Scientists protest plan to loosen patent protection on genetic research

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University of Wisconsin-Madison officials are lashing out at new recommendations from an influential federal panel that could dramatically weaken patent protection for the university's genetic research.

Among other things, the panel recommended essentially exempting genetic tests for cancer and other diseases from patent protection -- meaning that anyone could use genetic diagnostic research from UW-Madison or any university without obtaining licenses.

"They are making reckless policy recommendations," said Andrew Cohn, who spearheads government lobbying efforts on behalf of the Wisconsin Alumni Research Foundation, UW-Madison's patent-management arm. "This is an incredible precedent, a bad precedent."

The 300-page study was drafted by an advisory committee to the Secretary of Health and Human Services. It focused specifically on genetic tests that are often associated with diagnostic work on cancer, heart and neurological conditions.

The committee, which voted Thursday to accept the study's recommendations, argued that patent ownership of genetic science creates single commercial providers of such genetic tests. Physicians then are forced to send blood and tissue samples to specific providers for analysis. That creates a patchwork of different testing labs, some without agreements from Medicare or Medicaid to pay for the work.

"As we did the report, we had one major constituency in mind, and that was patients," said James Evans, a medical professor at the University of North Carolina at Chapel Hill who chaired the subcommittee on gene patents and licensing practices for the committee.

Evans said the study asked, "How can the system be narrowly adjusted so we can enhance patient access to these new technologies?"

The report now will be edited before the committee releases it to the public. It then goes to Health and Human Services Secretary Kathleen Sebelius, encouraging her to support legislation that would change patent law accordingly.

"Obviously, I hope the secretary will act on our recommendations," Evans said.

The Biotechnology Industry Organization, the nation's biggest biosciences trade group, also protested the committee's report.

"Enacting these recommendations would risk thousands of jobs across the country by stifling university-industry partnerships and undermine the country's global leadership in biotech innovation," BIO president Jim Greenwood said in a statement. "We must strongly disagree with its recommendations."

Both WARF and the biotech organization had representatives testify at a hearing of the committee Thursday.

The report includes a second recommendation that triggered a rebuke from WARF.

It encourages Sebelius to explore whether her department has the authority to compel universities and companies that use federal funding

for their technology research to license their inventions freely to as many users as possible.

The idea, Evans said, is to limit the use of exclusive license arrangements that keep medical innovations in the hands of a few.

Cohn at WARF called the recommendation a "cookie cutter" approach that undermines the letter and spirit of the 1980 Bayh-Dole Act, which allows universities and small businesses to control the licensing and commercial use of their inventions even if those inventions resulted from federal funding.

"The recommendations have the potential to gut the Bayh-Dole act," Cohn said.

Policy makers in Madison have no doubt that Bayh-Dole plays a significant economic role. Before it was enacted, only about 25 universities engaged in technology transfer, and university-generated patents gathered dust in federal government vaults without being used, Cohn said. After the law passed in 1980, that number is above 300, Cohn said.

The report inflames the debate between adherents of the patent system and those who argue that the 20-year monopoly afforded by a patent can limit the use of medical breakthroughs.

Both WARF and the biotech group contend the report fails to substantiate that patent protection limits the use of genetic testing and research. Patent attorney Eugene Quinn, author of the IPWatchdog.com Web site, criticized the "shocking and surprisingly unfounded conclusion" that patents do not serve as incentives for genetics research.

"We knew from the outset, when we started these deliberations, that

there would be dissenting opinions," the committee's Evans said.

Efforts to weaken patent protection raise alarms for those who argue that the patent system encourages research and technology. But in the field of genetics, patents have triggered emotional debates for several years, often on ethical grounds.

The report, which took five years to produce, came from a 16-member committee that Evans said included academics, genetic researchers, biotechnology industry representatives, patient advocates and a law professor.

The recommendations come at a time when obtaining a patent has never been more difficult.

In a series of stories in August, the Journal Sentinel documented that U.S. Patent and Trademark Office has been unable to keep pace with the torrent and complexity of applications it receives.

As it has struggled with a growing backlog that reaches 1.2 million applications, the agency in recent years added hurdles, delays and rejections that have handicapped start-up businesses and entrepreneurs and impeded the nation's economic competitiveness.

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