

## Report Session IV



### Policy of the European Commission in Intellectual Property Matters

Moderator and Speaker: Martin Sick NIELSEN  
(Lawyer, Denmark)

Speakers: Mirjam SÖDERHOLM  
(European Commission, IP Unit-MARKT/D-2, Belgium)

Thomas SEUSS  
(European Patent Attorney, Schering AG, Germany)

#### Summary:

The purpose of the session was to provide the delegates with an update on the current initiatives of the European Commission within the field of intellectual property. Further, the sessions included the viewpoints of an industry representative as a basis for a discussion of the adequacy and sufficiency of these initiatives.

#### Mirjam SÖDERHOLM

From the perspective of the Commission it is in the common EU interest to get the regulatory framework right so that innovation can thrive, and a balance between rewarding innovation and competition can be achieved.

This is confirmed in the Lisbon strategy, according to which innovation is crucial for the competitiveness of European industry and economic growth, and that EU consequently has an imminent need to promote innovation.

Taking this into consideration, the Commission finds that

- 1) An agreement on the Community patent remains vital
- 2) It is necessary constantly to strive for a simplification and improvement of the regulatory framework (to provide "better regulation"), and
- 3) The enforcement of IPR is more important than ever, in particular as part of the ongoing combat against counterfeiting and piracy.

*But how well is Europe doing?*

With respect to the draft directive on the patentability of computer implemented inventions, the Commission proposal was rejected by the European Parliament 6 July 2005 with an overwhelming majority.

The Community patent is a major single initiative under the Lisbon strategy. According to the common political approach of 3 March 2003, the costs of a Community patent for 25 member states (translations costs combined with annuity fees) would be no more than the costs of an EP patent in 5 countries, but irrespective hereof a final agreement on the Community patent in the Council is still missing. The reason for the missing decision seems to be two outstanding issues on translations, namely the legal effect of incorrect translations, and the time for filing translations.

Already in 1998, the OECD estimated counterfeiting and piracy to be between 5 and 7% of world trade, and between 1998 and 2004 the seizures of counterfeit goods made by EU customs have increased by 1000% with the consequence of lost business, jobs, taxes, etc.

To counter this challenge the Commission has not only amended the Customs Regulation (EC 1383/2003), but also laid down an IPR Enforcement strategy towards third countries, and adopted the Enforcement Directive (04/48/EC).

No criminal sanctions are included in the Enforcement Directive, but the Commission has supplemental to the Enforcement Directive proposed a Criminal Sanctions Directive and a Framework Decision in July 2005. The ECJ has confirmed (C-176/03) that criminal measures can be included in Community instruments when this necessary to enforce the Community policy.

The effort of the Commission to improve the enforcement of IPR generally and to combat counterfeit and piracy specifically will be an ongoing effort.

### **Martin Sick NIELSEN**

Complementary to the presentation of Mirjam SODERHOLM, the following initiatives of the Commission was outlined:

#### *Regulation on compulsory licensing*

On 29 October 2004 the Commission has proposed a regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, which is expected to be adopted in October or November 2005.

The proposal is an implementation of the Doha declaration on the TRIPS Agreement and public health, and the decision of the WTO General Council on implementation of paragraph 6 of the same with a view to obtain uniform rules in the EU, and direct and immediate application in each member state.

According to the proposal it is possible to obtain a compulsory license on patents and SPC's for the manufacture and sales of pharmaceutical products intended for export to WTO member states affected by public health problems, if negotiations with the patent holder to reach a license on reasonable commercial terms have failed.

#### *Amendment of Fee Regulation*

As part of a general review of the CTM System and already preceded by amendments of the CTMR and CTMIR, the Commission had proposed an amended of the Fee Regulation with a view to fix the fees of the Office at such a level that the revenues thereof is sufficient for the budget of the Office to be balanced.

The proposal was reducing in particular filing and renewal fees, and increasing in particular opposition and invalidation fees, but met substantial resistance in particular from certain member states.

On 20 September 2005 a revised proposal was agreed upon in the Committee on Fees, etc. The revised proposal must formally be adopted and published by the Commission, but is expected to enter into force before 1 November 2005 from which renewal fees can be paid to the Office.

The new fees are available on the website of the Office at [www.oami.eu.int](http://www.oami.eu.int).

### *Amendment of Design Directive*

In accordance with the Design Directive the Commission has submitted an analysis of the consequences of the directive for industry, and proposed an amendment of the directive to complete the internal market with respect to what effectively means spare parts.

The analysis concludes that excluding design protection in the aftermarket for spare parts is the only effective one to achieve an internal market, and in accordance herewith the Commission has proposed a new Art. 14 (1) of the directive, which corresponds to Article 110 (1) CDR, and a new Art. 14 (2) to ensure that consumers are duly informed about the origin of spare parts.

### *Collective management of copyrights*

In the past the Commission has been very active in harmonizing substantive copyright law, and a recent review of the current regulatory framework has concluded that no revision, but only a fine-tuning of certain issues is required.

On this basis the Commission has now turned its focus on how copyright is commercially exploited, in particular on how the collecting societies work, and prepared a study on a Community initiative on the cross-border collective management of copyright.

The very preliminary proposal of the study is to give right-holders the choice to authorize collecting societies of their choice to manage their online rights for the entire EU.

## **Thomas SEUSS**

From an industry viewpoint the basic requirements for an IP system can be described as follows:

- 1) legal certainty (prosecution, registration, invalidation and enforcement)
- 2) protection of all kinds of intellectual property (patents, copyrights, trademarks, designs, etc.)
- 3) reasonable costs for all proceedings
- 4) speed of proceedings (prosecution, registration, invalidation and enforcement)
- 5) effective enforcement (incl. preliminary and cross border injunctions)
- 6) effective defences

### *The Community patent*

The key problems, which block the adoption of a Community patent are:

- 1) languages
- 2) court system (for enforcement and invalidation)

The EU needs an answer to the question of languages. As much as cultural diversity including language diversity is appreciated, it is unacceptable that patents require translation into in all languages. As outlined above legal certainty combined with reasonable costs is required.

And what about the court system? The last proposal was to provide for a central European court that hears all cases of infringement and invalidation. However, there must be a way to include the knowledge and experience of the existing European courts in the Community patent system. Otherwise the existent experience would become lost, which would be an incentive not to use the Community patent system as the users would be scared of the legal uncertainty following from the lack of experience.

### *Biotechnology directive*

The directive was discussed for more than 10 years until adopted in 1998 with a deadline of two years for the member states to implement the directive in their national laws. In some member states an intense debate started resulting in delays of the implementation. The ECJ had to confirm the directive in a dispute raised by the Netherlands and Italy, and the Commission had to bring legal actions against other member states not implementing the directive in time.

On 28 February, 2005 – almost 5 years past the deadline for implementation – the directive has finally been implemented in German law, but in a way which deviates from the directive in that “gene sequences or partial sequences that are identical to natural human genes” are excluded from patentability. The Commission cannot be blamed for this deviation, it is however interesting that the Commission remain silent on this issue even in its report of July 2005 (the so-called Art. 16C-report) and seems to be satisfied with the German implementation of the directive.

The same is the case for France which has deviated from the directive in an even more complex way when implementing the directive in its national law.

From an industry point of view, this lacking harmonisation is dissatisfactory, and it provides legal uncertainty.

### *The Doha declaration on “Access to Medicine”*

It is important to give people in all countries access to medicine, but is intellectual property the main reason why people from third world countries are prevented from being healthy?

The health problems of the third world are not obesity and not erectile dysfunction. The real problems are infections, tuberculosis, malaria, diarrhoea, cholera and others – all of them treatable with medicines that are off-patents for a long time. The reasons for these diseases still existing is therefore more likely the lack of infrastructure, knowledge on prevention and treatment and financial resources to buy even the cheapest medicine.

The only exception to this is HIV. Modern anti-retroviral medicine is usually protected by patents and it is expensive, but the pharmaceutical industry supports a number of initiatives providing information as well as actual medicine to help the poorest countries.

The concern of industry is that such programs are misused, and even more that a system of compulsory licensing will be misused. Although the intention is good the result might be damaging to industry, and any legislation in this area therefore has to be very carefully drafted and enforced.

### *Enforcement and Anti-Counterfeiting and Piracy Measures*

With respect to enforcement and anti-counterfeiting and piracy measures, the Commission seems to be on the right track.

It is not only manufacturers of luxury products which are affected by counterfeit products, but also the manufacturers of other products, some of which may cause a risk to public health. In certain countries more than 25% of the pharmaceuticals are counterfeit – some with no active ingredient at all or even with toxic ingredients.