IN brief

Lawsuits rock Jackson

Lee Pettet/istockphoto

Litigation over models may inflate prices.

The Jackson Laboratory has unwittingly found itself ensnared in patent disputes. In June, the nonprofit laboratory mouse developer located in Bar Harbor, Maine, was cleared of a patent infringement allegation—the first in the laboratory's 80-year history—and now faces a second allegation by another party. Jackson's mission of making its repository of more than 5,000 mouse strains available to researchers at affordable prices could be challenged if it is forced to continue defending itself in expensive lawsuits, says David Einhorn, the laboratory's in-house attorney. In Jackson's first scuffle, the Central Institute for Experimental Animals (CIEA), a Kawasaki, Japan–based nonprofit, in 2008 sued Jackson for distributing a mouse model particularly useful for grafting human tissue. Both groups in the 1990s separately developed these immunodeficient mice by starting with a strain of nonobese diabetic mouse (NOD), crossing those with mice carrying the scid mutation for immunodeficiency, and crossing them again with mice whose gene for a key immune signaling molecule, interleukin-2 receptor γ, was knocked out. Jackson has distributed the mouse to more than 1,000 research groups worldwide, says Einhorn. But the laboratory didn't patent its mouse, whereas CIEA did. On June 1, a US District Court judge ruled that the Jackson Laboratory had not infringed CIEA's patent. What ultimately swayed the judge to side with Jackson was that the CIEA, in its patent application, described the mouse but didn't claim it. In his decision the judge cited the Guidelines for Nomenclature of Mouse and Rat Strains, which state mice inbred for more than 20 generations can be considered a different strain, and Jackson's mouse line had been separately inbred many times. Michael Rader, attorney with Wolf, Greenfield & Sacks in Boston, who represented Jackson, says this was likely the first time nomenclature rules have been used to help decide a lawsuit. Now Jackson faces another lawsuit involving transgenic mice with mutations useful in Alzheimer's disease research. The Alzheimer's Institute of America in February sued Jackson and six biotech and pharma companies for patent infringement. Despite the high costs of the two lawsuits, Einhorn says Jackson won't alter its mission of making laboratory mice accessible. But he notes that if the suing trend continues, "the most obvious way to recoup the costs is to charge more for mice." He adds: "That falls on the backs of scientists who do the research." *Emily Waltz*

JASON REED/Reuters/Corbis

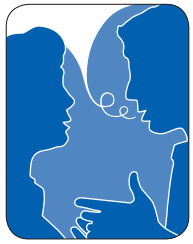
The FDA's Transparency Task Force is proposing to increase access to the agency's decision letters about products or drugs. Such a move would challenge small biotech.

vice president of clinical and regulatory affairs at Hudson, Massachusetts–based Clinquest. McLane points out that releasing more data earlier will also stretch the agency's resources because there will be pressure to analyze many more signals quickly and thoroughly. "It's a tremendous overreach," he says. "A lot of people do not think this will go through." McLane says he'd rather see the agency bring their transparency rules in line with the Sarbanes-Oxley Act of 2002, which set new standards for US boards, management and accounting firms. "A lot of what the FDA is asking for here is competitive information," he says.

The agency was accepting comments through July 20. In the autumn, the task force will consider the public comments as well as the "priority, operational feasibility, and resource requirements" of each proposal, according to Afia K. Asamoah, director of the FDA's transparency initiative. BIO submitted one set of comments in April, and Emmett says the group will submit more before the deadline. Even if the agency decided to go through with all the proposals, though, some of the changes could not be implemented without new legislation.

Malorye Allison *Acton, Massachusetts*

IN their words



"They have grown so fast and so suddenly that people are still skeptical. But we should get used to it." Rasmus Nielsen, a geneticist at the University of California at Berkeley, who collaborates with Chinese colleagues, on China's sudden boom in sequencing output. (*The Washington Post*, 28 June 2010)

"Until the capacity issues can be addressed, this will not be an effective agent." Chris Logothetis, head of prostate cancer research at the University of Texas MD Anderson Cancer Center in Houston, on the year-long wait patients currently face for Dendreon's prostate cancer vaccine Provenge. (*Pharmalot*, 28 June 2010)

"Everyone can claim victory, except of course Mr. Bilski himself." Dan Ravicher, of the Public Patent Foundation, the organization leading the attack on Myriad, on the Supreme Court's decision in *Bilski v. Kappos*. (*GoozNews*, 28 June 2010)

"Now that the full integration has taken place, it's the Genentech guys who are being promoted and getting the key positions." Allianz Global Investors' Joerg de Vries-Hippen on how Genentech is the strongest in the marriage with Roche. (*Bloomberg Businessweek*, 1 July 2010)