

Patent Settlements and Reverse Payments Under EU Law

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The purpose of this contribution is to explore the status types that settlements and reverse payments could have under Article 81 EC. It seeks to identify the elements of the legal tests which could possibly be applied to assess the legality of such settlements and, in particular, those providing for a value transfer from the originator to the generic firm. This will be done as follows: Section 2 summarizes the main findings of the Final Report on settlement agreements; Section 3 makes an inventory of relatively old case law that dealt with comparable issues or those related to patent settlement agreements; and Section 4 makes an attempt to distill a legal test from the two previous sections for the assessment of patent settlement agreements between originator and generic firms under EC competition law.

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I. Introduction

On July 8, 2009, the Directorate General for Competition of the European Commission (“the Commission”) officially presented its Final Report on the pharmaceutical sector inquiry (“the Report”).¹ This 500 page report essentially deals with two issues in which patent protection plays a central role, namely the delay in generic entry and a decline in innovation. Pharmaceutical companies not only rely on a wide range of patents (patent clusters and divisional patents) to oppose generic entry, but they also use their patents as defensive tools to prevent other originator companies from carrying out Research and Development (“R&D”) activities. The report conveys the impression of a deficient European patent system combining a semi-unified patent delivery system and 27 different modes of patent protection. This system offers many possibilities to use patent laws for other purposes than stimulating innovation. It is therefore not surprising that the Final Report recommends the creation of a real community patent system supported by a unified judiciary. Nor is it surprising that this recommendation has the full support of the generic and innovating industry.

However, patent and regulatory issues relating to market authorizations and reimbursement rules are not the only causes of the delay in generic entry and declining innovation. The Report also refers to various commercial practices that could fall foul of antitrust rules. Concerning delayed generic entry, the Report distinguishes between two types of practices. The first category is unilateral in nature. It refers to smart and excessive use of patents, market authorizations, and reimbursement rules created by the originators concerned by the drop in prices and profits that normally occurs as a result of generic market entry. According to the Report, practically all originator companies have developed a tool-box of measures destined to delay such entry. The Commission’s decision fining *Astra Zeneca* for having misled regulatory authorities offers an example of the unilateral use of some of these tools.²

The second category of measures is bilateral in nature. These measures involve both originators and generic companies. This category concerns settlement agreements, including settlement agreements providing for a value transfer from the originator to the generic firm, either in the form of a direct (reverse) payment, a license, or a distribution right. The Final Report notes that this type of agreement has attracted the attention of the U.S. antitrust authorities and cites various examples of the American case law, including the recent *Cephalon* and *Solvay* cases.

The Commission seems keen to explore whether these precedents can also be followed in the European context, so as to speed up generic entry. On the day of

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the presentation of its Final Report, the Commission announced that it had initiated formal proceedings against Les Laboratoires Servier. The Commission is investigating whether the settlement agreements which this originator concluded with several generic companies concerning the marketing of the generic version of perindopril infringe Article 81 EC. In the absence of precedents, this procedure will break new legal ground.³

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II. Settlement Agreements and the Sector inquiry

The Report characterizes a settlement agreement as a commercial agreement pursuant to which parties settle their patent related disputes, opposition procedures, and litigation. Settlement agreements can give rise to competition concerns where they lead to the delay of generic entry in return for a payment from the originator to the generic company. It should be noted, however, that the agreements with such features represent a relatively small minority. During the sector inquiry, the Commission examined 207 agreements concluded between 2000 and 2008. Most of them (52 percent) did not restrict generic market entry. As regards the other 48 percent, entry was restricted in various ways: an absolute ban on entry, postponed access, or access under a license from the originator.

In addition, of these 48 percent, most agreements did not provide for value transfers. Only 45 percent of the restrictive agreements provided for value transfers in the form of lump sum payments, the grant of distribution rights, or compensation for legal costs and/or the purchase of assets, such as stocks of products in the possession of the generic company. Moreover, these payments occurred in both directions: payments flowing from the originator to the generic firm and payments from the generic to the originator. This being said, the amounts of money transferred from the originator to the generic (200 million EUROS) are significantly higher than amounts flowing in the opposite direction (7 million EUROS).

In total, the Report gives a relatively dispersed picture of settlement agreements, which can be summarized as follows: 108 agreements without entry restrictions (of which 69 percent were without value transfer and 31 percent with such transfer) and 99 agreements with entry restrictions (of which 55 percent were without value transfer and 45 percent with value transfer). This picture does not justify the finding that payments from the originator to the generic firm are necessarily linked to entry restrictions. Value transfers and restrictions on generic entry are two different concepts that may or may not coincide, especially since value transfers can also take place from the generic to the originator. As the Final Report observes, patent settlements are fact-specific and are difficult to categorize in general terms.

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Even so, the Commission also sought to identify the reasons why pharmaceutical companies entered into settlement agreements. These considerations vary from originator to generic companies. For originators, the Final Report lists two main reasons: the relative strength of the patent rights at stake and the revenues generated by the patented products. In assessing the strength of their patent rights, originators particularly focus on the ability to obtain interim injunctions against generic entry. For generic firms, the relative strength of the patent rights also plays an important role, but less so than the litigation costs, suggesting that generics seem to prefer a settlement agreement over a legal war of attrition.

Interestingly, both the originator and generic firms attach much importance to the position of other generic entrants. If there are more generic firms likely to enter the market, the incentive for the originator to enter into a settlement agreement increases, because the agreement keeps his patent rights in place and, hence, their deterrent effect *vis-à-vis* other generic contestants. For the generic firm, it is important to secure a position as the first generic on the market. In general terms, prices of pharmaceutical products rapidly erode once several generic entrants have penetrated the market. Entering into a settlement agreement might mean that the generic contracting party is the only generic on the market.

Finally, the Report notes on several occasions that the description of the agreements and the U.S. enforcement practice against such agreements do not provide any guidance on whether certain types of agreements could be deemed compatible or incompatible with EC Competition law. The Report indeed states that “such an assessment would require an in-depth analysis of the individual agreement, taking into account the factual, economic and legal background.”

This leads us to the next section, which deals with the question where such guidance can be found.

III. Guidance From Old Precedents

A. TRADEMARK DELIMITATION AGREEMENTS

As mentioned above, there are no precedents under EU competition law dealing with settlement agreements concluded between originator and generic pharmaceutical firms. However, in the earlier phases of EU competition law, the Commission and the Court of Justice had the chance to assess comparable issues when dealing with the compatibility of trademark delimitation agreements with Article 81 EC. These cases concerned the settlement of conflicts between owners of trademarks, which could be considered as giving rise to confusion. Where

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these settlements involved companies from different Member States, the settlement could lead to the allocation of national markets, and hence to splitting up the common market.

Obviously, this allocation of territories raised questions as to its compatibility with the market integration objective which, at that time, was still listed high on the Commission's priority list

for antitrust enforcement. The Commission sought to reconcile this tension by assessing, or second guessing, what the outcome of the trademark conflict would have been. In the presence of a genuine trademark conflict, the Commission considered that trademark delimitation conflicts could not be regarded as restrictive in nature.

The *Sirdar/Phildar* case of 1975 shows, however, that this approach did not correspond to the Commission's initial position.⁴ The case concerned a trademark settlement, pursuant to which Sirdar was allowed to use this trademark for the supply of knitting yarn in its home state, the United Kingdom, and its French counterpart, the Phildar trademark in France. Elsewhere, the trademarks would coexist. The Commission bluntly found that the agreement had as its object to restrict competition, since it restricted the possibility for both companies to sell in each other's territories.

Two years later, the Commission followed a more nuanced approach when assessing the trademark delimitation agreement concluded between two textile companies, namely J.C. Penney Co. from the United States and the Anglo-Irish ABF Group, which sold its products under the Penney's trademark.⁵ The Commission considered that the agreement offered the least restrictive alternative to solve the dispute.⁶ It noted that the application of national trademark law would have allowed each party to oppose imports by the other party in each other's territories. In addition, the exports affected by the agreement represented relatively small quantities.

The last official decision dealing with trademark delimitation issues dates from 1982.⁷ It concerned a dispute between two producers of tobacco products, namely Segers and BAT. Their agreement sought to put an end to the alleged confusion between the Toltecs and Dorcet trademarks in Germany. In this case, the Commission also analyzed whether the agreement, which prevented Segers from importing certain products under the Toltecs trademark from the Netherlands into Germany, led to a more restrictive result than the result to which the unilateral assertion of trademarks right would have led. When applying this test, the Commission found that there could be no serious ground for phonetic or visual confusion between the Toltecs and Dorcet trademarks. It also noted that Segers had not availed itself of the possibility to have the Dorcet trademark removed from the German trademark register, despite the fact that this trademark was not effectively used. The Commission, therefore, qualified the settlement agreement as restrictive in nature, especially since BAT, the owner of the Dorcet trademark, had entered into a series of similar agreements.

BAT challenged the 50,000 EUROS fining decision before the European Court of Justice.⁸ It held that the Commission was not competent to assess whether there was a real risk of confusion or not. This was, according to BAT, a matter of German trademark law and not of Community (competition) law. The Court rejected this argument. It acknowledged that trademark delimitation agreements are “lawful and useful if they serve to delimit, in the mutual interests of the parties, the spheres within which their respective trademarks may be used, and are intended to avoid confusion or conflict between them.”

However, such agreements may be caught by the cartel prohibition of Article 81(1) EC, “if they also have the aim of dividing up the market or restricting competition in other ways.” The Commission is therefore competent to intervene against such agreements. The Court specified in this respect that the “Community competition system does not allow the improper use of rights under any national trademark law in order to frustrate the Community’s laws on cartels” (ground 33). As regards the facts of the case, the Court shared the Commission’s analysis that the settlement agreement basically imposed undue restrictions on Segers’ ability to import tobacco products in Germany. The agreement did not clearly specify to which tobacco products the conflict related. Nor did it contain any explanation why Segers waived its right to claim priority rights for its trademark. It also contained a restriction on advertising that did not bear “even the semblance of a connection with the question of the use of the trademark as such.”

It follows from this overview that the Commission, as well as the Court, consider that trademark settlement agreements are not caught by Article 81 if they genuinely seek to avoid a real dispute between the parties, and that antitrust authorities are competent to make their own assessment of the risk of confusion and therefore of the authenticity of the dispute. The cartel prohibition applies, however, if the dispute is sham and if the settlement agreement just covers up a

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market-sharing agreement. The prohibition also affects restrictive provisions that go beyond what is required to solve the dispute. In other words, the cartel prohibition does not apply to trademark delimitation agreements that are necessary and proportionate in view of solving a trademark conflict.

B. PATENT NO-CHALLENGE CLAUSES

There are no precedents under EU competition law explicitly dealing with patent settlements, but there are various decisions and judgments concerning no-challenge clauses: *i.e.* contractual provisions, which often appear in distribution, licensing, or joint venture agreements, and which prohibit the licensee from contesting the validity of the patents covering the licensed products. This case law may be relevant for assessing the legality of patent settlements under EU competition law, because no-challenge clauses are an integral part of most, if not all, of these settlements. Such clauses often embody the outcome of the settlement by specifying the respective patent rights of the parties and their commitment to respect these rights.

In the early stages of European competition law, no-challenge clauses were treated with suspicion. In the old *AOIP/Beyrard* case, the Commission held that a contractual restriction on the licensee's ability to contest the validity of the patent was contrary to the public interest:

“Even if it is the licensee who is best placed to attack the patent on the basis of the information given to him by the licensor, the public interest in the revocation of patents which ought not to have been granted requires that the licensee should not be deprived of this possibility.”⁹

This statement reflects a certain distrust in patents. They are seen as obstacles to commercial freedom.

This negative approach also influenced the Commission's legislative policy. The Commission indeed systematically excluded the benefit of its block exemption regulations for agreements containing no-challenge clauses: “Article 81(1) shall not apply to agreements including certain obligations, provided that these obligations are without prejudice to the (...) right to challenge the validity of the (...) patent.”¹⁰ This position changed with the adoption of the block exemption currently in force. Article 5(1) sub(c) of Regulation 772/2004 excludes patent no-challenge clauses from the scope of the block-exemption for technol-

ogy transfer agreements; but, unlike the preceding regulations, the presence of such a clause in a license agreement no longer implies that the entire agreement loses the benefit of the block-exemption.¹¹

The Court's approach to patent no-challenge clauses also evolved over time. In the *Windsurfing* case, it followed the same rigorous approach as the Commission did in its early decisional practice.¹² The case concerned the legality of several contractual restrictions imposed by Windsurfing on its licensees. The Commission held that Windsurfing only held a patent on the rig and that the controversial licensing provisions were seeking to extend the scope of the patent protection to the board. In this context, the Commission objected to a clause that prevented Windsurfing's licensees from challenging the patents. Windsurfing did not accept this reasoning and appealed against the prohibition decision before the European Court of Justice.¹³

Windsurfing argued in the first place that the Commission was not entitled to assess the scope of its patents. This was, in its view, a matter of national law. Relying on similar grounds as those put forward in the *BAT* case referred to above, the Court acknowledged that the Commission is not competent to determine the scope of a patent, but accepted that the Commission can assess a patent's scope where this is relevant to determine whether or not Community competition rules have been infringed. This assessment is carried out only in the context of competition law procedures and does not bind national courts when they have to rule on the validity or scope of the patent under national law.

After having thus clarified the Commission's competence in patent-related matters, the Court examined the appeal against the Commission's prohibition of the patent no-challenge clause. The Court ruled that such a clause was not covered by the patent right itself and that it was contrary to the public interest:

“such a clause clearly does not fall within the specific subject matter of the patent, which cannot be interpreted as also affording protection against actions brought in order to challenge the patent's validity, in view of the fact that it is in the public interest to eliminate any obstacle to economic activity which may arise where a patent is granted in error.”

Without any further reasoning, the Court qualified the no-challenge clause as an unlawful restriction of competition.

In 1988, however, the Court of Justice took a more liberal stance regarding patent no-challenge clauses.¹⁴ The case concerned a patent settlement between

Bayer and Mr. Süllhöfer who each held patents for construction panels. Under that agreement, Süllhöfer granted Bayer a non-exclusive, royalty-free license with the right to sublicense its patents in Germany, and a non-exclusive license subject to royalties in other Member States. From its side, Bayer granted Süllhöfer a royalty-bearing, non-exclusive license. Bayer also undertook not to challenge the validity of Süllhöfer's patents. The truce which this agreement was supposed to bring about was of short duration. Soon after its conclusion, the parties started to argue about its interpretation. In this context, the German courts stayed proceedings and requested the Court of Justice to rule on the validity of a patent no-challenge clause under Article 81 EC.

During the proceedings before the Court, the Commission argued that a non-challenge clause could not be considered as restrictive, when it is included:

“in an agreement whose purpose it is to put an end to proceedings pending before a court, provided that the existence of the industrial property right which is the subject-matter of the dispute is genuinely in doubt, that the agreement includes no other clauses restricting competition, and that the no-challenge clause relates to the right in issue.”

The Commission thus took the same position as the one adopted for the assessment of trademark delimitation agreements.

Bearing in mind that it had followed a similar approach in the *BAT* case, the Court's reaction to the Commission's argument can be qualified as surprising. The Court discards the suggestion that the legality of the no-challenge clause should be assessed in conjunction with the settlement agreement which it is supposed to support. The Court isolates the clause from the context of the settlement and analyzes it directly. It holds in the first place that where the license is granted for free, there can be no restriction of competition, because “the licensee does not suffer from the competitive disadvantage involved in the payment of royalties” (ground 17). Moreover, even where a license had been subject to payment, a no-challenge clause is not restrictive, “if the license relates to a technically outdated process which the licensee undertaking did not use” (ground 18). Finally, the Court pointed out that:

“if the national court were to consider that the no-challenge clause contained in the license granted subject to payment of royalties does involve a

limitation of the licensee's freedom of action, it would still have to verify whether, given the positions held by the undertakings concerned on the market for the products in question, the clause is of such a nature as to restrict competition to an appreciable extent (ground 19).”

C. PRELIMINARY CONCLUSIONS

The case law examined above is relatively old; one should therefore be cautious in drawing conclusions. Even so, one can be relatively confident that the Commission and Courts will still apply the “least restrictive alternative test” as developed in the case law on trademark delimitation agreements. If the outcome of settlement is less restrictive than what the outcome of (protracted) litigation would have been, the settlement agreement can hardly be considered as restrictive. There is one proviso to this test: The agreement should not only be necessary, but also proportionate to solve the conflict. Restrictions that have no bearing with the underlying dispute will not benefit from the presumption that they are not restrictive in nature.

The Court accepts that the application of this test implies some form of second guessing of the relative strength of the patent rights at stake by the competent antitrust authority. It should be noted that this assessment is only made for the purposes of applying EC competition rules, and that it does not bind national courts when they are requested to determine the validity of patent rights under national patent law.¹⁵

It follows from the Commission's position in *Bayer v. Sülhörer* that no-challenge clauses are, in its view, an integral part of settlement agreements, and that their legality should be assessed in conjunction with those agreements. The Court of Justice, however, seems to consider that the question as to whether or not a no-challenge clause restricts competition must be assessed in isolation.

However, it is also possible to interpret the *Bayer v. Sülhörer* precedent in another way. It may indeed be considered that the facts of the case did not justify a complex assessment of the underlying patent dispute. Since the no-challenge clause related to a technology which Bayer did not use in any event, and for which it did not have to pay, applying EC competition rules can be regarded as a relatively hypothetical issue which did not merit much judicial attention.

The *Bayer v. Sülhörer* case contains one important proviso; namely, the fact that a contractual provision which restricts the freedom of action of one of the parties does not suffice to trigger the prohibition of Article 81. Any agreement

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must be assessed in its economic and legal context and will only be caught by this prohibition if it appreciably restricts competition. This applies to all agreements, including settlement agreements that cannot be justified by the underlying patent dispute. The least restrictive alternative test discussed above simply means that settlements meeting this test are generally not caught by Article 81 EC, but it does not inevitably mean that agreements failing this test are necessarily prohibited. Sham agreements are not necessarily restrictive agreements; they will therefore only be caught by Article 81(1) EC if they appreciably restrict competition in their economic and legal context.

IV. Assessing Patent Settlement Agreements Under Article 81

The requirement that all agreements must be assessed in their legal and economic context implies that there is, unlike U.S. competition law, no *per se* rule which could possibly apply to settlement agreements. It should be noted that this approach also applies to so-called hard-core restrictions such as price-fixing, market-sharing, or output restrictions. The fact that these restrictions cannot benefit from the presumption of legality conferred by the Notice of minor importance does not dispense the Commission or Courts from assessing whether they can, by their object or effect, restrict competition in a given legal and economic context.¹⁶ In any event, one cannot reasonably argue that settlement agreements are akin to hard-core or naked restrictions which can be presumed to be anticompetitive. As shown by the Final Report on the sector inquiry, there is a large variety of settlement agreements and only a minority of these agreements is likely to give rise to competition concerns. Settlement agreements must therefore be assessed on a case-by-case basis.

The first step of this analysis concerns the question whether the settlement agreements have, as their object or effect, restricting or delaying generic market access. If they do not, they are unlikely to be caught by Article 81 EC. Some settlement agreements may even be pro-competitive. This is the case, for example, with settlement agreements which allow the generic firm to launch its product or which allow it to create generic market presence.

The issue of value transfers from originator to the generic is not relevant when assessing the restrictive nature of a settlement agreement. As shown by the Final Report, payments may take place in all sorts of manners and under all sorts of settlement agreements, including those that do not restrict competition. Reverse payments by themselves are and cannot be restrictive.

The second step of the analysis only applies to settlements that delay or restrict generic market access. Applying the trademark case law discussed under Section 2 by analogy, one could argue that Article 81 does not apply to such agreements where they are less restrictive than the outcome of patent litigation between the

originator and the generic. Indeed, if the originator fully succeeds in enforcing its patents, there will be no generic entry whatsoever. In other words, Article 81 does not apply to settlement agreements which produce restrictive effects which are less or equal to those resulting from the judgment on the merits of the originator's patents. The application of this "least restrictive alternative" test implies that the authority must make its own assessment of the relative strength of the patents at stake. This judge or authority must, in a certain sense, second guess what a specialized patent court or authority would have decided if the parties to the agreement had fought their dispute until the bitter end.

Here again, the presence or absence of payments does not seem relevant for carrying out this assessment. As a rule, the relative strength of a patent is a technical issue and not a financial one. Even so, a significant value transfer to the generic firm in a scenario where the originator's patent is *prima facie* weak, may constitute an indication that the originator was paying the generic firm to not enter the market, in particular when the parties to the agreement do not have any plausible explanation for the disproportionate nature of the payment. In other words, reverse payments may, in certain scenarios, offer circumstantial evidence for finding that the settlement agreement does not constitute the least restrictive alternative.

This brings us to third step of the analysis. The fact that a settlement restricts generic entry and that this effect cannot be justified by the patents invoked does not suffice to trigger Article 81(1) EC. This fact simply implies that the agreement restricts competition between the contracting parties, but does not imply that it significantly restricts it in the Common Market, as required by Article 81(1) EC. This last condition implies, as stated above, that the settlement agreement in question must be assessed in its legal and economic context. There are various situations in which a restriction of the competition between the parties does not necessarily lead to a restriction of competition in that wider context.

If the parties concerned only have a small market presence, the agreement is unlikely to have such an effect. The Notice on agreements of minor importance lays down the presumption that agreements involving parties whose market share does not exceed 10 percent do not appreciably restrict competition. So, if the market share of the parties to the settlement agreement remains below this threshold, the agreement is unlikely to lead to an appreciable restriction of competition.

However, the application of market share thresholds obviously requires the definition of a relevant market. Under its decisions to date, the Commission has defined relevant markets in the pharmaceutical sector on the basis of therapeutic indications: All drugs which can be prescribed for the same therapeutic indication are considered to be part of one and the same product market.¹⁷ One may wonder, however, whether this traditional market definition method is always adequate to assess settlement agreements between originators and generics. As

illustrated by the Report on the sector inquiry, price levels in markets where no generic entry has taken place are significantly higher than the price levels prevailing in markets which have already turned generic.¹⁸ A settlement agreement that delays generic entry may effectively keep price levels high and thus significantly restrict competition, if it is concluded between an originator and the first potential generic entrant. Such an agreement would prevent the market from

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turning generic and hence protect the higher price levels. By contrast, a settlement agreement concluded between firms that already operate in a market with generic market presence is unlikely to produce such effects.

Seen from this angle, it is also possible to refer to what the Court meant to say in *Bayer v. Sülhölfer* case. Agreements restricting the use of products that are not going to be used regardless, are unlikely to have a significant market impact triggering Article 81(1). If the pharmaceutical products covered by the settlement agreement are unlikely to be used or sold, the settlement agreement does not merit much attention from the antitrust enforcers.

This last comment leads to the more general question concerning the expediency of antitrust enforcement against settlement agreements. Obviously, fighting agreements which delay market entry and which create unnecessary costs for social security schemes is a good cause. It is less obvious that settlement agreements contribute significantly to this delay. The Final Report does not quantify the societal costs that could possibly be allocated to settlement agreements that delay market entry. It rather conveys a picture of a wide variety of agreements. The majority of these settlements do not restrict generic market entry.

Moreover, distinguishing restrictive settlement agreements from neutral or even pro-competitive settlement agreements is a complex task. A radical and harsh condemnation of settlement agreements and reverse payments is hard to reconcile with this complexity and may even have a counterproductive effect. If generic firms lose the option of concluding settlement agreements when they enter the market at the risk of being sued for patent infringements, they may decide not to enter the market at all. Finding the right dosage also applies to antitrust enforcement. ▼

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- 1 Pharmaceutical Sector Inquiry, Final Report, DG Competition, Staff Working Paper, 08.07.2009, available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.
 - 2 2006/857/EC: Commission Decision of 15 June 2005, (Case COMP/A.37.507/F3 — AstraZeneca), O.J., L 332, 30/11/2006, p. 24 – 25.
 - 3 Please note that this article does not deal with settlement agreements concluded between originator firms.

- 4 Commission Decision of 5 March 1975, (IV/27.879 - Sirdar-Phildar), *O.J.*, L 125, 16/05/1975, p. 27 – 30.
- 5 Commission Decision of 23 December 1977, (IV/29.246 - Penneys), *O.J.*, L 060, 02/03/1978 p. 19 – 27.
- 6 The settlement agreement also provided that Penney America would pay ABF a certain sum in installments. The Commission’s analysis did not deal with the legitimacy of these payments.
- 7 Commission Decision of 15 December 1982, (IV/C-30.128 Toltecs-Dorcet), *O.J.*, L 379, 31/12/1982, p. 19 – 29.
- 8 Judgment of the Court of 30 January 1985, BAT Cigaretten-Fabriken GmbH v Commission of the European Communities, Case 35/83, *E.C. Reports* 1985, p.363.
- 9 Commission Decision of 2 December 1975, (IV/26.949 - AOIP/Beyard), *O.J.*, L 006, 13/01/1976 p. 8 – 15.
- 10 Article 2 of the Commission Regulation (EC) No 2349/1984 of 23 July 1984 on the application of Article 85 (3) of the Treaty to certain categories of patent licensing agreements, *O.J.*, L 113, 26/04/1985, p. 35; See also Commission Regulation (EC) No 556/1989 of 30 November 1988 on the application of Article 85 (3) of the Treaty to certain categories of know-how licensing agreements, *O.J.* L 61, 04/03/1989, p. 1.
- 11 Commission Regulation (EC) No 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements, *O.J.*, L 123 , 27/04/2004 p. 11 – 17.
- 12 Commission Decision of 11 July 1983, (IV/29.395 - Windsurfing International), *O.J.*, L 229, 20/08/1983, p. 1 – 21.
- 13 Judgment of the Court (Fourth Chamber) of 25 February 1986, Windsurfing International Inc. v Commission of the European Communities, Case 193/83, *E.C. Reports* 1986, p. 611.
- 14 Judgment of the Court of 27 September 1988, Bayer AG and Maschinenfabrik Hennecke GmbH v Heinz Süllhöfer, Case 65/86, *E.C. Reports* 1988, p. 5249.
- 15 This is an important nuance to the primacy rule laid down in Article 16 of Regulation 1/2003 according to which Commission decisions are binding for national courts and authorities having to rule in the same case.
- 16 Commission Notice on agreements of minor importance which do not appreciably restrict competition under Article 81(1) of the Treaty establishing the European Community (de minimis), *O.J.*, C 368, 22/12/2001, p. 13 – 15 ; Judgment of the Court of 30 June 1966, Société Technique Minière (L.T.M.) v Maschinenbau Ulm GmbH (M.B.U.), Case 56-65, *E.C. Reports* 1966, p. 235 ; Judgment of the Court of First Instance of 2 May 2006, O2 Germany v Commission, *O.J.* C 154, 01/07/2006, p. 15.
- 17 *AstraZeneca*, *supra* note 2., §358 and f.
- 18 Pharmaceutical Sector Inquiry, Final Report, *supra* note 1., p. 77 and f.