

RESEARCH ETHICS

Germany Gets in Step With Scientific Misconduct Rules

BERLIN—Five years after a major fraud scandal rocked the scientific establishment, Germany's universities are about to get their first binding standards of ethical research. Universities must implement the new rules by the end of this month or risk being ruled ineligible for grants from the country's main research funding body, the Deutsche Forschungsgemeinschaft (DFG).

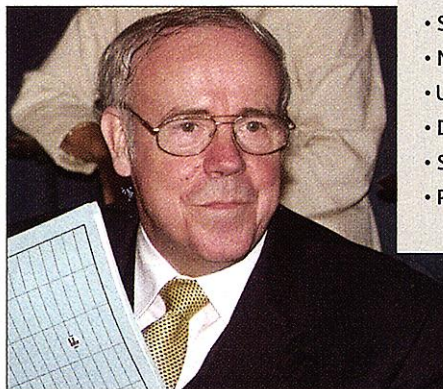
The rules follow international norms in defining scientific misconduct as "deliberate or grossly negligent falsification or fabrication of data." Other serious transgressions listed are deceit, plagiarism, and damage to the research of others. Possible sanctions include the loss of research contracts and the revocation of academic titles. Moreover, says DFG president Ernst-Ludwig Winnacker, "failure to cooperate with investigations will be considered an admission of guilt."

The regulations are a welcome tonic for a community embarrassed by misconduct inquiries that have dragged on for months or years and in some cases held little consequence for implicated individuals. The rules also try to ease the publish-or-perish pressures that, some argue, tempt young researchers to commit fraud. According to the new code, promotion decisions should no longer be based on quantitative measures—such as publication volume—but on quality and originality. "This is a crucial point, especially in clinical research," says Ulf Rapp, a cell biologist at the University of Würzburg.

The misconduct rules are the fruits of much soul-searching after a DFG-funded task force found falsification in dozens of papers authored by a pair of cancer researchers, Friedhelm Herrmann and Marion Brach (*Science*, 23 June 2000, p. 2106). A special DFG commission developed the regulations in consultation with international fraud experts. Any institution that receives DFG funding—meaning the vast majority of Germany's research centers and universities—has until 30 June to implement the rules. The threat of falling into DFG's disfavor has so far motivated 70% of Germany's research institutions to adopt

the guidelines. Most others expect to have them in place by the deadline.

It's unclear, however, whether the rules will apply uniformly to all scientists. For those holding permanent jobs as public servants, it is up to ministerial employers—rather than DFG—to punish misconduct, and proving deliberate or



Laying down the law. Stonewalling misconduct investigations is tantamount to guilt, says DFG president Ernst-Ludwig Winnacker.

gross negligence in data fabrication is notoriously difficult. However, talks are currently under way over possible changes to the employment law.

Under the new rules, institutions must appoint an independent ombudsperson who will initiate probes of misconduct allegations while protecting whistleblowers. In addition, to speed up future investigations, the new rules state that—wherever possible—primary research data must be stored for 10 years. This "is probably the one area in which researchers are most careless," says Johannes Dichgans, a neurologist and ombudsperson at the University of Tübingen. Failure to archive research records, or their deliberate destruction, could be judged as gross negligence and hence be punishable.

Some experts are less impressed with the new regulations. Hans-Jürg Kuhn, an anatomist at the University of Göttingen, says that the rules often "state the obvious" while being hard to follow in practice. He is

currently leading an investigation into alleged fraud in a cancer vaccine trial. The inquiry has been going for 16 months and is under mounting pressure from the media and from scientific leaders to deliver a verdict. Kuhn says he is not convinced that the rules, if they had been in place earlier, would have speeded up his investigation, which he says has been thwarted by slow access to patient information. "Privacy protection laws make it virtually impossible to store patient information in a manner that is easily accessible to later investigations," he

GERMANY'S MISCONDUCT DEFINITION

- Falsification and fabrication of data
- Selective use of data without making it explicit
- Manipulation of graphs and figures
- Use of false information in grant and job applications
- Destruction of primary data
- Sabotage of others' work
- Plagiarism

says—and the new rules don't change that.

After 30 June, DFG will assess how institutions have implemented the rules. Peter Hans Hofschneider, a professor emeritus at the Max Planck Institute for Biochemistry in Martinsried who raised the alarm in the Herrmann-Brach case, says that DFG should come down hard on any institution that fails to adopt the rules. "If our efforts to put the guidelines into place are to be taken seriously, the DFG should act decisively," he says.

—ADAM BOSTANCI

INTELLECTUAL PROPERTY

High Court Reins In Patent Pirates

The U.S. Supreme Court has scaled back a controversial lower court ruling that some feared would open the door to wholesale copying of patented inventions. Research universities and some technology firms are applauding last week's unanimous decision, saying it will help protect valuable discoveries. But others say it will do little to reduce the growing number of costly patent fights.

* *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* (www.supremecourtus.gov/opinions/01slipopinion.html).

CREDIT: (LEFT) HERBERT KNOSOWSKI/AP

China's expanding space program



The world's oldest boat?



Model organisms for evo-devo



"The decision is a slam dunk for universities," says attorney Susan Braden of Baker & McKenzie in Washington, D.C., who represented 20 research institutions and academic groups that saw the earlier ruling as a threat to the more than 16,000 patents that universities have won over the past 2 decades. Opponents are also claiming victory, however, saying that the ruling will make it harder for inventors to file frivolous infringement claims. And attorney Dan Bagatell of Brown & Bain in Phoenix, Arizona, who represented technology firms asking the court to uphold the ruling, thinks that the picture is still cloudy. "The patent system as a whole may not be any better off," he says, because the decision still leaves "a lot of uncertainty about what constitutes infringement."

The legal battle—dubbed "the patent case of the decade" by court watchers—focused on a 150-year-old legal concept called the "doctrine of equivalents." The doctrine bars inventors from making minor changes to a patented technology and then claiming it as their own. Companies that have patented proteins, for instance, have invoked the doctrine to prevent competitors from marketing molecules with slightly different amino acid sequences that perform the same biological function.

The decision came in a decade-old case involving a mechanical cylinder made by Festo Corp. of Hauppauge, New York, that has been used in everything from sewing machines to amusement park rides. Festo claimed that SMC Co. of Japan had infringed on its patent by producing a cylinder

that, although not an exact copy, was equivalent to Festo's. Two years ago, a federal appeals court stunned many experts by ruling that the doctrine of equivalents doesn't apply to patent claims that were narrowed during their review by the government. It's a process that most patents go through.

Festo appealed the decision to the Supreme Court, which was swamped by briefs from dozens of biotechnology, computer, and other firms on both sides of the issue (*Science*, 21 December 2001, p. 2460). In general, individual inventors and small companies said the lower court ruling left them with few options for battling infringement, whereas companies with vast patent estates backed the decision because it clarified their vulnerability.

In a 17-page opinion, Justice Anthony Kennedy handed Festo and its allies a partial victory by declaring that the earlier ruling went too far. Because "language remains an imperfect fit for [describing an] invention," Kennedy wrote, the holders of narrowed patents should still be able to employ the doctrine of equivalents to fight infringement. But the justices also put more of a burden on inventors to prove that a competing invention infringes on their discovery. In sending the case back to the lower court, the justices also hinted that Festo might lose to SMC under the tougher standards.

Overall, the decision "enhances the economic value of patents" and restores to judges the leeway to decide infringement claims on a case-by-case basis, says attorney Edward W. Gray of Fitch, Even, Tabin, & Flannery in Washington, D.C. That is good news for critics of the earlier ruling, who warned that it could undermine 1.2 million existing patents—including university patents that have generated more than \$4 billion in income.

But Bagatell says the high court gave little comfort to corporate executives who would like to know if a new technology might be covered by someone else's patent before they invest in it. Uncertainty about the outcome of a doctrine-of-equivalents claim, he adds, might cause companies to pay up on even weak legal challenges to avoid further litigation. The justices were willing to accept such costly uncertainty "because they believe that the [patent] system works and promotes

innovation," says Braden. Applying the doctrine of equivalents "is an art, not a science," she adds, a warning to scientist-inventors that going from discovery to commercialization might include a roller-coaster ride.

—DAVID MALAKOFF

BIOMEDICAL RESEARCH

Australia Pushes Stem Cell Advantage

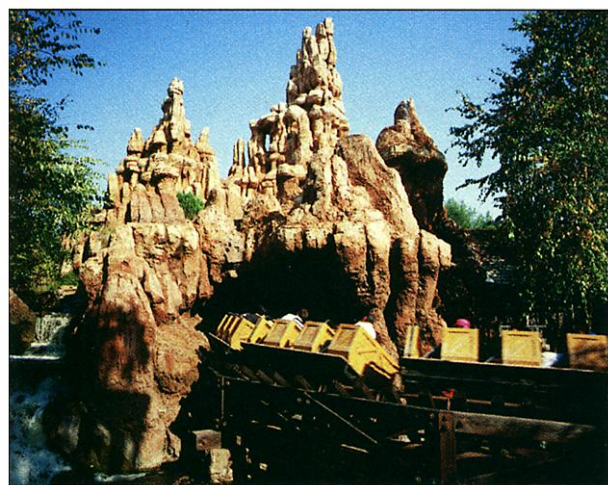
SYDNEY—Australia's new policy on embryonic stem (ES) cells has already started to pay big dividends for researchers. Last week the government announced that it will invest \$25 million in a new Center for Stem Cells and Tissue Repair at Monash University in Melbourne that will work to develop therapies for blood and tissue diseases based on new and existing ES cell lines. "We want to take stem cells all the way through to the patient," says cell biologist Alan Trounson, head of the Monash Institute of Reproduction and Development and director of the new center.

The center, a consortium involving some 300 scientists at a dozen institutions, won a stiff competition to become the country's first National Biotechnology Center of Excellence. (Last month the government also selected a center of excellence in information and communications technology.) The biotechnology center is a direct outgrowth of an agreement struck 2 months ago in Canberra between federal, state, and territory leaders to allow scientists to work with established ES cell lines and derive new cell lines from surplus in vitro fertilization embryos created before 5 April (*Science*, 12 April, p. 238).

Those rules are much less restrictive than the ones federally funded U.S. researchers have to follow: They can use ES cells only from cell lines created before 9 August 2001 (*Science*, 17 August 2001, p. 1242). Curt



All smiles. Prime Minister John Howard (left) and Monash's Alan Trounson welcome new center.



Legal roller coaster. This amusement-park ride at Disneyland uses a technology that is at the center of a high-stakes patent fight.

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