INTELLECTUAL PROPERTY

Decision on NF-κB Patent Could Have Broad Implications for Biotech

In what one patent expert called a potentially "huge, huge case," a federal jury last week unanimously upheld a biotechnology patent that critics describe as exceptionally broad. If the verdict survives appeal, it could set a new precedent for the enforcement of patents on biological discoveries upstream of actual drugs.

Contrary to some predictions (*Science*, 31 March, p. 1855), on 4 May, a Boston jury ruled that Eli Lilly's osteoporosis drug Evista and sepsis drug Xigris infringed a patent held by the Massachusetts Institute of Technology (MIT), Harvard University, and the Whitehead Institute and licensed exclusively to Ariad Pharmaceuticals, a Cambridge, Massachusetts, biotech company. The jury awarded at least $65.2 million in back royalties to Ariad, which could continue collecting 2.3% of sales of the two drugs until the patent expires in 2019.

The patent covers methods for inhibiting NF-κB, a protein discovered 20 years ago at MIT by David Baltimore, now president of the California Institute of Technology in Pasadena, with help from fellow Nobel Prize winner Phillip Sharp and Harvard biologist Thomas Maniatis. (Sharp and Maniatis both testified for Ariad at the trial.) Because NF-κB, a prolific "transcription factor" that turns more than 175 other genes on and off, is so important in biology and disease—it has also been implicated in arthritis, cancer, diabetes, and stroke—the Lilly case could be the first of many involving the protein. Hundreds of compounds, including many drugs already on the market, are known to inhibit NF-κB.

It is that broad reach that has prompted debate. Ariad CEO Harvey Berger calls the patent claims "very specific" and typical for both industry and academia. "We had a very strong, crystal-clear case," he says. Law professor Arti Rai of Duke University in Durham, North Carolina, on the other hand, calls Ariad's NF-κB patent "a very broad patent." She says that an ultimate Ariad victory would herald a major change in the patent landscape, because previous decisions by the federal appeals court have led to the assumption that biotech patents must be narrow. If the Ariad patent survives appeal, "conventional wisdom gets thrown out the window," Rai says. Lilly spokesperson Philip Belt is more outspoken, calling the verdict "shockingly inconsistent with current patent law."

The patent still faces several legal hurdles. The case in Boston does not end with the jury verdict; a separate trial will be held by federal Judge Rya Zobel to decide certain legal challenges to the patent's validity and enforceability. Lilly vows to appeal last week's verdict if the judge rejects these arguments. And in late April, Amgen, a biotechnology company in Thousand Oaks, California, filed suit against Ariad to invalidate the patent and certify that its blockbuster arthritis drug Enbrel, and a second arthritis treatment, Kineret, don't infringe. Amgen spokesperson David Polk called the lawsuit "a preemptive move," because the company expected Ariad to eventually sue over Enbrel and Kineret. Berger won't comment on the Amgen claims except to say they're without merit and that licenses are available to commercial entities. (Academic scientists do not need a license, he stressed.)

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High-profile witness. Nobel Prize winner Phillip Sharp, who helped discover NF-κB 2 decades ago, testified for MIT and Ariad Pharmaceuticals in the patent-infringement trial.

Berger considers the jury verdict "good for academic research, good for universities, and in the end, good for … discovering new drugs, because it speaks to important technology." But Rai sees it differently. Asked whether the verdict could hinder innovation in the drug industry, she replied: "If, as a precedent, it then led to lots of upstream players deciding that they would try to follow the lead of Ariad and try to cash in on their upstream patents, [then] yes, I think it could." **–KEN GARBER**

Ken Garber is a science writer in Ann Arbor, Michigan.

Venus Express Blues

Europe's Venus Express spacecraft, orbiting the veiled planet since 11 April, has jammed a mirror on its Planetary Fourier Spectrometer, a key instrument that looks for volcanic hot spots.

Project scientist Håkan Svedhem of the European Space Agency says the problem is "completely unrelated" to a short-lived hitch with a similar instrument on the agency's Mars Express spacecraft in 2005. "It looks like the mirror is starting to move again," says Svedhem, promising a "careful approach" to tests.

–GOVERT SCHILLING

From Lunar Hitchhiking …

NEW DELHI—After more than a year of navigating U.S. red tape, the Indian space agency and NASA have agreed that U.S. instruments will ride India's first moon mission. Concerns about both technology-sharing and security had blocked the agreement, but officials finally inked a deal earlier this week in Bangalore.

Under the pact, the Chandrayaan-I mission will carry a miniature radar to search for elusive water and a mineralogy mapper to help find helium-3 for future fusion power. NASA chief Michael Griffin, who met Indian Space Research Organization chair G. Madhavan Nair to sign the accord, hopes the launch, slated for 2008, will open a new era of Indo-U.S. space cooperation. Officials hope this summer to iron out proprietary technology agreements for future joint missions.

–PALLAVA BAGLA AND ANDREW LAWLER

… To Moon-Mulling

NASA plans to send a bevy of missions to the moon in coming years, and it has asked the National Academies' National Research Council for advice on what to do there. Among other things, NASA Science Mission Directorate Chief Scientist Paul Hertz last week told researchers that the agency wants to know what kinds of experiments could fit into a suitcase-sized box that future astronauts could deploy on the surface, similar to what Apollo astronauts left behind during their forays in the 1970s.

The work raises fears of further science budget erosion at NASA (see p. 824), and Hertz warned that "there isn't new money to do [lunar] science, but there are new opportunities." An interim version of the fast-track report is due to NASA in September, and the final report will be completed late next spring.

–ANDREW LAWLER

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