IN brief

Compulsory license bandwagon gains momentum

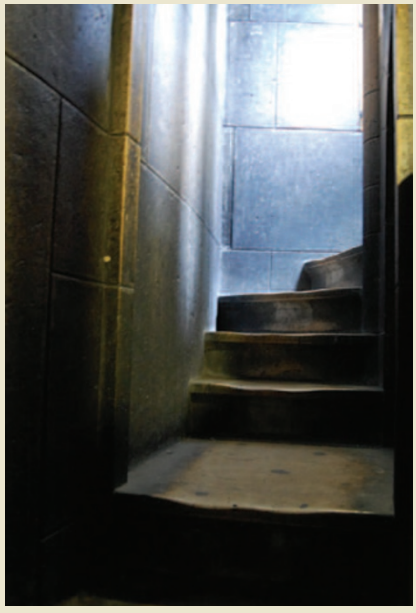
India's decision in March to grant its first-ever compulsory license, which allows a company to make and market a drug that the patent holder has not been able to make sufficiently affordable and accessible, has drawn cheers from healthcare activists and opprobrium from the pharma sector. The licensee, Hyderabad-based Natco Pharma, will sell its generic version of Bayer's liver and kidney cancer drug Nexavar (sorafenib) for 3% of the patented drug's price in return for paying 6% royalty on sales to Leverkusen-based Bayer. Nata Menabde, India's representative to the World Health Organization, told CNBC-TV18, "India has taken a good political stand on compulsory licenses and we respect that move. [A compulsory license is] an important tool that governments have in their arsenal and they should be using it as appropriate, as per national legislation, and keep public health interests above any other interests." Pharma companies and Western patent offices such as the US Patent and Trademark office have registered their opposition, and Bayer appealed the Indian government's decision. Court arguments were heard in August. However, until the decision is reversed, the precedent means that other Indian companies may seek similar arrangements with the government. Compulsory licenses have previously been used in Brazil, Thailand and South Africa, and just last month China amended its intellectual property laws to allow for compulsory licenses. *Michael Francisco*

IN their words

"We cannot on the one hand be marketing our green image and on the other hand growing GM crops. European consumers will not be fooled by this duality." Gillian Westbrook, manager of the Irish Organic Farmers and Growers Association, after the Irish Agriculture and Food Development Authority approved testing of a blight-resistant transgenic potato. (*The Independent*, 2 August 2012)

"I personally believe those [biologics] are the future of drug development in our industry, they just need time to continue to germinate." Following AstraZeneca's $15.6 billion acquisition and doubling of the workforce at MedImmune, CEO Peter Greenleaf of the Gaithersburg, Md., biotech emphasizes the need for a long term perspective, given just one approved product (a swine flu vaccine) and no drug programs in late development. (*Washington Post*, 5 August 2012)

Biotechs opt for alternative floatation strategy



The rising popularity of Form 10 filings is letting companies consider raising funds and going public in a stepped process.

The Jumpstart Our Business Startups (JOBS) Act, passed into law in the US in April, has revitalized the practice known as a Form 10 filing. This type of public floatation is considered more efficient and less risky than a traditional initial public offering (IPO), and though it existed before the JOBS Act, there has been heightened interest in the process since the legislation passed. "The JOBS Act put into the public consciousness that it's important to find new ways to do IPOs," says William Hicks, a partner in the New York office of the law firm Mintz Levin, and that has led to a renewed focus on Form 10, adding, "It could become the new normal for" for emerging growth companies.

In a Form 10 fundraising, a company prepares a prospectus document to go public, but raises money through a private placement before filing the prospectus. Because the private placement is predicated on also going public—and therefore eventually having a publicly traded stock—the process broadens the investor base for the private placement by allowing the participation of so-called 'crossover' investors who would normally invest only in public companies that have greater liquidity than those in the biotech sector.

A key characteristic of the Form 10 process is that the company decides when its stock begins trading, as opposed to a traditional IPO, where a company goes through a filing and disclosure process, gains momentum and then prices its shares at the end—when perhaps the climate for the deal has changed. "People are using Form 10 as part of a conscious de-risk strategy," says Hicks. "If the market's not good, with a traditional IPO you can have a horrible deal and not get what you thought you were going to get. With this process, you raise the money first, then you go public." (Though, much like with a shelf offering for public companies, firms are not required to sell shares on the open market.)

Using the Form 10 process for going public "could become the new normal."

Form 10 can also be used to create a public shell company into which a biotech firm can merge—a strategy used successfully by Los Angeles-based Cougar Biotechnology (now a division of Johnson & Johnson) in 2006. This is cleaner than a reverse merger with an existing company, which may carry the risk of litigation or other liabilities.

The strategy also may also give companies more leverage in acquisition discussions. "Now, the threshold for doing a traditional IPO is so high," it isn't a viable exit option for investors and potential buyers know it, says Hicks. Ovascience, a fertility company in Cambridge, Massachusetts; KaloBios Pharmaceuticals, an antibody developer in San Francisco; and Fresh Medical Laboratories, a diagnostics company in Salt Lake City, Utah, are among the companies with recent Form 10 filings. If those and others are successful, Form 10 could provide a consistent, alternative exit path for investors, and help small biotechs put pressure on buyers in negotiations.

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