IN brief

Conflicts of interest go online

EMA transparency

In October, the European Medicines Agency (EMA) launched a new database aimed at increasing the transparency of expert advisors' financial ties to industry. The new policy is a reaction to accusations that EMA was not complying with EU legislation that states that members of its scientific committees and expert advisors should not have financial or other interests in the pharma industry that could affect their impartiality. The French government is also considering a law that would fine experts who advise the government on medical treatments up to €30,000 ($40,000) for failing to disclose any conflicts of interest. The US is taking the opposite stand, with the US Food and Drug Administration facing pressure to loosen conflict-of-interest rules (see page 1062). But in Europe, industry and the scientific community largely applaud the new policy. "There is no way other than full transparency," says Richard Bergström, director general of the European Federation of Pharmaceutical Industries and Associations. The EMA now requires all advisors, and scientific experts serving on any of EMA's committees (and their families) to declare annually any direct or indirect financial ties to industry or any other conflicts of interest. Previously, declaration forms were only available from the agency by request. Now they will be posted on the EMA's website and can be searched alphabetically or by country. But Bergström is concerned over how restrictions will play out in practice. Industry ties don't necessarily represent a conflict of interest, he says. To become an expert in clinical research, for example, one must have been involved in studies that are usually funded by industry, he adds. The agency will rank committee members into risk categories ranging from 1 to 3, with 3 being the highest risk category applicable to experts with direct financial ties to industry anytime within the past 5 years. Being classified in the highest risk category won't necessarily exclude an expert from EMA activities, however, but may severely restrict their participation. Although the risk ranking will not be made publicly available, Tony Mayer, member of the Euroscience Governing Board and specialist in research integrity says, "Assigning risk levels is a reasonable way of managing risk in this situation." The new database lists approximately 5,000 experts, but so far only about half of the entries include declaration-of-interest forms. EMA expects to publish the remaining forms over the next several months. *Gunjan Sinha*

Aidan Courtney, CEO of Roslin Cells in Edinburgh, Scotland, takes a more optimistic view, stating, "I think everyone always thought it was going to be impossible to get patents on hESCs; the CJEU ruling clarifies this, and clarity is good. And there are many ways to build a defensible product—through process, data and marketing authorization."

Some others have suggested a positive outcome for European researchers. Removing intellectual property rights will make it easier for investigators, as they need no longer worry about infringing any patents. But as Andrews points out, this "insidious" ruling could lead to more secrecy and become a barrier to research. "Remember patents give you commercial rights, but you are required to disseminate information and show how you have done what you claim," he says. Of course, European companies can still get patents in the US and Asia, but Johan Hyllner, CEO of Cellartis AB of Göteborg, Sweden, which owns 30 proprietary hESC lines, says, "It will certainly mean some patents are never applied for: if you patent in the US you will have to give out information that you could keep as a trade secret in Europe."

Rob Buckle, head of regenerative medicine at the UK's Medical Research Council agrees that any greater freedom to operate comes at the cost of greater secrecy, though he notes that UK guidelines require researchers who are licensed to carry out hESC research to disclose information and deposit any cell lines they derive in the UK Stem Cell Bank.

Whether the taint implied by the ruling will make academics go elsewhere to pursue their work remains an open question. Andrews thinks people will remain undeterred, providing research funding is available. Buckle points out that the UK Medical Research Council–funded research should remain unaffected. In his view, the CJEU is not saying research in hESC is unethical; "it's a statement about patentability," he says. Following the ruling, the MRC announced it is sticking to its plan to put £130 ($205) million into stem cell research and regenerative medicine over the next four years.

> "The critical thing is that this ruling is not allowed to destroy investor sentiment."

In the 1990s, the UK made great play of attracting two leading US academics Roger Pedersen and Stephen Minger to the country on the back of its liberal regime and the availability of public funding. But Buckle adds that "scientists move anyway for all sorts of reasons—[public] investment being one of these." Brüstle agrees the question of whether research will shift away from Europe will boil down to personal decisions. In Germany, despite federal funding for translational research on hESCs, there has been no show of support for hESC research. Indeed, he notes that even the

Timeline for the demise of the Brüstle patent

The CJEU will not decide the dispute over Brüstle's European Patent 1040185 itself, but will refer it back to the Bundesgerichtshof to rule in accordance with the ECJ's decision. The CJEU's judgement is binding on the national courts of all 27 EU member states when dealing with any related cases. The chronology of 1040185's demise is shown below:

1997 Oliver Brüstle files a patent on a neuronal precursor cell derived from hESCs.
1998 The European Directive on Biotechnology (Directive 98/44/EC), intended to harmonize legislation on "patents on life" across Europe, comes into force.
September 1998: Brüstle's patent 1040185 issued by European Patent Office 1999.
2004 Greenpeace contests the patent on the grounds it is immoral.
2006 Germany's Bundespatentgericht (Federal Patent Court) rules the patent invalid.
2008 Separately, in a case relating to the University of Wisconsin WARF patents, the European Patent Office rules that products involving the use of a human embryo cannot be patented.
2010 Following an appeal by Brüstle to Germany's Bundesgerichtshof (Federal Court of Justice), the case is referred to the CJEU, which is asked to define the term human embryo, as laid down in the European Directive on Biotechnology.
March 2011 A preliminary opinion from the CJEU on the Brüstle case holds products based on embryonic stem cells cannot be patented.
October 2011 The final ruling from the CJEU confirms this opinion saying, "The Court holds that an invention is excluded from patentability where the implementation of the process requires either the prior destruction of human embryos or their prior use as base material." **NM**