By Alain Strowel, 3 October 2010

Challenging pharmaceutical patents : a « death spiral » for generic companies ?

I remain puzzled by an article in the Financial Times (1 Oct. 2010) which highlights recent doubts of the US generic pharmaceutical industry with regard to the strategy of challenging drug patents in the courts. The article quotes Mr Paul Bisaro, president of Watson Pharmaceuticals (one of the US's largest generic drug companies) and head of the US Generic Pharmaceutical Association : « Perhaps we have got too good as an industry in challenging patents ». A clear result of the court cases initiated by generics companies is that the period of patent exclusivity, during which the innovator companies can sell at high price, has been considerably reduced. According to Mr Bisaro, drug patents are now challenged within six months of the first marketing of the new drug. (Apparently, the generic companies are even able, in certain cases to have prototype, generic versions of drugs that are not yet on the market.) This seems to have modified the incentives for innovative companies : they now try to get a return on their investment very quickly, before any court can overturn their patents. Originator companies appear now to focus on complex, biologically-based drugs which can not be easily copied by generic companies, as opposed to the more classical chemical-based drugs. More troubling, those originator companies might now be discouraged from developing new drugs, which in turn means that generic companies are destroying their own future source of income. Are the generic companies « eating their own young » ? Is the pharmaceutical industry engaged in a «death spiral » ?

If this analysis and those comments were backed by facts, this could shed new light on the ongoing debate in the EU about the impact of patents in promoting the development of new medicines. This question comes at at time when DG Competition is pursuing its review of the practices in the pharmaceutical sector, in particular the patent settlement agreements and their possible anticompetitive effects. On 5 July 2010, DG Competition released a Report on the monitoring of patent settlements in the pharmaceutical sector (here). It seems that the number of settlements that may be problematic from a competition perspective – those that limit generic entry and foresee a value transfer from an originator to a generic company – decreased significantly (see Commission press release IP/10/887). The 2010 Report on settlements is a follow-up to the pharmaceutical sector inquiry conducted by DG Competition (see the Final Report of 8 July 2009 here). For a summary of the outcome of this inquiry with a focus on patent issues, you can look at my presentation (Pharmaceutical inquiry 2010). Also, a conference on the same topic has been jointly organised by the CIPI of the FUSL and the IEJE of the University of Liège in January 2009 (see programme and presentations here). The 2009 pharmaceutical sector inquiry has been criticised as giving too much weight on short term competition objectives and somewhat neglecting the positive impact of pharmaceutical patents as an indispensable incentive for further research and development of drugs. It is not yet clear whether the erosion of patent exclusivity

has already reduced the level of investment in drug development, but the story about the US generic industry referred to in the Financial Times gives additional food for thought.