

Welcoming Address

**of the Federal Minister of Education and Research
Edelgard Bulmahn**

on

**the Opening of the BMBF/OECD Conference
"Genetic Inventions, Intellectual Property Rights
and Licensing Practices"**

in Berlin

on January 24, 2002

Ladies and Gentlemen,

I welcome you to the conference "Genetic inventions, intellectual property rights and licensing practices" at the Federal Ministry of Education and Research. I am pleased that the OECD has accepted my invitation to organize this meeting in Berlin and would like to welcome Mr. Dryden, OECD Deputy Director of the Department for Science, Technology and Industry, as well as Mr. Gillespie and Ms. Callan, who have organized this meeting with great commitment. Thank you very much for your efforts.

Last year, the OECD has taken up once more the topic of patenting of biotechnological inventions after having published some important publications on this topic in the 1980s and early 1990s. I would also like to give a warm welcome to Professor Straus of the Max Planck Institute for Patent Law in Munich, who participated even in the early phases of this work. I would also like to thank you for your support and cooperation in the organization of this conference.

Why, then, has the OECD taken up again the issue of patenting of biotechnological inventions at this moment? – There is one main reason: Since the early 1990s, the life sciences have made tremendous progress. A highlight of this development was the decoding of the human genome in June 2000.

On the one hand, this progress has aroused high **expectations**. Expectations of being able to better treat severe and often still incurable diseases, such as cancer or cardio-vascular diseases by understanding their genetic origin and to develop new forms of prevention, diagnosis and therapy.

On the other hand, it is **feared** that research necessary to develop new and, above all, low-cost drugs might be hampered or even blocked if a few companies hold far-reaching patents on individual genes.

A core issue of the current discussion is the question of the necessity and scope of so-called **product patents**. How far-reaching must patent protection for biological material be in order for companies to reap the benefits of developing and marketing new products? And how tight must the limits be in order not to hamper research by others?

Under **German patent law**, the **patenting of substances is permitted in principle**. Court rulings have reconfirmed this time and again: An inventive merit, particularly in the area of costly biotechnological research and application, must pay off for companies. And there must also be an economic incentive for discovering a substance and its function.

Companies are prepared to make big investments in research and development only if they can be sure that, in the end, they will be able to make a profit from the marketing of new products. Uncertainty in this point would lead to a situation where industrial research would be restricted or would not even be taken up in the first place.

A standstill in health research, however, would mean a step backwards. We cannot and do not want to allow this to happen in such an important and sensitive area. I want to make this absolutely clear.

An important step in answering the question of how far-reaching product patents should be was taken by the European Union in 1998 through its **Directive on the legal protection of biotechnological inventions**. Under this directive, the discovery of a gene or the isolation of a gene sequence alone are not patentable. **Patents are only granted for inventions, i.e. only in connection with the discovery of a specific function of a gene or gene sequence**. The possible commercial use must be described in detail in the patent application.

The crucial point is that the gene alone cannot be patented. It remains free for research.

In incorporating the EU directive into national law, the German Parliament wants to **further clarify the need for a patent to relate to functions** and thus create greater clarity for researchers and companies. I am confident that the Bundestag will soon pass the incorporating law.

A development similar to that in the European Union can now be seen in the US. The American patenting authority (USPTO, US Patent and Trade Office) last year amended the provisions for patent examination and now demands of gene patents "to claim a specific, substantial and credible utility". It is therefore expected that the US authority will no longer grant as far-reaching biopatents as in the past.

This shows that in the US as well as in Europe, we are following the right path. With clear provisions we ensure **that researchers – without being hampered by far-reaching patents – can work on genes and can actively pursue the development of new drugs and therapies. And companies are given the certainty that they can reap the benefits of their R&D investments.**

Ladies and Gentlemen,

There is hardly any other legal text which is of equal interest to the European public and has polarized it as much as the **Directive on Biopatents**. Some impatiently await its incorporation into national law, others dread it.

For me, the **benefits** of this Directive are obvious:

It gives researchers leeway.

It provides companies with legal certainty.

In addition, this directive is the precondition for an EU-wide harmonization of patenting of biotechnological inventions. This is beneficial to biotechnology companies, which mostly act with Europe-wide or worldwide operations, which therefore need patent protection for their inventions not only at home but also in as many other countries as possible.

However, we should also listen to **sceptical voices**. A number of countries are still hesitant to incorporate the Directive into national law. The reason for this is often uncertainty about the effects on industry, research and the healthcare system of a patent law harmonized in a European framework. Ethical reservations about patenting of genes, of human genes in particular, which might be important for medical treatment, also play a role.

But public discussion in these countries is characterized by arguments pointing to possible consequences rather than to facts. The discussion therefore remains speculative and statements are difficult to disprove.

Speculations are no good basis for political action. What we need is **facts** providing information on how patenting and licensing of inventions works and where there are possible weak points. On the basis of thorough analysis, **recommendations for political action** can then be developed. The OECD has always tried to make facts available to and usable by political decision-makers. This is one of the reasons why you are here today.

In almost all OECD countries, there is now practical experience with patenting and licensing of biotechnological inventions. We must make better use of this experience in order to give sound answers to the essential questions:

- Do too far-reaching patent claims actually hamper research?
- Do they prevent work in areas in which there are already many patents?
- Or do they perhaps draw researchers' attention to new areas which have so far been little studied?

- And how far should claims go which we grant patent holders?

Answers to these questions will be the basis for a fact-based discussion on the pros and cons of different provisions, for specific recommendations for action and therefore also for setting the future political course.

I am looking forward to the results of this conference.

I would like to thank you all for participating in the conference and wish you good and interesting talks which will be an enrichment to all of you and provide new impetus to the discussion on biopatents.