

Patent Settlements: A Comparative EU-U.S. Antitrust Analysis

Research project

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Abstract:

Patent settlement agreements are commercial agreements to settle patent-related disputes over questions such as infringements or patent validity. During the last decade, the number of patent settlements has increased on both sides of the Atlantic.

Consequently, patent settlements have also been subjected to the scrutiny of the European Commission and the U.S. antitrust enforcement agencies. Concerns arise especially with regard to patent settlements in the pharmaceutical sector which may lead to the delayed entry of a generic drug in return for a value transfer (e.g. a payment) by the patentee company to a generic drug company. Such agreements are frequently referred to as either pay-for-delay settlements or reverse payment settlements (because they involve a money transfer from the patentee to the alleged infringer rather than the reverse situation, where the patentee obtains a license fee for the use of its patent).

Last year, the Commission issued its third 3rd Report on the Monitoring of Patent Settlements. In its Report, it classified patent settlements into different categories and was particularly critical about settlements that involve a value transfer. In this regard, the Commission has sent statements of objection to several pharmaceutical companies and is currently investigating their practices.

The critical view towards particular types of patent settlements is also reflected by a separate section dedicated to this issue in the current draft of the revised Technology Transfer Guidelines that accompany the Technology Transfer Block Exemption Regulation. According to the draft guidelines, settlement agreements between competitors which include a license for the technology and litigated market but which delay or otherwise limit the ability for the licensee to launch the product in this market may under certain circumstance be caught by Article 101(1) TFEU. Hence, the Commission considers these settlement agreements between competitors as problematic, where the licensor provides an inducement, financially or otherwise, for the licensee to accept more restrictive settlement terms than would be accepted based on the merits of the licensor's technology.

Also the Federal Trade Commission in the U.S. has become increasingly aware of the potential anti-competitive effects of such patent settlements. Since 2003, Congress has required that litigants notify the federal antitrust authorities of their pharmaceutical patent settlements. Also legislative amendments for the assessment of the validity of these agreements under antitrust law have been suggested, but none of them has become law. Rather, the formulation of substantive standards was left to the courts and their application of the general antitrust principles. However, facing different fact situations underlying the various cases, some courts have concluded that reverse payment settlements constitute an antitrust violation, while others have upheld similar agreements. In December 2012, the Supreme Court announced that it would hear arguments in the case of *Federal Trade Commission v. Watson Pharmaceuticals, Inc.* During oral arguments, the justices opined that such settlements could harm competition and delay the market entry of cheaper generic drugs, but also admitted that the generic rivals sometimes have valid reasons for entering into such settlements. It remains to be seen whether the Supreme Court will establish new antitrust principles in this case.

The aim of this research project is to analyze the antitrust standards applicable to patent settlements in the EU and in the U.S. and to identify similarities and differences in the situations that are most likely to raise antitrust issues.