

## Australian agency proceeds cautiously with Hwang patent

The head of Australia's patent office has admitted to being "uncomfortable" about granting a patent to a group from Seoul National University Industry Foundation that includes the disgraced researcher Woo-Suk Hwang.

The patent application is for a stem cell line, which the group of 18 researchers claimed was produced by a procedure known as somatic cell nuclear transfer but has since been revealed to have been created by parthenogenesis (the development of an embryo in the absence of fertilization).

Philip Noonan, the director-general of IP Australia, the country's patent-granting agency,

told a Senate committee in Canberra that the application had passed the examination stage and might have to be granted, despite his misgivings.

"I am uncomfortable about granting a patent where the applicant has engaged in behavior like this," Noonan said. "The Patents Act does not deal directly with this type of situation."

Noonan was responding to questioning on 23 October by Australian Senator Ron Boswell of the conservative National Party. Boswell was a vocal opponent of legislation passed in 2006 that allowed licenses to be granted to Australian researchers who want to clone

human embryos for therapeutic purposes using somatic cell nuclear transfer.

Senator Boswell began his questioning by pointing to IP Australia's stated commitment to a "robust and reliable" rights granting process. "Is it robust and reliable to grant a fraudulent researcher a patent on fraudulent work?" he asked.

However, although the application made false claims about the method used to create the stem cell line, Noonan said this did not alter the status of the product: "it is generally accepted that the line of stem cells exists and is a new invention. But it is now generally accepted that they were not derived by somatic cell nuclear transfer but by another process called parthenogenesis."

"The Patents Act requires IP Australia to be satisfied that there is an invention [...] that [has] not been discovered before. The new line of stem cells is such an invention," Noonan added. He said the application was still being investigated by IP Australia even though it had passed examination after no objections were lodged. According to him, suspension of the decision might continue through early December "or longer if necessary."

Australian law does not allow government ministers to intercede in the patent application process. Noonan said that if the patent is granted, IP Australia will "have to advise the minister about what can be done about that."

Once granted, the minister or any other person may begin legal action to have a patent revoked.

"The grounds upon which the court can revoke a patent are somewhat broader than the grounds upon which the grant of a patent can be refused in the first place," Noonan said.

Matthew Rimmer, an intellectual property specialist at the Australian National University in Canberra, disagrees with IP Australia's position that there is no basis to refuse a patent if the supporting data was fabricated.

"If Woo-Suk Hwang has engaged in criminal conduct, the patent application will be contrary to law, and able to be rejected," Rimmer says.

According to Rimmer, the Australian patent regulator's difficulty in this case flowed from the Australian government's failure to amend intellectual property legislation to comply with a free trade agreement signed with the US in 2004.

"IP Australia is really using the current dispute to push for the standard of utility to be considered at the stage of examination," he says.

*Simon Grose, Canberra, Australia*

## Biomedical sector takes steps to handle harsh financial realities

The financial crisis has not been kind to the pharmaceutical and biotechnology sectors, with prominent names such as Merck and DeCode Genetics taking recent blows.

DeCode, the pioneering Icelandic genetics and genomics company, watched its share price plunge from a 52-week high of \$4.39 last December to 34 cents at closing on 13 November. This month, the company is scheduled to ask a panel convened by the NASDAQ stock exchange not to delist it now that its market capitalization has fallen below \$50 million, the minimum required to trade on the tech-heavy exchange.

Although deCode is perhaps the most

visible biotech struggling to survive, it is hardly alone. The Washington DC-based Biotechnology Industry Organization reported last month that nearly 100 publicly traded biotech companies have less than six months of cash remaining.

The picture is not much prettier on the pharmaceutical side, where, by the end of October, the AMEX Pharmaceutical Index, a composite of widely held, big pharmaceutical companies, had plunged more than 21% for the year.

New Jersey-based Merck was among the companies taking drastic action to trim costs. In October, as it reported a 28% drop in profits for the third quarter, it announced it would cut 7,200 jobs—more than 10% its workforce.

"We will get past this," says Mark McClellan, a former US Food and Drug Administration commissioner who now directs the Engelberg Center for Health Care Reform at the Brookings Institution, a Washington, DC think tank. But he predicts that in the long run the current economic setback, combined with the financial pressure resulting from the growth of mandatory spending programs such as Medicare and Medicaid, will mean growing scrutiny for biotech and pharmaceutical companies: "There will be increasing attention to the question: are these products truly valuable? Are they making a real difference in the health of Americans, given how much money we're spending on them?"

*Meredith Wadman, Washington, DC*



From banks to biotech: The crisis spreads