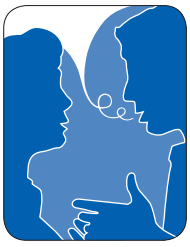
IN brief

JAK pot for Galapagos

Big deal over JAK

In late February, biotech Galapagos entered a pact with Abbott Laboratories worth $1.35 billion over rights to the experimental rheumatoid arthritis drug GLPG0634. The Abbott Park, Illinois–based pharma agreed to pay $150 million upfront for Galapagos' small-molecule Janus kinase 1 (JAK1) inhibitor, currently in phase 2. The Mechelen, Belgium–based biotech may cash in a further $200 million if phase 2 endpoints are met, and another $1 billion in milestone payments and double-digit royalties. Oral JAK inhibitors are a new class of oral drugs expected to rival biologics such as Abbott's rheumatoid arthritis drug Humira (adalimumab) that last year earned the company $7.9 billion. The advantage of JAK inhibitors is that they target a signaling pathway downstream of multiple cytokines, rather than blocking one at a time (*Nat. Biotechnol.* **29**, 467–468, 2011). Galapagos' early phase 2 data attracted several suitors, who "were all very eager because they have a lot to lose," says Jan De Kerpel, an analyst at KBC Securities, Brussels. The size of the deal reflects Galapagos' business prowess. "They knew that several pharma companies… were aiming to protect their RA [rheumatoid arthritis] franchise," he says. Galapagos also "cleverly secured an entry ticket into phase 3," De Kerpel adds, as Abbott assumes sole responsibility for final phase 3 studies and manufacturing. Pfizer's JAK inhibitor tofacitinib in phase 3 is the front-runner for this new wave of oral rheumatoid arthritis drugs. *Gunjan Sinha*

IN their words



"Medical research will wither in our universities, and as a result, more people will suffer and die." Former British Science Minister, Paul Drayson criticized airlines and ferry companies for halting the transport of animals for medical research, capitulating to pressure from animal rights activists. (*Mail Online*, 13 March 2012)

"When you're building a team today, you need to have people with enough former company T-shirts to knit together a quilt in a nursing home." Bruce Montgomery, founder and CEO of Seattle-based Cardeas Pharma on the multi-tasking involved in taking a biotech company forward. (*Xconomy*, 4 April 2012)

to what claims for diagnostic procedures would now meet the Court's measure of patentability. One alternative strategy is "to keep trade secrets, which may have a more chilling effect on innovation, contrary to the Supreme Court's claim."

"We're advising clients not to keep their inventions secret, but to revise claims in their patent applications, hopefully to satisfy the Prometheus [ruling]," says attorney David Resnick of Nixon Peabody in Boston. Officials in the US Patent and Trademark Office are not likely to declare all medical diagnostic technologies ineligible for patenting, Resnick says. So, notwithstanding the ruling from the Supreme Court, "we're advising our clients to apply for patents today, because who knows what standards will be applied in five years—things shift."

"At first I was surprised, but Justice Breyer ruled in Prometheus exactly as he did before," says Christopher Holman of the University of Missouri-Kansas City School of Law. "I think it won't be that devastating, but companies focused on diagnostics and personalized medicine will be the most hurt. It's hard to see a clear path to patents for those companies." In the short term, clinical labs will do tests "without patents in their way," allowing them to "cherry pick, letting companies invest and develop some of those tests."

"Maybe big pharma could benefit in some ways from Prometheus, making money on drugs but with no patents on companion diagnostic tests," Holman continues. Moreover, smaller companies with proprietary diagnostics or biomarker tests that are linked with specific therapeutic products might find themselves depending on the US Food and Drug Administration (FDA) not only to approve those tests in confidence but also to help make the case that costs for such tests should be reimbursed. If that scenario becomes a trend, it could be a setback for small biotech companies. "The historical interplay between FDA regulations and trade secrets has been an entry barrier for competing companies," he says. "As patents are weakened, this secrecy may play a more important role for biotech companies in the healthcare sector. People talk about there being only a few big companies in agricultural biotech, where there is more secrecy. Patents give startup companies a chance, and the more you move to secrets, the more big companies are favored."

The Prometheus ruling seems to contain a "possible invitation to take up this issue with Congress" for those who are dissatisfied with its implications, according to Bill Gaede of McDermott Will & Emery LLP in Menlo Park, California. One big problem is the sharp divide between medical organizations and patient-advocacy groups, which favor the demise of the patents, and biotech companies, which expected them to be upheld. Without wider agreement, appealing to the US Congress to amend patent law is a steep climb unless the Prometheus decision is extended in ways that "catch the attention of Congress," he says.

The looming question is what will happen in *AMP v. Myriad* now that the Supreme Court has sent the case back to the CAFC for further review. "It's good it was sent back, and I doubt the Federal Circuit will change its mind about Myriad in light of Prometheus," Resnick says. "But I'm not sure about the Supreme Court." At the center of the lawsuit were patents on breast cancer susceptibility genes held by Myriad Genetics and the University of Utah, both of Salt Lake City. The biotech carries out commercial testing for mutation in these genes in its BRACAnalysis diagnostic services. In July 2011, the Federal Circuit ruled that isolated DNA sequences are patentable but Myriad's analytic methods were not (*Nat. Biotechnol.* **29**, 771–772, 2011).

In the Myriad case, there are two types of claim: one dealing with DNA patentability, and one dealing with "straight-up" diagnostic methods, Worrall says. The Federal Circuit "may well construe the methods claims as unpatentable. But will they revise their views on the patentability of DNA? Those broad claims are very important for biotech companies."

Perhaps Myriad "doesn't need patents now," Holman says. In its testing of women for their genetic risk of developing breast or ovarian cancers, the company has developed a "huge proprietary database that is valuable for the patients, and people will want to go to them. This further shifts the model for personalized medicine to look outside patents for secrecy."

Meanwhile, questions unrelated to the case itself but to the legal standing of the parties that brought this lawsuit could stall deeper deliberations about the legal substance of these issues, Worrall says. Conceivably, this could enable the Federal Circuit to shelve the whole case—a result, however unlikely, that would be "really negative," because it would leave these issues unresolved for far longer than if that Court rules and the case returns to the Supreme Court in a more timely fashion, a process that could take about two years.

Jeffrey L. Fox *Washington, DC*