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I. INTRODUCTION

On July 8, 2009, the European Commission's Directorate General for Competition ("DG Comp") issued the much-anticipated Final Report (consisting of a Commission Communication and Staff Working Document) of its sector inquiry into competition in pharmaceuticals ("Sector Inquiry"). One of the areas examined in detail during the course of the Sector Inquiry was the conclusion among originator and generic manufacturers of settlement agreements relating to patent litigation.

This paper argues that the Final Report's apparent suspicion of patent settlement agreements that involve a "reverse" value transfer (i.e. from the originator to the generic)—and the presumption that they are anticompetitive—may be misplaced, and indeed moving EU competition law "in reverse" in the sense that it goes back to an outdated position in the U.S. courts which has now been abandoned.

DG Comp's main conclusion on settlement agreements is set out in its Commission Communication:

> Agreements that are designed to keep competitors out of the market may also run afoul of EC competition law. Settlement agreements that limit generic entry and include a value transfer from an originator company to one or more generic companies are an example of such potentially anticompetitive agreements, in particular where the motive of the agreement is the sharing of profits via payments from originator to generic companies to the detriment of patients and public health budgets.
>
> To reduce the risk that settlements are concluded at the expense of consumers, *it would seem useful for the Commission to consider further focused monitoring*, within the context of the existing legal framework, of those settlements with a potential to adversely affect European consumers. This monitoring would have to take duly into account the administrative burden imposed on stakeholders and will be limited in time until the Commission has gathered sufficient information on the subject matter to decide whether further action is needed.[2] (Emphasis added.)

It is unfortunate that so little guidance is forthcoming after an 18-month investigation involving an unprecedented amount of resource both within DG Comp and among companies responding to frequent and substantial requests for information.

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[2] Final Report Commission Communication, at page 20. At: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf

It is thought that the introduction of some form of notification system was considered for patent settlement agreements, but the Final Report leaves industry with no substantive guidance and with a worryingly vague indication of "further focused monitoring."

II. DG COMP'S REVIEW OF PATENT SETTLEMENT AGREEMENTS

Putting aside for the moment the question of whether patent settlement agreements are problematic under EU competition rules, it is worth noting that the Final Report is arguably misleading in its presentation of findings relating to patent settlement agreements. In the Commission Communication and the accompanying Staff Working Document,[3] DG Comp presents much empirical information in relation to patent settlement agreements. However, the information presented in relation to patent settlement agreements is: (i) different to that presented elsewhere in the report; and (ii) presented in an ambiguous and confusing manner.

First, as regards the information presented, DG Comp notes at paragraph 739 of the Commission Staff Working Document, that:

> Whereas the majority of the findings in this report are based on a selection of some 219 INNs [i.e. 219 pharmaceutical products], the findings in this chapter are not limited to that particular selection. Companies were asked to submit all settlements, irrespective of the INN concerned.

One important consequence of the decision to broaden the scope of investigation in relation to patent settlement agreements is that DG Comp is able to present more striking figures on the total number of patent settlement agreements and their total value than would have been the case had it adopted a consistent approach across the entire Final Report.

Second, DG Comp also presents some of its empirical findings on patent settlement agreements (based always on the expanded sample size) in an ambiguous and confusing manner. For instance, Table 22 presents a summary of generic companies' responses to a question asking which factors they considered to be most important when deciding to enter into a settlement agreement. More than one possible answer was permitted. The most often-cited factor was: "expected costs/avoided costs of litigation and impact on personnel cost" (75 percent). The next most often-cited factors were: "inherent uncertainty involved in patent litigation" (67 percent) and "strength of the company's position in the case" (also 67 percent).

At paragraph 739, however, DG Comp summarizes the information in Table 22 thus: "[f]or the vast majority of generic companies (75 percent), avoiding the costs related to litigation and also the impact on personnel costs are their major concerns." But

[3] At: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf and http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part2.pdf

that does not follow from Table 22. Generics were not asked to identify the *single* most important factor in entering into a settlement agreement. Rather, they were permitted to identify *multiple* factors. Nor is it apparent from Table 22 that generics were asked to rank the multiple factors in order of importance. Indeed, had they been asked to do so, the popularity of the other factors identified (e.g. uncertainty and strength of position) means it is highly unlikely that a majority, never mind a "vast majority," of generics would have identified litigation costs as their major concern.

The point may appear a small one but it is important for two reasons: (i) it enables DG Comp to structure an argument that the incentives of generics and originators in deciding to enter settlement agreements differ significantly; and (ii) as with the points on the expanded sample size above, it may be indicative of wider efforts by DG Comp to present what empirical information it has on patent settlement agreements in a somewhat skewed manner.

Turning to DG Comp's assessment of the agreements themselves, in identifying the "reverse payment" settlement agreements that are considered problematic, DG Comp divides agreements into three main categories:

A: Agreements containing no limitation on generic entry;

B.I: Agreements "limiting" generic entry but not involving a value transfer from originator to generic; and

B.II: Agreements "limiting" generic entry and involving a value transfer from originator to generic.

The content and tone of the November 2008 Interim Report[4] led stakeholders to be concerned that B.II. "reverse payment" agreements were at risk of being viewed by DG Comp as automatically anticompetitive. Despite some softer language in the Final Report, the conclusions cited in the introduction to this paper confirm that the classification of an agreement as type B.II. will be extremely important for the pharmaceutical industry going forward. However, the classification methodology set out in DG Comp's Final Report is arguably flawed and raises a fundamental issue of how far competition law should go in questioning the validity of patents.

The thesis underlying DG Comp's classification is that the patent-in-suit is weak or invalid and the reverse payment settlement agreement deprives consumers of earlier generic entry. The reverse payment is assumed to compensate the generic for delaying entry beyond the point when it would have occurred—*absent* the payment—under a settlement based solely on the likely result of the litigation and the economic incentives on each side.[5] DG Comp therefore views agreements containing reverse value transfers

[4] At: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf
[5] It is for this reason that such agreements are also referred to as "pay for delay."

with suspicion. The text box at paragraph 742 of the Final Report gives further color to DG Comp's suspicion of reverse value transfer settlement agreements:

> The generic company's entry can be limited in several ways. The clearest *limitation* of generic entry is when the settlement agreement contains a clause explicitly stating that the generic company recognizes the validity of the originator company's patent(s) and refrains from entering the market until the patent(s) have expired. […] [Emphasis added.]

Paragraph 742 demonstrates in clear terms that DG Comp's suspicion is based on an assumption that the patent in suit is either weak or invalid. Where the patent-in-suit is *valid*, the generic company would, in any event, have been prevented from entering the market with an infringing product until expiry. In general, it is precisely in order to affirm that situation that originators launch the infringement proceedings that can result in settlements, including of the reverse payment type. If one were to assume that the patent-in-suit were *invalid* then any delay in entry in exchange for payment may be questionable from a competition law perspective. However, other areas of law do not presume invalid patents which have been correctly registered and granted and which have survived any opposition proceedings. There is no good reason for EU competition law to be any different.

Patents granted by expert authorities (who are infinitely more qualified in the assessment of patentability than DG Comp) must be presumed by DG Comp to be valid. Indeed, as DG Comp itself points out in the last of its 13 short paragraphs on the principles of EU competition law of relevance to the Sector Inquiry: "EC competition rules do not call the existence of intellectual property rights into question." This being the case, EU competition law must presume granted patents to be valid.

In addition, competition authorities must proceed with caution in analyzing the motivations for entering into reverse value transfer settlements. The assessment of the financial and corporate policy-related advantages and disadvantages of a proposed settlement can be an extremely complex process for the parties themselves, let alone for a competition authority. As such, there are many pro-competitive and legitimate reasons why a payment or value transfer "in reverse" might be made in the context of a settlement agreement (including simple risk aversion, reluctance to incur expenditure on litigation, and the ability in the context of a settlement agreement to conclude other mutually beneficial—and pro-competitive—cooperation arrangements). Against this background, DG Comp's determination of whether an agreement merits "further monitoring" and should attract closer antitrust scrutiny appears over-simplistic and ill-conceived.

It follows from the above that neither a clause explicitly stating that the generic company recognizes the validity for its term of the originator's patent nor the presence of a reverse value transfer should be used as determinative in identifying "limitations"

on generic entry with which a competition authority should be concerned. Unless the patent can be shown to be invalid, the same limitation on generic entry existed before the settlement agreement, meaning that the settlement agreement itself does not impose a further limitation. In addition, reverse value transfers may be included in legitimate, pro-competitive settlement agreements for a variety of perfectly acceptable reasons. As such, insofar as DG Comp persists with a classification of settlement agreements, it should consider altering the manner in which it determines whether a given agreement "limits" generic entry.

III. RELEVANT JURISPRUDENCE OF THE U.S. COURTS

In its Final Report, DG Comp refers in a number of areas to the assessment under U.S. antitrust law of patent settlement agreements. The U.S. courts and agencies have significant experience in dealing with patent settlement agreements and DG Comp may well be justified in looking to the United States for guidance on the assessment of these kinds of agreements. However, if DG Comp looks to the United States for guidance, it must look not just to the enforcement practices of the agencies but also to the jurisprudence of the U.S. courts. This is particularly important given that the U.S. courts appear to disagree with the view of the Federal Trade Commission ("FTC") that reverse payment settlements are inherently suspect.

There have been a number of high-profile recent judgments in relation to patent settlement agreements. Arguably the most significant judgment to date was that handed down by the Court of Appeals for the Federal Circuit on October 15, 2008 in *Ciprofloxacin*. That judgment adopted the fundamental positions that had been previously adopted by the Second Circuit Court of Appeals in the *Tamoxifen* case, the Eleventh Circuit in the *Schering-Plough v. FTC* and *Valley Drug* cases, and, *in dicta*, the Seventh Circuit in the Asahi Glass case. These recent judgments have settled on a nuanced approach, applying a rule of reason analysis and linking the terms and effect of the settlement agreement to the so-called "exclusionary potential of the patent[s]" at issue. The case law has evolved significantly from a relatively early case—*In re Cardizem*—which suggested that reverse payments might be deemed *per se* violations of Section 1 of the Sherman Act. Three key points come out of the *Ciprofloxacin* line of cases that may be of relevance to DG Comp's consideration of the standards to be adopted in relation to settlement agreements.

First, in determining whether a settlement agreement constituted a restriction of competition going beyond the so-called "exclusionary zone" of the patent, the Federal Circuit considered it appropriate to determine the time and other conditions according to which the generic was permitted to market its equivalent product. Naturally, if the term or scope of any agreement not to enter went beyond the term or scope of the relevant patent, there might be a presumption of a restriction of competition. However,

a settlement that restricts competition only within the exclusionary potential of the patent is presumed not anticompetitive.

Second, there should be no detailed assessment in an antitrust context of the relative strength of the patent at issue. Patents that have been granted are deemed valid unless a party can demonstrate that the patent has been fraudulently obtained.

Third, a reverse payment is not to be considered inherently anticompetitive. Settlements are a crucial element of litigation systems. In general, they should be encouraged. In principle, regardless of whether there is a reverse payment, a settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled—i.e. a monopoly over the patented invention.

A reasonable summary of the current U.S. jurisprudence would be that, absent restrictions of competition going beyond the exclusionary effect of the patents in question, patent settlement agreements should not be found to infringe Section 1 of the Sherman Act—even where they involve payments to generic challengers.

DG Comp's final report makes mention of the judgment of the Eleventh Circuit in the *Schering-Plough v. FTC* case but focuses its summary of U.S. antitrust more on FTC practice and prioritization statements and possible future legislative initiatives, than on the jurisprudence of the U.S. courts. Indeed, DG Comp makes no mention whatever of the judgment of the Court of Appeals for the Federal Circuit in *Ciprofloxacin*. We respectfully submit that there is more to be learnt from U.S. antitrust law in relation to patent settlement agreements than DG Comp sets out in its Final Report. Any learnings to be imported from the United States into DG Comp's enforcement practice under Article 81 EC must be based on a balanced assessment of all relevant jurisprudence, not a skewed sample of FTC statements and summaries of possible future legislative initiatives.

IV. WORKABLE PRESUMPTIONS

DG Comp itself states at paragraph 13 of its brief summary of the principles of EU competition law of relevance to the Sector Inquiry:

> EC competition rules do not call the existence of intellectual property rights into question. However, for example intellectual property rights are not exempted from the application of competition rules. The exercise by a company of its intellectual property rights can amount to an agreement restricting competition under Article 81 EC or an abuse of a dominant position under Article 82 EC.

This existence/exercise distinction is fundamental to the interrelation of intellectual property rights ("IPRs") and EU competition law.[6] As set out in section II of

[6] The dichotomy between existence and exercise was first explained by the European Court of Justice in its judgment in Consten and Grundig v Commission (Cases 56 and 58/64 [1966] ECR 299, [1966] CMLR 357, p. 375). It has been referenced consistently thereafter, including in seminal cases such as Deutsche Grammophon Gesellschaft v Metro-SB-Grossmärkte GmbH (Case 78/70 [1971] ECR 487).

this paper, above, any application of EU competition law must not be premised on a presumption of the invalidity of a registered and granted patent. To do otherwise would clearly be to "call the existence of intellectual property rights into question" and would be to afford third parties a way of undermining valid IPRs outside of the relevant registration, grant, opposition, and specialist court procedures. The U.S. jurisprudence summarized in Section III of this paper accepts this fundamental position and has arrived at a set of presumptions operative in an antitrust context that serves to simplify the assessment of settlement agreements in the United States.

DG Comp notes in footnote 483 to its Commission Staff Working Document that:

> In the context of the public consultation, some stakeholders, relying on certain US case law, submitted that the legal test for assessing the legality of a settlement agreement should be whether the settlement agreement restricts competition beyond the exclusionary zone of the patent (unless the patent is a "sham patent") and that European competition authorities should adopt a similar approach. As mentioned above, this report does not aim to provide guidance on the legal assessment of certain agreements.[7]

The relegation to a footnote of the most important global learning on the antitrust assessment of patent settlement agreements is somewhat regrettable. However, given that DG Comp is to "consider further focused monitoring" of reverse payment settlement agreements, and is yet to pronounce any clear guidance on the subject (despite its 18-month long investigation); officials may still be considering how best to assess such agreements. We submit that the U.S. courts may already have provided DG Comp with answers to its questions in the form of clear and workable (rebuttable) presumptions, which could easily be converted into formal guidance in the context of any future monitoring exercise.

The Sector Inquiry has correctly identified serious weaknesses in the European patent system. However, expert bodies and specialist procedures exist in order to determine questions of patent law and practice. The fact that certain of those bodies or procedures might be in need of reform is not reason enough for DG Comp to disregard the principles of patent law and have recourse instead to EU competition law as a means of addressing the perceived weaknesses. Rather, it is reason to propose reforms of those bodies or procedures.

[7] In the remainder of footnote 483, DG Comp makes a series of points the relevance of which to the proposed test is unclear.