

## India-US biotech ties inch closer

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*It began in a small way. The cooperation between the US and India in high technology area, particularly biotechnology, has been increasing steadily. It was most evident in June meeting of the Indo-US High Technology Cooperation Group (HTCG) in Washington DC in mid-June. Easing of restrictions for the transfer of biological materials from the US to India and the need for data exclusivity in clinical trials of drugs in India dominated the discussions. An exclusive report from Washington DC by BioSpectrum Editor Narayanan Suresh*

Since the signing of the agreement between the then Prime Minister A B Vajpayee and US President George Bush in 2001, the biotechnology sector, one of the four chosen areas, has pushed the friendship ties very well. A number of issues identified for action between the two government have been completed and it was time to pick out more issues for implementation.

"I don't want even want to mention the word intellectual property right (IPR) as all the demands have been met and is no longer an issue," remarked Krishna M Ella, co-ordinator of the program from FICCI on the Indian side during his opening statement. "Let us move on to other substantial issues."

The who's who of Indian biotech was around to represent India: Science and technology minister, Kapil Sibal, Department of Biotechnology secretary M K Bhan, FICCI's Ella and CII's Gautam Thapar and Hari S Bhartia.

The US heavyweights were David A Sampson, acting deputy secretary, US Department of commerce, Benjamin Wu, Assistant Secretary for technology policy, US Department of Commerce, Ron Somers, president, US India Business Council

and Lt Gen (ret'd) Daniel Christman, senior VP, US Chamber of Commerce.

With IPR issue out of the way, Sibal and Bhan stressed the need for the US to liberalize the biological materials transfer arrangements which was standing in the way of India getting crucial biological materials for research and development. "We understand the US concerns over this due to the dual use possibilities in biological warfare. We are willing to set up all the safeguards and export controls and transfer these materials safely to researchers," stressed minister Sibal. "Let us collaborate to enable India become the vaccine maker of the world. We already have the advantage in this sector. We have the capacity and capability to provide the world with all the vaccines it needs, cost effectively."

Sibal reiterated that India was bound to become the clinical trial hub of the world. This would help reduce the astronomically high cost of drug development (\$800 million to \$1.2 billion) by at least a third and help the middle class in the US too. "We need the US regulator (FDA) to tell us what protocols are needed to enable acceptance of trial data done in India. And train our people also in this field," Sibal emphasized.

US minister David Sampson said India's new entrepreneurship system was increasingly engaging with the US side. He pointed out that US has relaxed the high tech export control regime to India since 2003 and the US was keen to increase the investments in the country. For this the investment rules have to be more transparent and predictable.

Dr Bhan highlighted the policy measures that seek to reduce the time for various regulatory clearances, 100 percent FDI in biotech, and the government policy to set up 20 globally recognized clinical research centers in India. A massive overhaul of the scientific research system in India was underway and it was crucial for India and US to work together to make it happen efficiently.

The meeting was attended by over 150 people from both sides, which was one of the largest such gathering between the two countries. The cooperation has certainly moved to the next level, and the development of Bangalore as a major center of innovation was highlighted by speakers from both sides.