French refuse to implement biotech patent directive

The deadline for the European Union (EU) member states to alter their national law in line with the EU 98/44 directive on the legal protection of biotechnological inventions was July 30, but France is refusing to comply. Even though France originally ratified the directive, opponents within the French government now claim that some of its wording could be misinterpreted to allow patenting of raw DNA without knowledge of its utility. Industry representatives fear the controversy, which highlights the importance of national debate, could damage an already weak biotech industry.

The 98/44 directive describes patentability of biological material. It stipulates that only those DNA sequences that constitute an invention—that is, that show utility—can be patented. According to paragraph 3 of article 5, "The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application."

However, French MP Jean-François Mattéi claims some of the wording in paragraph 2 is too vague and open to misinterpretation. Specifically, "An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene may constitute a patentable invention, even if the structure of that element is identical to that of a natural element." Mattéi is calling for the directive to be changed so that it allows the patenting of "a process or a technique using an element isolated from the human body," as opposed to an "element isolated from the human body."

Mattéi sparked the current controversy in April 2000, when he (and a German counterpart, Wolfgang Wodarg) launched a petition calling for the directive to be altered before being implemented. (By July 15, there were about 7, 000 signatories, including former Science Minister Hubert Curien, and Nobel Laureate Bernard Barataud, head of Cystic Fibrosis Patient's organization AFM.)

On June 7 at the National Assembly, Justice Minister Elisabeth Guigou added that the directive, which will override national law, is "not compatible" with existing French legislation, specifically "the 1994 bioethics law, the industrial property code, and the civil code, which forbid commercialization of the human body."

And the National Consultative Ethics Committee (Conseil Consultatif National d'Ethique; CCNE) got in on the act on June 14, calling for a renegotiation of the directive so as to allow researchers free access to human genes. CCNE argues that, as well as risking "instrumentalization of the human body," granting gene patents will significantly slow down research in France. "We risk being in the same situation as if the four letters of DNA—A, C, T, G—could have been patented. Genome sequencing would have then been impossible," explains Thierry Jean, chair of the French drug discovery company Cerep.

The 98/44 directive has existed since 1998, when the EU member states—including France—settled on and voted in the directive after 10 years of negotiation and two re-drafts. Opposition is emerging only now, says Mattéi, because at the time there was no public discussion about the directive in France.

That may be so, but it is the responsibility of national governments to ensure their country is informed, points out a commission official for the EU Internal Market directorate: "There is no excuse if they vote for something and turn around and say no afterwards."

Johnathan Todd, spokesperson for the EU Internal Market directorate agrees. "The European Commission has no intention of renegotiating the directive."

In any event, the French protest seems somewhat misguided for several reasons. For instance, claims that patents will thwart research illustrate misunderstanding of the purpose of a patent, says Bo Hammer Jensen, head of the EuropaBio task force on intellectual property. "This feeling that. . .you should not be able to patent DNA molecules lies in false understanding of what a patent is," he says, "You cannot use a patent to limit people's ability to do research."

Moreover, it is already possible to patent some DNA applications under existing French patent law, which was based on the European Patent Convention before the directive was even formulated. "The patenting of DNA molecules is not prohibited by law for applications such as genetic diagnostics," says Jensen. However, the terms of patenting DNA are not clearly specified. What the directive does is actually clarify these terms, explicitly requiring disclosure of utility for patents on DNA sequences. "There is a need for [this] clarification in order to show that the patent law is not a property right but a right on an invention," says Martine Hiance, director of the French Patent Agency INPI (Institut National de la Propriété Industrielle).

The French bioindustry fears that without the biotech patent directive and the clarification it provides, French biomedical R&D will suffer significantly. Although, technically, the directive could still prevail in France via Europe-wide patents granted by the European Patent Office, such patents could be subject to revocation proceedings for non compliance with national law, says Jean-Philippe Muller, patent examiner at INPI.

Biotechnology in France is already at a competitive disadvantage because of the country's lack of entrepreneurial culture and its strict finance and tax laws. Lack of intellectual property protection would further damage growth of the industry by putting a stop to R&D revenues generated from licencing. According to Pascal Brandys, chairman of the bioindustry association France Biotech, "[A moratorium on the directive] would kill the French bioindustry at embryonic stage while it is already considerably handicapped in comparison with its American, British, and German counterparts."

Meanwhile, France could be penalized by the European Court of Justice (ECJ) for infringement of community law. Although EU member states are allowed to dispute a directive after it has been finalized, they must do so by first implementing the directive into national law and then filing a challenge with the European Court of Justice. The European Commission threatened legal action against France on 8 June for refusing to follow proper procedure. As a result, France could be fined up to € 631,771 ($600,000) by the ECJ for each day the directive is not implemented.

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