WHITE & CASE

Client Alert

Pharmaceuticals

20 December 2013

Patent Settlements as an endangered species: DG Comp's latest Monitoring Exercise on Patent Settlements in Europe

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Executive Summary

On 9 December 2013, DG Comp published its fourth report on the monitoring in Europe of patent settlements. Like its predecessors, the report welcomes the continuously low level of settlements that may give rise to antitrust concerns and trumpets that the overall number of settlements has increased, which it says demonstrates that criticisms of DG Comp's enforcement policy against patent settlements are unfounded.

A critical review of the report and its predecessors shows however a completely different reality. By promising the "*highest antitrust scrutiny*" to settlements containing any limitation on the generic's freedom and a value transfer, the monitoring exercises have not surprisingly had a chilling effect -- deterring companies from entering into settlements containing any form of real compromise. The only two significant categories of settlements that remain are so-called "surrenders", in which either the originator (A-type settlements) or the generic company (B.I settlements) gives up. These are in truth not real settlements and DG Comp's announcement that the number of "settlements" has increased is thus meaningless. To the contrary, the monitoring exercise displays a picture that is concerning both from an IP litigation and a competition standpoint.

A definition problem

The monitoring report perpetuates the distinction – originating from the sector inquiry – between three categories of settlements: A, B.I, and B.II, depending on two criteria, i.e. whether they contain (i) a limitation on the generic ability to enter with its own product and (ii) a value transfer. Agreements containing both are classified as B.II settlements and "*are likely to attract the highest degree of antitrust scrutiny*".

The first problem is that DG Comp is using the wrong benchmark. Instead of considering the impact of a settlement on competition as a whole, the report focuses on whether a generic can sell its own product freely. But the existence of a "*limitation of the generic ability to enter with its own product*" cannot be equated to likely anticompetitive harm or likely delay in generic entry, as the report suggests. For example, the settlement of a patent dispute by means of a license or a distribution agreement, when there is a risk that the patent blocks generic entry, is generally viewed as pro-competitive even in the Commission's own technology transfer guidelines (§206). Such an agreement may also have pro-competitive effects if the generic company is experiencing difficulties in manufacturing a product of

sufficient quality or in obtaining a marketing authorization. In such a case, the license or distribution agreement may offer a way onto the market, thus increasing competition. Yet, such agreements would be seen by DG Comp as limiting generic freedom. The only exception would be if the settlement includes a royalty free license allowing immediate entry of the generic company with its own product.[1] Any other form of license, e.g. allowing immediate entry but bearing a royalty, or royalty-free but allowing deferred entry only, is viewed as a limitation on the generic company, and will therefore be suspect.

The second criterion, the existence of a value transfer, is equally broadly defined. It includes all sorts of concessions from the originator to the generic: money payment, distribution agreement, side deal, or "a license to the generic enabling it to enter the market". Of course, every broad release of claims conceivably involves "value" so that even a walkaway resolution confers something of value on the generic – taken to its logical extreme. The fourth monitoring report even says that a non-assert clause may also "technically" – whatever this means – be viewed as a value transfer.

The report makes one exception for early entry agreements which, although they are said to constitute a value transfer and a limitation on the generic company, and therefore are categorized in the problematic box, will however "*not likely [..] attract the highest degree of scrutiny*" (§12). This vague statement raises more questions than answers – and it is not very comforting, as medium scrutiny can be serious.

In sum, if the generic company's freedom is restricted in any way and the originator makes some concession to reach a compromise, like any settlement of a dispute in any sector would need, the agreement will be categorized as B.II and be met with the "*highest degree of antitrust scrutiny*". This is like using a sledgehammer to examine the design of a nut. DG Comp challenges the legality of a vast array of agreements without making any effort to look at their actual or likely effects on competition, to catch a few that may be anticompetitive depending on the actual circumstances of each case.

That approach can usefully be contrasted by the position adopted by US Courts. In its recent *Actavis* decision, the US Supreme Court rejected the FTC's plea for a *quick look* approach and decided instead that the rule of reason should be applied to settlements involving a payment to the generic company. While the presence of a *large and unexplained payment* from the originator to the generic may signal possible antitrust problems, this is very far from the general suspicion (indeed worse than a suspicion, an assumption) cast by DG Comp over agreements containing *any* limitation on the generic freedom and *any* value transfer. Further, under the rule of reason, the key issue is whether the agreement brought about anticompetitive effects, not whether the generic's freedom was in any way restricted, and the US courts will analyze whether in fact the agreements under review restricted competition. This may be contrasted with DG Comp's characterization, in on-going cases, of settlement agreements as restrictions by object, i.e. illegal without DG Comp even having to bother examining if they have any negative effects.

The direct consequence of DG Comp's hard stance on B.II settlements has been – as one would have expected – the quasi-disappearance such settlements. Whereas they represented 22% of all settlements during the sector inquiry, the proportion fell to 10% in 2009, and even 3% in 2010 and 7% in 2012. And the 7% include some very anodyne settlements indeed – pure early entry, early entry with a license, early entry with a license and

[1] But there is no clear safe harbor from the Commission, with the result that in the Commission's eyes conceivably even this could be suspect as the generic accepts the validity of the patent against the terms of the license, and such agreement is still classified as a B.II settlement (see Sector Inquiry Final Report, p. 269).

supply, all of which would likely be legal under an effect test. Only 1% of all settlements involved any payment and the two settlements concerned did not include standalone payments: the payments in question were to cover legal costs and purchase of old stock.

Defeats are not settlements

DG Comp is telling us that its hardline approach does not matter since the statistics show that overall the number of settlements have increased. To support the argument, the report disingenuously compares the 24 settlements per year during the 9 years covered by the sector inquiry against the 183 settlements in 2012 (§48). The comparison is however flawed. First, the number of settlements has increased since the sector inquiry at least in part because the sample of companies surveyed has significantly increased and notably as DG Comp sends targeted questionnaires to companies which have been reported in the specialized press to have entered into settlements.[2] This is no apples to apples comparison.

Second, DG Comp's report is entirely silent on the number of litigations. If the amount of litigation increased significantly, as reported in the sector inquiry, the number of settlements can be expected to have increased as well. The key question – not addressed in the report – would be whether on average, litigations are settled more or less now than before.

More importantly, 93% of the 183 settlements counted in the report are, in actual fact, defeats for one side or the other. In A-type settlements, the originator company essentially gives up, leaving the generic company free to enter. This is easily understandable in light of the fact 67% of A-type settlements were concluded when the relevant patents were not in force anymore. In such a situation, there is no reason for the settlement to contain any limitation on generic entry, since the generic product is free to enter. For those cases where relevant patents were still in force, the report is silent on the question of whether the originator still enjoyed market exclusivity at the time of the settlement. By contrast, the Final Report of the Sector Inquiry found that 90% of A-type settlements were concluded after one or more generic companies had entered the market (§750). In such situation again, there is no reason for the originator to compromise on the generic entry date.

B.I-type settlements are the reverse: it is the generic company that gives up the litigation and agrees not to enter. The 4th Report offers little explanation on the characteristics of these agreements other than that "*the generic accepted the validity of the originator patent*" which is obvious from the fact that in these cases the generic has agreed to stay out until patent expiry. However, the Final Report of the Sector Inquiry tells us that the main characteristics of the B.I-type settlements were that the originator had won the patent infringement case against the generic company, at least before the court of first instance, either by way of judgment on the merits or of a preliminary injunction (§759-760). Again, such agreements can hardly be considered as a compromise over the outcome of litigation. They merely record the generic surrendering in a litigation it had lost or was losing.

If A and B.I settlements are not real settlements, then the conclusion naturally flows that all real settlements lay in the B.II category, which takes us back to our starting point: the very broad criteria used by DG Comp to identify potentially problematic settlements result in any real settlement being problematic. Yet, DG Comp has yet to produce any empirical evidence that all B.II settlements are undesirable, or indeed likely to lead to a delay in generic entry. In fact, most B.II settlements set forth in the Report

[2] In other words, DG Comp is now looking for settlements and logically will find more settlements than during the Sector Inquiry which was not as targeted.

look likely to have had a positive effect, since they allowed generic entry with a license or distribution agreement.

Inefficient outcome

There is no doubt that settlements are desirable for the functioning of the litigation system.[3] This is particularly true in IP litigation, which is notoriously complex and costly, in particular in the EU, with the co-existence of so many national courts and a lack of consistency between them, (11% of disputes have different outcome in different Member States according to the Sector Inquiry, §664). Settlements provide for clarity of rights and often far more rapidly than patent litigation. Settlements typically involve some compromise as to entry date – which shaves time off the patent – if shortening patent exclusivity were a public good. As a matter of survival, national court systems encourage settlements, and so do the draft rules of procedure of the future Unified Patent Court. DG Comp has artificially created a class of presumptively bad agreements, on the basis of broad criteria which catch perfectly legitimate genuine settlements. This significantly and unnecessarily restricts the freedom to settle disputes for pharmaceutical companies (and in other sectors since competition rules are not sector-specific), even where the settlement may be pro-competitive.

Further, DG Comp is missing the point that barriers to exit are barriers to entry: making it more difficult or risky for generic companies to settle litigation even when a settlement is commercially justified (e.g. because the litigation has become too risky, the generic company does not yet have a product or a marketing authorization, etc.) will simply render litigation less attractive. In other words, this is a policy at war with itself: DG Comp's jaundiced view of patent settlements will actually have the effect of reducing patent challenges.

The need for debate

Finally, it is troubling that DG Comp takes unilateral positions having such a fundamental impact on the functioning of the patent system, without consulting other stakeholders. It is noteworthy that the points relating to settlements in the draft guidelines on technology transfers have raised numerous concerns from interested parties[4] and led to healthy debates within the Commission. It is undesirable that while this healthy participative process is on-going DG Comp publishes documents rendering entirely moot the efforts of stakeholders to achieve a more balanced policy vis-à-vis patent settlements. It should be a matter of concern for the Commission as whole. The new document, far from assuaging anxieties about DG Comp's policy, should exacerbate them.

[3] See §220 of the Commission's draft guidelines on technology transfer: "*Settlements can save courts and/or competent administrative bodies effort in deciding on the matter and can therefore give rise to welfare enhancing benefits*."
[4] See contributions here: http://ec.europa.eu/competition/consultations/2013_technology_transfer/index_en.html