

## Press Release Details

Title                    31 Aug 2005    Materials exchange deal meager boost to India's Biotech

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#### **Materials exchange deal meager boost to India's Biotech**

The Indian biotechnology industry is trying to get beyond being a service industry, but the cost of materials and of getting regulatory approval could confound such efforts.

India's service-oriented scheme for attracting clinical research risks making the country a servant to major drug firms.

An agreement in principle to enable the smooth transfer of microorganisms and biological materials from the US to India is an encouraging sign for Indian bioscience. But slow implementation of the country's broader biotech goals, including India's grandiose scheme to become the global hub of contract research and clinical trials, may threaten its goal of becoming a major player.

Discussions in mid-June between acting US deputy secretary of commerce David A. Sampson and an Indian delegation led by science minister Kapil Sibal led to the biologics transfer proposal. Under the plan, India's Department of Biotechnology (DBT) would procure biological materials from the American Type Tissue Collection (ATCC) and warrant against their misuse or subsequent acquisition by bioterrorists, with safeguards and export controls similar to those around nuclear technology. "We are in the process of resolving this important issue," declares DBT secretary Maharaj Kishan Bhan.

Although ATCC says its regulations for export and distribution of infectious agents did not change after 9/11 and that Indian scientists have full access to the public database, researchers claim problems working with the US-based repository. "ATCC is usually prompt, but if you ask for a type strain or a reference strain, they do not even respond," says a senior scientist at the Institute for Microbial Technology in Chandigarh, which operates the Microbial Type Culture Collection, MTCC, India's only such repository.

"I know of a case when a government lab in Kolkata [Calcutta] doing research on cholera could not get a strain of cholera bacillus from ATCC," notes Raghav Saha of the Department of Science and Technology. "The problem is really acute for vaccine developers," concludes Krishna Ella, managing director of Hyderabad-based Bharat Biotech and chairman of the biotech committee of the Federation of Indian Chambers of Commerce and Industry (FICCI). The hitch has delayed Ella's own project on hepatitis-E vaccine.

Easier access to ATCC would be a great relief but Ella, who was also a member of the delegation that met with the US's Sampson, argues that the Indian biogenerics industry still faces the problem of having to pay exorbitant prices for vectors, yeast, bacteria, viruses and expression systems needed for copying drugs whose patents will expire soon.

Industry scientists admit that they cannot document the source of many of the basic tools for making vaccines and drugs, a potential basis for challenging biogenerics patents. One solution, says FICCI, is to create a global bank that will compulsorily collect patent-protected biological materials and offer these to industries at a nominal cost, clearly establishing ownership.

By putting emphasis on services instead of innovation to become competitive, India's Department of

Biotechnology's policy is likely to spawn "clones of companies doing contract research, clinical trials and validation studies for multinationals"