measures fall within this realm. This type of political statement is likely to give domestic authorities comfort in the face of industry arguments that established tobacco packaging measures violate international trade and investment agreements.

As a legal instrument, it remains to be seen what the effect of the Declaration will be. Parties to the WHO FCTC did not express their understanding of the status of the Declaration in its text or during negotiations. In the context of WTO law, the instrument is likely to be viewed purely as a political instrument because under the WTO Agreement, only the Ministerial Conference of the WTO and the General Council have the power to issue authoritative interpretations of the WTO covered agreements.[12] In the context of international investment law, the issue is less clear. In this context, the instrument could be construed as a Declaration of customary international law, particularly with respect to the sovereign powers of states to regulate in the public interest. Alternatively, the Declaration might be viewed as a subsequent agreement of the parties to an international investment agreement, and on this basis be used in interpretation of the agreement.[13]

The Declaration comes at a time when the appropriateness of investor state arbitration is increasingly being called into question. It can be argued that claims such as that made by Philip Morris are unlikely to arise in systems where only states have standing. States tend to view the issues in a systemic manner and seek to avoid actions contrary to the public interest. It can also be argued that there are few checks at the international level that prevent an investor from bringing spurious or opportunistic claims in a context where many developing countries have limited capacity to defend investment claims and limited funding to retain outside counsel. These arguments suggest that the Philip Morris claim poses a very public challenge not only to global tobacco control, but also to the legitimacy of international investment arbitration.

12 Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 4 (1999), 33 I.L.M. 1144 (1994), Article IX:2.

13 Although, this is doubtful in the *Philip Morris v. Uruguay* dispute because Switzerland is not a WHO FCTC Party.

Pharmaceuticals

This section updates readers on the latest developments in pharmaceutical law, giving information on legislation and case law on various matters (such as clinical and pre-clinical trials, drug approval and marketing authorisation, the role of regulatory agencies) and providing analysis on how and to what extent they might affect health and security of the individual as well as in industry.

Reverse Payment Settlements in the Pharmaceutical Sector: A European Perspective

Pier Luigi Parcu and Maria Alessandra Rossi***

On 17 January 2011, the European Commission launched , a monitoring exercise of patent settlements in the pharmaceutical sector for the second time after the Pharmaceutical sector inquiry of 2009. As was the case for the first monitoring exercise launched in January 2010, a number of pharmaceutical companies were asked to submit copies of their patent settlement agreements concluded in the European Economic Area (EEA), together with any relevant annex, amendment or related agreement.

The rationale for the monitoring exercise derives from some of the findings of the Pharmaceutical Sector Inquiry, which had highlighted the possibility that some of the agreements reached by originators and generics to settle IP-related disputes (generally believed to be efficiency-enhancing tools to save money on litigation costs), may in fact turn out to have anticompetitive effects on the market. This is particularly the case for so-called "reverse payment agreements". These are settlements that involve a payment (in direct or indirect form) flowing in a direction that intuitively appears "reverse", as money is paid by the patent holder (the originator) to the alleged infringer – a generic firm. The main concern with regard to these agreements is that they imply a restriction of access to the market by one or more generic firms, agreed upon by the incumbent and the potential entrant, with clear negative implications in terms of prices paid by consumers.

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The anticompetitive nature of the agreements currently scrutinised by the Commission should not, however, be taken as an uncontroversial fact. Indeed, the issue whether or not "reverse payment settlements" should be considered anticompetitive has been the subject of strong controversy, particularly in the United States. The two US antitrust enforcement agencies – the Federal Trade Commission and the Department of Justice – and the various Circuits that have pronounced judgements on the matter have taken starkly opposing views.

The FTC has taken the most clear-cut stance in support of the anti-competitiveness of reverse payment settlements. Indeed, the FTC considers reverse payment settlements – "pay-for-delay" agreements, in its own words – presumptively illegal as they are interpreted as an undue extension of the protection granted by a patent beyond its legitimate scope. This is because, when a patent settlement is reached that envisages the acceptance by a generic firm of a substantial amount of money or other consideration in exchange for agreement to stay off the market, this may conceal the fact that the patent is invalid, so that, in the absence of an agreement, entry would in fact have occurred more rapidly. Consistently with this view, starting from the year 2000, the FTC has thus pursued many investigations and enforcement actions against companies involved in reverse payment settlements.

The Courts that have examined cases stemming from the FTC's enforcement action have, for the most part, so far upheld the agreements. Four Circuits have considered cases involving reverse payment settlements: the Second Circuit (in the case In re: Tamoxifen Citrate Antitrust Litigation[1]), the Sixth Circuit (in the case In re: Cardizem CD Antitrust Litigation[2]), the Eleventh Circuit (in the cases Valley Drug Co. v. Geneva Pharmaceuticals Inc.[3], Schering-Plough Corp. v. FTC[4] and Andrx Pharmaceuticals v. Elan Corp.[5]) and the Federal Circuit (in the Ciprofloxacin[6] litigation). All of the courts mentioned except the Sixth Circuit have expressed views that clash with the position taken by the FTC. While the range of arguments used in support of this position is relatively wide, the three courts that have taken the view that this sort of agreement should not be considered anticompetitive tend to emphasise that they fall within the legitimate scope of the patent, and that IP settlements involve social benefits predominantly in the form of saved litigation costs. Therefore most US courts have taken the view that reverse payment agreements do not raise antitrust concerns as long as they do not involve an extension of the patent term beyond its statutory limits and/or as long as it is likely that the generic would have infringed the patent(s) at issue. In both cases, in the view of the Courts, such settlements do allow social benefits to be derived and they fall entirely within the prerogatives conferred by the patent system.

The Sixth Circuit court is the only court that has affirmed the per se illegality of the settlement it has examined, on the basis of the conclusion that the agreement between generic firm Andrx and patent holder Hoechst, a pharmaceutical company acquired by Aventis in 2000, to postpone marketing of a generic version of the drug Cardizem CD in return for substantial monetary payments to Andrx, was meant to stretch the exclusion of generic entry beyond the statutory patent term and scope.

The position of the US Department of Justice (DoJ) is less clear-cut and seems to have evolved to some extent over time. Starting from a rather cautious position, the DoJ seems to be taking a more resolute stance in support of the presumption of illegality of reverse payment settlements, perhaps reflecting the overall political climate inspired by the Obama administration. The DoJ appears to be cognizant of the need to reconcile different policy objectives and proposes an evaluation based on whether the settlement agreement determines an extension of exclusion beyond the legitimate protection afforded by the patent. This evaluation should be based – in the DoJ's view – on an assessment of the merits of the patent claims.

Thus, while there are signs of evolution towards greater emphasis on the anti-competitive nature of reverse payment agreements, a prominent commentator has recently expressed the view that we will observe a "careening snowball of per se legality"[7], showing how difficult it is to state with certainty which position will emerge in the near future.

1 466 F.3d 187 (2nd Cir. 2006).

2 332 F.3d 896 (6th Cir. 2003).

3 344 F.3d 1294 (11th Cir. 2003).

4 402 F.3d 1056 (2005).

5 421 F.3d 1227 (11th Cir. 2005).

6 In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323 (Fed. Circ. 2008).

7 Michael A. Carrier, "2025: Reverse-Payment Settlements Unleashed", 2 *Competition Policy International Antitrust Journal* (December 2010).

On the European side of the Atlantic, reverse payment settlements have been the object of more recent attention. Patent settlements have traditionally been considered as not raising specific antitrust concerns, as their treatment is assimilated to any other inter-firm agreement which may be the object of antitrust scrutiny. As mentioned, however, the European Commission with the Pharmaceutical Sector Inquiry has taken the opportunity to explore the phenomenon in greater depth and has adopted a clearer position with regard to reverse payment settlements, clarifying that they may raise specific antitrust concerns. In line with this increased awareness of the potential anticompetitive effects of reverse payment settlements, the Commission has also taken concrete actions, opening formal proceedings against Les Laboratoires Servier and a number of generic pharmaceutical companies to investigate agreements which may have the object or effect of hindering market entry of generic perindopril (a cardio-vascular medicine originally developed by the Servier Laboratoires) on the EEA markets[8].

In view of these developments in both the US and Europe, it is worth asking at least two questions. First, is the Commission's higher level of scrutiny on pharmaceutical patent settlements opportune? Second, assuming a positive answer to the first question, will the steps taken by the Commission, and particularly the monitoring exercise, be sufficient to deter anticompetitive behaviour?

The answer to the first question revolves around two main issues, namely the quantitative relevance of patent settlements in Europe and the anticompetitive nature of reverse payment settlements. As for the first aspect, according to the recent European Commission Pharmaceutical Sector Inquiry, 23 reverse payment settlements have been made in the EEA between January 2000 and June 2008 and were reported to the Commission; the total amount of cash transferred from originator to generics companies came to more than €200 million. Thus, the phenomenon is certainly relevant in quantitative terms, although less relevant than in the US, where the single largest cash reverse payment settlement to date – the Cipro settlement – involved a payment of $398 million[9]. As for the second aspect, as the authors have articulated more fully elsewhere[10], to the extent that reverse payment settlements involve the postponement of the date of generic entry into the market, there can be few doubts that they should be considered to have anticompetitive effects. Indeed, the potential benefits associated with settlements are of an order of magnitude insufficient to outweigh the certain drawbacks that follow from holding back the increased competition resulting from generic entry.

In answering to the second question, it is interesting to consider the results of the Commission's report on the first monitoring exercise[11] (concerning the period July 2008 to December 2009). The report emphasised that the percentage of settlements that may raise antitrust concerns has lowered from the 22 % registered in the Sector Inquiry to 10 % and that the amount of cash transfers involved in settlements has also diminished, adding up to €1 compared with the €200 million during the period 2000–2008).

Thus, the report appears to point to the existence of a positive deterrence effect. However, the US experience may suggest that these figures should be taken with some caution. In the US, reverse payment settlements have been the object of periodical monitoring since 2003 but, as mentioned, courts began upholding reverse payment agreements since 2005. This has resulted in a change in the nature of pharmaceutical settlements that, since these developments, tend to involve indirect rather than direct payments in the form of over-payment for raw materials, licences or manufacturing, other side deals and especially the promise not to launch any authorised generics in the period immediately after entry of the generics on which the settlement agreement has been reached.

This sort of indirect payment has so far been rarely observed in the EU, as reported by the EU Commission inquiry, but it remains to be seen whether they will be observed more frequently in the future. If that were the case, some further steps to clarify the circumstances of per se illegality of at least some reverse payment settlements would be most opportune.

8 Memo Press Release 09/322, "Antitrust: Commission opens formal proceedings against Les Laboratoires Servier and a number of generic pharmaceutical companies", available on the Internet at <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/09/322&format=HTML&aged=0&languag>.

9 See Scott Hemphill, "Drug Patent Settlements Between Rivals: A Survey" (March 12, 2007), available on the Internet at <http://www.licensinglaw.net/Litigation_files/C_Scott_Hemphill.pdf>.

10 Pier Luigi Parcu and Maria Alessandra Rossi, "Negotiated foreclosure and IPRs: recent developments", forthcoming in G.Muscolo (ed.), *Competition Law and Intellectual Property*, International Competition Law Series (London: Kluwer Law International).

11 Memo Press Release IP/10/887, "Antitrust: Commission welcomes decrease of potentially problematic patent settlements in EU pharma sector".