

European Commission Criticizes Drug Manufacturers for Anti-Competitive Practices

By Kelly Hoffman

In November 2008, the European Commission issued a report sharply criticizing pharmaceutical companies for tactics used to delay the entry of generic drugs into the marketplace. While the report states that it is not a prelude to a lawsuit against major drug companies, antitrust suits against drug companies may be on the horizon. The Commission focused its criticism on strategies that drug companies use to extend their monopolies after their drug patents have expired.

The Commission observes that generic drugs often cost significantly less than the original medicines, which helps contain public health costs and increases consumer welfare. The entry of generic drugs into the marketplace also encourages drug companies to innovate and develop new drugs.

Generic drugs are unquestionably costly to originator drug companies. The Commission estimates that after a patent expires, generic drugs gain an estimated 30% market share in the first year, and a 45% market share in the second year. For drug companies, delaying the entry of generic drugs into the market can protect their profits by extending their monopoly over the drugs beyond the life of the patent.

The Commission highlights several drug company practices used to delay the entry of generic drugs into the market that it considers anti-competitive:

- **Patent clusters:** Companies file numerous patents for the same drug, in some cases as many as 1,300 patents for the same medicine. Patent clusters make it difficult for generic drug makers to know whether or not they are infringing a patent or when they can introduce generic medicines.
- **Patent Litigation:** Drug companies filed nearly 700 lawsuits against generic companies between 2000 and 2007. Of these cases, 149 ended in a final judgment. Generic companies won the majority (62%) of these cases, but the litigation lasted an average of 2.8 years and further delayed the entry of generic drugs into the marketplace.
- **Settlement agreements:** Nearly half the settlement agreements between originator drug companies and generic drug companies restrict the generic company's ability to enter the market. (See our recent article on "reverse payment" settlements between such companies in the U.S.)

The report explicitly states that it is not a prelude to litigation against the drug companies for these practices. However, when the report was released, European Union Competition Commissioner Neelie Kroes stated that the Commission would not hesitate to bring antitrust suits against any drug companies if the Commission believes that antitrust laws have been violated. It remains to be seen whether the Commission will act accordingly. ✧