WHITE & CASE

Client Alert

DG COMP's 5th monitoring report: time for guidance please!

December 2014

DG Competition of the European Commission just published its 5th patent monitoring report. It covers patent settlements entered into in 2013. Each year, the Commission claims that the report shows a "steady increase" of patent settlements in general, which supposedly would prove that the Commission's threat of vigorous enforcement against so-called reverse patent settlements does not prevent pharmaceutical companies from settling patent disputes. The Commission also claims a steady decrease of "problematic settlements", namely those including a value transfer and a limitation of the generic's ability to enter the market immediately with its own product.

We published a client alert last year warning that the Commission's conclusions were unsound. The criticism equally applies to this year's report, which is in substance the same as the previous one, with updated statistics. We further submit that if the annual monitoring report is unable to give concrete guidance to the industry, it is time for the monitoring exercise to be stopped.

The claim that the number of settlements has increased is meaningless if this number is not compared with the total number of court cases. DG Competition also stretches its own statistics: when Portugal is excluded (a special law in Portugal skews the statistics), the report shows that the total number of settlements is more or less stable since 2010 (90 – 120 – 122 – 97) – not really a "steady increase".

More fundamentally, the report perpetuates DG Competition's stigmatisation of patent settlements including 1) a value transfer and 2) a limitation on the generic's ability to market immediately its own product (so-called B.II settlements). Last year, our client alert explained in detail the risk of DG Competition's overarching condemnation of these settlements. In a nutshell, DG Competition's broad definition of these two criteria renders suspect any real settlement. Indeed, according to the report, only two forms of settlements are unproblematic, A and B.I, in which either the originator or the generic surrenders. These settlements are not settlements whereby two opponents by mutual concessions reach a compromise.

A key problem with the Commission's approach is the broad definition of "value transfer": even the most classic way of settling a patent dispute – a licence – will fall in the category of settlements (B.II) that will receive the "*highest degree of antitrust scrutiny*" unless it is royalty-free and allows for immediate entry.

It is striking that the report offers no further guidance on B.II settlements, despite five years of monitoring and two cases brought to an end.[1] At the end of the sector inquiry, the Commission promised that guidance would come through cases and further monitoring. Since 2009, DG Competition has been notified of a total of 611 settlements, including 48 B.II settlements. These 48 settlements presumably received the "highest degree of antitrust scrutiny". No case was opened following such scrutiny. Yet, DG

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[1] Case COMP/ AT. 39226 – Lundbeck; Case COMP/AT.39612 – Perindopril (Servier). These cases did not result from the monitoring exercises. The settlement agreements in these cases were entered into in 2007 and before.

Competition seems unable to narrow down the category of allegedly problematic settlements or to explain why these 48 settlements did not raise competition issues (presumably, if they did, cases would have been opened).

Why continue to define so broadly the notion of value transfer that even early entry agreements are caught? DG Competition seems reluctant to give any guidance: it is only in reading the footnotes (p. 15) that one finds out that a pure early entry agreement "*is not likely to attract the highest degree of antitrust scrutiny*". Why not say: early entry agreements are "typically unproblematic" from a competition law perspective, as the report says for A. and B.I settlements (§15-16)? B.I settlements are those under which the generic agrees not to enter until patent expiry. There is something paradoxical in suggesting that an early entry agreement allowing entry before patent expiry is more suspect.

DG also continues to promise that "*obviously, an assessment of each individual case [will] be necessary*". While this statement seems made to reassure that there will be no *per se* condemnation, it raises serious issues of legal certainty. Companies are not only told that B.II settlements will be closely scrutinised but also that the outcome of the assessment may vary in each case. It is thus unsurprising that only 11 B.II settlements were concluded in the whole of Europe in 2013, representing a total of 8% of all patent settlements (as opposed to 22% before the sector enquiry).

This would not be so important if B.II settlements were indeed something undesirable for the economy, a form of agreement by nature anticompetitive. But they are not. Patent disputes are complex, costly and highly uncertain. Ending them with a mutually satisfactory compromise is not a bad thing – indeed many national laws encourage settling disputes.

In a recent judgment, the highest EU court said that restrictions of competition by object should be limited to agreements that are by nature harmful to competition,[2] i.e. agreements so likely to generate anticompetitive effects that it is not necessary for the enforcer to look at their actual effects: they can be condemned *per se*.

B.II settlement agreements are not by nature anticompetitive, as confirmed by the mere fact that DG Competition has not opened a single case despite 48 notified B.II settlements. While some B.II settlements may be anticompetitive, others may be neutral or some even may be pro-competitive.[3] Yet, the threat of vigorous scrutiny and the absence of guidance will deter companies from entering into *any* of these agreements. Companies may instead elect not to settle, i.e. a "fight to the death scenario", or end the litigation with an A or B.I "settlement" (in reality a defeat for one side or the other), which DG Competition considers not to raise concern. Recall that B.I are settlements in which the generic company agreed to enter only after patent expiry (§42). Thus, it is very possible that some B.II settlements that would have led to entry before patent expiry are replaced, to avoid antitrust risk, by a B.I settlement, i.e. a *less* competitive "settlement". The combination of the lack of guidance and the threat of enforcement may thus lead to a suboptimal outcome.

In conclusion, we urge DG Competition finally to put an end to the seemingly endless sector enquiry, which has been going on for six years now, and instead provide long-overdue guidance to the industry. In particular, the Commission would do well to reconsider its qualification of patent settlements as restriction by object (as it did in the *Lundbeck* and *Perindopril* cases) and follow the US Supreme Court's example, which ruled that the rule of reason should be applied to these agreements (in Europe, an effect analysis). The fact that after five years of monitoring and over 600 settlements reviewed the Commission is unable to define which settlements are *by nature* anticompetitive suggests that there are none. We consider that the Commission would be well-advised to abandon any *form-based* condemnation of settlements (B.II) and instead focus its enforcement on patent settlements that have the *effect* of delaying generic entry. Presumably the patent monitoring exercises provided much information to the Commission to explain in which circumstances patent settlements may or may not have such an effect. It is time to make use of it.

[2] Case C-67/13 P *Groupement des cartes bancaires v Commission*, EU:C:2014:2204.

[3] For example, a generic company may, through a settlement, obtain the right to distribute the originator's product (which could be superior to its product) and resolve difficulties in getting a market authorization. It may also be able to enter before patent expiry, which it would not be able to do if it lost the litigation.