

2nd Report on the Monitoring of Patent Settlements (period: January-December 2010)

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1. Introduction

- (1) As announced in the Commission's Communication¹ concluding the pharmaceutical sector inquiry on 8 July 2009, it is considered important to continue monitoring the patent settlements between originator and generic companies. This second round of monitoring is a follow-up to the first monitoring exercise concluded in 2010². The main objectives of the monitoring exercise are to better understand the use of this type of agreements in the EU and to identify those settlements that delay generic market entry to the detriment of the European consumer possibly in violation of European competition law.³
- (2) Patent settlement agreements, as examined in this context, are commercial agreements to settle actual or potential patent-related disputes, e.g. questions of patent infringements or patent validity. They are concluded in the context of patent disputes, opposition procedures or litigation where no final adjudication has been handed down. Although the content of individual settlements will vary according to the circumstances of the case, the common aim of a settlement is to end the disagreement.
- (3) As in any other area of commercial disagreement, the parties concerned have a legitimate interest in finding a mutually acceptable compromise for their disagreement. In particular the parties may prefer to discontinue the dispute or litigation because it proves to be too costly, time-consuming and/or risky as regards its outcome. Settlements are thus a generally accepted, legitimate way of ending private disagreements. They can also save courts and/or competent administrative bodies such as patent offices time and effort to decide on the matter and can therefore have some positive impacts on the interest of society.
- (4) However, as pointed out in the Final Report of the sector inquiry (hereinafter: "Final Report"), some patent settlements in the pharmaceutical sector may prove to be problematic from a competition law perspective. Of particular interest are settlements that may lead to a delay of generic entry in return for a value transfer (e.g. a payment) by the originator company to the generic company. Other examples of possibly problematic agreements relate to settlements that contain restrictions beyond the exclusionary zone of the patent, meaning that they would reach beyond its geographic

¹ The full texts of the Commission Communication on the final report (hereinafter: Commission Communication) as well as the final report as technical annex to the communication are available at the website of DG Competition: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html> . See also Press Release IP/09/1098 and MEMO/09/321.

² The First Report on the monitoring of patent settlements is available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report1.pdf

³ Commission Communication, p. 20.

scope, its period of protection or its material scope, e.g. beyond the patent claims. Such agreements would not appear to be directly related to any IP rights granted by the patents concerned. Furthermore, problematic agreements include settlement agreements on a patent for which the patent holder knows that it does not meet the patentability criteria. An example for this would be a situation where the patent was granted following the provision of incorrect, misleading or incomplete information. Ultimately, it may be the consumer in such cases who pays the price for such a delay in market entry and therefore any benefits to society identified above are more than outweighed by the negative effects of the agreement between potential competitors. In this context, obviously, an assessment of each individual case would be necessary.

- (5) DG Competition launched the second monitoring exercise into patent settlements in January 2011 covering the time period from 1 January 2010 to 31 December 2010⁴. Formal requests for information were sent to originator companies and generic companies, which had cooperated with the Commission in the course of the sector inquiry and/or were reported in the specialised press as having concluded a patent settlement in the period in question.
- (6) This report sets out the results of the second monitoring exercise. In a first section it recalls the main classifications of patent settlements as set out in detail in the Final Report. It then provides the overview of the replies submitted by companies, including an analysis of the main characteristics of the settlements falling within particular categories. The final section contains some brief conclusions.

2. Classification of the agreements

- (7) In the Final Report the Commission proposed a categorisation of patent settlement agreements which will be also used for the purpose of the present report. In this context it has to be underlined that this report is written from a competition law perspective which does not put into question the patent system or its procedure or criteria of granting exclusive rights. In a nutshell it is based on two main criteria, firstly whether the agreement foresees a limitation on the generic company's ability to market its own medicine and secondly whether it foresees a value transfer from the originator to the generic company.⁵
- (8) For the purpose of the present analysis, a generic company's ability to enter the market can be limited in several ways: (i) The most straightforward limitation occurs when the settlement agreement contains a clause explicitly stating that the generic company will refrain from challenging the validity of the originator company's patent(s) ("non-challenge clause") and/or refrains from entering the market until the patent(s) have expired ("non-compete clause"). (ii) A licence granted by the originator company allowing market presence of the generic company is also categorised as limiting

⁴ Press Release IP/11/40.

⁵ For the purpose of this report it was deemed impossible to assess whether any settlement relates to patents, where the patent holder knows that his patent does not meet the patentability criteria, or whether it contains restrictions exceeding the exclusionary zone of the patent invoked.

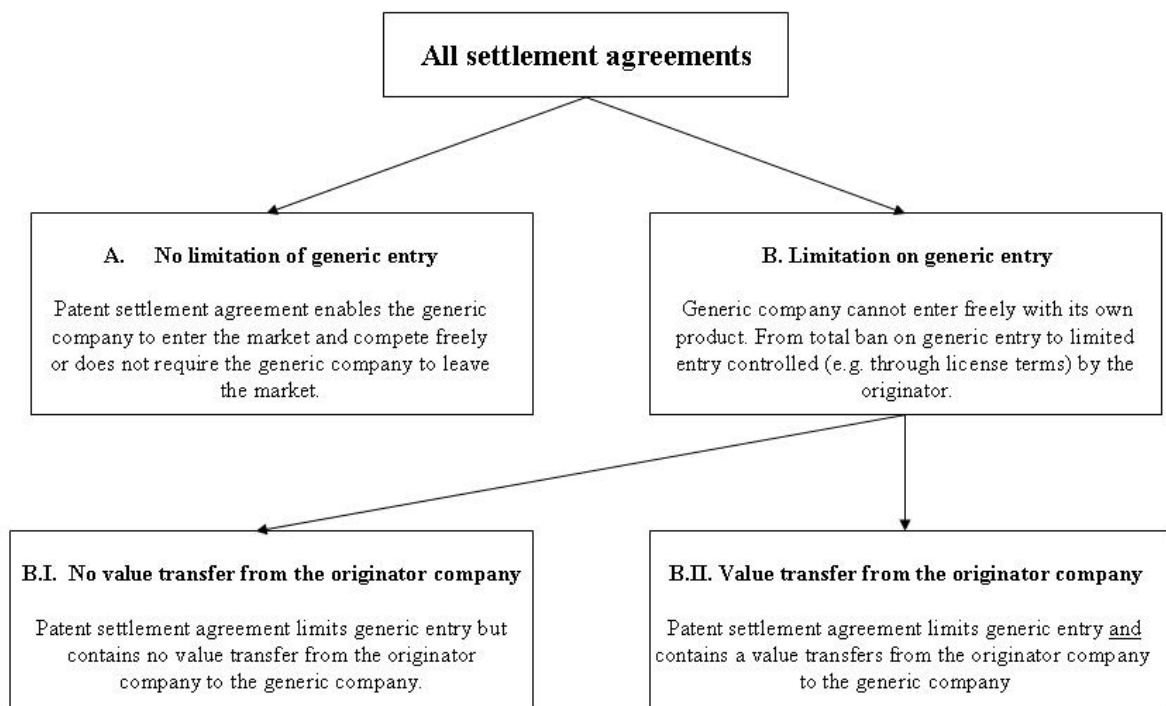
generic entry, because the generic company cannot enter the market with its own product or it cannot set the conditions for the commercialisation of its product freely.⁶ Accordingly, the generic company's entry is at least partly controlled by the originator company through the terms of the licence agreement⁷. (iii) The same logic applies to patent settlement agreements in which the parties agree that the generic company will be a distributor of the originator product concerned or if the generic company will source its supplies of the active pharmaceutical ingredient (API) from the originator company. It should be noted that the list of potential limitations is not exhaustive.

- (9) Also the value transfer from the originator company to the generic company can take different forms: (i) the most clear-cut form of value transfer is a direct monetary transfer (e.g. payment of a lump sum) from the originator company to the generic company. According to the settlement terms, such a monetary transfer can, for example, have the purpose to purchase an asset (e.g. the generic company's stock of own products), but it can also have the purpose – explicitly or implicitly - to pay the generic company for agreeing to the delay of the product launch and/or for the discontinuation of the patent challenge. It is considered that originator companies are able to afford such payments as the settlement allows the company to continue reaping the benefits of its well selling medicine. (ii) Other types of value transfer include distribution agreements or a "side-deal" in which the originator company grants a commercial benefit to the generic company, for example by allowing it to enter the market before patent expiry in another geographical area or by allowing market entry with another product marketed by the originator company. (iii) A value transfer could furthermore consist in granting a licence to the generic company enabling it to enter the market. Again the list of possible value transfers is not exhaustive.
- (10) For any of the value transfers observed in the present monitoring exercise, it was only investigated whether such a transfer was agreed upon without verifying the (net) amount of the transfer nor any possible justifications for it.
- (11) In line with the above, agreements that do not restrict the generic company's ability to market its own product on the market are categorised as A-type, while those limiting generic entry are categorised as B-type. Agreements limiting generic entry are further categorised in two groups: B.I settlements, which comprise those settlements where no value transfer from the originator to the generic company took place; and B.II settlements which foresee a value transfer from the originator to the generic company.
- (12) Typically category A settlements should be unproblematic from a competition law perspective, as they allow an immediate market entry of the generic company with its own product (obviously unilateral conduct of the originator company that might have caused generic delay would remain subject to competition law scrutiny).

⁶ This categorisation is done for competition law purposes only. It does not prejudice the right of patent owners to assign, or transfer by succession, the patent and to conclude licensing contracts as declared in Art. 28 (2) TRIPS.

⁷ An exception applies in case of royalty free licenses that allow immediate product launch without any further constraints.

- (13) The same applies to category B.I settlements, but it might be necessary to deviate from this line in exceptional circumstances such as settlements outside the exclusionary zone of the patents and/or settlement agreements on a patent for which the patent holder knows that it does not meet the patentability criteria, e.g. where the patent was granted following the provision of incorrect, misleading or incomplete information. Those types of settlement might attract competition law scrutiny.
- (14) Category B.II settlements are likely to attract the highest degree of antitrust scrutiny without suggesting that all agreements falling into this category would be incompatible with EU competition law. This needs to be assessed on the basis of each individual case and can lead to the conclusion that action is needed at national or European level or that the value transfer or the size of the market concerned are too small to warrant further investigations.
- (15) The subsequent figure provides an overview of the main categories as used by the Commission on the case of the sector inquiry and for the purpose of the monitoring exercise.



3. The Monitoring Exercise 2010

- (16) The monitoring exercise was launched in January 2011 and covered the period from 1 January 2010 to 31 December 2010. In total 59 originator and 70 generic companies were asked to submit to the Commission a copy of all patent settlement agreements relevant for the EU/EEA markets. These companies were selected from the originator companies and generic companies, which had cooperated with the Commission in the

course of the sector inquiry⁸ and/or were reported in the specialised press as having concluded a patent settlement in the period in question. In order to minimise the administrative burden on the companies, they were asked to submit a copy of the agreements together with copies of all annexes, related agreements and amendments concluded between originator and generic companies and only limited additional background information. The possibility of supplementary questions was envisaged and made use of in a few instances. The Commission ensured that it received replies from all relevant operators.

- (17) The statistics provided below, which are based on the companies' replies, concern only patent settlements in the narrow sense (i.e. settling a patent dispute, opposition procedure or litigation). Where other agreements were submitted within the monitoring exercise, they were also analysed with respect to the question whether they amount to a side deal/related agreement and otherwise disregarded.

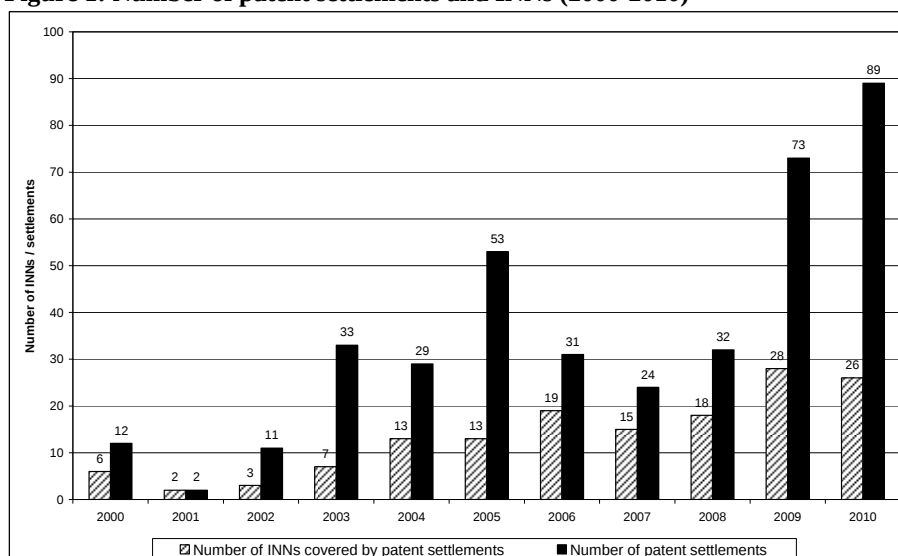
3.1. Some general statistics of the patent settlements submitted to the Commission

- (18) The information gathered during the monitoring exercise allows describing the development of patent settlements from the beginning of 2000 until the end of 2010 by consolidating the data obtained in the course of the sector inquiry and in the course of the first monitoring exercise with the newly acquired information. Compared to the sector inquiry and the first monitoring exercise, a significant number of companies were added following, in particular, information found in the specialised press on the conclusion of settlement agreements. In any case, the sector inquiry already covered 80% of the overall turnover of the market suggesting a high degree of representativeness.
- (19) Figure 1 shows the yearly numbers of patent settlements concluded during 2000 – 2010 as well as the numbers of INNs⁹ covered by the patent settlements in each year.

⁸ During the sector inquiry 43 originator companies and 27 generic companies had been selected for in depth analysis.

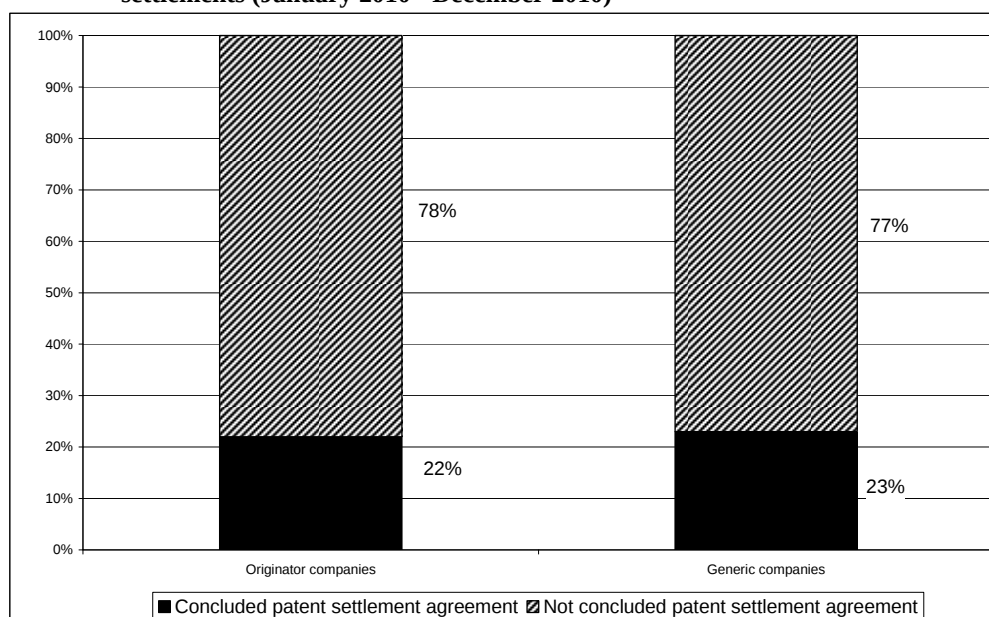
⁹ An INN is the international non-proprietary name for a pharmaceutical substance.

Figure 1: Number of patent settlements and INNs (2000-2010)



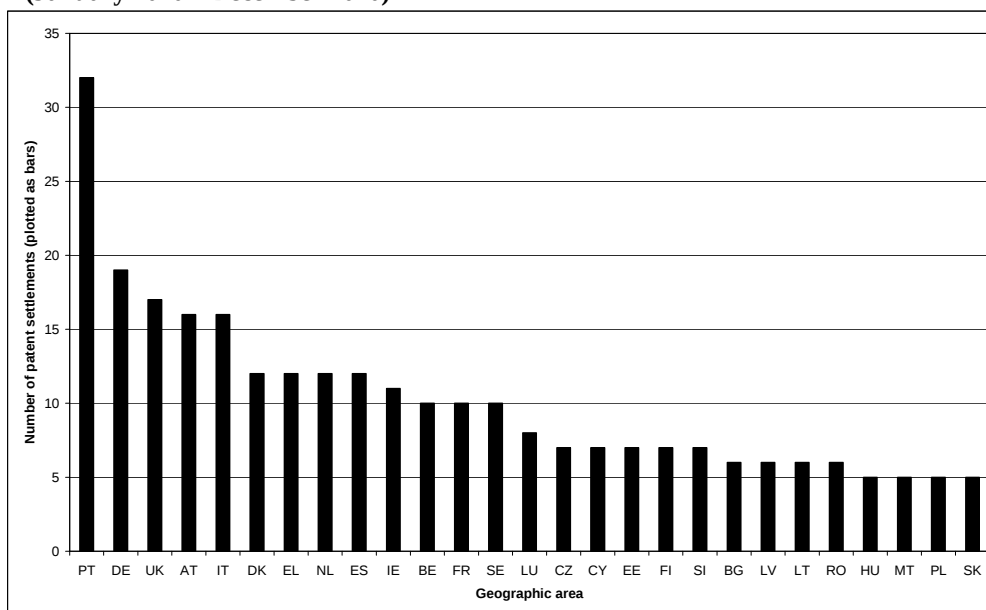
- (20) As already pointed out in the Final Report, the numbers of patent settlement agreements at the beginning of this period (2000-2002) were comparatively low, whereas thereafter a significant increase can be observed (with three peaks: 53 settlements in 2005, 73 in 2009 and 89 in 2010). The sharp increase of patent settlements concluded in the last two years may be due to a variety of different reasons, such as the medicines losing patent protection, a general increase in litigation and disputes that lead to a higher number of settlements, the higher readiness of both parties to settle. The increase however cannot be explained by the number of companies added in the monitoring exercise vis-à-vis the sector inquiry as the added companies had hardly any effect on the number of settlements (they amounted in fact to less than 3%).
- (21) Out of the 59 originator companies selected for the reporting period of 1 January 2010 to 31 December 2010, 13 companies (22%) concluded patent settlements. This corresponds to the development for the generic sector: i.e. almost 23% of the generic companies in the sample concluded a patent settlement (16 out of 70). These statistics are reflected in Figure 2.

Figure 2: Percentage of originator companies and generic companies that had entered into patent settlements (January 2010 - December 2010)



- (22) Figure 3 breaks down the number of patent settlements by geographic areas covered by the agreements. Every agreement covered at least one EU Member State. Some of the settlements covered more than one Member State. For the purpose of this figure settlements relating to more than one Member State are counted as a separate patent settlement for each Member State (which explains that the sum of the settlements per Member States exceeds the total number of settlements reported). Four settlements covered the whole EU 27. In addition some agreements also covered countries outside the EU, and some were global (not indicated in Figure 3). Only two settlements concerned states outside the EU but within the EEA. Like in the sector inquiry, figure 3 shows the wide geographic coverage of settlements in the EU with certain Member States such as Portugal and Germany attracting a higher number of settlements.

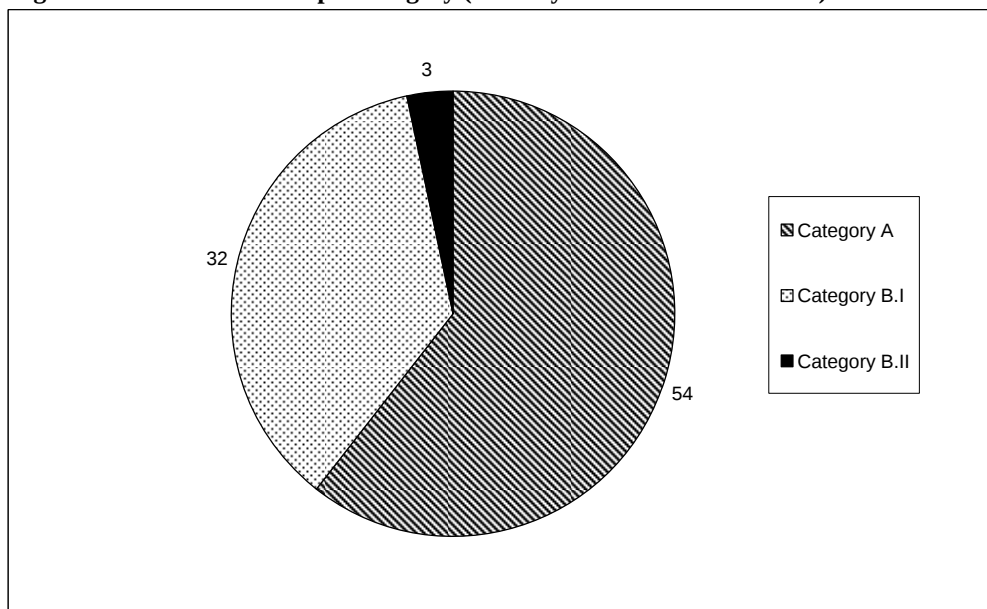
**Figure 3: Number of patent settlements per EU27 Member State
(January 2010 – December 2010)**



3.2. Categories of patent settlements

- (23) The subsequent section describes in more detail the different types of patent settlement agreements concluded between generic and originator companies in the period from 1 January 2010 until 31 December 2010.

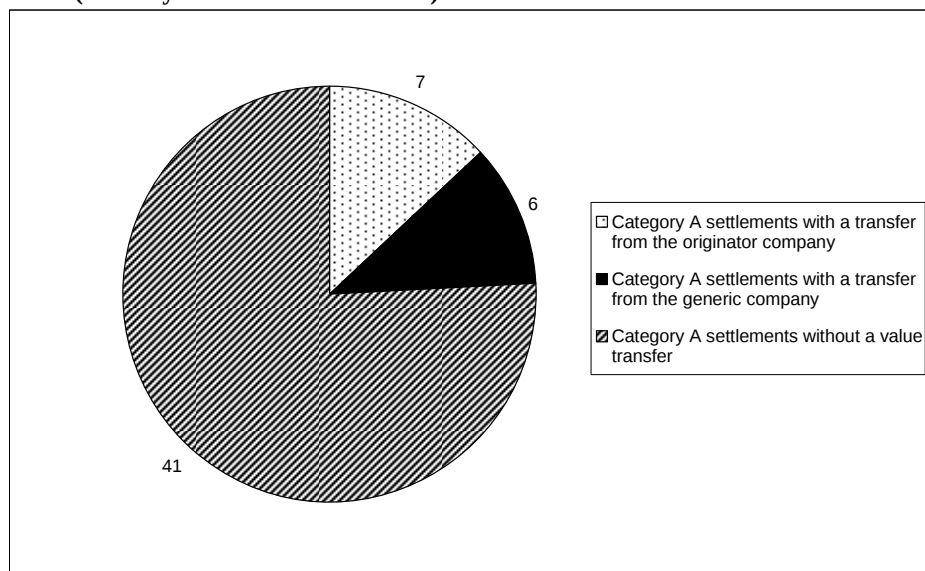
Figure 4: Patent settlement per category (January 2010 – December 2010)



Category A Settlements: Settlements that do not limit generic entry

- (24) As presented in Figure 4, 54 of the total of 89 patent settlements (= 61%) did not limit the generic company's entry into the market (category A). The generic company was thus free to market its own generic product in the geographic market concerned, under the conditions chosen by the generic company itself.
- (25) Litigating parties may enter into category A settlement agreements for a variety of reasons. The terms of the settlement agreements took various forms, depending amongst others on whether or not the generic company had entered the market (at risk) or whether the settlement was concluded close to the time when the originator company lost exclusivity anyhow.

**Figure 5: Category A settlements with or without value transfer
(January 2010 – December 2010)**



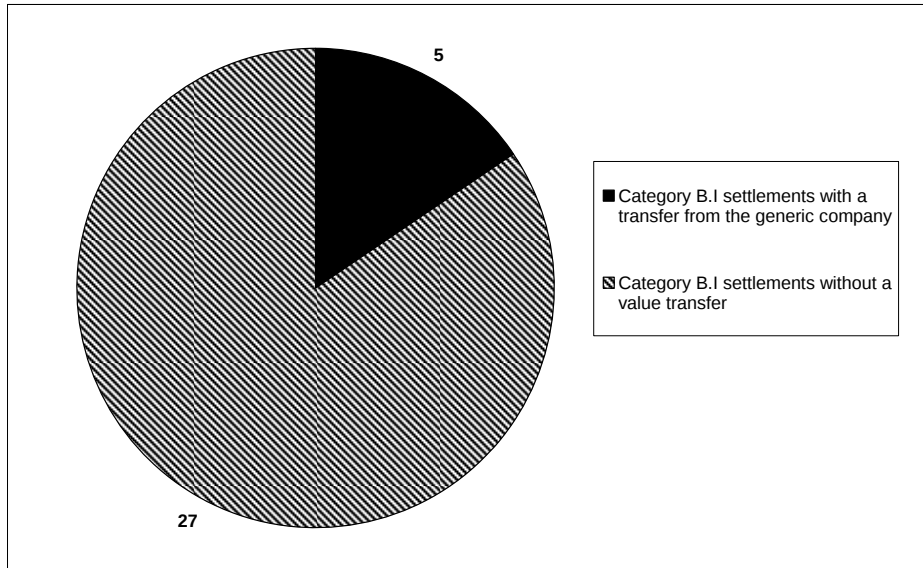
- (26) As presented in Figure 5, 41 of the category A settlement agreements (= 76%) did not include any payment, but were concluded on a so-called "walk-away" basis, i.e. settlements where both parties agreed to simply discontinue their litigation without any further commitment/obligation on any of them. Such an agreement would appear to be the most likely outcome if both parties believe that continuing the litigation would be a waste of time and/or resources.
- (27) A value transfer from the originator company to the generic company took place in 7 of the category A settlements, for example when an originator company had originally obtained an interim injunction against a generic company's product, but later feared to lose the main case. Under such circumstances, the generic company could claim damages for lost sales it incurred whilst it was prevented from marketing its product. The value transfer flowing to generic companies in category A settlements consisted in payments from the originator company to the generic company (e.g. for damages or litigation costs).

- (28) It is important to note that in cases in which the originator company transferred a value to the generic company following such a settlement, the damages actually suffered by the generic companies might be fully compensated. However the compensation in the context of such a settlement does not reimburse the damage suffered by the consumers and health insurers/public health schemes that might be caused by delayed generic entry and therefore might not be entirely satisfactory for consumers whose interests are not represented in the settlement discussions.
- (29) In six cases a value transfer from the generic company to the originator company took place. An example for such a settlement could be that the generic company had entered the market at risk. However the patent subject to the parties' litigation was later assumed to be valid in the assessment of the parties. In those cases the generic company paid compensation to the originator company, covering legal fees and possibly additional damages.

Category B Settlements: Settlements that limit generic entry

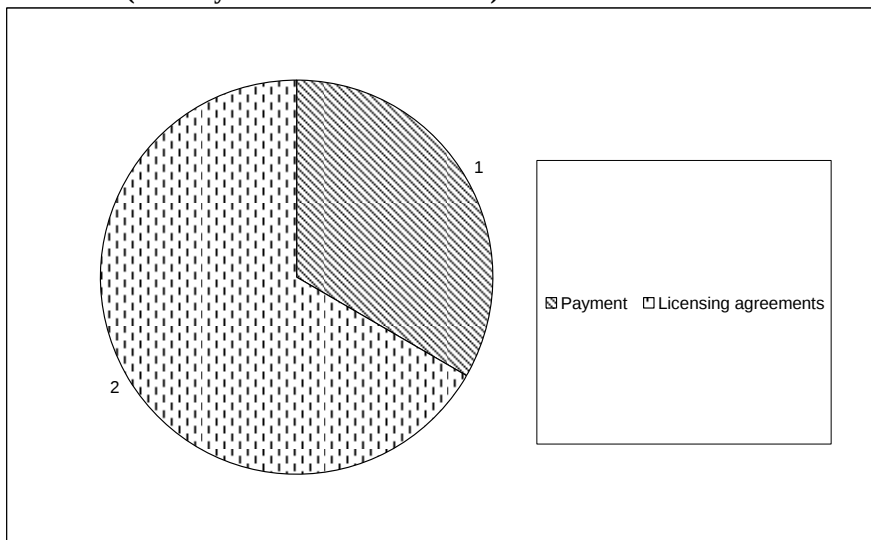
- (30) In the period investigated 35 agreements containing a limitation on the generic company's ability to market its own product were concluded (category B). 32 of these 35 (= 91%) included an explicit limitation of the market entry for the generic company, but no value transfer to the generic company (category B.I.). In these agreements the generic company agreed to enter only after the patent(s) at issue had expired. The main characteristic of this category seems to be that in the assessment of the parties the originator company had a strong case. In five of these instances, the generic company also agreed to pay damages to the originator company for having infringed the originator company's patents through its early entry (see figure 6). In a number of the agreements the generic company also undertook to accept the court ruling(s) as final, rather than appealing against it and agreed not to challenge the validity of the patent in the future.

**Figure 6: Category B.I settlements with and without value transfer from the generic company
(January 2010 – December 2010)**



- (31) As presented in Figure 7, of the total number of 89 agreements, three patent settlement agreements limited the generic company's ability to market its own product and included a value transfer from the originator company to the generic company (category B.II).
- (32) The value transfer flowing to generic companies in the settlement agreements took only two forms. One agreement included a direct payment, whereas the other two agreements included a licensing agreement with the generic company.

**Figure 7: Number of B.II patent settlements per type of value transfer
(January 2010 to December 2010)**



- (33) This report merely summarises the results of the monitoring exercise and no decision has been taken or implied on further investigation of any of the settlement agreements reported under this category. In any event an assessment on the basis of each individual case has to be undertaken.¹⁰ This can also lead to the conclusion that action if any might be more appropriate at national level or that the value transfer or the size of the market concerned are too insignificant to warrant any investigations.

4. Conclusion

- (34) The second monitoring exercise undertaken by the Commission covered the period of 1 January 2010 until 31 December 2010, i.e. 12 months. It unearthed that 89 agreements were concluded. In line with the upward trend described in the first monitoring report covering the period July 2008 to December 2009, the present exercise has confirmed the increasing use of patent settlements in the European pharmaceutical sector measured by the number of patent settlements concluded. Also the number of INNs, which were subject to settlements, remained at a very high level compared to the years covered by the sector inquiry.
- (35) It is noteworthy that the number of B.II settlements, i.e. settlements which restrict generic entry and show a value transfer from the originator to the generic company and which might attract competition law scrutiny, have decreased significantly compared to the period investigated in the course of the sector inquiry. In the period of 2000 until mid 2008, covered by the sector inquiry, B.II settlements constituted 22 % of the settlements reported (45 out of 207). In the period covered by the first monitoring exercise, the B.II settlements decreased to 10 % of all concluded settlements (9 out of 93). In the present monitoring exercise covering the year of 2010, only 3 % of the settlements were B.II settlements (3 out of 89). An explanation for these developments may be the increased awareness of companies and their legal advisors regarding the question whether such agreements might attract competition law scrutiny. The fact that the Commission announced a continued monitoring of patent settlements and the ongoing competition proceedings in the Servier and Lundbeck cases might have had a deterrent effect.
- (36) At the same time the results of the second monitoring exercise show that the Commission's announcement to continue scrutinizing B.II category settlements in the future has not hindered companies from concluding settlements in general. In fact the number of category A settlements regarded by the Commission as *prima facie* unproblematic from a competition law viewpoint has increased from 52% during the period examined in the sector inquiry to 57% during the first monitoring reporting period and has reached 61% in 2010. The trend concerning B.I settlements is very similar: they had increased from 26% to 33% and have reached 36% in 2010. In this light the statements of certain stakeholders during the sector inquiry that the Commission would be forcing companies to litigate each patent dispute until the end

¹⁰ Such investigations will also consider arguments raised by parties pointing to possible pro-competitive effects of the settlements.

has proven to be unfounded. Companies are able to solve their disputes in a manner that is typically considered unproblematic from a competition law perspective.

- (37) In order to assess whether this trend is confirmed, to better understand the use of this type of agreement in the European pharmaceutical sector and to identify settlements that delay generic market entry in a potentially anti-competitive manner the monitoring exercise will be continued for at least another year to see whether any further action is needed.