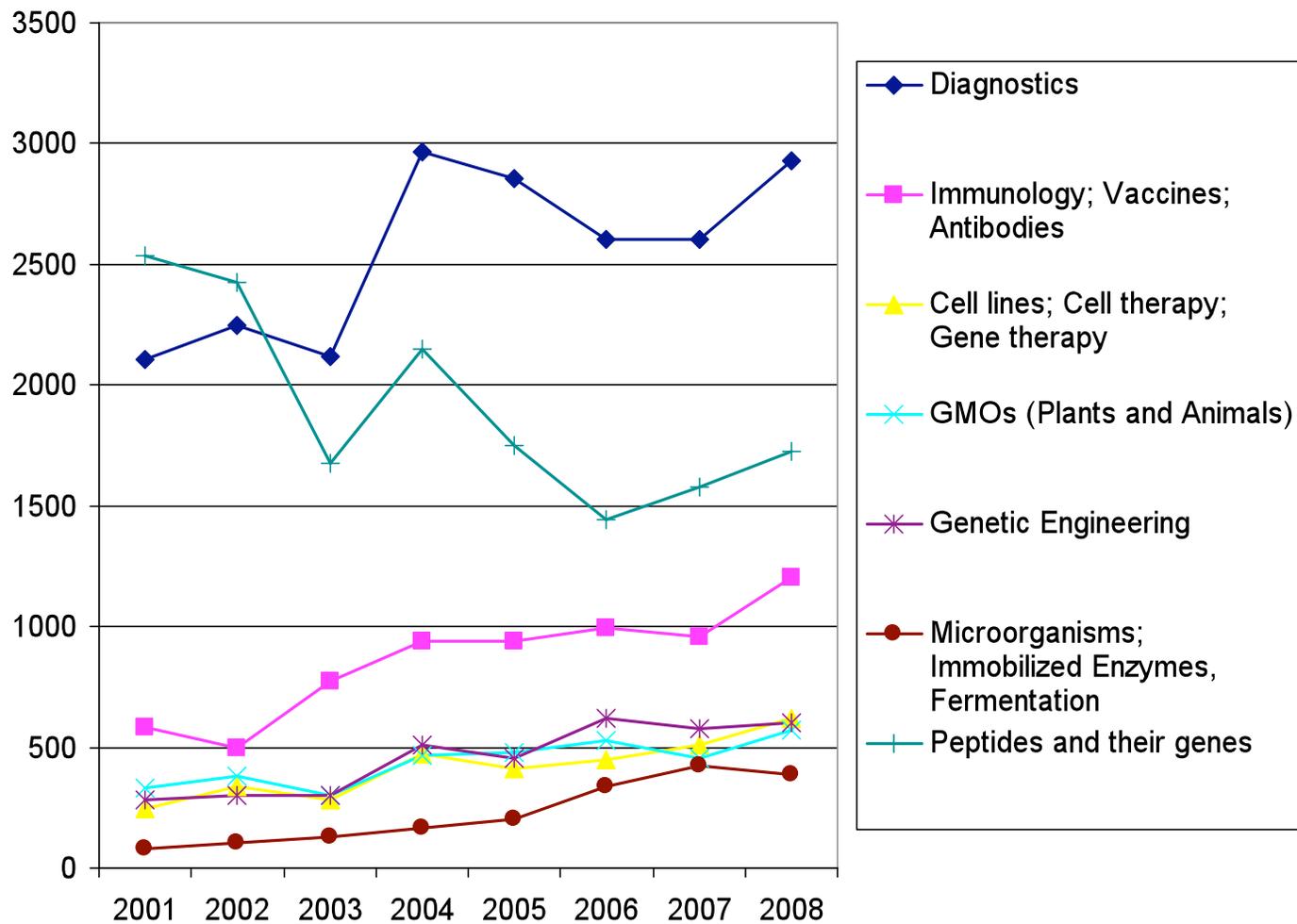


Source: Synthetic Genomics Inc.

Patenting activity (Nov. 2009):

3.051 patent applications worldwide (several members per family)
437 EPO applications
44 EPO patents granted

Patent filings Biotechnology EPO



Possible differences to classical Biotech

- Complexity: 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

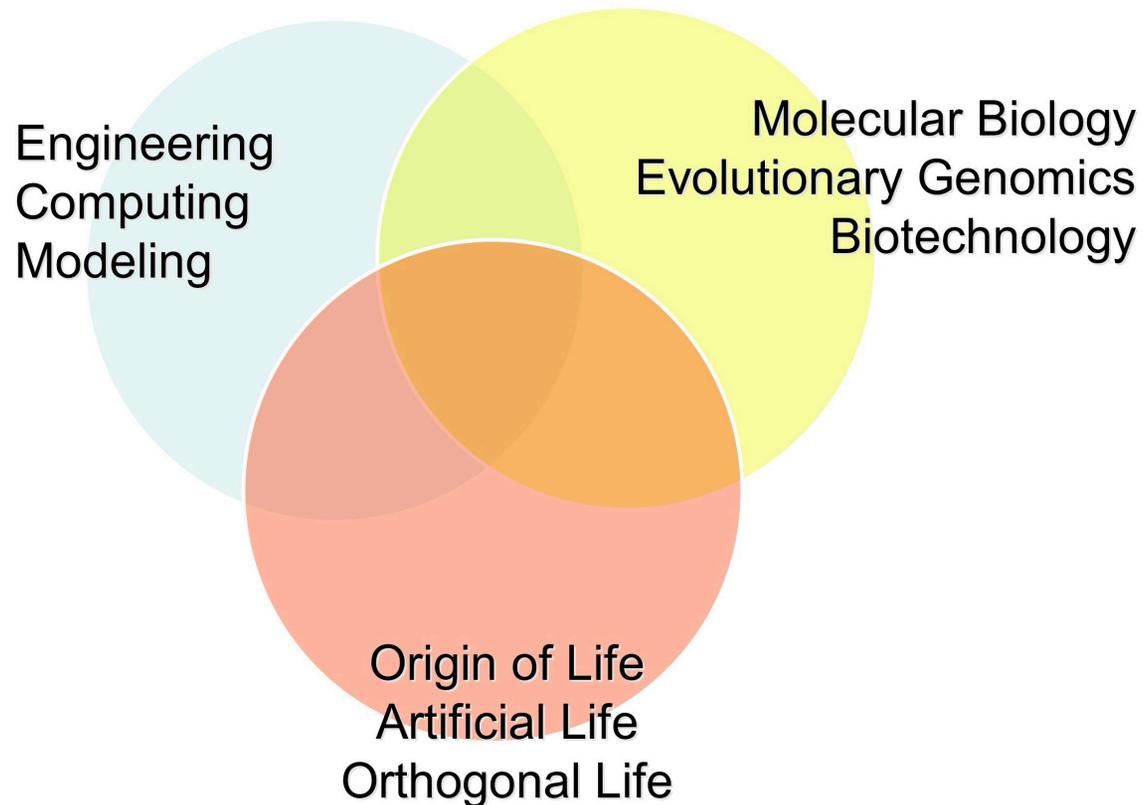
Possible problems arising (2)

Interoperability and Standards → patent blockage



Possible problems arising (3)

Interdisciplinarity → difficulties in patent search and examination: Who's the expert?



What can we (and others) do?

- Raising the bar
 - rigorous application of search and examination standards
- Improving efficiency / Increasing legal certainty
 - closing procedural loopholes
 - reducing pendency times (e.g. divisionals)
- Adapting fee structure
 - steering applicant's behaviour (quality of applications, timely procedures)
- Reducing complexity and costs
 - London Agreement
 - European patent litigation system
 - European Community Patent (ComPat)
- 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!

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