community has also been adding to the list of known mutations related to breast cancer. Myriad, the lawsuit contends, has not always incorporated other well-known mutations in its test in a timely fashion. Other researchers also argue that most gene research is funded by the US National Institutes of Health (NIH) in Bethesda, Maryland, so why should companies, and not taxpayers, profit disproportionately from it?

Next-generation sequencing and comparative genomic hybridization arrays are raising other issues. "The technology is so different now," says Sherri Bale, president and clinical director of Gaithersburg, Maryland–based GeneDx. "For new tests, we are looking at hundreds of thousands of genes across the genome." The company has spent "tons of money" trying to figure out which of these mutations are already patented, "but we don't even know if this technology falls under the prior claims," she says. ACLU's Park says these types of "patent thickets" harm patients by slowing research. With extremely rare diseases, the problem is even bigger because there is so little financial incentive for creating tests to begin with.

"Athena and Myriad are the two who have built a business model around cornering the market on particular tests," says Arthur Beaudet, chairman of the Department of Molecular and Human Genetics at the Baylor College of Medicine in Houston, Texas. He points to the listings on various web sites (for example, http://www.genetests.com/) as one bit of evidence that most other patent owners license out their tests more widely.

"There are many genes, such as [those related to] cystic fibrosis, where people are generously sharing inventions," says Gert Matthijs, of the Center for Human Genetics in Leuven, Belgium. Giving one company complete control of a gene patent, he and others argue, can hamper access. For example, AMP's lawyers contend that some state Medicaid programs have failed to negotiate licensing deals with Myriad, leaving patients with no way to be reimbursed for tests. "California and New York are notorious for not paying for tests to be done out of state," says Beaudet. Athena released a statement to *Nature Biotechnology* saying that "all labs in the US have access to Athena testing," but the company would not respond to specific questions.

Myriad and Athena's tight hold on their patents can also result in bizarre reporting schemes; for instance, the *connexin 26* gene: GeneDx holds a patent to certain mutations related to a condition known as KID (keratitis-ichthyosis-deafness syndrome), whereas Athena has rights to different mutations that cause hereditary deafness. When GeneDx tests patients, the company is not allowed to reveal if they carry any of the Athena mutations.

Sharon Terry, CEO of the Genetic Alliance in Washington, DC, which represents multiple advocacy groups for genetic diseases, says the problem starts with university technology licensing departments who want to make "a killing" by selling an exclusive license to a company; some companies then try to milk the test for all it's worth. Because the diseases are usually so rare anyway, "nobody ends up making any money off most of these patents," says GeneDx's Bale.

The other side of this argument is about innovation, and whether companies will pursue new tests, especially for rare diseases, if they can't own a monopoly on them. "As much as it makes people uncomfortable, medicine is commerce, and we need to keep innovation alive, which means letting companies have profits," says Terry.

Many, including Terry, view *AMP et al.*'s chances with skepticism. "How do you sue a company for patenting a gene when that's legal?" he asks. "If there is a problem, I'm not sure if this lawsuit is the right approach." Resnick doesn't even think *AMP et al.* have standing to sue. "In this type of situation, the people who can challenge patents are people who have been sued by the patent's owner."

Ironically, Myriad's patent lawsuit is not the case most experts are watching. "*Myriad* is a nuisance, but *Bilski* could be a big problem," Resnick says. Keith Batchelder, of Charlestown, Massachusetts–based Genomic Health Strategies, concurs. "*Bilski* is the scary one" because it could redefine what types of inventions are patentable, he says.

In early June, the US Supreme Court agreed to hear *Bilski v. Doll*, a case that involves the patent eligibility of methods for hedging risk in commodities trading. Although that might not seem immediately applicable to biotech, it could have serious implications for molecular diagnostic patents by narrowing what is patentable.

In a recent ruling on the case, the US Court of Appeals for the Federal Circuit narrowed the patentability of "business methods," making it clear that to be classed as a "method" it must involve either a "machine, or a transformation." Resnick says the USPTO is already rejecting biotech-related claims based on the *Bilski* decision. He advises diagnostic companies to name the specific technology they have used to find a biomarker or set of markers (for example, gene expression analysis or immunohistochemistry) or risk having their entire patent thrown out.

Malorye Allison *Acton, Massachusetts*

IN brief

Budget winners

The Obama administration has laid out ambitious spending plans for scientific R&D and the Food and Drug Administration (FDA) in its fiscal year 2010 budget. Budget details released in May include a doubling in R&D spending over the next decade at three agencies: the National Science Foundation, the Office of Science within the Department of Energy and the National Institute of Standards and Technology within the Department of Commerce (**Fig. 1**). The budget also set a goal of spending 3% of the gross domestic product for scientific R&D. Both Jim Greenwood, head of the Biotechnology Industry Organization, and Billy Tauzin, head of the Pharmaceutical Research and Manufacturers of America, praised this federal spending goal as key for promoting innovation and economic growth in the pharmaceutical and broader biotech sectors. The administration also proposes a budget of $3.2 billion for the FDA in 2010, an increase of 19% over 2009, with some of that revenue to come from higher user fees. Despite the proposed increase of nearly 20% for FDA, that figure is "not nearly enough because it comes off a small number," says Peter Pitts of the New York–based Center for Medicine in the Public Interest. "Ultimately, FDA needs its budget to double to do its job properly." *Jeffrey L Fox*

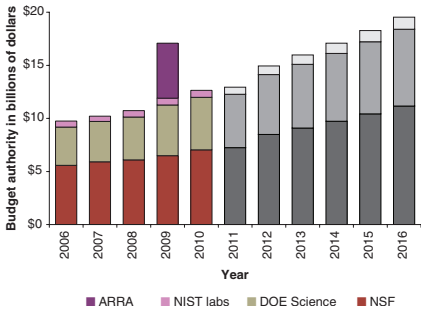

Figure 1 President Barack Obama plans to double federal investment in basic research. ARRA, American Recovery and Reinvestment Act of 2009; NIST lab, National Institute of Standards and Technology laboratories; DOE Science, the Department of Energy's Office of Science; NSF, National Science Foundation.

IN their words

"Richard and I tried to engage with some of the directors, but they were escorted out behind guards before we could talk to them."

Alex Denner, one of Carl Icahn's backed directors for Biogen, comments on the frosty reception that he and Richard Mulligan received from the rest of the biotech's board, who left the annual meeting without shaking their hands. (*Xconomy*, June 4, 2009)