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CLIENT MEMORANDUM

The European Commission's Fifth Report on Pharmaceutical Patent Settlements: Is it Safe to Settle?

December 10, 2014

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On December 5, 2014, the European Commission published its fifth report on the monitoring of patent settlements in the pharmaceutical sector, which covers patent settlements concluded in 2013 between originator and generic companies. The Commission began its annual monitoring exercise in 2009, in the wake of its pharmaceutical sector enquiry, "to better understand the use of this type of agreement in the EEA and to identify those settlements that delay generic market entry."[1] The fifth report should be read in connection with the recent prohibition decisions adopted in the *Lundbeck*[2] and *Servier*[3] cases, where the Commission concluded that so-called "reverse-payment settlements," that is, settlements containing restrictions on generic entry and involving a "value transfer" from the originator company to the generic firm, are by object restrictive of competition.

1 Fifth report, at 1.

2 http://europa.eu/rapid/press-release_IP-13-563_en.htm.

3 http://europa.eu/rapid/press-release_IP-14-799_en.htm.

Overview

This fifth report analyzes the data collected by the Commission in connection with patent settlements covering the time period from 1 January 2013 to 31 December 2013. The Commission classifies the patent settlements in three categories: category A, which covers settlements involving no restriction on generic entry (deemed unproblematic); category B.I, which includes settlements limiting generic entry with no "value transfer" from the originator to the generic company (also not problematic, except if they fall outside the scope of the patent); and category B.II, which includes settlements limiting generic entry and involving a "value transfer." Those B.II settlements are, according to the Commission, "likely to attract the highest degree of antitrust scrutiny."[4]

The report contains several assertions by the Commission that are designed to justify its recently adopted enforcement policy against patent settlements in the pharmaceutical sector. The content of the report, however, does not support those assertions.

Does the Commission's policy have deterrent effect on settlements?

According to the Commission, scrutiny of the allegedly problematic B.II settlements "has not hindered companies from concluding settlements in general" but rather has benefited competition, as "[t]he number of B.II settlements . . . have stabilized at a low level." The report concludes, "[t]he statements of certain stakeholders . . . that the Commission would be forcing companies to litigate each patent dispute until the end has proved to be unfounded."[5]

However, the fact that the number of settlements reviewed by the Commission has increased since the pharmaceutical sector inquiry does not prove that the Commission's policy has no deterrent effect on the settlement of bona-fide intellectual property disputes. The report, in particular, does not compare the evolution of the number of settlements with that of the number of patent disputes. Yet only the proportion of patent disputes that ended in a settlement could help determine whether or not the Commission's policy has a deterrent effect on patent settlement agreements. Also, the statistics of the report are somewhat biased by the inclusion of settlements covering Portugal, where a new law automatically brought about the conclusion of many settlements, as originators were required to initiate arbitration proceedings shortly after the publication of a generic marketing authorization application. Remove the Portuguese settlements, and the total number of settlement agreements has continually decreased since 2011.[6]

In addition, none of the "unproblematic" agreements considered in the report (that is, the agreements falling under the A or B.I categories) concern disputes involving a genuine uncertainty as to the outcome of the litigation. Rather, they relate to situations where either the originator (A settlements) or the generic firm (B.I settlements) has concluded that its case

4 Fifth report, at 5.

5 Fifth report, at 16, 17.

6 Fifth report, at 7.

has no merit (*e.g.,* the originator and generic companies have simply discontinued the litigation without any commitments – they have "walked away" – or the generic company has agreed to enter the market only after patent expiry).

The report thus does not disprove the assertion that the Commission's current policy has a negative impact on the ability of pharmaceutical companies to effectively settle bona fide intellectual property disputes.

The criteria for identifying "problematic" settlements are broad and elastic.

The criteria used by the Commission to classify settlements agreements in the B.II category (*i.e.*, settlement agreements with a restriction on generic entry and a "value transfer") cover virtually all settlements that fall short of a "walk-away" agreement. In fact, the report's approach far exceeds the recent ruling adopted by the U.S. Supreme Court in the *Actavis* case.[7]

By way of illustration, as to the possible restrictions on generic entry, the report includes even immediate generic entry with "[a] licence granted by the originator company . . . because the generic company cannot enter the market with its own product or it cannot set the conditions for the commercialization of its product freely."[8] As to value transfers, the report considers not only monetary payments but also "side deal" agreements that are *prima facie* procompetitive, such as agreements allowing the generic company to enter the market before patent expiry in another geographical area. The report even considers that a non-assert clause "whereby – even without a license – the originator binds itself not to invoke the patent against the generic company, thereby allowing the generic medicine to come onto the market"[9] constitutes a value transfer.

In sum, although the Commission asserts that all settlement agreements, including the B.II agreements, should be examined on a case-by-case basis,[10] the categorization offered by the report, in direct resonance with the *Lundbeck* and *Servier* decisions, virtually deprives pharmaceutical companies, originator and generic alike, of any safe harbor for the conclusion of genuine settlement agreements.

7 FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

8 Fifth report, at 3.

9 Fifth report, at 4.

10 Fifth report, at 2.

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December 10, 2014