Committee on Legal Affairs

Working Group on Intellectual Property Rights and Copyright Reform

Meeting of 26 May 2016, from 14:00 to 16:00

Brussels, room: P6B054

Draft minutes

Mr. Cavada (Coordinator) chaired the meeting.

1. Adoption of agenda.

The agenda was adopted.

2. Approval of minutes of meeting of 16 March 2016.

The minutes were approved.

3. Roundtable discussion on patents, plant breeders' rights and the Biotech Directive / legal protection of biotechnological inventions

The following spoke: Mr Jean-Marie Cavada (Coordinator), Mr Jean Bergevin (Head of Intellectual Property and Fight Against Counterfeiting Unit, European Commission), Mrs Margot Fröhlinger (Principal Director Patent Law and Multilateral Affairs, European Patent Office - EPO), Mr Francesco Mattina (Head of the Legal Unit of the Community Plant Variety Office - CPVO), Mr Philippe de Jong (Partner at Altius, Brussels), Pavel Svoboda, Miron Podgorean (Advisor of the Socialist Group).

Mr **Cavada** introduced the topic explaining that the aim of the meeting was to discuss the issue of the legal protection of biotechnological inventions in light of the recent developments in the field and after the decisions of the Enlarged Board of Appeal of the European Patent Office (decisions of 25 March 2015, G 2/12 (*Tomato*) and G 2/13 (*Broccoli*)). He then added that this raises the issue of legal certainty concerning the prohibition of patentability of products obtained by essentially biological processes and that it seemed important to have the opinion of experts and stakeholders on this complex and technical subject.

Mr **Bergevin** recalled that, under Article 4(1) of Directive 98/44/EC on the legal protection of biotechnological inventions, plant varieties and essentially biological processes for the production of plants or animals are not patentable but that products could be patented. He presented possible solutions: *i*) maintaining the status quo, but we would be left with

uncertainty regarding the patentability of products obtained by essentially biological products; *ii*) reopening the Directive which would imply reaching a new agreement on what is patentable, including discussion on other issues such as human stem cells with the risk of long and difficult discussions; *iii*) a rapid solution could be a Clarifying Notice from the Commission which would give certainty in the market but which has non-binding effect); *iv*) support cross-licensing and cooperation networks and promote the extension of PINTO database; *v*) a mid-term solution, which consists of judgments of the Court of Justice and the future Unitary Patent Office. He finally referred to the Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering published on 17 May 2016.

Mrs **Fröhlinger** presented the issue at stake from the EPO perspective. First of all, she underlined that the Directive 98/44/EC reflects the European Patent Convention (EPC) of 1973, which took more than 18 years to be ratified. Explaining how the Directive had been implemented in the EPC legal framework, she said that the Directive serves as a means of interpretation, including the interpretation by the ECJ which is usually likely to be taken over by the Board of Appeal. As far as plant varieties are concerned, she stressed the importance of the two decisions of the EPO Enlarged Board of Appeal. In the *Tomato/Broccoli I* case (decisions of 9 December 2010, G 2/07 and G 1/08) the Enlarged Board of Appeal stated that a process for the production of plants or animals which is based on the sexual crossing of whole genomes and on the subsequent selection of plants or animals is excluded from patentability as being essentially biological, even if other technical steps relating to the preparation of the plant or animal or its further treatment are present in the claim before or after the crossing and selection steps. In the *Tomato/Broccoli II* case (decisions of 25 March 2015, G 2/12 and G 2/13) the Enlarged Board of Appeal established that, according to Article 53(b) EPC, product claims, and product-by-process claims, directed to plants or plant material such as fruit or plant parts produced by an essentially biological process cannot be denied patentability. At the end, she welcomed a possible Notice from the Commission on the interpretation of Article 4 of the Directive and mentioned the cooperation with CPVO.

Mr **Mattina** recalled that the Community Plant Variety Office (CPVO) was the EU agency granting IPR for plant varieties. He referred to the signature of the Administrative Arrangement between the CPVO and the EPO in February 2016. Its aim is to enhance their cooperation, to further strengthen their relationship through the exchange of knowledge and information in the area of plant-related patents and plant variety rights, as well as on definition of terms (e.g. "variety", "hybrids"). The EPO and the CPVO agreed to a number of measures, which will increase transparency between the two organisations by sharing working practices regarding the use of their databases and other work tools and by organising training activities to increase technical awareness and legal expertise.

Mr **de** Jong, lawyer specialised in patent and plant variety rights, shared his own experience in the field of intellectual property protection for plants innovation. He pointed out that he represented big and small companies for agricultural and non-agricultural innovations and that such companies use both patent system and plant varieties rights system. He stressed the

purpose of the two different systems for the protection of patents and plant varieties and essentially biological processes for the production of plants or animals. According to his own experience, patents are mainly used for ground-breaking innovation, whereas plants varieties rights system is used for more incremental innovation. Under the patent system there are principles and criteria of inventing step, which are not present in the plant variety right system. In addition, there is the criterion of distinctness, which is applied and interpreted very narrowly. He concluded that the protection could be granted more easily under the plant varieties system. However, the patent system is stronger than plant variety rights having regard to the scope, legal certainty (patent specifications vs. ad hoc description in the case of plant variety) and infringements regime (IPR applying to patent). He then explained that breeders are afraid of patent system because of two concerns: *i*) patents block for the breeding work, because using patented biological material is an exclusive right reserved to the patent holder and they cannot use it to do further breeding, and *ii*) due to the Unified Patent Court some Member States are currently adopting or preparing to implementing breeding exemptions. Finally, he referred to the costs of proceedings: patents are more expensive than plant varieties rights.

Mr **Cavada** asked the average time of protection for patents and plant varieties. Mr **de Jong** answered that as far as patents are concerned, it lasts 20 years from the date of application (also considering that to get a patent granted it takes from 5 or longer), whereas plant varieties rights protection lasts 25/30 years from the date of grant.

Mr **Svoboda** realized that there is not any proceeding before the Court of Justice concerning this topic. Then, he requested a basic explanation concerning the distinction between the patentability of the process versus of the product. Mrs **Fröhlinger** explained that in general, patents can protect a process, the end-product (plant) or both. But there is an exception in the area of plant/animal where a process cannot be protected if it is essentially biological. The question is: when does a biological process, by the adding of new technology (e.g. cross and select), cease to be "essentially biological"? In the *Tomato/Broccoli I* case the Board of Appeal held that the process remains a biological process because it is about crossing of genes and despite the use of technology. Then, in *Tomato/Broccoli II* case, the question was not the process but the patentability of the end-product (plant). The question was whether the exception of biological process covers only the process or also the plant. The Board of Appeal decided that the exception covers only the process and not the plant. Mrs Fröhlinger concluded saying that we end-up in a situation where the process is not patentable but the end-product of that process (the plant) is patentable as the breeder's exception must be interpreted narrowly.

Mr **Bergevin** added that this question is at the heart of the debate: what if the end product can be planted and what is the implication of the exception for the process. According to him, originally the legislation wanted to make the two systems (patent and plant variety registration) work together and that is the reason why we have this exception. However, at that time, the Directive did not mention the product. The work of the Commission is therefore to determine if it was implicitly to be covered or not covered, limiting itself to the

elements brought forward in the legislative discussion we had at that time. The Commission will give some clarity and will come up with a Notice. Mr Bergevin said that it is not only a legal question but also a question of market implication and that they will look at different kind of measures to allow the two systems to continue working together in a complementary fashion.

Mr **de Jong** specified that, under patent law, you can protect processes and products; and that none could deny that if the product is new it could be patentable, regardless the process, which is mainly based on crossing and selecting. He also observed that the reason for breeder's exemption and why the essentially biological process was excluded from patent was a political decision in order to allow anyone - breeders- to continue to cross and select.

A Socialist Group's advisor (M. Podgorean) underlined that the two texts (the Convention and the Directive) are similar and he suggested reviewing starting from the Convention. Mr **Bergevin** confirmed that the Commission would focus on the need for clarification.

4. Any other business

Mr Cavada informed that the Working Document on copyright reform had been finalised with the contribution of the political groups and had been approved by written procedure by the Members of the Working Group. It would be presented at the next meeting of the Legal Affairs Committee.