

Biotechnology at the bar

Science is moving too fast for the legal system to keep up. But lawyers and scientists have a solution — a body that would help courts tackle cases involving the latest research. Nicola Nosengo investigates.



Italian judge Amedeo Santosuosso and biologist Carlo Alberto Redi (far right) talk to judges and scientists at the University of Pavia.

This October, Franklin Zweig will face one of the most difficult cases in his career as a judge. A radioactive, mercury-laden waste sludge has been deposited on both banks of a river that forms the border between two countries. The heavy metal is seeping into nearby water sources, which supply hundreds of thousands of people.

One country wants to apply a genetically modified, radiation-resistant bacterium that can immobilize the mercury. But on the other bank, activists who fear the transgenic bacterium more than radioactivity and heavy-metal poisoning have asked a court to block the project. "How can a judge obtain the scientific information that is necessary to resolve such a case?" asks Zweig.

Luckily, this case is hypothetical — an imaginary scenario designed to test the International Science and Technology Reference Forum, an ambitious initiative developed in response to the increasingly difficult relationship between the law and science, particularly fast-moving fields such as biotechnology. "Discussions between scientists and legal experts have reached a common conclusion," says

Zweig, a former legal adviser to the US Senate. "A new institution is necessary to mediate between science and the legal environment."

Hard cases

Advocates of the forum hope that by providing a permanent team of legal experts and scientists, it will help national courts to resolve disputes like the one described above. Independent advice is needed, says Zweig, because biotechnology is forcing judges to deal with science in a way that they never had to before. He is currently president of the Einstein Institute for Science, Health & the Courts, a non-profit organization in Bethesda, Maryland, which is promoting the new initiative.

Take cloning, for example. If a human is ever cloned, courts could potentially face tortuous questions about the legal relationship between an egg donor, her husband, the person being cloned, a surrogate mother and the resulting child. They might also have to decide what legal rights, privileges and immunities a cloned child could claim in a jurisdiction that bans human reproductive cloning.

Such issues should be resolved in advance by national parliaments, says Zweig. But parliaments are generally slow to act, so policy decisions about emerging technologies are often made in court. This was the case with the long-debated issue of whether patents could be granted for living organisms obtained through artificial genetic modification.

In 1972, Ananda Chakrabarty, a microbiologist at the University of Illinois at Chicago, applied for a patent on a genetically modified bacterium that could break down crude oil (*A. M. Chakrabarty et al. Proc. Natl Acad. Sci. USA* **70**, 1137–1140; 1973). The US Patent Office rejected his request, saying that living things could not be patented. An appeal court reversed the decision, and the case reached the Supreme Court in 1980. In a landmark decision, the court awarded Chakrabarty the patent, declaring that "everything under the sun that is made by man is eligible for patenting". The decision, which was influential in shaping US biotech policy, was made before any specific law had been drafted to address the issue.

The Einstein institute was born just over a



Trading places: Judge Valentina Sellarolli loads a DNA gel (top); Ananda Chakrabarty with the first patent for a living organism, issued in 1981.

decade later, after even more responsibility for scientific law passed into the hands of US judges. In 1993, the Supreme Court imposed upon judges the duty of assessing the validity of novel scientific evidence. One of the new institute's first activities was to provide education programmes on genetics for judges. Since then, the institute has run scientific courses for more than 3,000 judges in the United States, Europe and Asia.

Institute staff soon realized that science was forcing the legal system to depart from its usual mechanisms. Scientific cases often force judges to look forwards rather than back, for example. "Judges typically study previous cases," Zweig explains. "To cope with science, they must try to forecast the future." Science also forces courts to think internationally, as certain issues, such as the spread of genetically modified crops, can be difficult to consider on a national level. "We faced a paradox," says Zweig. "Law is by definition local, but science is by definition global, and so are the legal problems that new technologies inspire."

An informal group of scientists and judges evolved to discuss such issues, and the forum has been developed in part to transform this community into a new international judicial institution. Its members hope that it will act as a kind of supreme court for complex cases involving scientific matters that national courts fail to resolve. If a national court decides to refer a case to the forum, one group of forum members will discuss the case, and their verdict will be reviewed by a separate team from within the forum. Their decisions will be founded upon analyses of the science and technology involved, risk assessment and the ethical and religious values that shape national legislations.

In addition to the courts, private parties and administrative, regulatory and legislative bodies will be eligible for the forum's assistance. Client courts will be free to use or ignore the forum's advisory verdict in resolving a high-profile dispute, and the forum itself will not seek to enforce its decisions. "Its legitimacy flows from independent, neutral knowledge power, not a police power," Zweig says.

The idea is now moving from concept to reality. The United Nations has already agreed to fund the initiative. Next month, the panel from the Einstein institute that is developing the forum will meet at the Missouri Botanical Garden in St Louis. With its collection of transgenic plants, the garden is a perfect setting for the first steps of an institution covering biotechnology law. Simulated case scenarios will be assessed, and foundation documents critiqued. The forum's provisional governing council is due to be elected in March 2004, and the forum could be operational a year later. It is likely to comprise a permanent team of judges, with scientist members acting as part-time consultants.

Independent view

According to Chakrabarty, who is chief scientific adviser to the project, scientists have just as many reasons to be interested in the forum as judges have. The organization might, for example, be asked by governments to produce a neutral assessment of the benefits and costs of technologies such as embryonic stem cells.

But not everyone is convinced that it is the best way forward. Italian judge Amedeo Santosuosso sits on the organizing panel and says that the forum could be particularly useful outside Europe and North America, where courts do not always have access to good scientific experts. But he fears that as a voluntary, non-binding institution, it could face difficulty in getting its verdicts widely accepted.

The rules on its composition, which are still to be decided, will be crucial, he says. He thinks that the forum will need a broad range of participants if it is to be perceived as neutral, independent and fully representative, but fears that too many members will make it inefficient. Potential problems like these are to be discussed at the St Louis meeting.

In the meantime, Santosuosso is promoting the European Network for Life Sciences, Health and the Courts, formed this June, and based at present at the University of Pavia in Italy. The network brings together legal experts and scientists from European countries, and organizes courses, seminars and conferences where judges and scientists can meet. Together with Carlo Alberto Redi, a developmental biologist at the University of Pavia, Santosuosso recently organized a science course where 12 judges spent a week at Redi's laboratory, working side-by-side with researchers and becoming acquainted with techniques such as DNA testing.

Bench law

"We were trying to make judges aware of what a scientist's work actually is," says Redi, "so that when they have to decide whether an expert opinion is acceptable, or whether an experiment is breaking the law, they know what goes on in a laboratory." Redi speaks from experience. In 1998, after members of his laboratory participated in the experiment that led to the first cloned mouse (T. Wakayama *et al.* *Nature* **394**, 369–374; 1998), he found the police waiting at the lab. At the time, Italian legislation banned any form of cloning, and the fact that the experiment took place in Hawaii did not spare Redi's team from police questioning.

The initiative will be extended elsewhere in Italy, and similar courses will start next year in Germany, Spain, Norway and Switzerland. "In the long run, smaller initiatives can be even more effective than the international forum," Santosuosso says. "They create opportunities where the world of life sciences and the world of law actually work together."

While acknowledging the importance of local initiatives, Chakrabarty points out that problems that defy national boundaries are best addressed by a permanent international body. He also acknowledges another potential problem: some parties may refuse to use the forum if they think scientific opinion will not back their case. Chakrabarty says this likelihood should be minimized if the forum tries to acknowledge all shades of scientific opinion, and allows the scientific evaluations to be filtered by its judicial members, who will take into account the economic, ethical and political angles of a dispute.

So will the forum succeed? With United Nations support, and a track record of dialogue between the legal and scientific communities, its backers are well placed to make sure it does. Zweig, for one, is in no doubt about the need for the forum. "Biotechnology is pushing society into a new area," he says, "where the letter of the law is grey, not black." ■

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Einstein Institute for Science, Health & the Courts

◆ einshac.org/EINSHAC_FRAME.html

European Network for Life Sciences, Health and Courts

◆ www.unip.it/BIOL/ENLSC.html