/THE FIRST WORD

European Patent Legislation: A Missed Opportunity

Last month, after nearly seven years of talking, drafting, redrafting, committeeing, and codecisionmaking, the European Parliament (EP) voted against a final draft of the Council Directive on the Legal Protection of Biotechnological Inventions [COM(88)496] that, in its original conception, would have laid out and harmonized Europewide rules concerning genetically altered organisms and other biological inventions.

Up to a few weeks before the vote, the legislation's passage was considered a *fait accompli*, as a Conciliation Committee consisting of representatives from the EP, the European Union's (EU) Council of Ministers (CoM, from the EU's 12 member countries), and the European Commission (EC) managed to stitch together what appeared to be an "agreed upon" set of amendments addressing various disputed points at a last-minute meeting in January.

As Mike Ward reported for *Bio/Technology* in February, the main sticking point was the extent to which patents on human body parts would be allowed. The EP wanted to ban patents on all body parts, while the CoM and the EC wanted to ban patents on body parts "as such"—which would have left the door open for patents on cells, genes, and proteins that are isolated from the body.

At the January meeting, EP members backed down and agreed to the CoM/EC position. But they asked for, and got, a clause stating that patents will only be awarded for inventions that include "industrially applicable body parts obtained in a technical manner," rather than for the body parts themselves. This language was a curious addition, as patents can only be granted if an invention has novelty and industrial application, so the EP must have had some extra meaning in mind.

The EP also asked for, and got, stronger language on policing gene therapy and animal suffering, as well as an agreement to incorporate any future laws on the rights of farmers to use patented animals for their own use without paying licensing fees into the directive.

It seemed then that, through its representatives on the Conciliation Committee, the EP got what it wanted and all conditions were go. So what happened?

Several things, the first of which was a procedural failure: The role of the Conciliation Committee in relation to the EP was not defined. Do EP representatives speak for the EP as a whole, or only for their own constituents, when they are part of a Conciliation Committee?

Second, special interest groups hijacked the legislation at the last minute. They just happened to be the wrong ones. The "no" vote is being touted as a victory by the Greens and an assortment of other groups who pinned their special needs on this legislative piñata very securely.

Third: European biotech lobbying groups, of which there is no shortage, failed to make, and maintain, their case. The original point of the patent directive in 1988 was to protect European inventors and investors as the U.S. Patent Office took a stab at protecting U.S.-derived biotechnology inventions. Social and political issues were allowed to overwhelm the original legal and economic agenda. What began as patent legislation came to be about farmers' privileges and animal "rights" and questions of the value and dignity of human life. These are all certainly issues that need to be addressed, but not in patent legislation. Where were various biotechnology advocates when the directive needed to be pushed back on course?

While some have now taken the position that this is a blow to the industry, others claim it doesn't matter much at all—it was merely a tidying-up exercise, case law will continue to provide the foundation for biotechnology patent protection, and business will continue as usual. Perhaps so, but I would argue that the setback is that biotechnology has still not figured out how to tell its story convincingly. In this instance, it has not been able to contain disagreement, much less obtain agreement or consent. It will have to do better with the oncomouse appeal before the European Patent Office later this year.

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