

Biotechnology Patent Statistics in US, EU, Japan and India

Life sciences and biotechnology are widely recognized as most promising and frontier technologies in the new knowledge-based economy. Biotechnology has captured the attention of all nations. Every country is prepared to spend large funds to promote research and development in biotechnology. In biotechnology inventions typically require high capital investments and it is generally recognized that effective patent protection is a crucial incentive to R&D and innovation.

The EU and US apply for patent at the European Patent Office (EPO) for the classes C12N (biotechnology) and C12N15 (genetic engineering)¹ from 1996 to 2000. The US filed the largest number of patents applications (4129) at the EPO in the biotechnology sector (around 45.4 per cent of total), followed by the EU Member States 3497 (around 38.8 per cent). Japan filed only around 817 (9 per cent) of patents in this period. Both EU Member States and the US increased their patent shares from the 1986-1990 to the 1996-2000 periods, with somewhat larger increases by the US.

At the US Patent and Trademark Office, the majority of patents granted in the genetic engineering sector between 1994-1997 went to US inventors (72.5 per cent). EU Member States had a 14.5 per cent share and Japan a mere 7.5 per cent. While the US and Japan shares both dropped by about 3 percentage points from the 1984-1987 period, the EU Member States increased their share by 3.5 per cent. The data (Table 1) shows that EU Member States clearly lag behind the US in patenting activity. The EU Member States are not only behind the US

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Table 1: Country shares of patent applications in the biotechnology/genetic engineering sectors at the EPO compared to patent grants at the USPTO

| Country | EPO applications | | | | US grants | |
|---------|-------------------------|---------------------------------|-----------------------------|---|-----------------------------|-----------------------------|
| | Biotechnology (C12N) | Genetic Engineering (C12N15) | | Genetic Engineering (USPTO definition) | | |
| | 1986- 1990 | 1996- 2000 | 1996- 2000 (Per cent) | 1986- 1990 (Per cent) | 1994- 1997 (Per cent) | 1984- 1987 (Per cent) |
| EU | 37.4 | 38.8 | 38.3 | 36.6 | 14.5 | 11.0 |
| Japan | 19.6 | 9.0 | 8.5 | 17.5 | 7.5 | 10.8 |
| US | 38.4 | 45.4 | 46.3 | 41.1 | 72.5 | 75.4 |
| Others | 4.6 | 6.8 | 7.0 | 4.7 | 5.4 | 2.8 |

Source: Report from Commission to the European Parliament and the Council, Brussels.

in protecting their European markets, but also they have a comparatively small share of patents in US technology. Currently, the EPO is handling about 60 per cent of all international applications, 50 per cent of which come from the US. To ease the situation, the EPO has decided not to accept from US residents, under the Patent Cooperation Treaty (PCT), any application directed to biotechnology.

In India, patent filing in the area of biotechnology is based on the applications filed in the Indian Patent Office from 1995 to June 2003. A large set of scientific keywords and careful analysis of titles were utilized for capturing the applications in the area of biotechnology. A total of 2378 patent applications have been filed in India till June 2003. Out of 2378 applications, 716 are conventional applications and 774 are PCT applications.² The maximum number of applications is 451, which were filed in the year 2001 (Table 2). The Council of Scientific

Table 2: Trend in Biotechnology Patents in India

| Year | Number of Patents |
|--------------------|-------------------|
| 1995 | 172 |
| 1996 | 193 |
| 1997 | 279 |
| 1998 | 287 |
| 1999 | 162 |
| 2000 | 265 |
| 2001 | 451 |
| 2002 | 395 |
| 20003 (Jan.- June) | 155 |

Source: IPR Bulletin, Vol.10, and NO 6-7, June-July 2004, TIFAC, New Delhi.

Table 3: Biotechnology Patent filed till June 2003

| S.No | Area | No. of Patents field till June 2003 |
|------|------------------------------|-------------------------------------|
| 1 | Protein + Enzyme | 700 |
| 2 | Bacteria+ Bacillus | 236 |
| 3 | Fungi (includes fungicides) | 219 |
| 4 | Virus | 162 |
| 5 | Therapy | 138 |
| 6 | Gene | 136 |
| 7 | Vaccine | 123 |
| 8 | Sequence | 120 |
| 9 | Nucleic acid +RNA | 115 |
| 10 | Fermentation | 109 |
| 11 | Antigen | 88 |
| 12 | Vector (Plasmids and Phages) | 66 |
| 13 | Mutation | 54 |
| 14 | Transgenic | 47 |
| 15 | Microorganism | 45 |

Source: *IPR Bulletin*, Vol.10, and NO 6-7, June-July 2004, TIFAC, New Delhi.

and Industrial Research (CSIR) is the single major applicant in this field, with 202 patents filed in its name.

The main areas in which patents are filed in India are hybrid (44), tissue culture (15), embryo (18), cell line (10), enhancer (27), marker (31), transformation (33), promoter (40). Many of these applications may be products, drugs/pharmaceuticals, genetically modified micro-organisms, naturally occurring RNA/nucleic acids and genes. As per the current position, such applications may not qualify for grant of patents in India. Some of these may be taken as mailbox applications. The number of patent in micro-organism related applications are around 800. The protein, the product of genes has opened a new branch in biotechnology-proteomics. In the area of proteins, 700 patent applications were filed till June 2003, out of which 240 applications were convention applications and 228 were PCT applications. These applications also include 245 patent applications for enzymes. A closer look at patent applications in the field of protein year wise; for instance, they were 69 in 2000 and about 135 in the next year.³

Endnotes

- 1 Definition of "genetic engineering" differ between the USPTO and EPO due to different classification systems.
- 2 *TIFAC Bulletin*, Department of Science and Technology, Govt.of India, June-July 2004.
- 3 *ibid.*