Statistics in focus

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Biotechnology in Europe

Patents and R&D investments

Defining and measuring biotechnology is a challenge for statisticians. There is no single sector of biotechnology which can be easily and clearly distinguished from other technology sectors. The current publication illustrates different aspects of biotechnology with the help of different kinds of data such as patent applications, R&D intensity and R&D investment.

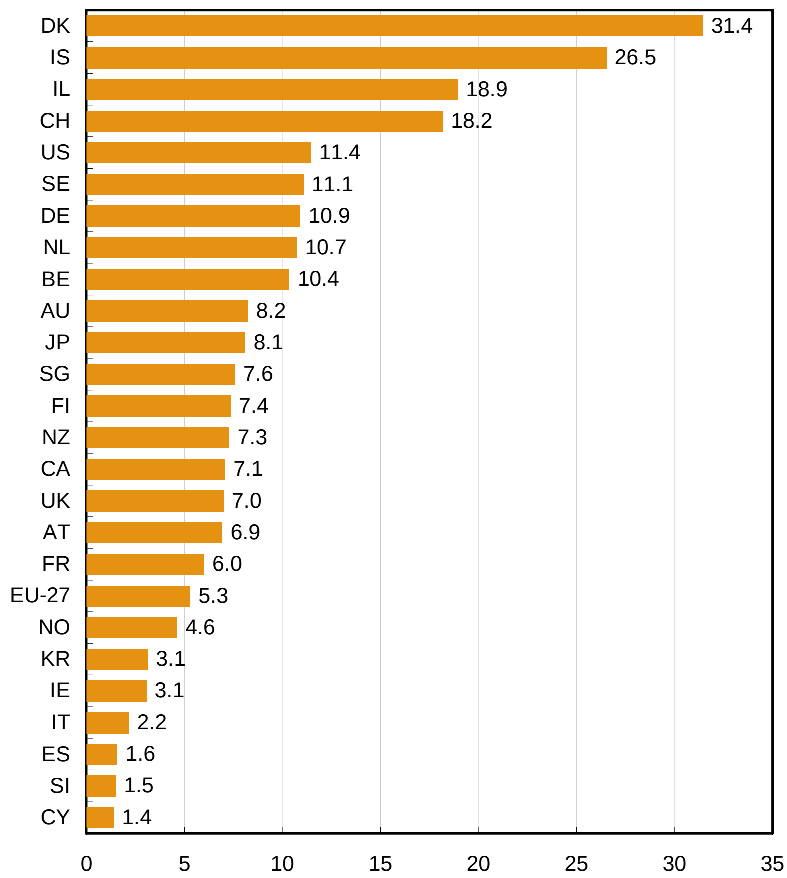
In 2003 Denmark was world leader in biotechnology patent applications to the EPO per million inhabitants, whereas in Europe Germany ranked first in absolute figures. The United Kingdom was the most active European country in biotechnology R&D investment.

This publication sheds light on both the statistical and the legal sides of biotechnology.

Denmark top in biotechnology patent applications to European Patent Office (EPO) per million inhabitants

With more than 30 biotechnology patent applications to the EPO per million inhabitants in 2003 Denmark produced nearly six times the EU-27 average of patent applications. At international level, Denmark ranked first, Iceland second and Israel third. Among the top ten countries, five were EU-27 Member States: Denmark, Sweden, Germany, the Netherlands and Belgium.

Figure 1: Biotechnology patent applications to the European Patent Office (EPO) by country, per million inhabitants, EU-27 Member States and selected countries[(1)], 2003



Source: Eurostat, Patent Statistics

[(1)] Countries with less than one biotechnology patent application per million inhabitants are not shown.

OECD definitions of biotechnology

The OECD has worked on biotechnology statistics for a long time now and built up a statistical database on this subject. In order to be able to collect comparable data the OECD proposes two closely linked definitions of biotechnology: a single and a list-based definition. Whereas the first gives an overall view, the second consists of seven different subjects described via several examples.

OECD definitions of biotechnology

The single definition

The application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.

The list-based definition

DNA/RNA: genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling, and use of antisense technology.

Proteins and other molecules: sequencing/synthesis/engineering of proteins and peptides (including large molecule hormones); improved delivery methods for large-molecule drugs; proteomics, protein isolation and purification, signalling, identification of cell receptors.

Cell and tissue culture and engineering: cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation.

Process biotechnology techniques: fermentation using bioreactors, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation, biofiltration and phytoremediation.

Gene and RNA vectors: gene therapy, viral vectors.

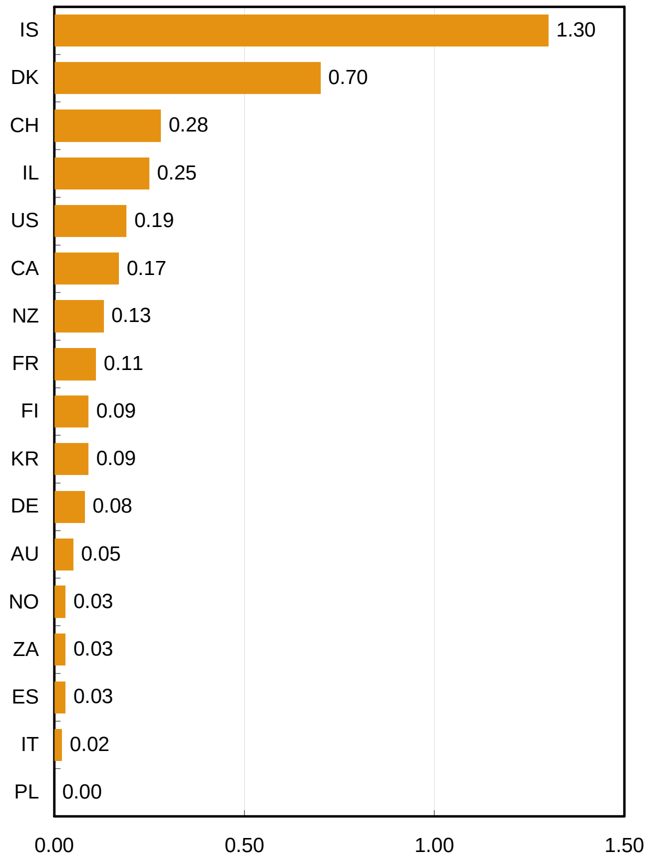
Bioinformatics: construction of databases on genomes, protein sequences; modelling complex biological processes, including systems biology.

Nanobiotechnology: applies the tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics, etc.

Source: OECD

Figure 2 takes a closer look to the biotechnology R&D intensity in the business enterprise sector (BES) for 17 countries worldwide. The R&D intensity is a ratio of the expenditure in a sector compared with the value added in the same sector. Iceland was leading by far in 2003, with a result of 1.3 for biotechnology R&D intensity in the BES. Denmark ranked second with 0.70 and Switzerland third with 0.28.

Figure 2: Biotechnology R&D intensity (biotech R&D expenditure/value added of BES) in the business enterprise sector by country, selected countries, 2003



Source: OECD Biotechnology Statistics, 2006

Exceptions to reference year:
2004: CH, NZ, KR, DE, ES, IT, PL; 2002: IL, ZA

How to measure biotechnology?

Different aspects of biotechnology can be measured using the OECD definitions. Besides patent applications and R&D intensity, which are more akin to indicators at macro-economic level, other indicators go down closer to enterprise level.

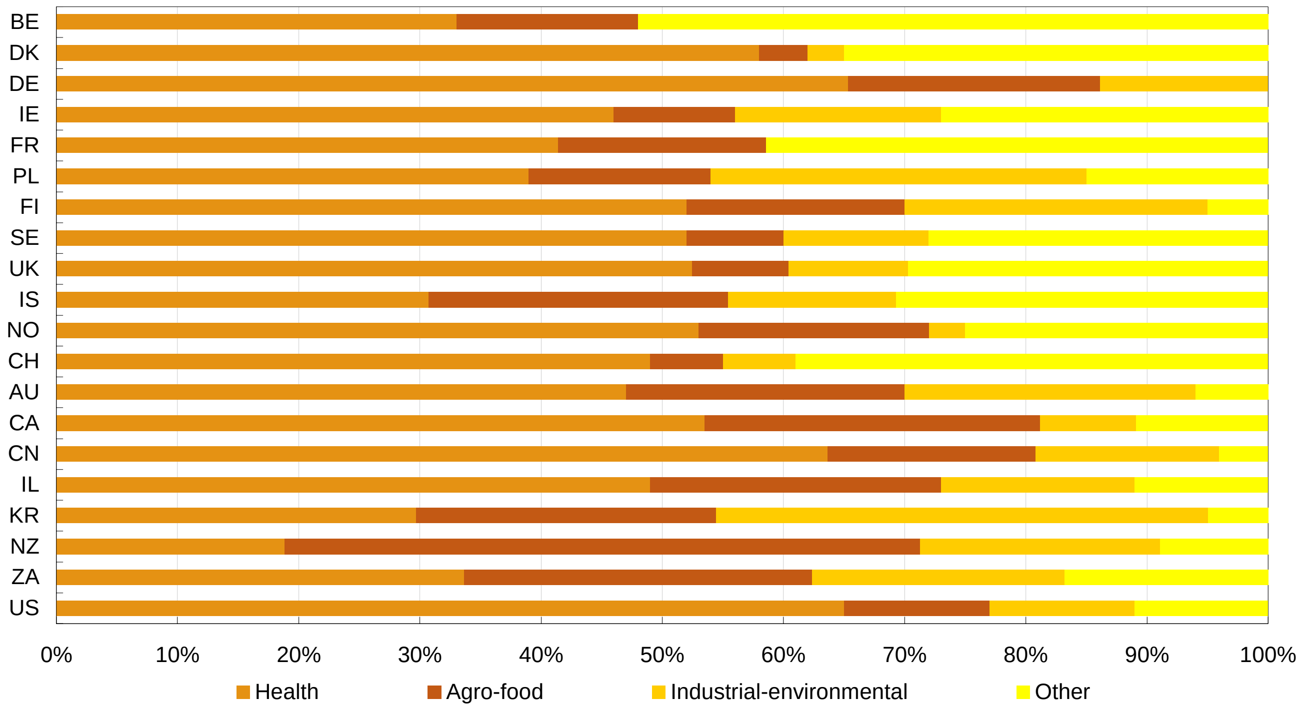
Biotechnology-active firms are defined as enterprises engaged in key biotechnology activities such as the application of at least one biotechnology technique (as defined in the box above) to produce goods or services, and/or the performance of biotechnology R&D.

Four different biotechnology application fields can be distinguished: '*health*', '*agro-food*', '*industrial-environmental*' and '*other*'. Health is the main application field in most of the countries shown in Figure 3, often involving nearly half of all biotechnologically active firms. In Germany two out of three enterprises occupied in biotechnology are active in the field of health applications. The United States and China have comparable shares, with respectively 65% and 63%. At the other end of the scale, in New Zealand only 19% of biotechnologically active firms work on health applications, but 53% focus on agro-food applications. European biotechnology-active enterprises are less active in the field of agro-food applications. In Denmark only 4% and in Switzerland only 6%, of biotechnology-active firms are devoted to that field.

Industrial-environmental applications of biotechnology play a less important role in most European countries. Exceptions are Poland and Finland. 13% of Polish, and 25% of Finnish, biotechnology-active firms work in industrial-environmental applications. South Korea accounts for 41% of the biotechnology-active enterprises in this field.

The application field 'Other' includes bioinformatics, support services that are not included in the three other fields, and also other applications not classifiable elsewhere. 52% of Belgian, and 41% of French, biotechnology-active firms fall under this definition.

Figure 3: Biotechnology-active firms by application field and by country, selected countries, 2003



Source: OECD Biotechnology Statistics 2006

Exceptions to reference year:
2005: NZ; 2004: CH, KR, DE, PL; 2002: IL, ZA; 2001: US

Protection of biotechnology inventions

In the past ten years protection of biotechnology inventions has been discussed intensively both at European and at national level. **Directive 98/44/EC** on the legal protection of biotechnological inventions was adopted on 6 July 1998. The Member States were asked to bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 July 2000.
Implementation took longer than the stipulated two years in most Member States. However (Table 5), some countries managed to adapt their legal framework on time. It must be said that biotechnology inventions are a very sensitive subject. The discussions concerning the Directive induced Member States to think about the limits of what is patentable and how to treat borderline cases.

Conclusions of the Communication from the Commission on the mid-term review of the **Strategy on Life Sciences and Biotechnology** (SEC(2007) 441)

The Commission will:

– Continue the implementation of the action plan up to 2010, while putting a specific emphasis on a focused set of biotech specific priority actions;

– Include biotechnology in the implementation of innovation strategies;

– In cooperation with Member States and stakeholders, improve the implementation of the Strategy.

Source: Brussels, 10.4.2007, COM(2007) 175 final

For the refocusing of the **Action Plan**, the Commission proposes to put specific emphasis on five interdependent biotech-specific priority actions:

– **Promote research and market development for bio-based products** and improve the uptake of new technologies including generation of knowledge under the 7th Research Framework Programme; establishment of public-private partnership to mobilise research funding; explore lead market initiatives for eco-efficient bio-based products.

– **Foster competitiveness by facilitating knowledge transfer and innovation** from the science base to industry, including development of best practices in licensing of genetic resources; improving links between research organisations and industry; facilitating the patenting system for Small and Medium-Sized Enterprises (SMEs); and considering incentives for Young Innovative Companies.

– **Encourage informed societal debates on the benefits and risk of life sciences and biotechnology**.

– **Ensure a sustainable contribution of modern biotechnology to agriculture** and use the potential of plant science for energy and environment applications, in particular to replace chemical processes and fossil fuels.

– **Improve the implementation of the legislation and its impact on competitiveness**. Unnecessary administrative burdens on research and industry should be identified and removed. Regulation should encourage, not hinder, innovation. Policy coordination should be improved, especially on cross-cutting issues and on newly emerging issues.

Source: EU puts emphasis on innovation in the field of biotechnology, IP/07/484 Brussels, 11 April 2007

In the past few decades biotechnology research has come a long way, and this in a relative short period of time. As this kind of research also involves major R&D funding, protection of these inventions is a key element. On the one hand, Europe does not want to lag behind, hampered by national laws which are no longer adapted to scientific progress. On the other hand, a legal framework is necessary to avoid abuse and to limit all kinds of possible misuse.

Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

The objective of the Directive is to clarify the distinction between what is patentable and what is not. It seeks in particular to confirm that the human body at the various stages of its formation and development, and processes for cloning human beings and for modifying the germ-line genetic identity of human beings, may not be regarded as patentable inventions.

In order to protect biotechnological inventions, Member States must ensure that their national patent laws conform to the provisions of the Directive.

Source: http://europa.eu/scadplus/leg/en/lvb/l26026.htm

Table 5: State of play of implementation of Directive 98/44/EC by Member State

Member States	Implementation date or entry into force
Belgium	28 April 2005
Bulgaria	9 November 2006
Czech Republic	1 January 2000
Denmark	26 May 2000
Germany	28 February 2005
Estonia	1 January 2000
Ireland	30 July 2000
Greece	22 October 2001
Spain	30 April 2002
France	8 December 2004
Italy	11 March 2006
Cyprus	9 August 2002
Latvia	29 December 2005
Lithuania	14 July 2005
Luxembourg	23 April 2006
Hungary	1 January 2003
Malta	1 January 2004
Netherlands	10 November 2004
Austria	9 June 2005
Poland	18 October 2002
Portugal	1 July 2003
Romania	22 May 2003
Slovenia	2 September 2003
Slovakia	1 November 2001
Finland	30 June 2000
Sweden	1 May 2004
United Kingdom	1 March 2002

Source: based on http://ec.europa.eu/internal_market/indprop/invent/index_en.htm

The debates on the legal protection of biotechnology inventions also give rise to numerous discussions on ethics. An expert group called the European Group on Ethics in Science and New Technologies (EGE) has been created at European level. The group evaluates all ethical aspects of biotechnology. It works together with the national ethics committees, international organisations and European institutions.

Each year the European Patent Office (EPO) receives a large number of biotechnological patent applications and also grants a lot of patents – applying strict standards in so doing. The Administrative Council of the European Patent Organisation, which supervises the EPO's activities and is composed of representatives of all the 32 contracting states to the European Patent Convention (EPC), decided on 16 June 1999 to incorporate the relevant provisions of Directive 98/44/EC into European patent law. Though not legally subject to this formal requirement, the European Patent Organisation decided that European patent law needed to be brought into line with the Directive in order to fulfil the requirement for uniformity in harmonised European patent law.

Biotechnology patenting – EU-27 ranked second worldwide

Table 6: Biotechnology patent applications to EPO by country(1), 1993, 1998, 2003 and AAGR

	Total			AAGR		
	1993	1998	2003	1993/1998	1998/2003	1993/2003
EU-27	920	2 155	2 576	18.6	3.6	10.8
Belgium	52	153	107	24.2	-6.9	7.5
Czech Republic	1	5	7	37.7	8.5	22.2
Denmark	75	120	169	9.9	7.1	8.5
Germany	202	564	901	22.7	9.8	16.1
Ireland	1	16	12	100.6	-5.7	37.6
Greece	2	2	7	6.9	23.1	14.7
Spain	9	32	66	27.9	15.5	21.5
France	157	329	370	16.0	2.4	9.0
Italy	42	70	124	10.5	12.3	11.4
Hungary	2	4	6	15.3	10.0	12.6
Netherlands	77	173	174	17.6	0.1	8.5
Austria	27	31	56	2.7	12.6	7.5
Poland	2	1	6	-15.7	44.2	10.3
Portugal	1	1	7	-3.1	47.4	19.5
Finland	20	37	38	13.4	1.0	7.0
Sweden	34	104	99	24.7	-0.9	11.1
United Kingdom	213	506	416	18.9	-3.8	6.9
Iceland	2	1	8	-19.8	67.5	15.9
Norway	10	19	21	13.9	2.4	8.0
Switzerland	36	75	133	15.9	12.0	13.9
Australia	54	116	165	16.5	7.2	11.7
Canada	66	231	224	28.7	-0.6	13.1
China	4	64	136	77.5	16.2	43.6
Israel	29	87	127	24.6	7.9	15.9
Japan	342	562	1 035	10.5	13.0	11.7
Korea	15	55	150	29.4	22.1	25.7
New Zealand	6	22	29	29.1	6.2	17.1
Russian Federation	12	30	35	20.9	3.0	11.6
South Africa	:	7	2	:	-19.5	:
United States	1 595	3 531	3 331	17.2	-1.2	7.6

Source: Eurostat, Patent Statistics

(1) Only EU Member States with at least five biotechnology patent applications are shown.

With 2 576 biotechnology patent applications submitted to the EPO, EU-27 ranked second worldwide in 2003 after the United States with 3 331 and before Japan with 1 035 applications. At European level, Germany occupied first place with 901 biotechnology patent applications to the EPO, followed by the United Kingdom with 416 applications and by France with 370.

All countries in Table 6 have positive average annual growth rates (AAGRs) for the whole observation period from 1993 to 2003, ranging from 7% (United Kingdom) to 44% (China). Splitting the observation period into two equal parts changes the overall result. For most of the countries the AAGRs for 1993 to 1998 were significantly higher than those for 1998 to 2003. In many countries patent activity in biotechnology slowed down in the second half of the observation period. Only Italy, Austria, Japan and some countries with very few patent applications had higher AAGRs in the second half of the observation period than in the first half.

Bio-Plastics: Shopping Bags Made of Starch

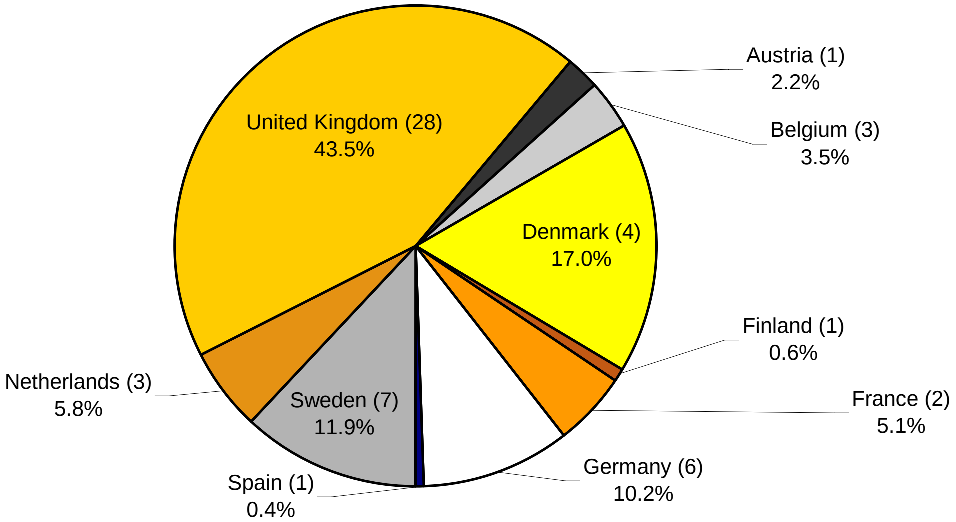
Traditional plastics are dirty to produce, they use up oil, and they don't decompose naturally. So are we stuck with them? No, because in the 1990s a group of Italian scientists found a way out of the vicious cycle developed bio-degradable plastics. Bio-plastics can be processed just like regular plastics, but when thrown onto a compost heap they fall apart in weeks – not in the hundreds of years it takes traditional plastics to decompose. Made from crops, bio-plastics reduce greenhouse gas emissions and the consumption of non-renewable resources.

What started out with just four scientists has now evolved into a successful medium-sized enterprise. With a turnover of €50 million in 2006, the company today employs some 120 people. The company still banks on innovation: it holds nearly 60 patents, and says it invests some 30 percent of its resources into research and development.

Source based on: http://www.epo.org/focus/innovation-and-economy/inventors/archive/2007/bastioli.html

United Kingdom leads in EU biotechnology R&D investment

Figure 7: Biotechnology R&D investment of EU companies by country, EU-27 Member States, 2005



In brackets: number of companies

Source: based on 2006 EU industrial R&D investment scoreboard,

Figure 7 and Table 8 are based on the data of the 2006 EU Industrial R&D Investment Scoreboard published by the European Commission. This Scoreboard ranks 1 000 EU companies and 1 000 non-EU companies according to their R&D investment. Whereas 57 EU companies out of the 1 000 are active in the biotechnology sector, there are 54 non-EU companies classified in the same sector. The Scoreboard first classifies companies' economic activities according to the ICB classification and then converts them into NACE.

Figure 7 gives more details of the EU companies investing in biotechnology R&D. A closer look at the EU companies reveals that nearly half of the 57 firms are situated in the United Kingdom (28). The second highest number of companies is located in Sweden (7), followed by Germany (6). But the number of companies investing in R&D is only one aspect. Another aspect is the amounts invested in R&D. There the United Kingdom is still leading with 44%, but is followed by Denmark with 17% and Sweden in third place with 12%.

Table 8 compares the companies investing in biotechnology R&D at international level. With an average of EUR 160 million in R&D investment per company, in 2005 the US companies spent close to eight times more than the EU-27 companies. This gap in biotechnology R&D investment between the EU and US companies is unlikely to narrow in the near future because R&D funding in biotechnology is growing faster in the United States than in Europe. Whereas R&D investment by the EU-27 companies is growing at a rate of 11%, this figure is more than double for the American companies – at 23%. EU-27 companies with high biotechnology R&D investment are relatively small compared to such companies in other countries. On average an EU-27 company active in biotechnology has about 444 employees, whereas in the other countries the average number of employees varies between 1 592 in the United States and 4 456 in Japan.

EU-27 biotechnology companies are much smaller than biotechnology companies in other countries, not only in terms of R&D investment and number of employees but also as regards market capitalisation.

Table 8: Biotechnology R&D investment and other main indicators by country, EU-27 and selected countries, 2005

Country	Companies	R&D Investment/ company	Biotechnology R&D Investment			Employees	R&D Investment/ employee	Market Capitalisation
			2005	AGR 2004/2005	AAGR 2002-2005			
	#	€K	€m	%	%	#	€K	€m
EU-27	57	21 186	1 208	11.1	7.4	25 312	47.7	17 125
CH	4	154 855	619	-0.8	13.9	6 491	95.4	7 903
JP	2	141 445	283	12.9	0.2	8 915	31.7	4 518
US	44	159 541	7 020	23.2	12.1	70 033	100.2	182 792
Other	4	50 428	202	26.0	8.1	7 364	27.4	6 866

Source: based on 2006 EU Industrial R&D Investment Scoreboard

Exceptions in number of companies on which the indicators are based: CH: employees (3 companies), US: market capitalisation, R&D investment 2002 (42 comps.), EU-27: market capitalisation (43 comps.), R&D investment 2002 (52 comps.)

➢ ESSENTIAL INFORMATION – METHODOLOGICAL NOTES

1. Patents statistics

In 2005, just one single raw database – mainly compiled on the basis of input from the European Patent Office (EPO), the US Patent and Trademark Office (USPTO) and the Japanese Patent Office (JPO) – was used to produce an extended set of tables and indicators on Eurostat's webpage. This will also be done in the years to come. The aggregated patent statistics are produced using a raw data set delivered by the OECD. This raw data set will be replaced by PATSTAT for the next data productions.

Since 2005 Eurostat has produced patent statistics using the priority year of the application, and not the year of filing as previously. The data values are, however, similar. These data are in general less extensive than the data released by Eurostat before 2005. This is because all PCT applications filed to the EPO (i.e. applications made in accordance with the procedure under the Patent Cooperation Treaty) are taken into consideration by Eurostat, whereas the OECD data sets do so only in part. The data produced provide a better reflection of the innovation and R&D performance of an economy.

Since 2004 the interinstitutional Patent Statistics Task Force has developed the concept of a worldwide patent statistics database (PATSTAT). PATSTAT has to be understood as a single patent statistics raw database, held by the European Patent Office (EPO) and developed in cooperation with the World Intellectual Property Organisation (WIPO), the OECD and Eurostat. PATSTAT should fulfil the user needs of the various international organisations which will use this raw database for production. Designed to be sustainable over time, PATSTAT operational since 2006 concentrates on raw data, leaving the indicator 'production' mainly to PATSTAT users such as the OECD, Eurostat and others.

For all further details, please see the Eurostat metadata on patent statistics posted on the webpage.

2. OECD Biotechnology Statistics

Biotechnology R&D Intensity: Biotechnology R&D expenditures in the business sector as a percent of value added in the business sector.

Business Enterprise Sector (BES): With regard to R&D, the business enterprise sector includes (i) all firms, organisations and institutions whose primary activity is the market production of goods and services (other than higher education) for sale to the general public at an economically significant price, and (ii) the private non-profit institutions mainly serving them. Frascati Manual, §163

Application fields:

- Health: includes human and animal health applications.
- Industrial-environmental: includes industrial processing, environmental, energy and natural resource extraction applications.
- Agro-food: includes agricultural and food processing, marine and silviculture applications.
- Other: includes bioinformatics, support services not included above, and other applications not included above.

3. 2006 Industrial R&D Investment Scoreboard

The Scoreboard was compiled from companies' annual reports and accounts with the reference date of 1 August of each year.
In order to maximise completeness and avoid double counting, the consolidated group accounts of the ultimate parent company are used. Companies which are subsidiaries of another company are not listed separately. Where consolidated group accounts of the ultimate parent company are not available, subsidiaries are however included.

Research and Development (R&D) Investment: Cash investment funded by the companies themselves. It excludes R&D undertaken under contract for customers such as governments or other companies. It also excludes the companies' share of any associated company or joint venture R&D investment. The amount shown in the annual report and accounts is given, based on the accounting definition of R&D. The definition is set out in the International Accounting Standard (IAS) 38 "Intangible assets" and is based on the OECD's Frascati Manual. Research is defined as original and planned investigation undertaken with the prospect of gaining new scientific or technical knowledge and understanding. Expenditure on research is recognised as an expense when it was incurred. Development is the application of research findings or other knowledge to a plan or design for the production of new or substantially improved materials, devices, products, processes, systems or services before the start of commercial production or use. Development costs are capitalised when they meet certain criteria and when it can be demonstrated that the asset will generate probable future economic benefits. Where part or all of R&D costs have been capitalised, the additions to the appropriate intangible assets are included to calculate the cash investment and any amortisation eliminated.

Number of employees: the average number of employees or the number of employees at the end of the reference period if the annual average is not available.

Market capitalisation: The share price multiplied by the number of shares issued at a given date. Market capitalisation data have been extracted from both the Financial Times London Share Service and Reuters. These reflect the market capitalisation of each company at the close of trading on 4 August 2006. The gross market capitalisation amount is used to take account of those companies for which not all the equity is available on the market.

Symbols/Abbreviations

:	not available
AGR/AAGR	Annual growth rate/Average annual growth rate

Country codes for non-EU countries:

AU	Australia	KR	South Korea
CA	Canada	NO	Norway
CH	Switzerland	NZ	New Zealand
IS	Iceland	SG	Singapore
IL	Israel	US	United States
JP	Japan	ZA	South Africa

Data presented in this Statistics in Focus reflect availability in Eurostat's reference database as at 8 May 2007.

Further information:

Data: EUROSTAT Website/Home page/Science and technology/Data

Science and technology

Patent statistics

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