Biotech innovators jump on biosimilars bandwagon

The end of February marked the formation of Samsung Bioepis, a joint venture between Biogen Idec of Weston, Massachusetts, and the Seoul-based Samsung Biologics. The venture is the result of a $300-million agreement between the two companies and will focus on developing and manufacturing biosimilars of products outside Biogen's portfolio. In another deal around biosimilars, Amgen of Thousand Oaks, California, signed a $400-million collaboration deal to make biosimilar versions of oncology drugs with Watson Pharmaceuticals in Parsippany, New Jersey. These moves by biotech giants Biogen and Amgen mark an inflexion point in their business strategy, which previously had been typified by aggressive defensive litigation against makers of biosimilar products in European markets. In light of the February release of draft guidances by the US Food and Drug Administration (FDA) and the unveiling of a potential commercial path to the US market, at least some biologic originators now appear to view their internal biomanufacturing expertise, marketing know-how, infrastructure and brand recognition as potential competitive advantages in the biosimilars market—a market previously of interest only to multinational pharmaceutical and generics companies or cut-price manufacturers in emerging markets.

According to Danbury, Connecticut–based market intelligence firm IMS Health, biosimilars had global sales of $378 million in the 12 months to the end of June 2011 and are forecast to rise to as much as $2.6 billion by 2015. Furthermore, patent expirations on monoclonal antibodies mean that biosimilars—so far confined to copying recombinant molecules—are now poised to break into the blockbuster cancer and autoimmune disease markets, where there is even less competition.

Nature Biotechnology approached several large biotechs for comment but there was a reluctance to even discuss the current state of play in the biosimilars market, let alone their specific strategy. There is still "real murkiness" on this in the industry, says Bill Ciambrone, senior vice president, technical operations at Shire Human Genetic Therapies, in Cambridge, Massachusetts, who is responsible for the company's biologics manufacturing. "But it's logical to think that [an innovator] getting involved at this stage is both offensive and defensive," he adds.

Originator companies have been calculating whether to ramp up legal attacks on biosimilars manufacturers, to capitalize on internal expertise and company confidential information on manufacturing, or to focus instead on souped-up (or biobetter)

STR New / Reuters

Biocon's president Kiran Mazumdar-Shaw. The Indian company is aggressively pursuing biosimilars in Western markets as well as pursuing innovator drugs.

IN brief

Pharma incubates without strings

Janssen open to biotechs

In January, Johnson & Johnson's (J&J's) Janssen Research & Development launched Janssen Labs, a 30,000 square feet research and office space innovation center, at the company's West Coast Research Center in La Jolla, California. Likewise, Bayer, of Leverkusen, Germany, carved out 6,000 square feet from its San Francisco laboratory space to help three to four companies develop treatments in areas the pharma is interested in. Announced in January, the space called CoLaborator is set to launch in late summer. Pharma-sponsored laboratory spaces are undoubtedly helping biotechs start out cheaply, but there's something in it for the hosts as well.

Constrained capital makes it "really difficult to start a biotech company today," said Diego Miralles, site head for the West Coast Research Center. Janssen Labs provides capital efficiency by sharing equipment and common space, and allowing flexibility, in the form of short-term leases and modular laboratory and office space. A professional management company, San Francisco–based Prescience International, will be at hand to help startups hit the ground running. Likewise Bayer plans to offer low-cost, ready-to-use laboratory space.

Although Bayer plans to seek preferred access to partner with the emerging companies it houses, Janssen Labs is technically a no-strings affair. There's a requirement that the startups be working on something J&J is "remotely interested in," which Miralles admits is fairly broad given the evolution of hypotheses during drug development. Rather than contractual access to the startups' innovations in the form of first rights of refusal or equity stakes, J&J expects to benefit from more subtle aspects of the arrangement, gaining preferential access through emotional bonds formed by helping the biotechs get started. "They're in our home," Miralles said, which should help J&J in partnership or acquisition talks.

Jeff Morhet, CEO of Diomics, La Jolla, one of the first companies selected to enter Janssen Labs, said not giving up rights early will help his diagnostics company drive value, while "having close proximity to [J&J] means that we have a partner that we can bring this to first." Biotech drug maker Biogen Idec of Weston, Massachusetts, also set up an innovation incubator in 2007, following a new business model. Called bi3, the incubator provided facilities and its own venture capital fund New Ventures. Last year, Biogen divested its venture fund, arguing that its senior executives and scientists are capable of identifying new technology on their own. *Brian Orelli*