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Competition DG

6th Report on the Monitoring of Patent Settlements

(period: January-December 2014)

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1. Introduction

(1) As announced in the Commission's Communication[1] concluding the pharmaceutical sector inquiry on 8 July 2009, it is considered important to continue monitoring the patent settlements between originator and generic companies. The main objectives of the monitoring exercise are to better understand the use of this type of agreement in the EEA and to identify those settlements that delay generic market entry to the detriment of the European consumer possibly in violation of European competition law.[2] This sixth round of monitoring is a follow-up to the five monitoring exercises conducted annually from 2010 to 2014.[3]

(2) Patent settlement agreements, as examined in this context, are commercial agreements to settle patent-related disputes, e.g. questions of patent infringement 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. In particular the parties may prefer to discontinue the dispute or litigation because it is too costly,

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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 Commission Communication, p. 20.

3 The five reports on the monitoring of patent settlements are available at:

http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report1.pdf,

http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report2.pdf,

http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report3_en.pdf,

http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report4_en.pdf,

http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report5_en.pdf.

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. Therefore, they can have some positive impact in the interest of society.

(4) However, as pointed out in the Final Report of the sector inquiry ("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 scope, its period of protection or its exclusionary scope. Such agreements would not appear to be directly related to the IP rights granted by the patents concerned. Furthermore, problematic agreements include settlement agreements on a patent which the patent holder knows does not meet the patentability criteria. An example of this is a situation where the patent was granted following the provision of incorrect, misleading or incomplete information. Ultimately, it may be the consumer who pays the price for a delay in market entry resulting from such agreements and therefore any benefits to society 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) The Competition DG launched the sixth monitoring exercise into patent settlements in February 2015 covering the time period from 1 January 2014 to 31 December 2014. 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 sixth monitoring exercise. The first section 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.

(7) As in the previous monitoring reports the classification of settlements is aimed at giving an indication on which kinds of settlements may merit further competition rules scrutiny and their relative importance. It needs to be underlined that any concrete case will have to be examined under its own individual circumstances and merits.

2. Classification of the agreements

(8) In its Final Report, the Commission proposed a categorisation of patent settlement agreements which will also be used for the purpose of this 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 for granting exclusive rights. In a nutshell, such classification 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.[4]

(9) For the purpose of this analysis, a generic company's ability to enter the market can be limited in several ways. 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) has(ve) expired ("non-compete clause"). For the purpose of this report, a licence granted by the originator company allowing market presence of the generic company is also categorised as limiting generic entry, if the generic company cannot enter the market with its own product or it cannot set the conditions for the commercialisation of its product freely.[5] Accordingly, the generic company's entry is at least partly controlled by the originator company through the terms of the licence agreement. Note though, that an exception applies in case of royalty free licences that allow generic companies to immediately launch their own product without any further constraints, i.e. concerning quantities, composition, pricing or other marketing conditions of their product. Hence, such licence agreements are not viewed as limiting generic entry.

(10) The same logic as referred to in paragraph (9) 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.

(11) Furthermore, agreements providing for an early entry of a generic medicine will be seen as limiting generic entry where entry is not immediate. It should be noted that the list of potential limitations is not exhaustive.

(12) Also, the value transfer from the originator company to the generic company can take different forms. 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 of purchasing an asset (e.g. the generic company's stock of own products), but it can also have the purpose – explicitly or implicitly – of paying the generic company for agreeing to delay the product launch and/or for discontinuing the patent challenge, even in situations where stock is bought at market price. 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. 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

[4] For the purpose of this report, it was not verified 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.

[5] 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 Article 28(2) TRIPS.

before patent expiry in another geographical area or by allowing market entry with another product marketed by the originator company. A value transfer could furthermore consist in granting a licence to the generic company enabling it to enter the market. Similarly, a non-assert clause, whereby - even without a licence - the originator binds itself not to invoke the patent against the generic company, thereby allowing the generic medicine to come onto the market, may technically be perceived as constituting a value transfer. In these cases, the generic gained marketable value as a result of the value transfer. However, an agreement which includes no other limitative provision than determining the date of the generic entry with the originator's undertaking not to challenge such entry (a "pure early entry") is not likely to attract the highest degree of antitrust scrutiny. Again the list of possible value transfers is not exhaustive.

(13) For any of the value transfers observed in this monitoring exercise, the Commission only investigated whether such a transfer was agreed upon, without verifying the (net) amount of the transfer or any possible justifications for it. There is no presumption of violation of competition rules. A case by case analysis would be required. For instance, in some cases, an early entry may be pro-competitive when compared to the parties' anticipated outcome of the litigation. In other instances, the conditions attached to the early entry (through a licence or a distribution agreement) may cancel out any positive effect on competition.

(14) In line with the above, agreements that do not restrict the generic company's ability to market its own product 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: (i) B.I settlements, which comprise those settlements where no value transfer from the originator to the generic company took place; and (ii) B.II settlements which foresee a value transfer from the originator to the generic company.

(15) Typically, category A settlements should be unproblematic from a competition law perspective, as they allow immediate market entry by the generic company with its own product (unilateral conduct of the originator company that might have caused generic delay would remain subject to competition law scrutiny).

(16) The same applies to category B.I settlements. Nonetheless, some settlement agreements in this category may attract competition law scrutiny. This may be the case for settlements concluded outside the exclusionary zone of the patent 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.

(17) By contrast category B.II settlements are likely to attract the highest degree of antitrust scrutiny since they limit access to the market and contain a value transfer from the originator to the generic. Nonetheless, this is not to suggest that agreements falling into this category would always be incompatible with EU competition law. This needs to be assessed on the basis of the circumstances of each individual case.

(18) Table 1 below provides an overview of the main categories as used by the Commission in the sector inquiry and for the purpose of the monitoring exercise.

Table 1: Categories		Limitation on generic entry	
		No	Yes
Value transfer from the originator company to the generic company	No	Category A	Category B.I.
	Yes		**Category B.II.**

Source: European Commission, 6th Patent Settlement Monitoring Exercise

3. The Monitoring Exercise 2014

(19) The monitoring exercise was launched in February 2015 and covered the period from 1 January 2013 to 31 December 2014. In total 54 originator and 57 generic companies replied to the Commission's request to submit a copy of all patent settlement agreements relevant for the EU/EEA markets. These companies were selected from the originator companies and generic companies that had cooperated with the Commission in the course of the sector inquiry[6] including the subsequent monitoring exercises and/or were reported in the specialised press as having concluded a patent settlement in the period in question. Hence it constitutes a representative sample of the industry. 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.

(20) 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 but were otherwise disregarded.

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

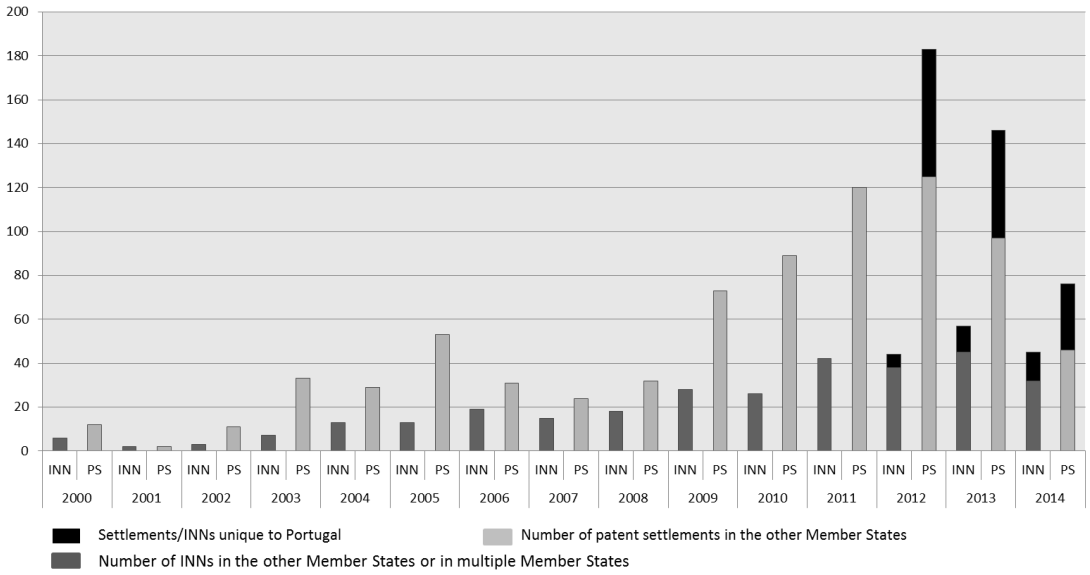
(21) The development of patent settlements from the beginning of 2000 until the end of 2014 can be described by consolidating the data obtained in the course of the sector inquiry and in the course of the previous monitoring exercises with the information newly acquired during this monitoring exercise.

(22) Figure 1 shows the annual numbers of patent settlements concluded during 2000 – 2014 as well as the numbers of INNs[7] covered by the patent settlements in each year.

[6] During the sector inquiry 43 originator companies and 27 generic companies had been selected for in-depth analysis.

[7] An INN is the international non-proprietary name for a pharmaceutical substance.

Figure 1: Number of patent settlements and INNs 2000-2014



Source: European Commission, 6th Patent Settlement Monitoring Exercise

(23) The number of patent settlement agreements at the beginning of this period (2000-2008) was comparatively low, whereas thereafter a significant increase can be observed, with a peak in 2012. After 2012, the number decreases.[8] However the number in 2014 is still higher than the average in the period 2000-2008. Variations in the number of patent settlements concluded may be due to a variety of reasons, such as the number of medicines losing patent protection[9], the greater readiness of both parties to settle[10], a general increase in litigation and disputes leading to a higher number of settlements or the introduction of new legislation[11]. Figure 1 also shows that the number of INNs remained relatively stable over the last years.

(24) Figure 2 shows the percentages of originator and generic companies involved in this monitoring exercise that have concluded patent settlements. 19 out of the 54 originator companies (35%) and 12 out of the 57 generic companies (21%) concluded a settlement agreement in 2014. These percentages compare as follows

8 A quite similar pattern can be noted in the US over the years 2004-2013 (2014 not yet published) https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/141222mmafy13rpt-1.pdf.

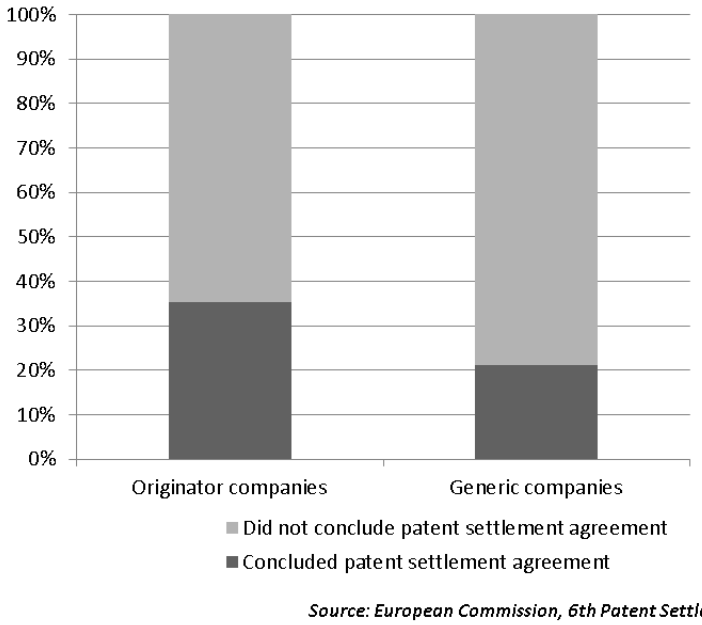
9 In the US, the number of new drug application approvals by the FDA peaked in 1996, declining to a relative low point in 1999, after which the number of approvals started increasing again. This could explain – in part – the noted peak in the number of settlements concluded as well as in the number of "patent cliff sales drops" in 2012, and their relative decline in the years 2013-2014 (as the maximum effective patent life time in the US is capped at 14 years).

10 The increase however cannot be explained by the number of companies added in the second monitoring exercise vis-à-vis the sector inquiry, as the added companies had hardly any effect on the number of settlements at the time.

11 As in 2012 and 2013, new legislation in Portugal, as described in paragraph (27), has entailed the conclusion of many settlements during 2014. If one withdraws the settlements related to this legislation ("PT-related"), the total number of settlements for 2014 is 46, which is about half of the level of the previous year.

with previous monitoring exercises: 22% of originator companies concluded settlement agreements in 2010, 44% in 2011, 38% in 2012 and 37% in 2013, whereas 23% of generic companies concluded settlement agreements in 2010, 16% in 2011, 30% in 2012 and 35% in 2013.[12]

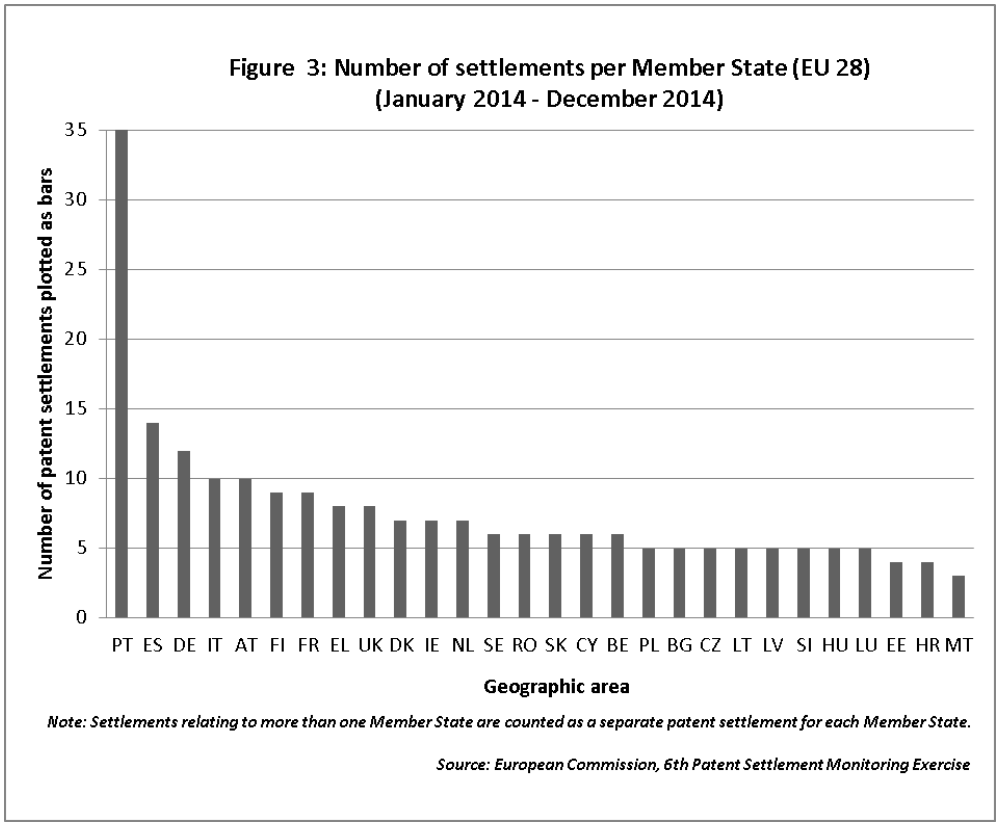
Figure 2: Percentage of originator companies and generic companies that entered into patent settlements (January 2014 - December 2014)



Source: European Commission, 6th Patent Settlement Monitoring Exercise

(25) Figure 3 breaks down the number of patent settlements by geographic area covered by the agreements. Every agreement accounted for in Figure 3 covered at least one EU Member State. A minority 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 why the sum of the settlements per Member States exceeds the total number of settlements reported).

[12] Regarding these figures and the comparison with the Sector Inquiry, please see also third monitoring report published in July 2012, p. 7, cited in footnote 3.



(26) Six out of the 76 settlements concluded in 2014 covered more than half of the EU Member States. All these 6 settlements also covered at least one EFTA country. Moreover, 64 settlements covered a single Member State. Figure 3 shows the wide geographic coverage of settlements in the EU. Smaller and more recent Member States tend to be covered by fewer patent settlements than older and larger Member States, in correlation with the size of the respective pharmaceutical markets.

(27) The large number of settlements in Portugal is likely explained by the implementation of Portuguese Law 62/2011 published on 12 December 2011.[13] In that regard, of the 35 settlements covering Portugal, 30 were related to this legislation and covered only that Member State. Nevertheless, it must be noted that it is difficult to estimate how many of these settlements would also have been concluded absent the new law.

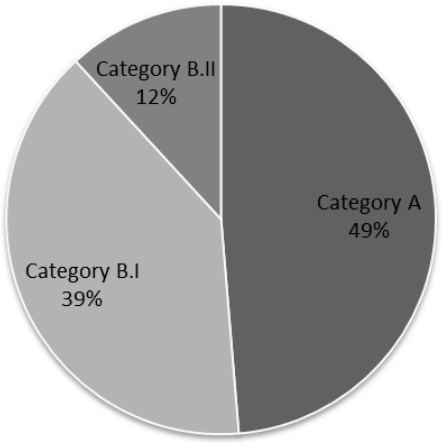
3.2. Categories of patent settlements

(28) The subsequent section describes in more detail the different types of patent settlement agreements concluded between generic and originator companies in the period concerned by this monitoring exercise.

[13] This law essentially provides that an originator must initiate arbitration proceedings within 30 days of the publication of a marketing authorisation application by a generic company. If they do not comply with this provision, the originators then lose the ability to assert their IP rights. Hence, originators in Portugal are, since 2012, obliged to systematically bring arbitration proceedings against all generics applying for marketing authorisations. Many of these proceedings, where there is no issue on the validity of the underlying rights, are settled very rapidly.

(29) The percentage of settlements according to the categories outlined above in section 2 is shown below in Figure 4.

Figure 4: Patent settlements per category (January 2014 - December 2014)



Category A: Settlements without limitation of generic market entry

Category B.I: Settlements limiting generic market entry, but without value transfer from originator to generic company

Category B.II: Settlements limiting generic market entry showing a value transfer from originator to generic company

Source: European Commission, 6th Patent Settlement Monitoring Exercise

(30) Thus 49% (37 out of 76) of settlements did not limit generic market entry at all (category A), whereas 39% (30) limited generic market entry but did not show a value transfer from originator to generic company (category B.I) and only 12% (9) limited generic market entry showing a value transfer from the originator to the generic company. If one puts aside the settlements related to the Portuguese law mentioned above, category B.I amounts to 7% (3 of 46) of all settlements, category A to 74% (34) and category B.II to 20% (9). This compares as follows with figures in previous years:

Table 2: Categories of patent settlements over the period 2000-2014

	2000 – 2008 (1st half)	2008 (2nd half) - 2009	2010	2011	2012		2013		2014	
					All	Excluding PT-related	All	Excluding PT-related	All	Excluding PT-related
Category A	52%	57%	61%	70%	43%	61%	45%	67%	**49%**	**74%**
Category B.I	26%	33%	36%	19%	51%	30%	47%	22%	**39%**	**7%**
Category B.II	22%	10%	3%	11%	7%	10%	8%	11%	**12%**	**20%**

Note: legislation was adopted in Portugal in 2012, which practically mandates arbitration proceedings between originators and marketing authorisation applicants. When the IPRs are not contested by the generic company, the proceedings are immediately settled. Hence, figures are provided which disregard settlements related to the Portuguese law. It must, however, also be noted that it is not known how many of these settlements would have still taken place absent this law. See footnote 13.

Note: percentages may not add-up to exactly 100% due to the rounding-up of figures.

Source: European Commission, Pharmaceutical Sector Inquiry and first six Patent Settlement Monitoring Exercises

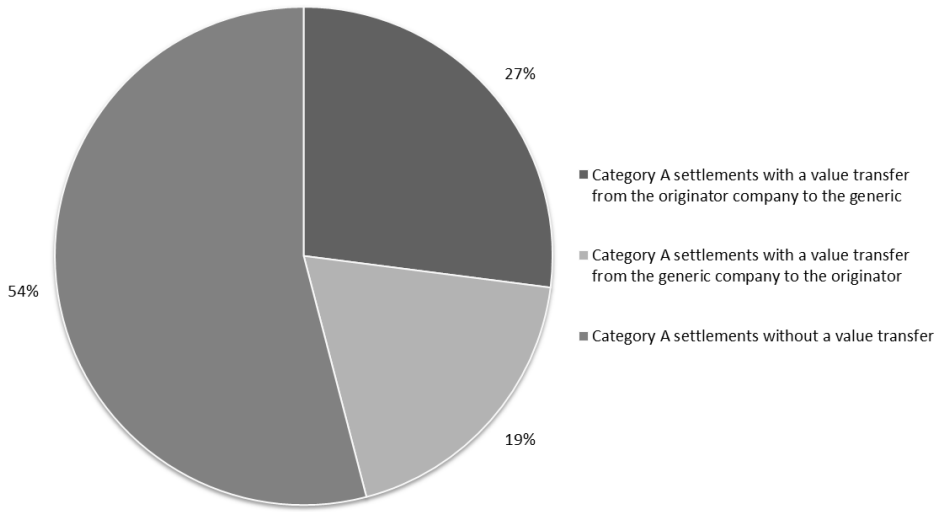
Category A Settlements: Settlements that do not limit generic entry

(31) As presented in Table 2 and Figure 4 above, 49% of all patent settlements (37 out of 76) 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.

(32) 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.

(33) Figure 5 below distinguishes between different category A settlements according to the value transfer connected to them, if any.

Figure 5: Category A settlements with or without value transfer (January 2014 - December 2014)



Source: European Commission, 6th Patent Settlement Monitoring Exercise

(34) This figure shows that 54% of the category A settlement agreements (20 out of 37) did not include any value transfer, 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.

(35) In addition, it appears that, while in 51% (19 of 37) of category A settlements the relevant patent(s) was not in force anymore at the time of signature, in the other 49% of cases the relevant patent(s) was still in force.

(36) A value transfer from the originator company to the generic company took place in 27% of the category A settlements (10 out of 37). In most cases these were payments covering litigation costs and/or damages. The latter happened, 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 the lost sales it incurred whilst it was prevented from marketing its product.

(37) In 18% (7 out of 37) of the cases a value transfer from the generic company to the originator company took place. An example of such a settlement could be one where the generic company had entered the market at risk and during the course of litigation the patents concerned expired. In these cases, the litigation could have continued e.g. if the originator wanted to assert the infringement committed by the generic company up until the time the patent expired in order to recover damages from the generic for such an infringement. Faced with a high probability that the courts would find such an infringement if the case were to proceed, the generic company decided to settle by paying compensation to the originator company, covering legal fees and possibly an additional amount in damages in order to avoid further litigation.

(38) For the sake of completeness it is worth pointing out that in one case an originator had granted a royalty free licence to the generic to enter with its own product. As mentioned above, this was not counted as a restriction, as the generic company was free to enter the market without any restrictions e.g. as to the composition, quantities, pricing or other marketing conditions of the product.

(39) This compares as follows with figures in previous years:

Table 3

	2000 – 2008 (1st half)	2008 (2nd half) - 2009	2010	2011	2012		2013		2014	
					All	Excluding PT-related	All	Excluding PT-related	All	Excluding PT-related
Category A with value transfer from originator company to generic	14%	25%	13%	18%	47%	49%	36%	37%	27%	26%
Category A with value transfer from generic company to originator	17%	7%	11%	9%	9%	9%	20%	20%	19%	21%
Category A without value transfer	69%	68%	76%	71%	44%	42%	44%	43%	54%	53%
Category A with value transfer in both directions	-	-	-	2%	-	-	-	-	-	-

Note: legislation was adopted in Portugal in 2012, which practically mandates arbitration proceedings between originators and marketing authorisation applicants. When the IPRs are not contested by the generic company, the proceedings are immediately settled. Hence, figures are provided which disregard settlements related to the Portuguese law. It must, however, also be noted that it is not known how many of these settlements would have still taken place absent this law. See footnote 13.

Source: European Commission, Pharmaceutical Sector Inquiry and six Patent Settlement Monitoring Exercises

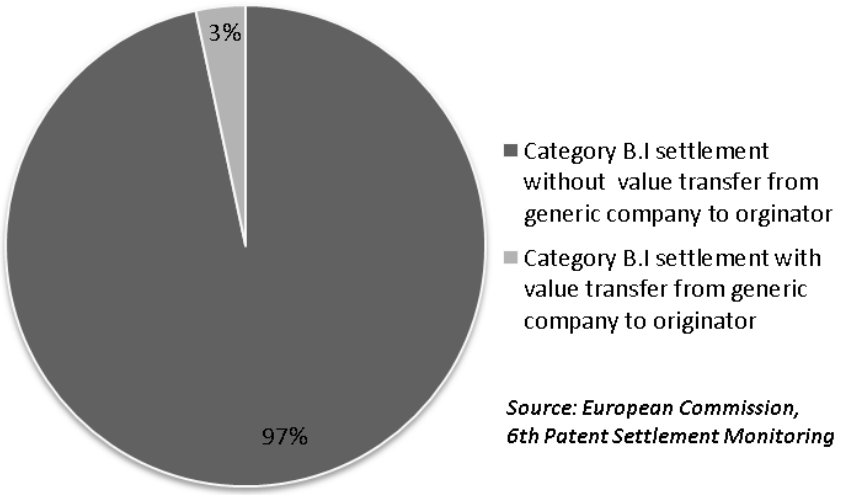
Category B Settlements: Settlements that limit generic entry

(40) As already explained in section 2, settlements that limit generic entry can be divided into two subcategories, namely those that do not include a value transfer from the originator to the generic company (category B.I) and those that do (category B.II). Both of them will be looked at in turn.

Category B.I Settlements: Settlements limiting generic entry without value transfer from originator to generic company

(41) In the period investigated, B.I agreements accounted for 39% (30 out of 76) of all agreements (see Table 2 and Figure 4 above). Within the category B agreements, they accounted for 77% (30 out of 39). The common features of the B.I settlements as analysed in this section are that they restricted generic entry but did not contain a value transfer from the originator to the generic company. Yet, some of those settlements showed a value transfer from the generic to the originator company. Thus, Figure 6 below breaks down the number of B.I settlements into those that contained a value transfer from the generic to the originator company and those that did not.

Figure 6: Category B.I settlements with and without value transfers from the generic company (January 2014 - December 2014)



Source: European Commission, 6th Patent Settlement Monitoring

(42) 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 the generic accepted the validity of the originator's patent or decided not to appeal an unfavourable first instance decision. In 3% (1) of these instances, the generic company also agreed to compensate the originator company with a lump sum for the full and final settlement of the pending proceedings (see Figure 6 above). The other 97% (29) of cases showed no value transfer from the generic company.

(43) It must be noted that 90% (27 of 30) of B.I. settlements were signed in the context of the new legislation in Portugal, as explained in paragraphs (27) and (49).

(44) This compares as follows with figures in previous years:

Table 4

	2008 (2nd half) - 2009	2010	2011	2012		2013		2014	
				All	Excluding PT-related	All	Excluding PT-related	All	Excluding PT-related
Category B.I with value transfer from generic to originator company	29%	16%	17%	2%	5%	12%	33%	3%	33%
Category B.I without value transfer from generic company	71%	84%	83%	98%	95%	88%	67%	97%	67%

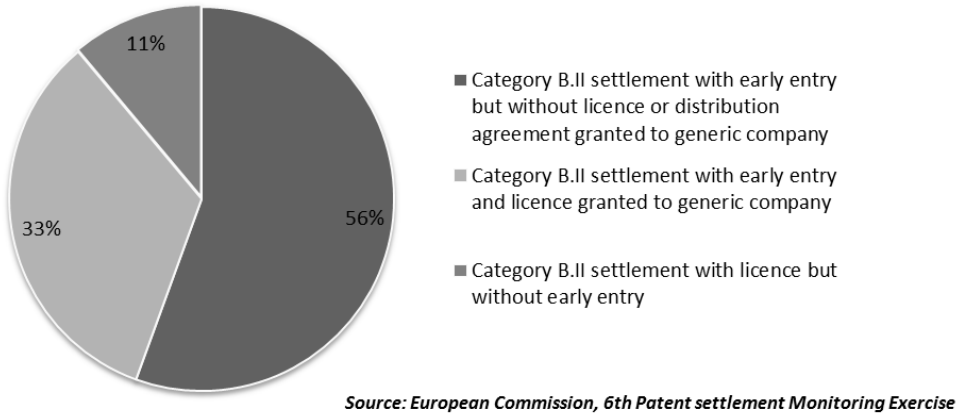
Note: legislation was adopted in Portugal in 2012, which practically mandates arbitration proceedings between originators and marketing authorisation applicants. When the IPRs are not contested by the generic company, the proceedings are immediately settled. Hence, figures are provided which disregard settlements related to the Portuguese law. It must, however, also be noted that it is not known how many of these settlements would have still taken place absent this law. See footnote 13.

Source: European Commission, six Patent Settlement Monitoring Exercises

Category B.II Settlements: Settlements limiting generic entry with value transfer from originator to generic company

(45) In the period investigated, B.II agreements accounted for 12% (9 out of 76) of all agreements (see Table 2 and Figure 4 above). Within the category B agreements, they accounted for 23% (9 out of 39). Figure 7 divides them according to the type of value transfer.

Figure 7: Number of B.II patent settlements per type of value transfer (January 2014 - December 2014)



Source: European Commission, 6th Patent settlement Monitoring Exercise

(46) The value transfer flowing to generic companies in the settlement agreements took different forms, sometimes in various combinations: early entry[14] and a licence. None of the B.II agreements included a payment to the generic company. Of the 9 B.II agreements, 5 (56%) enabled early entry without a licence or a distribution agreement, 3 (33%) combined early entry with a licence to the generic company, and 1 (11%) only included a licence.

(47) It should be noted that this report merely summarises the results of the monitoring exercise and no decision has been made or implied on further investigation of any of the settlement agreements reported under this or any other category. As mentioned above, if examined, an assessment of the particular facts of each individual case would have to be undertaken, e.g. whether a licence granted to the generic company may in fact have pro-competitive effects, depending on the restrictions and conditions within that licence.[15]

4. Conclusion

(48) The sixth monitoring exercise undertaken by the Commission covered the period between 1 January 2014 and 31 December 2014, i.e. 12 months. It confirmed the continued use of patent settlements in the European pharmaceutical sector measured by the number of patent settlements concluded, i.e. 76 patent settlement agreements in the EEA. This can be compared to the lower annual average of 24 patent settlements concluded in the period covered by the sector inquiry (from 1 January 2000 to 30 June 2008 - in total 207 settlements in eight and a half years).[16] Also, the number of INNs which were the subject of settlements increased significantly from less than 10 INNs in the first three years of the millennium to 45 in 2014. As with the former five exercises, the results of the sixth monitoring exercise show that the Commission's announcement that it would continue scrutinizing B.II category settlements in the future has not hindered companies from concluding settlements in general.

(49) The evolution of B.I settlements shows first a steady increase from 26% or six settlements on average per year (from 1 January 2000 to 30 June 2008) to 33% or 21 settlements per year (from 1 July 2008 to 31 December 2009) and 36% or 32 settlements in 2010. After a decrease in 2011 to 19% or 23 settlements in absolute terms, they increased in 2012 to account for 51% or 93 settlements in absolute terms. In 2013, they accounted for 47% or 69 in absolute terms. Nevertheless, if settlements related to the new law in Portugal are put aside, B.I settlements then

[14] A non-assert clause, whereby - even without a licence - the originator binds itself not to invoke the patent against the generic company, thereby allowing the generic medicine to come onto the market, may technically be perceived as constituting a value transfer. However, an agreement which includes no other limitative provision than determining the date of the generic entry with the originator's undertaking not to challenge such entry (a "pure early entry") is not likely to attract the highest degree of antitrust scrutiny.

[15] Hence, such investigations will also consider arguments raised by parties pointing to any potential pro-competitive effects of the settlements.

[16] With an average of 62 settlements per year in the period of the first monitoring exercise (mid 2008 - end 2009) and 89 settlements in the period of the second monitoring exercise (covering the year 2010).

accounted for 22% or 21 settlements in absolute terms. In 2014, B.I settlements accounted for 39%, or 30 in absolute terms (7% or 3 in absolute terms, if settlements related to the Portuguese Law are put aside).

(50) 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 stabilized at a low level. In the period covered by the sector inquiry (1 January 2000 to 30 June 2008), B.II settlements represented 22% of all settlements reported. This percentage has decreased over the years to reach 12% in 2014. Note that omitting agreements related to the new law in Portugal, this figure would be 20% (no B.II agreements relating to the Portuguese Law).

(51) The statements of certain stakeholders during the sector inquiry that the Commission would be forcing companies to litigate each patent dispute until the end has proved to be unfounded, given the strong increase in settlements after the sector inquiry. In addition, 88% of the settlements fall into categories that *prima facie* raise no need for competition law scrutiny. Companies, in most cases, are able to solve their disputes in a manner that is typically considered unproblematic from a competition law perspective.

(52) In the future the Commission may decide to continue the monitoring exercise in order to examine further the development of the foregoing trends.