

tuberculosis', said Eric Nuermberger from the Division of Infectious Diseases at Johns Hopkins University, USA. There are now several new compounds active against *M. tuberculosis* in mouse models in the drug discovery pipeline that need to be fully assessed, he said. Further animal studies 'will need to focus on the efficacy of novel combinations of these new compounds that include one or more first-line TB drugs and/or the new methoxyfluoroquinolone moxifloxacin'.

Tuberculosis causes two million deaths per year, according to the Global Alliance for TB Drug Development. Tuberculosis and HIV epidemics fuel one another and at least 11 million adults are infected with both pathogens.

#### Reference

- 1 Andries, K. *et al.* (2004) A diarylquinoline drug active on the ATP synthase of *Mycobacterium tuberculosis*. *Science* doi: 10.1126/science.1106753 (E-pub. ahead of print; www.sciencexpress.org)

## German stance on gene patenting at odds with the rest of Europe?

Kathryn Senior, [kathsenior@onetel.com](mailto:kathsenior@onetel.com)

In December, the Bundestag (lower House of Parliament) in Germany approved a biotechnology amendment to limit patent protection on human gene sequences. The limit means that a patent awarded under German law to a researcher on a human gene sequence used for a specific function would not cover a second function of the same gene, discovered later by a second researcher, according to Joseph Straus, Managing Director of the Max Planck Institute for Intellectual Property, Competition and Tax Law (Munich, Germany). This, Straus has said, contradicts the intent of the European Union (EU) Directive to give full patent protection to the discoverer of the human gene sequence.

German gene patenting law is subject to the Biotechnology Directive No. 98/44/EC, which governs all member EU states. This

means that in principle it does allow the patenting of gene sequences but, in order to be patentable, the 'inventor' must be able to identify the protein sequence for which that gene codes and must be able to state a possible commercial use for it, explains Eike-Henner Kluge (University of Victoria, British Columbia, Canada). Legally, in Germany as well as the USA, a technologically isolated gene sequence can be patented but a 'naturally' occurring gene sequence or a naturally occurring organism cannot.

#### Criteria for patentability

The EU, the USA and all countries agree that there are three central requirements for patentability: novelty, non-obviousness and usefulness, Kluge continues. 'Gene sequences can be patented but only if the protein encoded can be identified,' he says. Kluge disagrees with Straus' assertion and believes

that the new law passed by the Bundestag does not alter this specific and central aspect of EC Directive 98/44. 'What it does is limit the extent of the patent protection that Germany will recognize to only those functions of the gene that are specifically identified at the time of patent application' says Kluge.

#### A sign of discontent

Hans Radder (Faculty of Philosophy, Vrije Universiteit, Amsterdam, The Netherlands) observes that the extension of patent laws and regulations to the area of biotechnology during the last decades has led to a great public interest in the issue of patenting. 'The problem is that there is a gap between what has been actually invented and the scope of protection that is being claimed in the patent – the consequences of this are visible tensions in patenting practice' he says. This gap is very obvious in the case of product patents and broad patents, two types of patent that occur frequently in the area of biotechnology. 'I see the new German law as a legitimate expression of discontent with this practice of overbroad and unjustifiable patent claims,' he says.

#### A global law?

Looking beyond the specific German amendment, Kluge would like to see a globally binding law that deals with international patenting in general and with the patenting of genes in particular. 'At the present time, gene patenting is regulated through multilateral treaties, which lack a cogent logical as well as ethical basis, and this will need to be addressed,' he concludes.