

Intellectual property: Report of the First Meeting of the EU-China IP Working Group

Beijing, 18 October 2005 The first meeting of the EU-China IP Working Group took place in Beijing on 18 October 2005. It was co-chaired by Mrs. Li Ling (Inspector, Chinese Ministry of Commerce) and Mr. Luc Devigne (Head of Unit, DG Trade, European Commission). It involved the Ministries and agencies concerned with the diverse topics on the agenda on the Chinese side, as well as the participation of experts (EU Chamber of Commerce in China) on the European side, in particular for the part of the meeting devoted to Pharmaceuticals (afternoon session). This composition of the Group allowed a focused discussion.

The agenda was divided into two parts:

- one on "horizontal matters" (morning session) where the two main points raised were related to IP Enforcement and IP & Competition;
- one on "sectoral issues" (afternoon session), entirely devoted to the IP problems of the Pharmaceutical sector in China.

The discussion during the afternoon session was more open than during the morning, as China gave signs of true interest in improving its already quite comprehensive IP protection for pharmaceutical products. Concrete suggestions to improve the enforcement mechanisms in China will therefore have to be further examined by the Commission, in connection with all stakeholders.

The outcome of these discussions was as follows.

Horizontal IP issues

• IP Enforcement

The Commission underlined the need to simplify the sanction mechanism available against IP infringements in China. Too many competent - and sometimes competing - players, complex procedures, sanctions very often lacking deterrence, the whole system is complex to use for IP right holders. In particular, criminal prosecution should be improved, on the basis of the Judicial Interpretations on Handling Criminal cases of IP infringement issued by the Chinese Supreme People's Court and Procuratorate in December 2004. Some difficulties in the implementation of this text, such as the basis for calculation of financial thresholds opening way to criminal prosecution of IP violations or the fact that these thresholds are three times higher for companies than for individuals, shall be solved.

The Commission also requested the Chinese government to take resolute action to definitely clean out well known retail or warehouse markets selling counterfeit and pirated goods throughout China. The Commission supports the legal action taken by five European companies of the luxury sector (Prada, Gucci, Chanel, Vuitton, Burberry) against Beijing Silk Street Market. The Chinese side replied that Chinese law holds the market landlord liable for counterfeiting sold on his market, when he is aware of these activities. A first hearing in this case is scheduled in the forthcoming days.

• IP & Competition

In fields such as telecommunications or electronic home appliances, where standardization is a necessity, standards usually include technologies protected by intellectual property rights. Currently, the Chinese companies using technologies detained by European companies are not allowed to enter into negotiations on the amount of royalties due to the latter, when they use their essential patents in the

framework of open standards. The situation is highly detrimental to European companies and their complaint has been reflected in the European Chamber of Commerce in China (EUCCC) - IPR Working Group's Position Paper 2005. The Commission therefore urged the Chinese government to take action in order to ensure that those royalties are duly paid by Chinese companies.

Moreover, the EU side marked its interest in the ongoing adoption of an Anti-Unfair Competition Law and an Anti-Monopoly Law in China, both including some aspects related to intellectual property. The Commission and the European Chamber of Commerce in China were consulted on those texts, in particular on points related to IP, and wish to be kept informed of future developments on them. The Anti-Monopoly Law is now at the stage of being submitted to the State Council, before going to the National People's Congress for adoption. A new draft of the Anti-Unfair Competition will be available soon.

IP in the Pharmaceutical sector

- **Data exclusivity**

Data exclusivity: the protection of confidential test data, given by the drug originator in the course of applying for marketing approval for his innovative pharmaceutical product in China, is provided in article 35 of the Chinese Implementing Rule of Drug Administration Law.

As the functioning of this "data exclusivity" mechanism is not completely clear, the EU side asked China to give consideration to the drafting of guidelines giving details on the scope of products covered, application and approval process. The Commission undertook, in particular, to explain the EU definition of "new chemical entities" covered by the data exclusivity principle.

- **Supplementary protection beyond patent life**

China was receptive to the European "Supplementary Protection Certificate" (Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products). Work will therefore have to be pursued on prolongating the patent life for those products, in order to compensate for the long development and marketing approval periods of time.

The Commission would hope such an addition to the Chinese system to take place, for instance, in the context of the third revision of Chinese Patent Law to come. More generally, the EU side expressed its wish to be closely associated to this patent law revision process.

- **IP infringements**

The Commission insisted on the importance of preventing that products infringing a patent are put on the market. A mechanism of "letters of guarantee" and publication of marketing authorization applications on the Chinese State Food & Drug Administration's website is already in place but considered rather complicated to use. The Commission takes the view that a simple notification to the patent holder (drug originator) when another application for marketing authorization of the same product is made by another company would be simpler to handle for all parties. It would notably be quicker for SFDA, without involving this administration in the potential patent dispute that would stay in the hands of the patent holder and courts.

The fight against counterfeit pharmaceutical products should also be stepped up. The Commission suggested that criminal prosecution be made available against all counterfeiting of pharmaceutical products, irrespective of the quantity of active ingredient found in the product sold, the quantity and value of products sold. All

counterfeiting of potentially dangerous products should fall under the qualification of "serious circumstances" provided in the Judicial Interpretations on Handling Criminal cases of IP infringements of December 2004, allowing the case to be criminally prosecuted without having to meet any financial threshold and, therefore, without checking the value of fake goods.