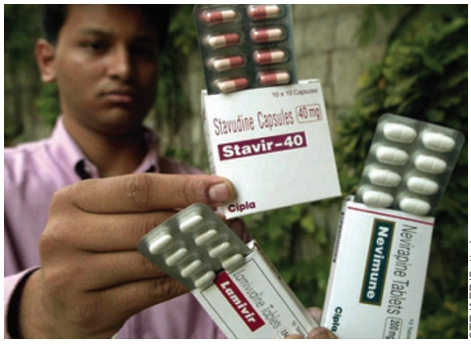
India's Cipla sets sights on Avastin, Herceptin and Enbrel

Indian generic giant Cipla has begun its foray into biosimilars with an eye firmly on biotech's blockbusters. The Mumbai-based chemical generics manufacturer is taking aim at top-selling biologics—Roche's Avastin (bevacizumab) and Herceptin (trastuzumab) and Pfizer/Amgen's Enbrel (etanercept)—which last year brought in a combined $17 billion. With no expertise in biologics, Cipla has had to shop around to build its biologic capabilities. To this end, on June 15, the company made a $65 million investment in Shanghai-based BioMab and Indian firm MabPharm located in Goa. Although low-cost versions of biotech's most successful brand biologics represents a substantial opportunity, Cipla will be not only playing catch-up but also competing for market share with multinational pharmaceutical companies that have already ramped up their capacity and expertise in producing biologics (*Nat. Biotechnol.* **27**, 299–301, 2009). On the other hand, if major generics players from emerging economies meet the technical standards required for entry into the Western biosimilars market, this may force big pharma to price their follow-on products more competitively.



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Cipla built its $1.17 billion generics business by offering cheap copies of anti-AIDS drugs. The Mumbai-based firm now aims to copy ten monoclonal drugs against rheumatoid arthritis, cancers and allergic asthma.

"This is a major decision," says Yusuf Hamied, Cipla's chairman, referring to the June announcement. The deal will be setting a precedent in that a player with very little presence in biotech extends its strategy to biologics by gearing up for antibody production. "A time will come when the world will be selling only biotech drugs. When that day arrives Cipla will be prepared," says Hamied.

The news was also welcomed by William Haddad, founder and long-time chair of the Generic Pharmaceutical Association in Arlington, Virginia, and currently chairman and CEO of New York–based Biogenerics. "The Cipla-China BioMab agreement should send shivers up the backs of the brand biotech companies as it undermines all the anti-generic biotech arguments," he said. "For me the great irony is that the third world will have access to lifesaving biotech medicines that are affordable, whereas patients in the so-called developed nations will not have access to them at prices they can afford or that insurance companies will cover."

At the outset, the Cipla-China partnership is targeting ten monoclonal antibody (mAb) drugs and fusion proteins against rheumatoid arthritis, cancers and allergic asthma for marketing in India and China, particularly drugs that are presently not protected by patent or whose patent term is due to expire.

"We are very happy to be partnering with Cipla," says Xu Shengping, CEO of Shangai-based BioMabs, which is setting up a new biosimilar facility in Shanghai under the collaboration with Cipla. Their technology will also be used by MabPharm's facility in Goa. "We expect to launch the first product at the end of 2011," Hamied says.

The Indian biosimilar space is already strewn with a handful of local firms developing and marketing a broad range of products (**Table 1**). The space has been bolstered by government incentives and the prospect of less stringent approval requirements than in the US and Europe. "We have a special scheme for biosimilar makers; it even goes as far as fully supporting clinical trials," says Department of Biotechnology secretary Maharaj Kishan Bhan. For instance, phase 1 and 2 trials for biogenerics have been waived by the drugs controller general of India under the Ministry of Health and Family Welfare (US Food and Drug Administration's Indian counterpart), and phase 3 trials with 100 patients are enough for establishing bioequivalence. This helps bring down development costs to $10–$20 million, enabling Indian companies to offer their biosimilars 25–40% cheaper than branded biologics, says Syamala Ariyanchira an independent pharma-biotech industry analyst in Bangalore.

Indian firms may be rushing into the biosimilar space now, but their interest is on the second wave of blockbuster products that will go off-patent between 2012 and 2016 in Europe and the US. Such products, which include mAbs and fusion proteins, present several challenges compared with simpler biologics, warns Jay

IN brief

TTO patent swap

Two medical research funders have agreed to exchange selected intellectual property (IP) assets in a bid to boost commercialization. Cancer Research Technology (CRT) of London and the UK's Medical Research Council Technology (MRCT) will offer each other the rights to discoveries funded by their respective parent organizations, the charity Cancer Research UK and the government-backed Medical Research Council (MRC). As part of the exchange, CRT will work on an MRC-derived project in cancer, whereas MRCT will reciprocate outside oncology with revenue sharing to be agreed on a case-by-case basis. MRCT and CRT are both 'super-TTOs', technology transfer offices, in that both run drug development facilities. CRT's Development Laboratory and MRCT's Centre for Therapeutics Discovery each produce preclinical data packages on small molecules and biologicals to add value to the original patented IP. Although the agreement between the two commercialization arms is broad in principle, the first swaps are likely to concern projects that would feed these internal development pipelines. According to Keith Blundy, CEO of Cancer Research Technology, "There are projects that both groups are already working on, but we are not necessarily 'kitted out' in the relevant clinical area. We may not have the biological models needed to progress the project." *John Hodgson*

Brazil bans Bayer

A judge has prohibited Bayer Cropscience from marketing Liberty Link corn, a genetically modified crop resistant to Ignite and Liberty herbicides, in Brazil. If the Leverkusen, Germany–based company fails to suspend marketing, planting, transportation and import immediately, it will be fined R$50,000 ($28,500) a day. This ruling issued in July by an environmental court in the southern state of Parana is only the second time a Brazilian court has overturned a commercial GM crop already approved by the country's technical commission on biosafety (CTNBio), says the commission's coordinator Jairon Nascimento. The first marketing suspension was in 1998 when a judge blocked Roundup Ready soybeans from Monsanto of St. Louis. It took a further six years to ascertain the commission's competence to make biosafety decisions related to GM crops, after which a flurry of commercial GM crop approvals followed. The court took action after a civil suit brought by several agriculture and consumer advocacy groups, who argued that CTNBio's May 2007 approval of Liberty Link maize relied on an inadequate review and neglected post-release safety monitoring. The judge in the Liberty Link case, Pepita Durski Tramontini Mazini, found that CTNBio failed to ensure adequate post-release monitoring of the crop or the potential effects on regional biomes. "The [post-release monitoring] plan is under analysis in CTNBio, but [the court] has not considered this fact," Nascimento says. *Lucas Laursen*