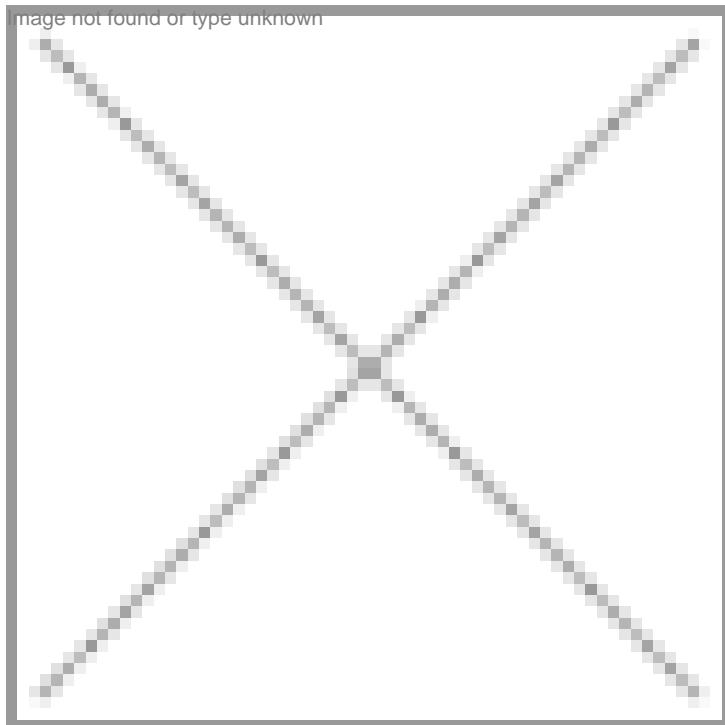


## The great mAbs race in disease therapy

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**The technology has been lapped up by the scientific community due to the technical superiority of its targeted therapeutic mechanism**

### Genesis

Dr Paul Ehrlich postulated that if a compound could be made to selectively target a disease-causing organism, then a toxin for that organism could be delivered along with the agent of selectivity. In 1988, Greg Winter and his team pioneered the techniques to humanize monoclonal antibodies.

### The Technology

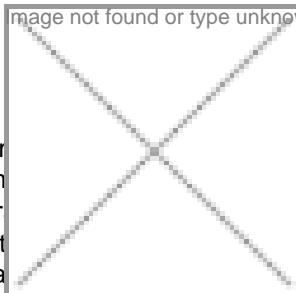
Monoclonal antibodies are monospecific antibodies (antibodies that have an affinity for the same antigen) because they are made by identical immune cells that are all clones of a unique parent cell. It is possible to produce monoclonal antibodies that specifically bind to almost any substance. They can then serve to detect or purify that substance. They directly target the specific disease afflicted cells, thus reducing a large array of side effects.

## The Impact

An analysis by GBI Research estimated the global monoclonal antibodies market to be valued at \$15.6 billion in 2010. The market is forecast to grow at a CAGR of 10.6 percent between 2010 and 2017 and to reach \$31.7 billion by 2017. There were at least six new mAbs under regulatory review and 100 in phase II clinical trials. In the year 2012, the world will see a greater impact of this technology with dwindling pipelines and patent expirations. By 2018, over \$10.6 billion worth of mAbs will lose patents and will be a focus of many pharma and non-pharma companies.

associated with chemotherapy and radiation, their cancer or due to toxicity and are expected to reduce overall treatment times.

**D**esignated as the medicine of the 21st century, the monoclonal antibodies (mAbs) segment represent the second wave of innovation in biotechnology following the success of recombinant proteins. Over the past two decades, since the first mAb product was commercialized in the market (Johnson & Johnson's Orthoclone OKT3 in 1986), the technology has been lapped up by the scientific community due to the technical superiority of



Unlike other defense mechanisms in combating diseases, it directly targets and destroys the afflicted cells using the human body's immune system, thus reducing toxicity levels and side effects often applicable for diseases such as oncology, arthritis, and diabetes. For example, conventional treatments of cancer through chemotherapy and radiation often result in relapse and patients ultimately die either from the disease or its side effects. mAbs are designed to demonstrate efficacy with low toxicity and low costs.

## Companies in pursuit

Globally, the mAbs market so far has been dominated by the big four companies: Roche, Genentech, Johnson & Johnson and Abbott. Growing at a compound annual growth rate of around 36 percent, the market is dominated by the big five blockbuster products: Avastin and Herceptin (for oncology); Humira and Remicade for autoimmune and infectious disease (AIID); and Rituxan for oncology and AIID.

The commercial success of these products prompted many Indian companies to make an aggressive foray into this space. Biocon and Dr Reddy's Laboratories have commercialized their mAbs products in the India market. Biogen Idec, Amgen, Novartis, UCB Pharma, Bristol-Myers Squibb and Sanofi-aventis too plan to expand their presence in the market. In India, Intas Biopharma (now integrated into Intas Pharma) has invested <sup>Image not found or type unknown</sup> 60 crore into a facility dedicated to mAbs in a memorandum of understanding with the Government of Gujarat. Other companies in the race are Serum Institute of India, Bharat Serums and Vaccines and Avesthagen.

However, there are challenges associated with the technology as mAbs are complex protein molecules and often there is a carbohydrate moiety attached to them. Characterization of such complex molecules is a challenge.

**Nayantara Som** in Mumbai