## Press Release Details

Title 23 Oct 2002 Bharat Biotech Wins Global Patent for Infection Drug

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## Bharat Biotech Wins Global Patent for Infection Drug New Delhi, 22nd October, 2002

Bharat Biotech International Ltd (BBIL), a domestic fore-runner in medical biotechnology, has obtained worldwide patent for its version of Lysostaphin, the recombinant DNA therapeutic protein intended for treating infections by virulent bacterium staph.

Worldwide patent on another version of the potential drug which is in pre-clinical development phase, is owned by Bionexus, a Nasdaq-listed US biotech company after it had licensed the molecule from AMBI Inc of the US in a \$15.4 million deal. AMBI still holds US patent on that version of the molecule.

Confirming the grant of patents (Patent Co-operation Treaty (PCT)/1B99/01704 and W001/29201A1), BBIL Managing Director Krishna Ella told Economic Times that the company's indigenously developed process to develop the protein as a drug would make the version superior to that of Bionexus. No opposition has been registered against the grant of patent to the Indian company till the expiry of the mandated time under the PCT. A US patent had earlier been obtained by the company.

Staph (Staphylococcus aureus) has the potency to cause fatal infections of vital organs like heart valve and kidney, and has lately become resistant to even latest class of antibiotics such as Vancomycin. With the pathogen remaining intractable, the estimated global market potential of Lysostaphin is about \$12 billion with both human and dairy applications.

"Unlike the other version, our molecule has the capability to be directly active, and could be applied externally also, even for eye and wound infections," Dr Ella said. The company has received the prehuman trial test licence for the GMP grade material from the Drugs Controller General of India (DCGI). Expectations are that the product would hit the world markets about two years from now, Dr Ella said. On the possibility of a licensing deal at this juncture, he maintained that the company was looking at developing the product on its own for the time being.

Experiments in transgenic animals had proven that Lysostaphin was safe and had the potential to develop as a therapeutic molecule, said Bharat Biotech Foundation director G S Khatri, Development of Lysostaphin by Bharat Biotech was with the technological support of the center for Biochemical Technology (CBT), New Delhi, an institute under the council for Scientific & Industrial Research (CSIR).

Another advantage of the Indian Technology is that the protein is developed from a safe organism-E.Coli. "We have opened up the possibilities of developing the product for human and animal therapeutic purposes". Dr Khatri said.