IN brief

Consumer genomics battle lines drawn

A California state bill claiming that personal genomics companies should be governed by rules different from other diagnostic tests has sparked a debate over the business of selling genomic information. The bill (SB 482), sponsored by California state senator Alex Padilla and Mountain View, California–based personal genomics firm 23andme, argues that companies that do not perform wet lab services, so-called post-CLIA (clinical laboratory improvement amendments) bioinformatics firms, should not be subject to the same rules as those that do. The companies argue that the services don't fit the current regulatory framework. Padilla, however, denies the new bill is an attempt to exempt them from regulation. "It's exactly the opposite," he says, pointing to provisions in the bill requiring companies to contract CLIA-laboratories, for instance. The privacy provisions outlined in the bill, however, don't go far enough, the American Civil Liberties Union (ACLU) of California points out. Gail Javitt of Johns Hopkins University's Genetics and Public Policy Center in Baltimore also notes: "CLIA also addresses how laboratories select tests and communicate tests results. There's more to laboratory oversight than the wet-lab portion," she says. The bill awaits approval by the state's judiciary committee before going up for a vote. In the absence of federal regulations on this issue, more states might consider similar legislation. *Laura DeFrancesco*

Biocon, Mylan in pan-biogenerics deal

India's Biocon has partnered with US-based Mylan to sell Indian-made biogenerics globally. Bangalore-based Biocon sees the collaboration with Mylan, the world's third-largest generics producer, as a strategic opportunity to take generic versions of insulin, monoclonal antibodies and other protein therapeutics in its pipeline, to regulated markets such as the US and Europe. The new alliance combines Biocon's cost-efficient biologics manufacturing with the Pittsburgh-based company's global commercial reach and regulatory expertise. The two companies will share development, capital and certain other costs of bringing the products into global markets, although financial details have not been disclosed. Monoclonal antibodies will be the cornerstone of this pact, Kiran Mazumdar-Shaw, Biocon's chairman, told shareholders at a recent meeting. Hareesh Parandhman, until recently at Ahmedabad-based Intas, agrees that the business strategy makes sense if Mylan absorbs the development and regulatory expenses, as Europe and the US do not allow generics without clinical trials in their countries. "I cannot imagine Biocon or any Indian biogenerics company going to Europe or the United States on its own," he says. But Krishna Ella, CEO of Hyderabad-based Bharat Biotech points out that, "Europe and the US will not be [an] easy walkover considering that the patent issue is more complicated in the case of biologicals, where product as well as the processes used are covered by patent." *Killugudi Jayaraman*

The potential financial rewards are also considerable. "People have compared this with Gleevec (imatinib mesylate) in terms of its specificity, and that's a billion dollar drug. When someone pays $500 million for a company [as Sanofi-Aventis did for BiPar], it's a pretty good indicator" of the market's potential, says Kranda.

Meanwhile, researchers are searching for other applications for PARP-1 inhibitors. The enzyme is frequently upregulated in tumors as it likely dampens the effects of radiation and DNA-damaging therapeutic agents such as Platinol (cisplastin). Valeria Ossovskaya, director of preclinical development at BiPar, has shown that PARP-1 is highly activated in breast, ovarian and uterine cancer, but not kidney or prostate cancer, and particularly intensely in TNBC. "We're taking (PARP1) overexpression as a cue to overall genomic instability. It's a clue that ovarian cancer might be an attractive target, and we see it in lung cancer, and that's another (potential target)," says Barry Sherman, BiPar's executive vice president of development.

Many now pin their efforts on widening the synthetic lethality approach. "We would like to [pursue] a broader strategy, not focused on specific genes. The applications of PARP-1 inhibitors might be much broader than [for] tumors that are deficient in BRCA1 and BRCA2," says Ossovskaya.

Researchers are also looking for other synthetic lethal combinations. Other genes that play a role in homologous recombination have been shown to be lethal with PARP-1, as well as genes required for other DNA repair processes. Some checkpoint genes also form lethal combinations with PARP.

"[PARP-1] is the first case that I can think of where the concept of synthetic lethality has been demonstrated with a clinical study. To me it's not just about PARP-1, it's about this entire approach," says Pearl S. Huang, vice president and oncology franchise integrator at Merck. The company is enrolling patients for a phase 1 clinical trial that will focus on ovarian cancer, although not exclusively.

The company is currently applying its genomics and RNA inhibition programs to screen for other synthetic lethals in signal transduction and other pathways. "We're applying (synthetic lethality) broadly in oncology discovery," Huang says.

Jim Kling *Bellingham, Washington*

IN their words

"What's very troubling is that if you have a piece of skin from anybody—Albert Einstein, Marilyn Monroe, Michael Jackson—you could create a child."

Robert Lanza, chief scientific officer at Advanced Cell Technology in Worcester, Massachusetts, indulges in some hand-waving after Chinese researchers succeed in growing healthy living mice using induced pluripotent cells derived from mouse skin cells. (*Los Angeles Times*, July 24, 2009)

"I keep saying that the sexy job in the next 10 years will be statisticians. And I'm not kidding."

Hal Varian, chief economist at Google, doles out advice to today's students based on the rising rank of statisticians. (*New York Times*, August 5, 2009)

"We personally can only regret that Mr. Vasella was not present in the home when it burned."

A press officer of the Animal Liberation Front expresses disappointment on failing to add murder to arson, after setting light to Novartis' CEO Dan Vasella's summer home in Austria. (*In-Pharma Technologist*, August 6, 2009)

"This child is very thoughtful and focused, so I suggest she go into management."

Huang Xinhua, a scientist from the Shanghai Biochip Corporation, after examining the results from a child's DNA test, which the company claims can extract information about IQ, emotional control, focus, memory, athletic ability and more. (*CNN, Asia*, August 5, 2009)

"My only disappointment with his departure is that he's no longer a candidate for my Worst Biotech CEO of the Year award."

Analyst Adam Fuerstein comments on Robert Capetola's resignation from Discovery Laboratories. (The Street.com, August 14, 2009)

"Who is ever going to go into a deal with the White House again if they don't keep their word? You are just going to duke it out instead."

Billy Tauzin, president and CEO of pharma companies' lobby group PhRMA, comments on the White House's alleged agreement not to extract cost savings from the industry beyond the $80 billion already pledged. (*New York Times*, August 5, 2009)