2. Competition Between Originator and Generic Companies – The Issues

(462) The present chapter examines the competitive relationship between originator and generic companies which market pharmaceutical products in the European Union. As explained in Chapters B.1.1., B.1.2. and C.1., originator companies produce and sell pharmaceutical products developed during a lengthy and costly research and development (R&D) process, involving substantial commercial risks. The resulting originator products are protected by intellectual property rights (in particular by patent rights), which give the originator company the opportunity to recoup investment costs and provide incentives to originator companies to continue innovating, which can make important contributions to meet interests patients need.

(463) This chapter does not question the value of (incremental) innovation. Neither does it aim to provide guidance on whether certain types of practices could be considered compatible or incompatible with the EC competition law. Such an assessment would require in-depth analysis of the individual practice taking into account the factual, economic and legal background. The Commission will further investigate whether individual company behaviour may have fallen foul of the competition rules.

(464) Originator companies compete with other originator companies (see Chapter C.3.) as well as with generic companies. In principle, generic companies produce and market an equivalent version of the originator medicine once patent protection of the medicine has expired. However, competition between generic and originator companies may begin before patent expiry if the generic company finds a way of entering the market without infringing the patent protecting the originator product, or if the patent relied upon by the originator company is not valid, in particular if it is annulled prior to the formal patent expiry date.[344]

(465) As explained in Chapter B.1.3., the prices of generic medicines are substantially lower than those of originator products. The entry of a competing generic product on the market inevitably results in a significant decline in the price and market share of the corresponding originator product. Therefore, originator companies may seek to protect their market position using various means ranging from strategic patenting around the product to patent litigation and interventions before national regulatory authorities.

(466) The purpose of the present chapter is to examine to what extent originator companies employ instruments of the "tool-box"[345] to delay or block the entry of competing generic products on the market. Therefore, the following issues are examined:

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344 As explained above, protection can also stem from SPC and/or data/market exclusivity. (The latter does not however provide legal exclusivity.)

345 The analysis of general strategy documents of originator companies confirmed that this terminology is commonly used in the industry. It should not be misunderstood to mean that all companies us all instruments for the protection of their products. Nor does the use of the term in this report suggest that the individual instruments would be illegal.

Patent strategies of originator companies: the first section examines the various patent strategies employed by originator companies with the aim of maximising profit derived from their patented products and shielding them from competition. The section focuses in particular on patent strategies involving patent clusters[346] and divisional application and their intended effects.

Patent-related contacts, disputes and litigation: the second section examines the patterns and the outcome of patent enforcement by originator companies both in patent-related exchanges out of court (such as contacts and disputes) with generic competitors and in patent-related litigation cases before national courts. The section also looks, in greater detail, at costs related with patent litigation, divergence of decisions and interim injunctions.

Opposition and appeals: the third section studies the patterns and outcome of patent opposition procedures and appeals filed by generic companies at the European Patent Office (and at national patent offices), in order to establish whether this provides an alternative route for generic companies to secure their market entry.

Settlements and other agreements: the fourth section analyses the various types of agreements concluded between originator and generic companies. It focuses on settlements of patent disputes, litigation and opposition procedures, and other agreements (such as licence and distribution agreements) and examines companies' considerations for entering into such agreements. This section also contains a brief overview of the established patent settlement practise in the USA as compared with the EU.

Other factors affecting generic entry: the fifth section examines strategies and actions of originator companies aimed at national regulatory bodies (such as marketing authorisation and pricing and reimbursement bodies), other stakeholders (e.g. doctors and pharmacists) as well as distributors and API producers. This section examines pre-litigation contacts and disputes as well as litigation in which originator companies are involved.

Life cycle strategies for follow-on products: the sixth section analyses the relevance of follow-on products and the mechanisms employed by originator companies to switch patients from an earlier generation to follow-on products. In particular, the practices which may facilitate such patient switches are examined.

Cumulative use of practices: the seventh section examines various life cycle tools which may be used cumulatively by originator companies and may affect the entry of the generic product into the market.

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346 This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying intentions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

2.1. Patent Filing Strategies

(467) For the purpose of this section the term "patent strategies" should be understood to encompass all strategies of a company concerning the use of the patent system to the benefit of the company in relation to generic competition.[347] The term includes strategies on the timing and scope of filing as well as the manners in which patents are applied for.

(468) As already mentioned, in addition to the primary functions of exclusion/protection and information, patents have a multitude of other functions such as creating "freedom to operate", bargaining, standardisation, and company image. Furthermore in some cases originator companies might also have incentives to maintain and use patents for their effect of blocking or delaying the development of a generic product.

(469) In fact, patent strategies can form part of a company's tool-box[348] which are used in order to protect continuous revenue streams from pharmaceutical products by preventing or delaying generic entry.

(470) This section will look at different scenarios that may entice an originator company to employ patent strategies with the aim of preventing or delaying generic market entry.[349] It will then examine the use of patent clusters and the use of divisional applications. Thereafter it will examine the intended effects of this strategy, including litigation strategies in the context of patent enforcement.

(471) For the purpose of illustration a number of quotes have been added, which form only a part of those obtained in the course of the sector inquiry. They may be taken from general policy documents or concrete instructions for individual cases. Most of the quotes were taken from documents obtained during the unannounced inspections by the Commission in January 2008.

(472) It is not the purpose of this sector inquiry to provide guidance as to the compatibility of certain practices with EC competition law. The Commission will further investigate whether individual company behaviour may have fallen foul of the competition rules.

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347 In so far as patent strategies specifically aim to prevent other originator companies from developing or marketing products competing with a product of an originator company, they will be analysed in a separate section, see below Chapter C.3.1.

348 For the different elements of life cycle strategies see above: Chapter B.1.2. During the public consultation the use of the term "tool-box" in the preliminary report has been criticised as giving it a "pejorative" meaning. This term however has not been invented for purposes of this report. Rather it has been found to be used by several originator companies within their strategy documents. Moreover, the use of various instruments varies from company to company and from product to product. In the present chapter, the instruments most observed were analysed.

349 During the public consultation it has been submitted that terms, such as "delaying" and "blocking" were used for certain practices of originator companies, which would discredit their behaviour. These terms, however, have not been invented for purposes of the report. Rather they have been found to be used by originator companies within their strategy documents as can be seen in the quotes shown in the subsequent subsections.

2.1.1. Scenarios of Generic Market Entry Addressed by Patent Strategies

(473) Information and data gathered in the course of this inquiry, in particular from companies' strategy documents, indicate that the ultimate aim of protecting the market share of a product is pursued by some major originator companies by obtaining the most efficient, broadest and longest possible patent protection for this product and variations thereof.

(474) An originator company issued internal guidelines as how to draft applications with regard to generic competitors:

> "*The description should include sufficient specific reproducible examples to make the scope of claim a reasonable generalisation of the examples. Our primary objective is to obtain claims that will be effective against generic competitors."*

(475) Two scenarios seem to be particularly noteworthy in this context:[350]

- How can an originator company ensure that its (blockbuster) pharmaceutical product enjoys exclusivity at least until the end of the patent protection period of the base patent[351] in cases where generic companies threaten the base patent by challenging its validity?

- How can an originator company prolong the exclusivity period beyond the expiry of the base patent? This may serve to simply preserve continuous revenue streams, where no follow-on product has been developed or to bridge a gap between the loss of exclusivity and the market launch of a follow-on product which is intended to take over market shares of the old product (for life cycle strategies for follow-on products, see also Chapter C.2.6.).

(476) To ensure exclusivity at least until the end of the patent protection period of the base patent, originator companies may file for a multitude of patent applications (on process, reformulation, etc.) protecting the product in addition to the base patent with the aim of creating several layers of defence. Such a multitude of patents is often referred to as a "patent cluster"[352]. Thus where generic companies might manage to

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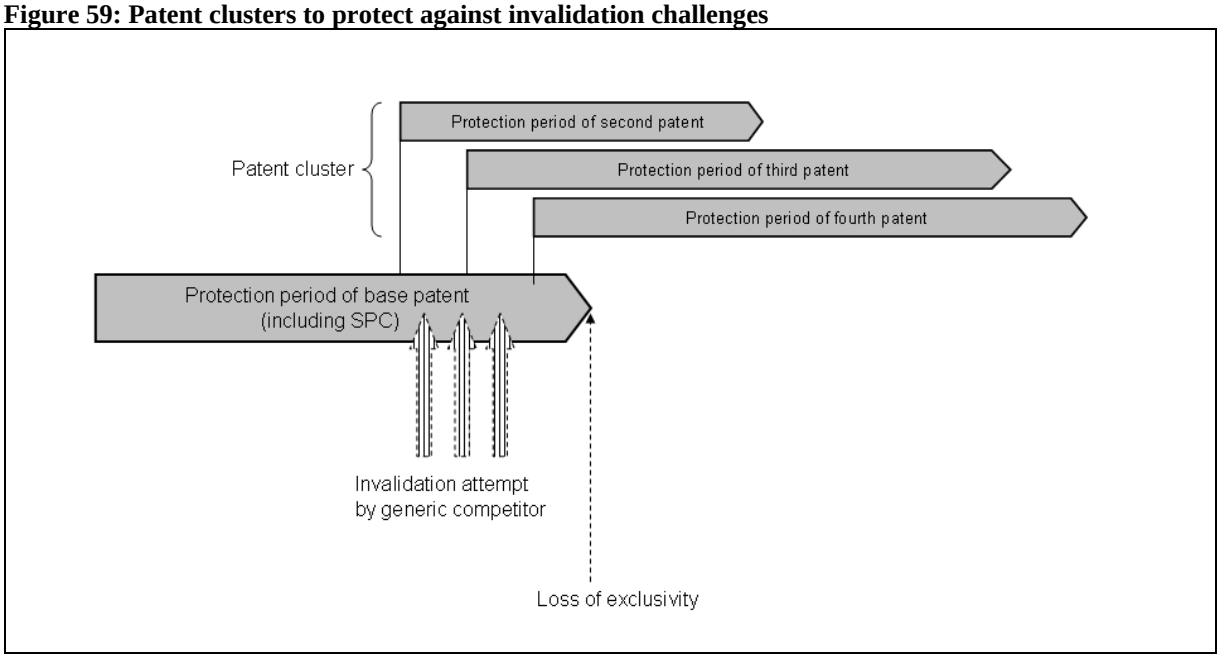
350 This section focuses on patent strategies employed by originator companies. Patenting strategies may also be employed in the context of life cycle management, i.e. a commercial switch to a follow-on product, yet this aspect will be looked at in more detail in Chapter C.2.6. While generic companies tend to file for patent applications nowadays as well, in particular for different salt forms of a particular substance when its base patent expires, the majority of patents are obviously being held by originator companies; see above Chapters B.1.2. and C.1.2.

351 While such base patents, usually claiming the invention of a new active substance, often constitute the first patent to protect a product, there are also cases where a secondary patent turns the active substance into a medicine.

352 This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive

invalidate the base patent before its regular expiry they still cannot enter the market, if the originator company has succeeded in creating what some originator companies call "a multilayered defence" by other patents for such aspects as different dosage forms, the production process or for particular pharmaceutical formulations. This is illustrated in Figure 59:

Figure 59: Patent clusters to protect against invalidation challenges

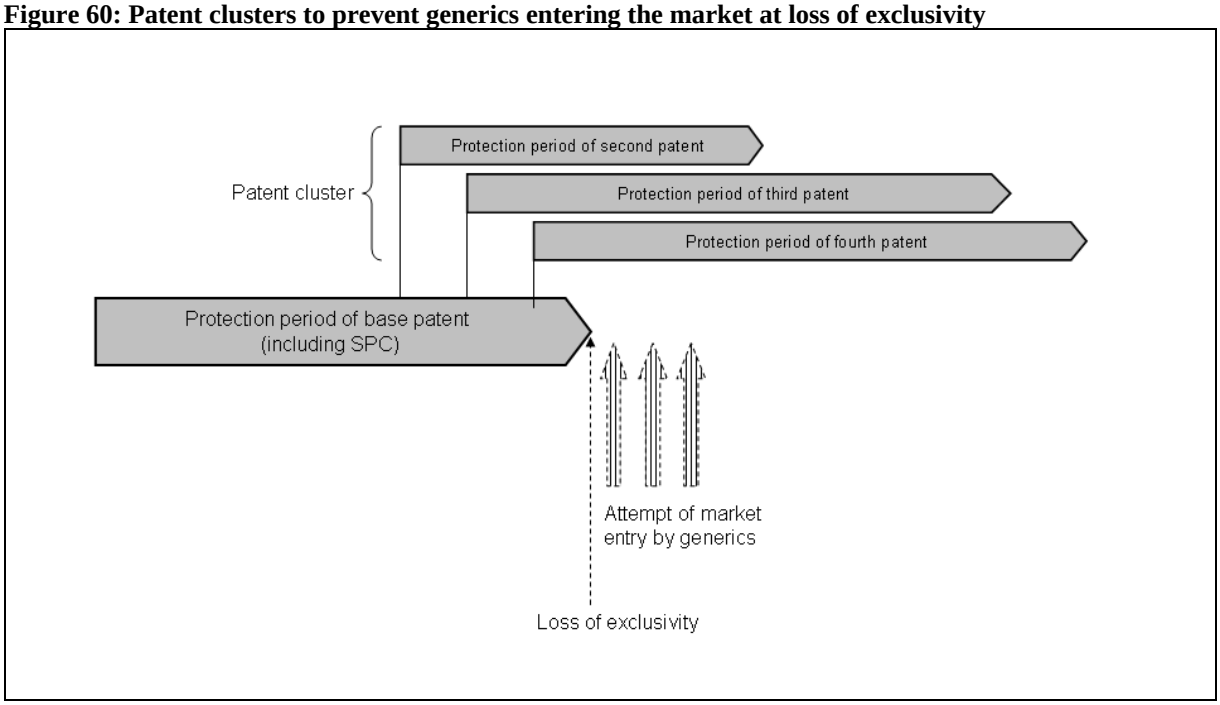


Source: Pharmaceutical Sector Inquiry

(477) The second scenario shows a situation where an originator company obtains a multitude of patents (on process, reformulation, etc.) protecting the product, i.e. a patent cluster, during and towards the end of the protection period of the base patent, with the aim of keeping generics off the market beyond expiry of the first patent. This is illustrated by the following figure:

step and (3) industrial application. The underlying intentions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

Figure 60: Patent clusters to prevent generics entering the market at loss of exclusivity



Source: Pharmaceutical Sector Inquiry

(478) It has been submitted by a UK based research body dealing with all aspects of intellectual property law that the more likely scenario of the two would be the latter one as generic companies would wait until the expiry of the base patent before contemplating launch which is also supported by the fact that patent litigation mainly concerns secondary patents[353].[354]

(479) It goes without saying that for both scenarios a company can rely on the same patents constituting the patent cluster surrounding the base patent. Thus, the scenarios overlap to the extent that the same set of patents may (i) disable generic entry before the end of the protection period stemming from the base patent, while they may also (ii) postpone generic entry after the base patent expired.[355]

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353 Patent law does not make a distinction between "primary" and "secondary" patents, and patents need to be evaluated on the basis of the statutory patentability criteria, not on the basis of the stage in which applications are made. The notion of "secondary patent" should not be understood to mean that these patents are of a lower quality or value, but merely that – from a time perspective – follow the primary patents. Yet the term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices, see also Chapter A. Introduction of this report.

354 For further details see Chapter C. 2.2.

355 During the public consultation it has been submitted that a later patent cannot extend the protection period or scope of an earlier patent as each patent is for a different invention. This, however, has never been claimed in the preliminary report. It is rather extending the exclusivity period of a product that the filing of patent applications towards such aspects as a different production process or for particular pharmaceutical formulations can be aimed at as the quotes from strategy documents below show. Furthermore, contrary to a statement made by an originator companies' association, subsequent patents

(480) Under certain circumstances the patent strategy might also pursue a more specific objective, namely to facilitate the switch to follow-up inventions or second generation products, criticised as "evergreening" by the generics industry, which will be analysed in more detail in Chapter C.2.6. below.

(481) A patent cluster may consist of granted patents as well as pending applications. Under certain circumstances, originator companies may also multiply the number of pending applications by filing for divisional patent applications dividing out from a parent patent application one or several (narrower) applications, which, after that division, all have a procedural life of their own, however, without extending the protection period of the parent application.

(482) Furthermore, according to Article 67 of the EPC in connection with Article 64 thereof, an application can from the date of its publication provisionally confer upon the applicant the protection of a patent, including damage claims, if provided for under national law. This is also applicable for divisional applications.

(483) In the following, patent cluster and divisionals are analysed, before their intended effects are examined.

2.1.2. Patent Clusters

(484) It can be observed that originator companies' patent applications may be very broad in scope and claim a multitude of different innovations surrounding the original compound, including e.g. formulations, dosage regimes, processes etc.[356]

(485) Such patents may signify an increase of incremental innovation, which can be of significant importance. Following the filing of a basic patent application, further research into a particular development candidate (or series of candidates) can give rise to the need for further patent protection for improvements of the basic active agent such as salt forms, metabolites or polymorphs. Similarly, problems with the administration of a therapeutic agent might lead to the need for formulation patents, whilst clinical trials may reveal new medical uses.

(which were filed for after the initial product had already been launched) were invoked in relation to attempted entry of generic versions of the initial product copying the essential elements of the latter in about one third of the cases examined (both in terms of INNs and individual litigation cases). For further details see Chapter C.1.2.

[356] This corresponds with findings of an OECD study that patenting has increased in the last ten years in particular in the sectors of ICT, pharmaceuticals and chemicals, where companies reported that they now patent inventions that they would not have sought to patent 10 years ago. This trend was most pronounced in chemicals industry followed by the pharmaceuticals and ICT industry, see OECD pp. 91, 92., see: Patents, Innovation and Economic Performance: OECD Conference Proceedings,Science & Information Technology 2004, vol. 2004, no. 13, at: http://masetto.sourceoecd.org/vl=1083396/cl=28/nw=1/rpsv/ij/oecdthemes/99980134/v2004n13/s1/p1l. For the different types of patents in the pharmaceutical sector see Chapter B.2.1. and Annex: Claim Types (Annexes to Chapter B).

(486) For some companies the trend towards broader and more patents aiming at protecting a product constitutes a change, as the following quote of an originator company illustrates:

> *"Before end 80s: Products mainly NCEs which where protected by the one patent- […]*
>
> *Late 80s – early 90s[…] Expansion of the portfolio to cover lifecycle initiatives, to extend protection time for product and the brea[d?]th of the protection trying to keep competition further away."*

(487) Of the 43 originator companies asked, seven stated that they did not have specific patenting strategy documents. The remaining 36 submitted such documents indicating that as a general policy they filed for a multitude of patent applications surrounding the first patents of a successful compound and its product in order to protect their position. The use of patent clusters is illustrated in a strategy document from an originator company:

> *"Clustering – protecting the companies (sic) products and processes…Clustering involves three components*
>
> *- Broad Scope*
>
> *- Maximizing Patent Term through innovation*
>
> *- Layered protection"*

(488) As the analysis of patent portfolios in Chapter C.1.2. confirmed, many INNs, in particular the commercially important ones, are surrounded by a multitude of patents and patent applications. The analysis showed that the number of granted patents and pending applications significantly increases with the value of the INN, in particular as regards the 20 top-selling INNs. In fact, blockbuster medicines can even be protected by up to nearly 100 INN-specific EPO patented bundles and applications (sometimes also referred to as patent families), which in one particular case lead to 1,300 patents and applications across all the EU Member States.[357] Despite the lower number of underlying patent families based on EPO applications, looking from a commercial perspective, a challenger may need to analyse and possibly confront the sum of all existing patents and pending patent applications in those Member States in which the generic company wishes to enter.

(489) The ratio of primary to secondary patents[358] (and their applications) is 1:7. As mentioned earlier, as regards to the top 20 INNs by total sales, claims of their

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[357] During the public consultation it has been submitted the number of 1,300 patents should be reviewed to remove the so-called "Member State" effect avoiding double counting of patents being part of the same patent family.

[358] During the public consultation it has been submitted that the distinction between primary and secondary patents is irrelevant under patent law. Whilst this is acknowledged it has to be underlined, however, that this distinction has not been invented for the purposes of the preliminary report. Rather, it has been found

secondary patents mostly concern formulations, processes and non-formulation products (excluding NCEs), such as salts, polymorphic forms, particles, solvates and hydrates.

(490) During the public consultation it has been submitted that the distinction between primary and secondary patents is irrelevant under patent law. Whilst this is acknowledged it has to be underlined, however, that this distinction was not invented for the purposes of the preliminary report. Rather, it has been found to have been employed by several originator companies in their strategy documents as e.g. quotes in the subsequent paragraphs show (see also Chapter C.1.2.). Thus, the term is being used by the report, as it constitutes part of the terminology and concepts employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices.[359]

(491) In this context, another originator company explained:

> *"To maximize patent coverage on our commercial products, patent applications will also in general be filed to cover any novel potentially commercially important aspect of products such as processes, formulations, additional pharmaceutical or other indications and salts/solvates/physical forms (so called 'secondary' or 'subsidiary' patent protection)."*

(492) The consequence of maximising patent coverage in such a way is the creation of a web of patents. In such a situation any attempt to develop a generic version of the medicine in form of a salt, a crystalline or amorphous form would inevitably infringe a patent (for example a patent for the relevant salt, crystalline or amorphous form of the medicine).

(493) Originator companies could thus use their web of patents to prevent or delay generic entry, as illustrated by the following originator company's quote:

> *"We were recently successful in asserting the crystalline form patent in [name of country], where we obtained an injunction against several generic companies based on these patents by 'trapping' the generics: they either infringe our crystalline form patent, or they infringe our amorphous form process patent when they convert the crystalline form to the amorphous form. […] The availability of 'trapping' strategy will be evaluated on an on-going basis."*

(494) In a similar way the following quote of an originator company demonstrates how salts and intermediates are used in order to create such blockades:

> *"I suppose we have all had conversations around "how can we block generic manufacturers". […] Don't play games in patenting new salt forms too late, the*

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to have been employed by several originator companies in their strategy documents as e.g. quotes in the subsequent paragraphs show. See also Chapter C.1.2.

359 See also Chapter A on the use of terminology.

generics are starting earlier and earlier. Get claims on key intermediates that cover a number of routes. Process patents are not the biggest block but can put generics off if a superior chemistry job is done."

(495) This quote also confirms that timing is of crucial importance. As shown above, many patent applications are filed in the period prior to lapse of patent protection of the existing product, possibly in an attempt to prolong the originator's term of protection. Typically, such patent applications are filed in anticipation of imminent generic entry. This is evidenced by the following quote of an originator company:

"Our intelligence reveals that [generic company name] is developing a [salt form] of [patented pharmaceutical]. […] Fortunately we had anticipated the possibility of such a threat and last year filed several applications to alternative salts, including two for the [salt form]."

(496) In fact, the analysis in Chapter C.1.2. confirms that patent applications are filed at regular intervals over a 20-year period following the first filing of an application for a given INN. Many of the top-selling INNs, i.e. those which generate substantial revenues, do not have a traditional patent portfolio life cycle. Instead, a significant increase in the number of patent applications filed is seen towards the end of the lifetime of the first patent in the portfolio.

(497) Incremental innovation can be of significant importance, e.g. when developing new administration routes, dosages or revealing new medical uses, as already explained above. Such innovation can lead to an increase in secondary patents.

(498) However, generic companies their associations and consumer associations have submitted that the filing of numerous patent applications in order to create patent clusters around one product can also lead to "weak patents".[360]

(499) Generic companies maintained that originator companies obtain "weak patents" since in their opinion novelty and inventive step requirements, in particular for secondary patent applications, were too easily considered to be met by the EPO, an argument which was also reiterated during the public consultation.[361]

(500) In this context it needs to be pointed out that certain types of prior art may be "unsearchable" and thus not easy to detect for the EPO. Furthermore, examination by the EPO does not include any experiments to verify applicant allegations.[362]

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360 The use of the term "weak patent" in this context has been criticised by originator companies, their associations and intellectual property associations, claiming that a patent once granted cannot be described as weak or strong but only as valid or invalid if declared so by the relevant office or court.

361 For further details see Chapter D.1

362 See Chapter B.2.1.

(501) As later shown the final outcome in 60 % of opposition and appeal procedures against originator company's patents examined in this report was a revocation of the disputed patent. In addition to this, the scope of the patents was reduced in another 15%.[363] These procedures almost exclusively concerned secondary patents. Furthermore in 55 % of the patent litigation cases between originator and generic companies that involved a question of the disputed patent's validity and that reached a final judgement, the patents were annulled (43 of 78 cases).[364]

(502) Originator companies and their associations have submitted that these outcomes do not give any substantial indication on the quality of patents in patent clusters, in particular secondary pharmaceutical patents, as generic firms will only tackle those patents that they consider to be most contentious and that are protecting commercially viable and interesting products. In this context, it has to be said that existing patent litigation is the only tangible parameter of assessing the validity of such pharmaceutical patents.[365] Furthermore most patent clusters, in fact, concentrate on commercially viable, i.e. successful products such as blockbusters.[366] Thus it is only logical that these patents are disputed through litigation by originator companies eager to protect their products and generic companies that are eager to enter the market. Furthermore the commercial success of the products in question points to an important patient demand that has been met. Thus from society's viewpoint if numerous patents protect such products their validity is of particular importance.[367]

(503) Remarks by originator companies themselves indicate doubt as to the inventiveness and strength of their patents and suggest that the purpose of obtaining secondary patents was to keep generic competitors off the market, as is illustrated by the following quote taken from an inspection document:

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363 For further details see Chapter C.2.3.

364 See Chapter C.2.2.

365 Also, it must be noted that even if only a limited number of cases reach final judgement, it is interesting to record their outcome as they can provide insights into the current situation. Furthermore, it must also be noted that the fact that certain patents have not been challenged in court does not necessarily provide certitude as to their ultimate solidity.

366 For further details on numbers of patents protecting blockbuster medicines see Chapter C.1.2.

367 For further details see Chapter C.2.2.

"Late 80s – early 90s […]

- Some of those patents are inevitably more vulnerable and more likely to be challenged [...]

- Strategy – better to have patent which might not be "rock solid" than no patent.

All patents and applications create a hurdle/problem for a competitor […]"

(504) The originator company goes on to specify that nowadays the weakness of patents is taken into account when seeking to extend the protection period:

"Today [...]

Inevitably there will be patents covering products on the market that can be, and will be challenged […] The strategy today is to try and provide a solid protection for the substance (has a limited time though) and a portfolio protecting different aspects of product providing extended protection both in brea(d)th and time but inevitable less solid and robust."

(505) In general, originator companies will be very discreet about the relative strength or weakness of their patents and urge their employees not to commit any evaluation of their patents on paper, as the following quote from internal communications of an originator company shows:

"I am sure you are aware that we prefer to communicate opinions regarding the strength of our patent property verbally, rather than in writing, which can result in an overly wide circulation, and no doubt you will bear this in mind when advising your regulatory colleague."

(506) Generic companies increasingly view the practice of broad patenting of secondary patents around the basic product, which they often describe as "patent thickets"[368], as an obstacle, which is only being pursued in order to *de facto* extend the exclusive position of the originator in respect of the active ingredient.[369]

[368] This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying interventions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology."

[369] For further details see Chapter D.1.

2.1.3. Divisional Patent Applications

(507) The increased use of filing of divisional patent applications, in particular before the EPO, has been an object of complaints by the generic industry as a potential instrument to prevent or delay generic entry.

(508) Therefore, this section does not want to question the legitimacy of divisional patent applications as such which are foreseen under patent law. It rather seeks to examine in how far the use of the application procedure for such divisional patents may under certain conditions affect generic entry.

(509) As already explained,[370] a divisional patent application is created where the applicant, either voluntarily or at the request of the examining office, divides out from a patent application ("parent patent application") one or several (narrower) patent applications ("divisionals"). Such a division must be undertaken as long as the parent patent application is still pending. However, once created, a divisional has a life of its own, i.e. even if the parent patent application is refused or revoked, the divisional would still be pending. The divisional will have the same priority and application date as the parent patent application. In other words, if granted, a divisional will, in principle, provide the same duration of patent protection as the parent application. Furthermore the divisional application cannot go beyond the scope of the parent application.[371]

(510) As shown above, the vast majority of divisional applications before the EPO in 2008 for A61K*, the closest proxy for pharmaceutical patents, were created voluntarily by the patent holders whereas only about 20% were divisional applications requested by the EPO. The increase of voluntarily created divisional applications also seems to reflect a new trend within the pharmaceutical sector.[372]

(511) Of the 43 originator companies addressed, eleven companies declared that in the period 2000 to 2007 they had filed for divisional patent applications where the corresponding parent application had subsequently been refused or withdrawn. The numbers of individual divisionals varied between 1 and 30.

(512) The sector inquiry unearthed a number of situations, where stakeholders claimed that originator companies insisted on pursuing the grant procedure for divisional patents, even if the parent patent application was subsequently refused or withdrawn.

(513) For example, for some originator companies, the divisional appeared to be a means to expedite prosecution for certain more unproblematic or interesting claims, while other claims of the parent application might still be questioned by the EPO or be of less scientific or commercial interest to the applicant.

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370 For further details see Chapter C.1.2.

371 For further details see Chapter B.2.1.

372 For further details see Chapter C.1.2.

(514) One purpose of divisional patent applications, namely to protect the existing product, is illustrated by the following reflection of an originator company in one of its strategy documents:

> *"Secondary patents*
>
> *What can be done apart from extending the basic patent on the active compound (API)? File divisionals or new applications relating to the specific API - narrower claims are easier to defend and enforce."*

(515) Another reason given by some companies for using divisionals where parent applications were subsequently refused or withdrawn was to gain more time to answer objections made by the patent office examiners to claims in the parent application. Thus one originator company explained:

> *"The divisionals were filed because the time granted by the examiner to reply to the objections against the patentability of the respective parent applications was not sufficient. Filing a divisional application in these cases gives more time for preparing the answers adequately."*

(516) Similarly another originator company explained:

> *"The divisional was filed in order to reset the acceptance deadline clock and allow more time for prosecution."*

(517) Generic companies pointed out that divisionals may be filed to prolong the period of legal uncertainty, since an applicant could use this procedure to "reset the clock" and gain more time for patent examination, thus extending the period where applications are pending. Also, as pointed out during the public consultation, each divisional application has to be assessed individually. Thus a successful challenge of a parent application will not create legal certainty as long as several other divisional applications are still pending.

(518) Generic companies emphasised that in such cases it is virtually impossible for them to predict when which divisional application will possibly be granted. As a consequence they are unsure as to what they can reproduce without infringing any patents, even if the parent patent application has been refused or revoked. This is particularly pertinent, as a divisional application, as already explained, can confer claims for reasonable compensation on the applicant and under certain conditions lead to damages claims. [373]

(519) Of the 27 generic companies 16 claimed that they have had problems with divisional filings (12 of which inter alia referred to the same INN) as one generic company claimed:

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[373] It has been submitted during the public consultation that divisionals neither extend the duration nor the scope of patent protection. It should be noted that this has never been stated in the preliminary report.

"[…] mainly, because they are creating additional uncertainties on our projects."

(520) Another generic company agrees with the assessment that divisionals mainly serve to create uncertainty in this context:

"Filing of divisional applications also enables the originators to maintain the uncertainty generated by parent patent application .... Multiple divisional patent applications combined with abusive patent litigation and preliminary injunctions hinder the development of generic medicines."

(521) Other stakeholders that frequently deal with IP law issues have confirmed the potential of using divisionals to create legal uncertainty in the context of the public consultation. Thus, an intellectual property law firm stated that

"Filing as many divisional patent application(s) as wanted by the applicant, at any time during the pendency of a parent application, generates legal uncertainty and unpredictability for third parties facing the pending patent application(s)."[374]

(522) Also in this context the EPO in its submission explained that it considered the preliminary report

"… interesting for the Office as it gives further insight into certain patterns of applicant behaviours which may increase legal uncertainty, some of which are already under careful scrutiny within the EPO. In particular, internal policy discussions are ongoing with respect to a tightening of the rules governing the filing of divisional applications."

2.1.4. Intended Effects of Patent Clusters and Divisionals

(523) The intended effects of both patenting strategies as analysed above are identical: in some case both patent clusters and divisionals seemingly serve to prevent or delay generic entry. While this, during the period of exclusivity, is generally in line with the underlying objectives of patent systems, it may in certain cases only be aimed at excluding competition and not at safeguarding a viable commercial development of own innovation covered by the clusters.[375]

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374 This firm also pointed to cases where the EPO's Enlarged Board of Appeal had approved the practice of filing multiple divisional patent applications, including divisional patent applications from a divisional patent application, all using at their respective filing dates the exact same description and the exact same claims as for the parent patent application. An institute dealing with issues of IP Law acknowledged in its submission that there may be potential scope of misuse of the system.

375 During the public consultation the EPO has rightly pointed out that the purpose for which an application has been filed is not relevant to the decision-making process within the European patent system and that this should remain so. The EPO would have neither a mandate nor the resources to analyse such intentions. It goes however, without saying that the description of the underlying intentions is relevant to understand how companies use existing legislative framework for their purposes. The intention can also be taken into account in competition law assessments.

(524) In this context, it has to be pointed out that from a patent law perspective the intention behind companies' use of these patenting strategies is and should not be of relevance.[376]

(525) The denser the web created by the patent clusters and/or the divisionals is, the more difficult it will be for a generic company to bring its generic version of the original pharmaceutical to the market. That is to say, even though the main patent protecting the product, e.g. the basic substance patent, may have expired, the generic version may still infringe one of the multiple patents surrounding the original pharmaceutical. This can occur either because patents cover all economically interesting or viable salt forms, enantiomers or formulations of the compound or all efficient ways of its manufacturing. In other words patent clusters and divisionals seem to be aimed at creating legal uncertainty for generic competitors, as the following quote from a generic company illustrates in relation to patent clusters:

> *"The entire point of the patenting strategy adopted by many originators is to remove legal certainty. The strategy is to file as many patents as possible on all areas of the drug and create a 'minefield' for the generic to navigate. All generics know that very few patents in that larger group will be valid and infringed by the product they propose to make, but it is impossible to be certain prior to launch that your product will not infringe and you will not be the subject of an interim injunction."*

(526) An originator company's quote confirms this purpose:

> *"Purpose: Establish an effective barrier to generic competition by extending the term of the existing compound patent and by filing patents on further inventions that last beyond the expiry of the compound patent…The objective [of scope of patent claims] is to secure an optimal competitive position for [our company's] products in the market by blocking competitors."*

(527) Another originator company specifically emphasises the delay function of secondary patenting:

> *"Secondary patents will not stop generic competition indefinitely but may delay generics for a number of years, at best protecting the originator's revenue for a period of time."*

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376 During the public consultation the EPO has rightly pointed out that the purpose for which an application has been filed is not relevant to the decision-making process within the European patent system and that this should remain so. The EPO would have neither a mandate nor the resources to analyse such intentions. It goes however, without saying that the description of the underlying intentions is relevant to understand how companies use existing legislative framework for their purposes. The intention can also be taken into account in competition law assessments.

2.1.4.1. Limitations of Generic Entry as an Immediate Consequence of Patenting

(528) As shown above, patent strategies can lead to significant uncertainty concerning the possibility of a legitimate and commercially viable generic entry. Patent clusters and/or divisionals may without further enforcement action by originator companies, thus delay generic entry until the patent situation is clearer or even discourage more risk sensitive generic companies from entering altogether.

(529) An originator company explained how it expected the use of its secondary patents to reduce generic uptake (and consequently to slow originator decline) over a relatively long period post-patent expiry:

> *"Key factors resulting in slow decline:*
>
> *Patent factors: secondary manufacturing process patent or patent formulations result in limited (2-3) generic competitors over 2-3 years. […]*
>
> *Key factors resulting in medium decline:*
>
> *confusing or unclear molecule patent position combined with robust defence results in 2-3 generic competitors in first year."*

(530) The impact such patent strategies can have on generic entry could also be observed in a case study based on the findings of the sector inquiry where an originator company had filed for more than 30 patent families translating into several hundreds patents in the Member States in relation to one product. More than a quarter of these patent applications were, in fact, filed after the launch of the product. These applications interfered with several generic companies' plans to develop and/or bring their generic versions of the original product to the market, led to several opposition procedures and subsequent legal disputes and in one case to abandoning the development of the generic product.

(531) In one of its latest working papers the EPO has assessed the abuse of divisional applications in the following way:[377]

> *"There is a trend for applicants to abuse these procedural possibilities by using the divisional application procedure to achieve a "duplication" of the proceedings … This is detrimental both to legal certainty for third parties and to patent office workloads."*

(532) As a consequence the Administrative council of the EPO, composed by its contracting states has agreed on a reform proposal of the EPO to introduce time limits for the filing of divisional applications.[378]

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[377] EPO paper CA/145/08 Rev. 1, subject: Divisional applications, Munich, 15.01.2009; http://www.sipf.se/admin/photo/big/hearinginbjudan/CA14508Rev.1.pdf. For further details see Chapter C.2.1.

(533) The statement of a generic company below illustrates the possible delays if the use of divisionals creates uncertainty:

> *"The three divisional applications are identical or practically identical to each other. It can be expected that they will be held pending and – if possible be brought to issuance – one by one so there is a constant threat and uncertainty to generic companies over years. Several opposition proceedings are pending against the [number of divisional] patent. The opposition proceedings can be expected to take about four to five years. Thereafter, nullity proceedings before the […] Court are possible […], which can be expected to take another two to four years."*

(534) A second generic company pointed out:

> *"Obviously, [originator]'s strategy is to file numerous identical or practically identical divisional applications from one basic application – which has been found invalid by the EPO! – and keep them pending. Should the grant of one of them be denied, the other still pending applications are such a threat to the generic companies that many of them are extremely reluctant to enter the market. […] The grant [meant is: EPO decision on the patent application] can be delayed for years by [originator]."*

(535) Apart from causing delays, generated uncertainty may also lead to abandonment of development of generic versions as shown in the following testimony by a third generic company:

> *"The filing of divisional patent applications by another company has interfered with our plans to develop a generic pharmaceutical composition… On [date], the European Patent Office ("EPO") granted to [originator company] the European patent [number] related to the use of [INN] for treating [condition] in a [details of dosage], despite the fact that [earlier] an Opposition Division of the EPO revoked its parent patent related with the same dosage regime. The divisional European Patent EP [] is currently being opposed at the EPO by […] companies […]. The uncertainty generated by the decision granting European patent [number of patent above] forced our company to abandon the development project related to [originator's product name] generic drug […]."*

(536) Originator companies, their associations, IP law firms and bodies dealing with IP law issues have submitted that generics are not necessarily forced to abandon their projects due to perceived legal uncertainty. Rather they claim that there exist several ways to clear the way such as the opposition procedure as well as litigation procedures. As explained in the respective chapters of this report these are time consuming and costly.

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[378] As of 1 April 2010, voluntary divisional applications will need to be filed within a period of two years from the first communication by the EPO examining division in respect of the parent or an even earlier (in case of a "chain" of applications) application. For further details see the Decision of the Administrative council of 25 March 2009 amending the Implementing Regulations to the European Patent Convention (CA/D 2/09) under: http://www.epo.org/patents/law/legal-texts/decisions/archive/20090325.html.

2.1.4.2. Procedural Enforcement of Patent Rights

(537) Patents are proprietary, exclusive rights and enforcing one's patents against parties infringing them is a legitimate procedural dimension of the material right granted to the patent holder. It furthermore is part of the fundamental right to a fair hearing before court as manifested in Article 7 of the European Convention of Human Rights (ECMR).

(538) The preceding subsection showed that the use of patent clusters and divisionals by some companies may deter or delay generic entry merely by their existence. In other cases, companies may proceed with the development of generic versions with a view to enter the market at risk. In such cases, patent clusters and also divisionals are an indispensable asset for originator companies' implementation of their procedural enforcement strategies. These strategies will typically lead to patent litigation, but can also result in settlements, as discussed in subsequent chapters.[379] Such patent positions may also be an argument originator companies raise in their interventions vis-à-vis the marketing authorisation, pricing and reimbursement bodies etc.[380]

(539) The present subsection focuses on litigation as the most immediate aspect of procedural enforcement of patent clusters, as well as divisionals. Patenting strategies appear to be coupled with assertive effort of judicial enforcement.

(540) Originator companies, in their strategy documents and internal communication emphasise the necessity to enforce patents wherever they perceive an infringement by third parties, such as the following quote shows in an exemplary manner:

> *"We defend our patent rights vigorously against third party challenge with respect to validity and enforceability."*

(541) Another originator company put it more bluntly by saying:

> *"[…] we will legally exploit all opportunities to get generics out of the market."*

Patent litigation as signal to the generic companies

(542) An important part of this patent enforcement through litigation is signalling to the generics industry that patent infringements will not be tolerated by the patent holding originator company. As one originator company declared in its internal communication:

> *"We should as a matter of principle defend our intellectual property. Failure to do so will not only impact on sales of current generic products but will create a perception of weakness which may damage future patent expiries".*

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379 For further details see Chapter C.2.4.

380 For further details see Chapter C.2.5.

(543) Sending such a signal relating to patent defence of the original product can be particularly important to an originator company where a second generation product is about to be launched, as follows from this internal communication at another originator company:

> *"My view is that we ask for interlockatory [sic] injunctions for two reasons: 1) […] 2) we send a strong signal to the generics that we haven't softened which is important for possible IP issues with [name of second generation product] in beginning [year]."*

Consequences of patent litigation for generic companies

(544) For generic companies patent litigation with an originator company can in itself create obstacles to market entry namely by creating costs and by using interim injunctions, preventing the sale of the generic product. As described above, sometimes the threat of incurring substantial litigation cost or issuance of an interim injunction can in itself deter entry.

(545) While larger generic companies may have the financial resources for long and costly litigation – in fact some of the latter have reserved a significant part of their overall budget for litigation and damages – smaller companies may be affected more substantially by litigation.[381] In fact, patent enforcement litigation can aim at financially overburdening them, in particular where a big originator company obtains interim injunctions against the generic product being put on the market. This creates an uphill struggle for the generic firm, as its litigation costs rise without mirroring revenues from its generic pharmaceutical whereas the originator company will continue to collect revenues from its product.

(546) In certain cases, when enforcing patent clusters and/or divisionals, an originator company may bring numerous patent infringement actions against a generic company in several Member States on each supposed infringed patent, even where the originator company does not believe to have a chance of being successful. An illustrative example pointing in this direction, in particular with respect to obtaining an interim injunction, is the following internal communication at one originator company:[382]

> *"Our strategy is clear. We want to send a signal (by applying for interim injunctions well knowing that we will not be granted a ban) that we do not accept early [generic] entry and then later we withdraw everything."*

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381 This is of course no particularity of the pharmaceutical sector, however, as explained in the introduction the originator companies subject to this inquiry were typically significantly larger than even their larger generic companies.

382 In this context it is interesting to note that concerning the sample examined in the sector inquiry the ultimate success rate of cases where such interim injunctions were granted was not in clear favour of the applicants. For further details see Chapter C.2.2.

Summary

The findings of the inquiry suggest that in recent years originator companies have changed their patent strategies. In particular, strategy documents of originator companies confirm that some of them aimed at developing strategies to extend the breadth and duration of their patent protection.

Filing numerous patent applications for the same medicine (forming so called "patent clusters" or "patent thickets") is a common practice. Documents gathered in the course of the inquiry confirm that an important objective of this approach is to delay or block the market entry of generic medicines.

In this respect the inquiry finds that individual medicines are protected by up to nearly 100 product-specific patent families, which can lead to up to 1,300 patents and/or pending patent applications across the Member States. Despite the lower number of underlying patent families based on EPO applications, looking from a commercial perspective, a challenger may, in the absence of a Community patent, need to analyse and possibly confront the sum of all existing patents and pending patent applications in those Member States in which the generic company wishes to enter.

When the number of patents and in particular of pending patent applications is high (patent clusters), this can lead to uncertainty for generic competitors – affecting their ability to enter the market. Statements in internal documents collected in the context of the sector enquiry point at the awareness by patent holders that some of their patents might not be strong.

A second instrument used by originator companies could be identified as filing voluntary "divisional patent" applications, most prominently before the EPO where most patent applications in the pharmaceutical sector are filed. Voluntary divisional patent applications, which are foreseen in patent law as a legitimate way to split an (initial) parent application, cannot extend the content of the original application nor the protection period. But they can extend the examination period of the patent office, as the examination of divisional applications continues even if the parent application is withdrawn or revoked, which, under certain conditions, can add to the legal uncertainty for generic companies. Enforcing patent rights in court is legitimate and a fundamental right guaranteed by the European Convention on Human Rights: it is an effective means of ensuring that patents are respected. Like in any other industry the inquiry's findings show, however, that litigation can also be an efficient means of creating obstacles for generic companies, in particular for smaller ones. In certain instances originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants.

2.2. Patent-Related Exchanges and Litigation

(547) The purpose of this section is to describe practices of enforcing and challenging patent rights before and out of court without drawing any conclusions as to their compatibility with EC competition law. This section first examines contacts and disputes between originator and generic companies out of court and then looks at patent litigation before the EU Member States' courts.

(548) It should be noted from the outset that enforcing patent rights in court is legitimate and constitutes a fundamental right guaranteed by the European Convention of Human Rights.[383]

(549) However, the inquiry's findings show that, like in any other industry, litigation can also be an efficient means of creating obstacles in particular for smaller companies. In certain instances originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants.

(550) It is not the purpose of this section to provide guidance as to the compatibility of certain practices with EC competition law. The Commission will further investigate whether individual company behaviour may have fallen foul of the competition rules.

2.2.1. Patent-Related Exchanges between Originator and Generic Companies out of Court

(551) This section examines the enforcement of patent rights by originator companies through patent-related exchanges out of court. In particular, originator and generic companies were asked to report on all contacts and disputes[384] in which they were involved across the EU in the period 2000 to 2007 and which had not ended in litigation.[385]

(552) Classifying a given exchange between an originator and a generic company as a contact or dispute is not always straightforward and can be open to interpretations.

(553) Contacts and disputes between an originator and a generic company may have an impact on the decisions of the generic company regarding the launch of a competing product. Although not (always) leading to court proceedings, such patent-related exchanges can have a dissuasive effect and thus affect planned generic entry, in

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383 See Chapter C.2.1.

384 For the purpose of the sector inquiry, disputes are defined as referring to any exchange of views between an originator and a generic company in which, in particular, the actual or potential infringement, non-infringement or invalidity of one or several patents concerning a specific INN have been raised and which has not (yet) ended in litigation, whereas contacts refer to all out of court patent-related exchanges reported, which respondent companies did not classify as disputes.

385 The data provided by respondent companies are based on the records available at the date of companies' replies to the requests for information.

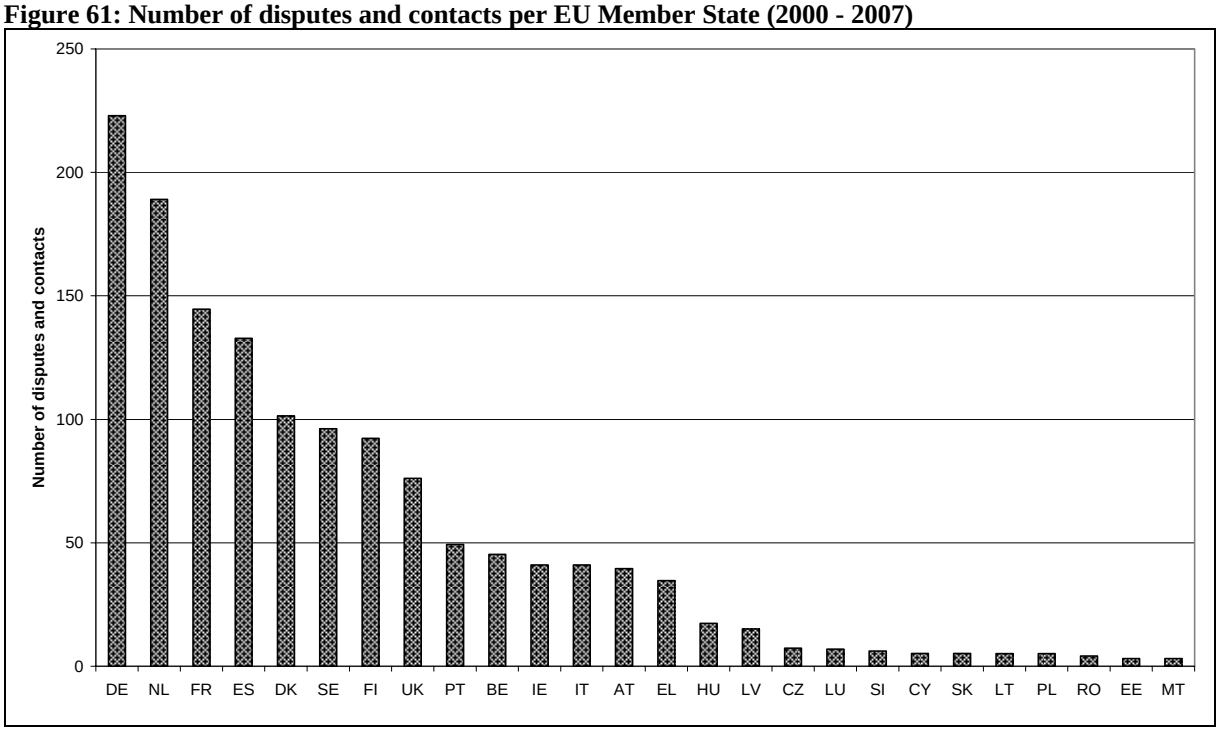
particular as a result of the threat of costly litigation and the risk of the grant of interim injunctions and, eventually, damages.

(554) The present section will therefore examine the number of contacts and disputes concerning market entry of generic products which were initiated by originator and generic companies in EU Member States in the period 2000 to 2007 and the INNs most often invoked in such patent-related exchanges. The section goes on to look at the number of disputes started in the EU by category and type of the patent in dispute, and the percentage of disputes ending in settlement. Finally, an overview of the percentage of patent disputes in relation to the date of expiry of the disputed patent is provided.

2.2.1.1. Number of Contacts and Disputes between Originator and Generic Companies in the EU and INNs Most Often Concerned by Contacts and Disputes

(555) Figure 61 provides an overview of the number of contacts and disputes (patent-related exchanges) initiated by originator and generic companies per EU Member State in the period 2000 to 2007. Respondent companies reported a total of 1,337 disputes and contacts initiated in the EU in the period under review.[386]

Figure 61: Number of disputes and contacts per EU Member State (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

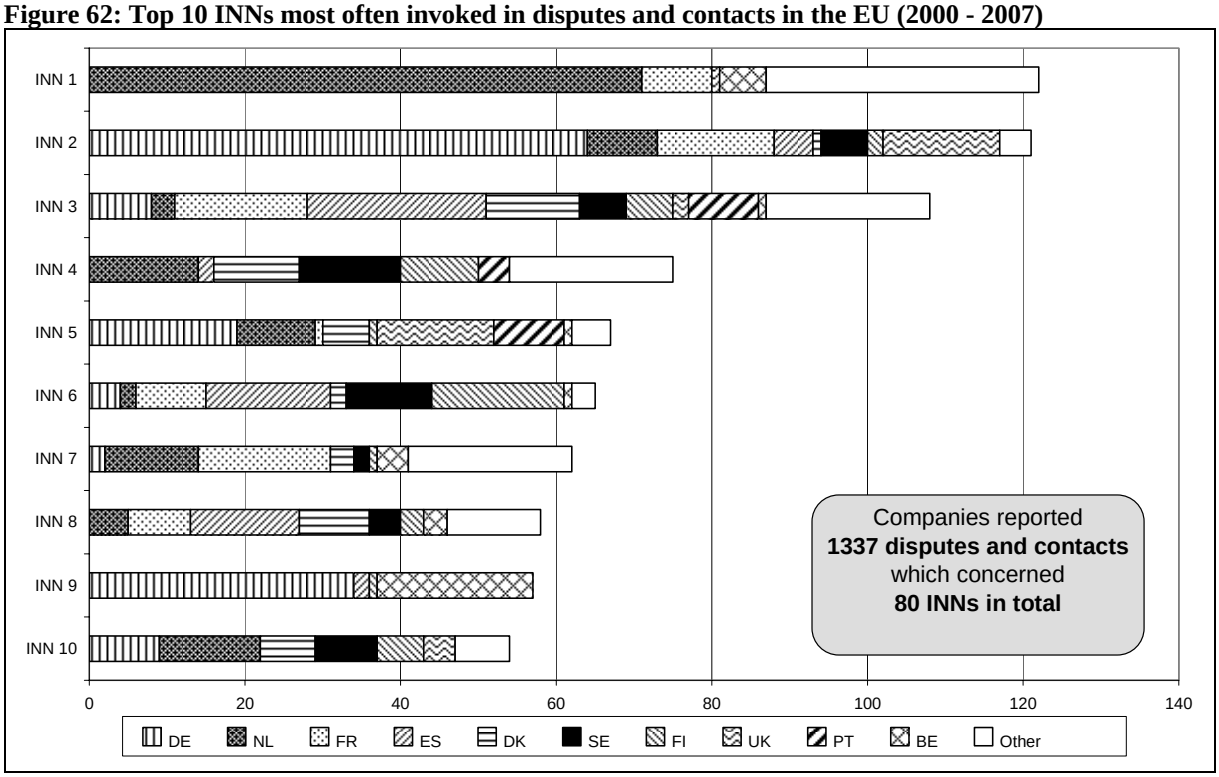
(556) As shown above, the highest number of disputes and contacts concerned Germany (223 or 16% of the total), followed by the Netherlands (189 patent-related exchanges

386 The total number of disputes and contacts shown on Figure 52 above is slightly higher (1390) since the disputes and contacts reported by respondent companies as concerning EU-27 were equally added to all the Member States.

or 14%), France (145 exchanges or 10%) and Spain (133 exchanges or approximately 10%). After these countries come Denmark, Sweden, Finland and the United Kingdom, with roughly 5 to 7% (70 to 100) of patent-related exchanges.

(557) Figure 62 presents an overview of the top 10 INNs which were most often the object of contacts and disputes between originator and generic companies in the EU in the period 2000 to 2007. Respondent companies reported a total of 1,337 disputes and contacts which concerned 80 INNs.

Figure 62: Top 10 INNs most often invoked in disputes and contacts in the EU (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(558) It should be noted that contacts and disputes relating to the top 10 INNs listed in Figure 62 above accounted for 59% of all contacts and disputes between originator and generic companies reported during the period examined.

(559) Contacts and disputes concerning INNs 1 and 2 were the most frequent, each accounting for 9% of all patent-related exchanges. INNs 3 and 4 were the object of 8% and 6% of patent exchanges, respectively. INNs 5 to 7 were invoked in 5% of patent-related exchanges, compared to 4% for INNs 8 to 10.

(560) On the major national markets, INNs 1 and 3 were among the best-selling medicines (T50) and among the best-selling medicines which faced loss of exclusivity (E75).[387] Overall, each of the top 10 INNs belonged to at least one of the two aforementioned groups.

[387] For more information on the T50 and the E75 lists, please refer to the Annex: Methodology (Annexes to Chapter A).

(561) As shown on Figure 62, contacts and disputes concerning INN 1 and relating to the Netherlands accounted for the majority (71%) of all patent exchanges for this INN. Furthermore, most of the patent exchanges concerning INN 2 involved Germany (53%), France and the United Kingdom (12% for each). INN 3 was the subject of a substantial number of contacts and disputes concerning France and Spain (18-21%), while most patent exchanges concerning INN 4 involved the Netherlands, Sweden and Denmark (19, 17 and 15% respectively). A similar pattern of unequal geographical distribution is also seen for the remaining INNs.

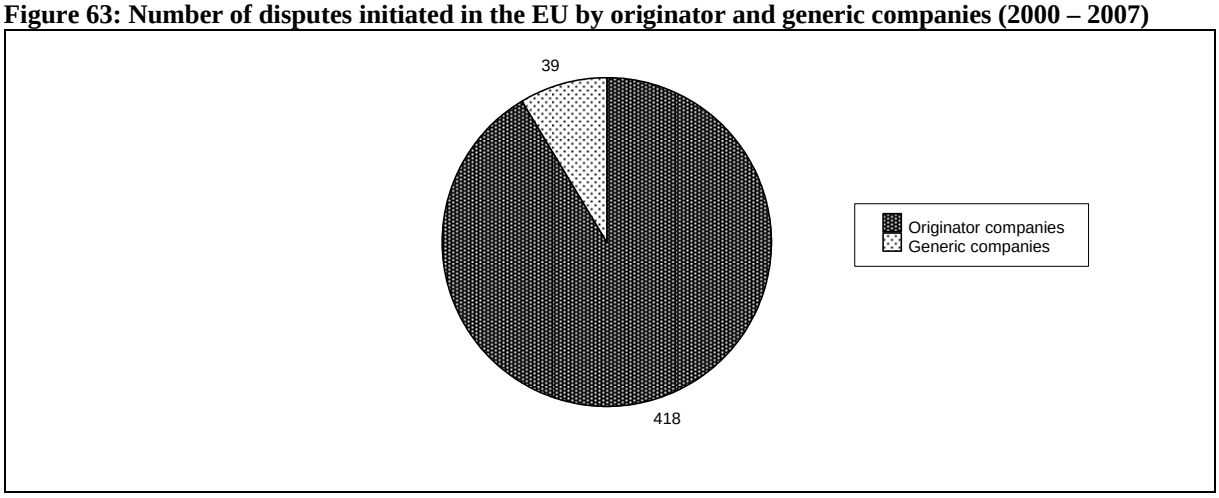
(562) All of the top 10 INNs were the object of contacts and disputes in at least four Member States (and most often in more than seven Member States). The reasons for which a dispute on any given INN was initiated in a specific Member State appeared to be case-specific.

(563) Thus, for the same INN, one observed a significant number of (often parallel) contacts and disputes between originator and generic companies concerning various Member States. This multiplication of contacts and disputes across Member States is a direct consequence of the current European patent system which lacks a unified Community-wide patent and is instead based on a bundle of national patents.

2.2.1.2. Number of Disputes Initiated in the EU by Originator and Generic Companies

(564) Figure 63 provides an overview of the number of disputes initiated by originator and generic companies in the EU in the period 2000 to 2007. Companies reported a total of 457 disputes initiated in the EU in the period examined. Data provided shows that nearly all disputes (91%) were initiated by an originator company, whilst generic companies launched only 9% of all disputes.

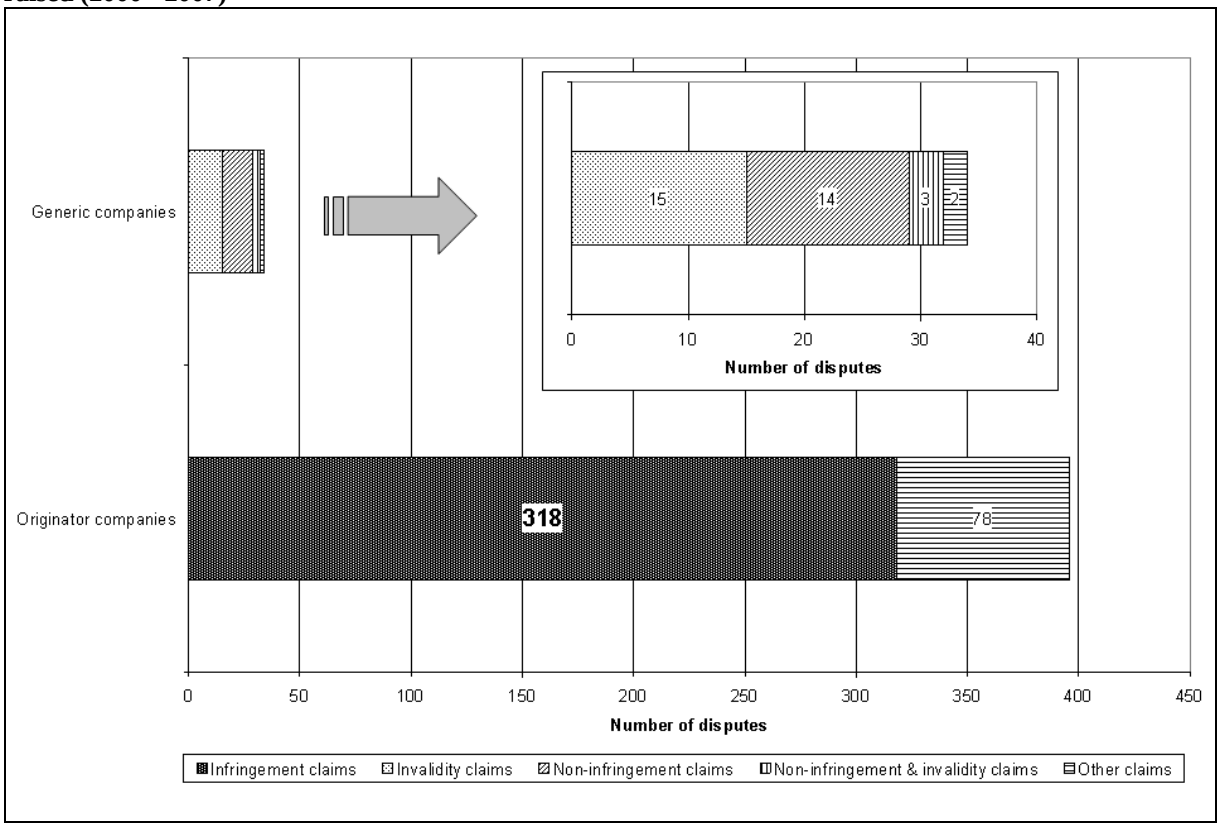
Figure 63: Number of disputes initiated in the EU by originator and generic companies (2000 – 2007)



Source: Pharmaceutical Sector Inquiry

(565) Figure 64 illustrates the number of disputes initiated by originator and generic companies in the EU in the period 2000 to 2007 by type of claim raised (infringement, invalidity, non-infringement, non-infringement and invalidity, and other).

Figure 64: Number of disputes initiated in the EU by originator and generic companies by type of claim raised (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(566) As already indicated above, nearly all reported disputes (91%) were initiated by an originator company.[388] This high percentage could be explained in terms of originator companies' strategies aimed at protecting patent rights and initiated at the point when an originator company becomes aware of the planned entry to the market by a generic company (e.g. by informing the generic competitor of its patent rights, the consequences of patent infringement and demanding that the generic product be withheld from the market). In 74% of disputes initiated by an originator company, the originator company claimed that the generic company was infringing its valid patent rights. The remaining 26% of disputes dealt with other claims.[389]

(567) In contrast, only about 9% of all reported disputes were started by a generic company. Those disputes raised claims of invalidity (15 instances), non-infringement (14 instances), non-infringement combined with invalidity (3 instances) and other claims (2 instances).

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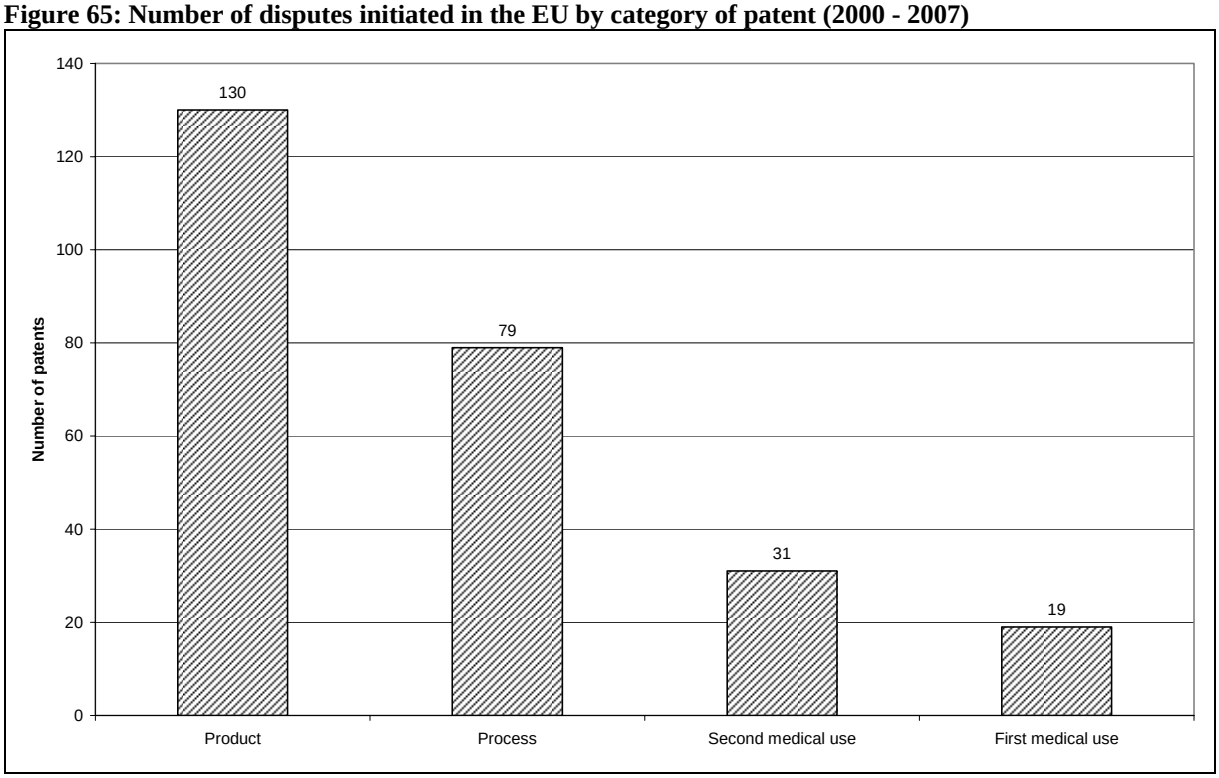
388 The total number of disputes initiated by originator and generic companies in the EU in the period 2000 to 2007 as shown on Figure 64 above is slightly lower than the one indicated on Figure 63. This may be explained by the lack of indication, for some of the disputes reported, of the type of claim raised.

389 Respondent companies have indicated that such other claims raised in disputes concerned *inter alia* letters drawing the attention of the generic company to the existence of the relevant patent.

2.2.1.3. Number of Patents in Dispute by Category of Patent

(568) Figure 65 illustrates, by category of patent, the number of patents which were the object of a dispute in the EU in the period 2000 – 2007.[390]

Figure 65: Number of disputes initiated in the EU by category of patent (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(569) Companies reported a total of 187 patents which were concerned by disputes in the period under review. As Figure 65 shows, more than two-thirds of disputed patents were product patents (70% or 130 patents). Process patents represented the second most disputed category of patents (42% or 79 patents). The percentage of first and second medical use patents in dispute was significantly lower (10% and 17% respectively). A similar pattern, described further on in this chapter (see Figure 76), was also observed in relation to litigated patents.

(570) As Figure 66 shows, primary patents were the object of disputes between originator and generic companies in over half (53%) of all disputes reported whilst the remaining 47% of all disputes involved secondary patents.[391]

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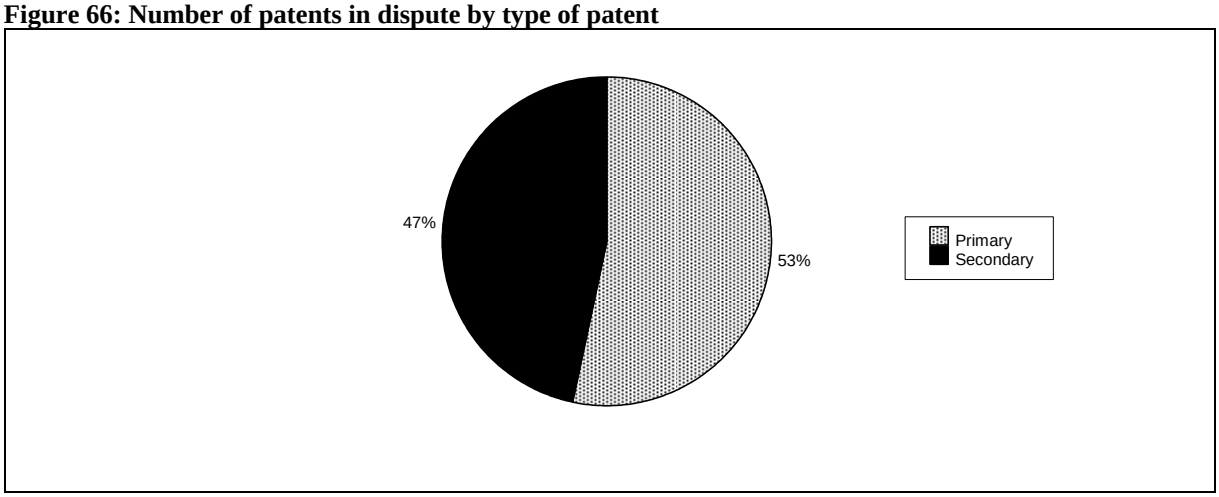
390 For more information on patent categories see Annex: Claim Types (Annexes to Chapter B). It should be noted that one patent may fall under one or more different patent categories. Hence, due to multiple counting, the aggregate number of disputed patents, if added across the four patent categories as listed in Figure 65, will exceed the total number of disputed patents reported by respondent companies.

Figure 66: Number of patents in dispute by type of patent

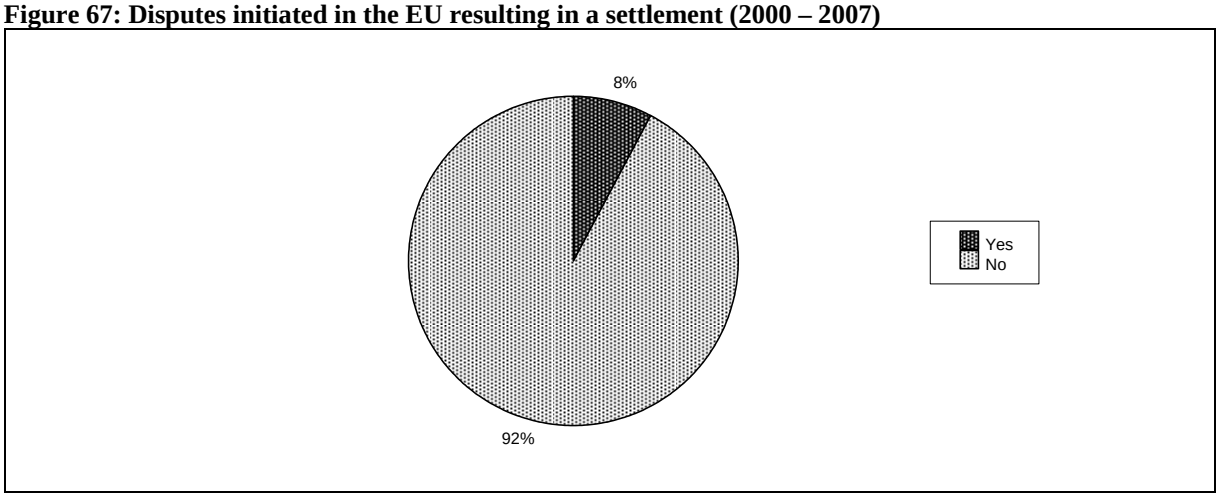


Source: Pharmaceutical Sector Inquiry

2.2.1.4. Disputes Resulting in Settlement

(571) Figure 67 shows that only 8% of disputes between originator and generic companies ended in a settlement. This can be seen as one illustration of the fact that, even without reaching the stage of litigation, patent-related disputes may have effects on generic entry.

Figure 67: Disputes initiated in the EU resulting in a settlement (2000 – 2007)



Source: Pharmaceutical Sector Inquiry

391 This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying interventions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

(572) The disputes, reported in this section, which did not lead to a settlement, were either not further pursued by originator companies (e.g. no legal action was brought to court) or may have led to litigation or ended with a settlement after 1 January 2008.[392]

(573) An originator company may decide not to further pursue a dispute because the generic company has refrained from entering the market. Even if there is generic entry, an originator company may still discontinue the dispute it has initiated if the lack of infringement has been established, or if it is not convinced of the existence of an actual infringement or of the strength of its patent.

(574) In the example given below, an originator company initiated a patent dispute when it became aware of the marketing of a competing generic product.

> *"It has come to the attention of our client that you [generic company] have received a marketing authorisation for [originator's product] and [originator's product]. [...] At the request and on behalf of our client [originator company], we seek your confirmation in writing that you [generic company] will refrain, for the duration of [the originator company's] industrial property rights from producing, offering and placing on the market or using [originator's product] and [originator's product]. We should receive your written confirmation by [date]. Our client explicitly reserves the right to initiate patent litigation in the future in relation to unlawful patent use."*

(575) However, the originator company did not pursue its claim further, even though the generic product remained on the market. Even if many disputes are not further pursued by originator companies, they can have a strong dissuasive effect on the entry of generic products on the market, in particular as a result of the threat of costly litigation and the risk of the granting of interim injunctions and, possibly, damages.[393] The data reported by respondent companies on patent litigation show that over half of litigation proceedings were preceded by prior disputes and/or contacts. This illustrates the strength of the link between patent-related exchanges and patent litigation.

2.2.1.5. Histogram with Patent Expiry Dates of Patents in Dispute

(576) Figure 68 provides a histogram of patents in dispute in the EU in the period 2000 to 2007 relative to patent expiry dates. It distinguishes between primary and secondary patents. The vertical axis shows expired patents as a percentage of the total number of disputed patents, while the horizontal axis lists the semesters in which individual patents were or are about to expire.

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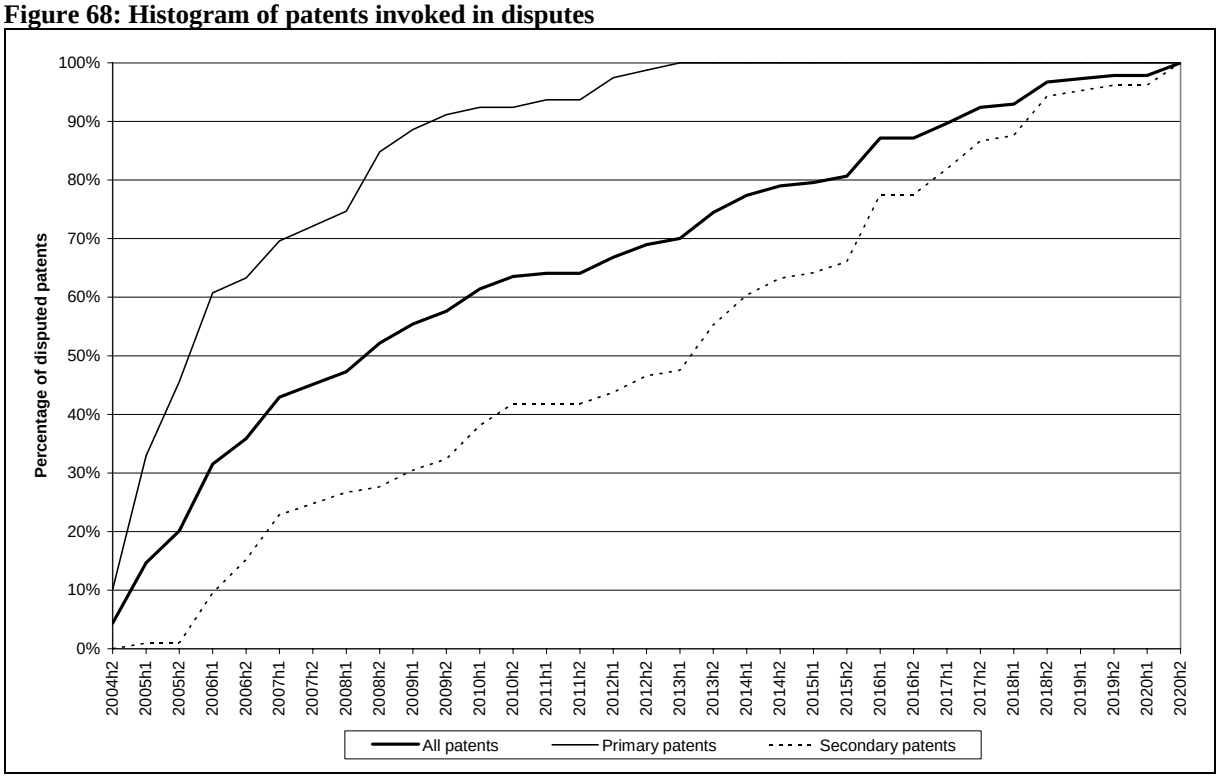
[392] In the requests for information, companies were asked to report the disputes between originator and generic companies, which had led to litigation, in the section concerning patent litigation.

[393] The findings of the sector inquiry show, with regard to all disputes reported by respondent companies for which an outcome to the dispute was indicated, that in nearly half of disputes, the generic company decided not to launch its product prior to the expiry of the originator company's patent.

Figure 68: Histogram of patents invoked in disputes



Source: Pharmaceutical Sector Inquiry

(577) Figure 68 shows that primary patents, which were the object of a dispute, have an earlier expiry date than secondary patents in dispute. For example, 92% of disputed primary patents will have expired by the first half of 2010 which stands in contrast to the 38% of secondary patents in dispute that were reported by originator companies to expire by the same time. This would indicate that secondary patents are the object of disputes much earlier in the process when the relevant expiry dates are relatively further away. The latest expiry date of an individual secondary patent reported in the section on disputes by respondent companies falls in the second half of 2020. Hence, it appears that originator companies tend to invoke secondary patents which were granted relatively recently.[394]

2.2.2. Litigation

(578) This section examines the enforcement and challenge of patent rights through litigation before EU Member States' courts. More specifically, originator and generic companies were asked to report on all patent-related litigation, to which they were a party, and which was launched in the EU in the period 2000 – 2007.

(579) The questionnaires that were sent to companies defined patent-related litigation as covering any type of court proceedings or other formal adversarial proceedings with

394 For further information on patent strategies used by originator companies see Chapter C.2.1.

the exception of patent opposition proceedings.[395] In particular, questions were asked concerning the main patent-related legal actions such as the action for infringement, the action for declaration of non-infringement and the action for annulment[396] (also sometimes referred to as "invalidity action").

(580) The action for infringement is launched by an originator company with the aim of having the court find that the generic product is (imminently or actually) infringing the originator's patent and prohibit its production and commercialisation until the date of patent expiry. The action for a declaration of non-infringement is brought (independently or as a counter-action) by a generic company seeking a declaration by the court that its product does not infringe the originator company's patent (e.g. because of the difference between the two products, processes etc.). This allows the generic product to enter or remain on the market free of patent claims.

(581) Generic companies may also bring an action for annulment of the originator company's patent, which would allow them to enter the market unless the product is protected by other patents which have not been invalidated.[397] The grounds for nullity most often invoked by generic companies concern the lack of novelty and/or inventive step of the originator product. If the patent is annulled, it is considered retroactively to be abolished *erga omnes.*

(582) A variety of scenarios of litigation may take place. Either the originator or the generic company may initiate litigation against the other party, bring a counter-action or merely defend themselves.[398]

(583) Patent litigation can influence the commercial decisions of generic companies. In particular, the threat of lengthy and costly patent litigation across EU Member States can dissuade smaller generic companies from launching a competing product, hence avoiding burdensome court procedures, before patent expiry, even if they consider the patent to be invalid or not to have been infringed. Even if generic companies are not put off by patent litigation and are willing to go to court, litigation can have an impact on bringing to market a generic version of the originator product. Most importantly, interim injunctions can oblige generic companies to withdraw their product from the market and refrain from further production and commercialisation until the main action

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395 For further information on patent opposition proceedings see Chapter C.2.1. and 2.3.

396 For further details see footnote 207.

397 For more information on the regulatory framework see Chapter B.2.1.

398 For instance, the generic company may bring an action for a declaration of non-infringement and/or an action for annulment and launch its product once generic entry has been cleared (or the patent has been annulled by the court). The generic company may also launch at risk while its action for non-infringement and/or annulment is still pending or launch its product without filing any action at all. In the event of a generic launch at risk before patent expiry, the originator company may seek to defend its patented product by bringing an action for infringement (and possibly requesting that interim injunctions be granted).

is decided.[399] It goes without saying that interim injunctions can also be a necessary and legitimate tool allowing patent-holders to effectively enforce their patent rights. However, the grant of interim injunctions can become particularly relevant when examined in the light of originator companies' overall patent and life cycle strategies which are aimed at maximising profit and shielding their products from competition.

(584) For the sake of example, it can be useful to refer to anonymised but real-life situations. In one of them an originator company started infringement proceedings and successfully obtained interim injunctions on one of the main national markets. That originator company lost subsequently its case which in turn allowed for generic entry many years before the patent expiry dates claimed in the court proceedings. Another originator company started infringement proceedings and successfully obtained interim injunctions on another national market just in order to subsequently settle the case, allow for generic entry many years before the patent expiry dates claimed in the court proceedings and on top of that transfer a substantial sum to its generic competitor. In each of these cases, the originators' involvement in litigation translated into an extended period during which no generic competition was present.

(585) The present section will examine the patterns of patent litigation in relation to generic entry (e.g. the total number of litigations initiated in the EU per launching party and per Member State, the duration of litigation, the types and categories of litigated patents etc.) and the INNs which were most often the object of litigation. It will also analyse the final outcome of patent litigation on the merits and the patterns of interim injunctions. Finally, this section will look at the cost of external legal advice in patent matters.[400]

2.2.2.1. Number of Patent Litigations Initiated in the EU and per EU Member State

(586) As illustrated in Figure 69, companies reported a total of 698 separate [401] cases of patent litigation which were initiated [402] in the EU in the period 2000 to 2007[403]. Of the

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399 Or until the patent expiry date (if it precedes the final judgement) or until such time as the judge may decide.

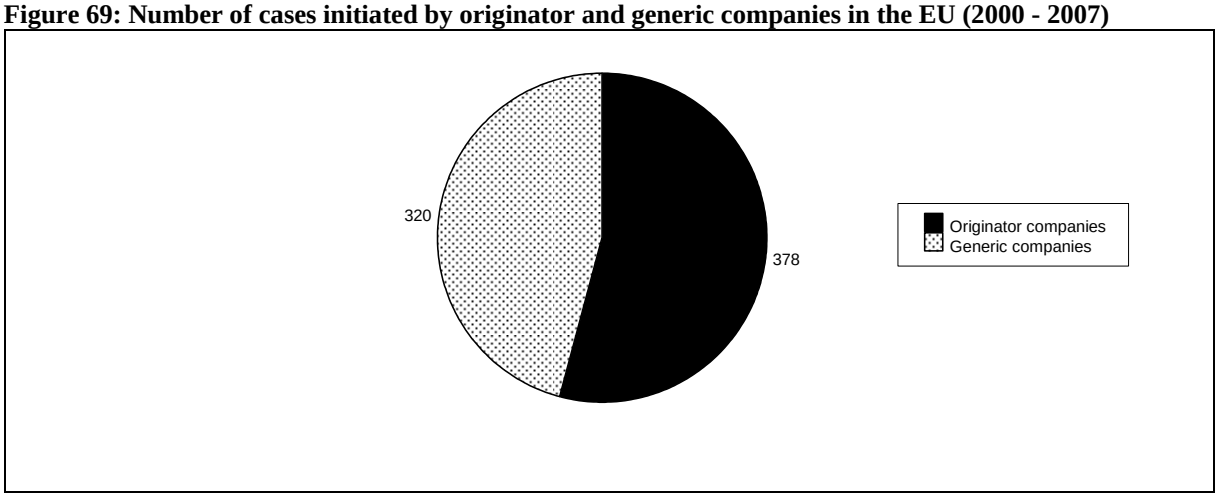
400 It is not the purpose of this section to provide a comparative analysis of the data on patent litigation as reported by pharmaceutical companies and data on patent litigation relating to other industrial sectors. Such a comparison would require the collection of extensive data through the use of investigative powers which do not fall within the Commission's current mandate relating to the pharmaceutical sector inquiry.

401 The term "separate litigation" refers to patent litigation cases in one Member State identified by a single court reference number independently of the number of patents concerned or parties and instances involved. Hence, a legal action brought in one Member State against several different defendants concerning several patents and examined by several instances is counted as one separate litigation if it is identified by the same, unique court reference number. Throughout this chapter, all references to patent litigation denote separate litigation cases.

402 Throughout this chapter, "initiation of litigation" refers to the first legal action started by a party which is the one taken into account for statistical purposes, independently of the existence of a counter-action (not included in the calculations).

total reported, the cases initiated by originator companies accounted for 54% (378 cases) as against 46% (320 cases) launched by generic companies.

Figure 69: Number of cases initiated by originator and generic companies in the EU (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(587) As shown in Figure 69, generic companies initiated a substantial number of litigations (although fewer than those started by originator companies). This can be explained by the fact that generic companies' have been proactive in initiating litigation to obtain a declaration of non-infringement of the relevant patent or its annulment in order to clear generic entry.

(588) Figure 70 illustrates the trend in the number of patent litigations initiated in the EU by originator and generic companies in the period 2000 to 2007. As it was argued in the context of the public consultation that new EU Member States may contribute significantly to an overall increase in the number of cases, Figure 70 distinguishes between the EU-27 Member States, including those which joined the European Union in 2004 and 2007, and the EU-15 Member States.

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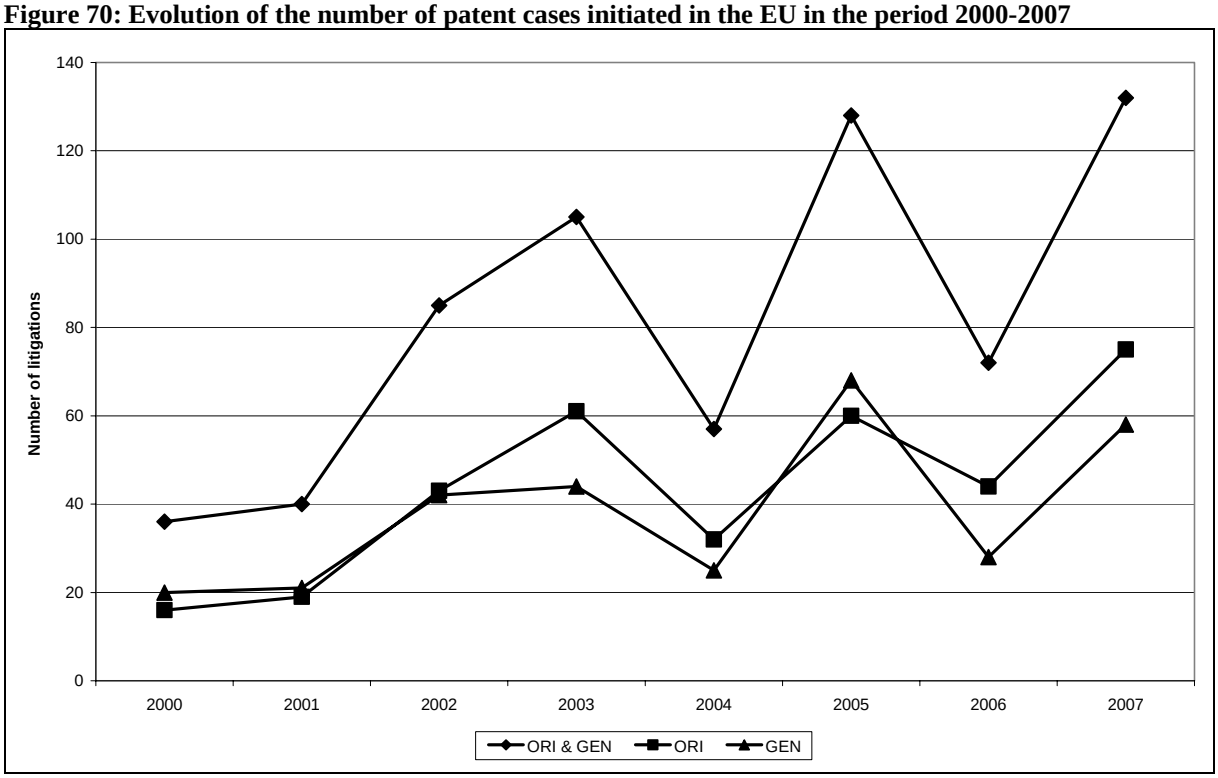
403 For the purpose of the sector inquiry, each separate litigation reported is accounted for since, due to the current European patent and judicial system, once validated in a Member State, each patent has an autonomous life of its own entailing a procedural and resource burden required to enforce it or challenge it in each relevant national court. If a generic company strikes down a patent in front of one national court, this does not change the patent situation in any of the other 26 Member States. Accordingly, the challenger needs to confront the sum of all national patents in all those Member States where a product launch is foreseen.

Figure 70: Evolution of the number of patent cases initiated in the EU in the period 2000-2007



Source: Pharmaceutical Sector Inquiry

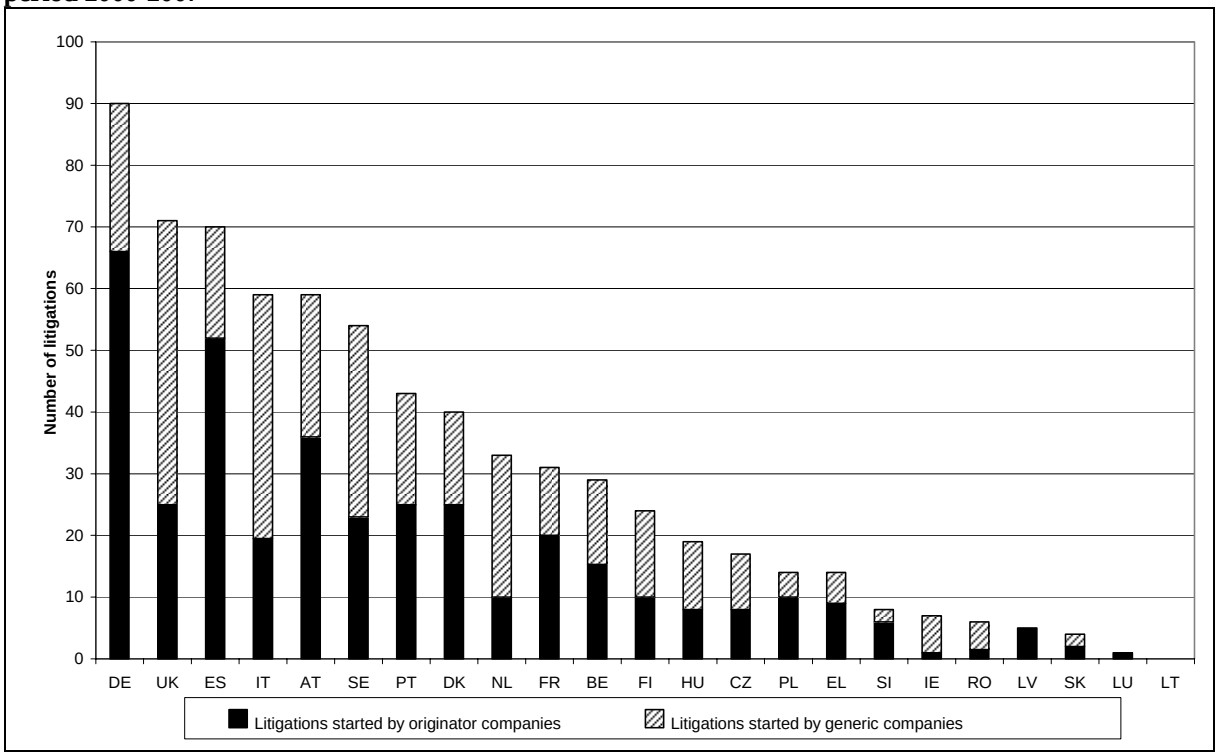
(589) Figure 70 shows that there was a substantial overall increase in the number of cases, which rose nearly fourfold from 36 in 2000 to 132 in 2007. The increase in the number of patent litigations was particularly marked in the initial period from 2000 to 2003 with the number of patent litigations increasing nearly three times. The year 2004 saw a sharp temporary decline in the number of patent cases by nearly half (by 48 cases) compared to 2003. However, in 2005, the number of patent cases sharply increased again more than twice (by 71 cases) only to fall by 56 cases in 2006. Nevertheless, this drop was reversed once again in 2007 when an increase of more than 60 cases was observed. At this point, the number of patent cases reached its highest in the period examined (132).

(590) The trend in the number of patent litigations initiated either by originator or generic companies (as shown on the graph) followed an essentially similar pattern.

(591) Figure 70 also shows that the 2004 and 2007 enlargement rounds of the European Union did not have a significant effect on the number of patent cases initiated in the EU by pharmaceutical companies.

(592) Figure 71 illustrates the distribution in the number of patent litigations initiated by originator and generic companies in the period 2000 – 2007 for all EU Member States.

Figure 71: Patent litigations initiated by originator and generic companies per EU Member State in the period 2000-2007



Source: Pharmaceutical Sector Inquiry

(593) We can see that Germany had by far the highest number of cases in the EU (90 cases), followed by the United Kingdom (71 cases) and Spain (70 cases). Between 40 and 60 patent litigations were initiated in Italy and Austria (59 cases), Sweden (54 cases), Portugal (43 cases) and Denmark (40).[404]

(594) Figure 71 shows that, in most Member States, the majority of cases were initiated by originator companies. Hence, originator companies were by far the most active litigators in Slovenia, Spain, Germany and Poland (with 71 to 75% of initiated cases). Likewise, originator companies launched a substantially higher number of cases in France, Greece, Denmark and Austria (61 to 65% of all cases). All reported cases in Latvia were initiated by originator companies.

(595) However, there are several Member States where the opposite situation was observed. Whilst the United Kingdom had the second highest number of patent litigations launched in the EU from 2000 to 2007, the vast majority of cases were initiated by generic companies (65 %). This contrasts sharply with the situation in Germany and Spain, as previously discussed. Like the United Kingdom, Italy had the fourth highest overall number of reported patent litigations in the EU, but litigations initiated by originator companies accounted for only 33% of cases as compared to 67% originating

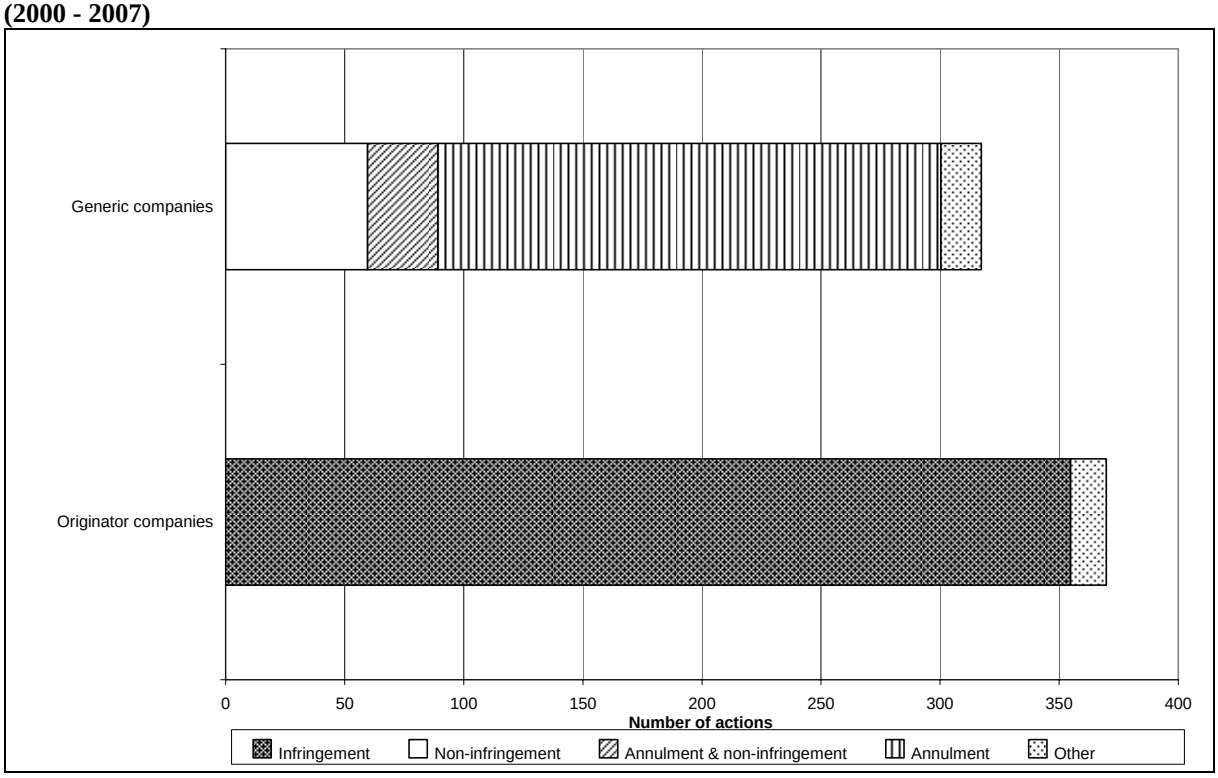
404 Figure 71 also shows that the 2004 and 2007 enlargement rounds of the European Union did not have a significant effect on the overall number of patent litigation cases. Only 10% of all reported patent cases were initiated in new Member States.

from generic companies. In the same vein, in Ireland, Romania, the Netherlands, Finland, Hungary, the Czech Republic and Sweden, only 14 to 47% of cases were initiated by originator companies.

2.2.2.2. Number of Patent Litigations Initiated in the EU by Type of Action and Initiating Party

(596) Figure 72 provides an overview of the types of legal actions that were initiated by originator and generic companies.

Figure 72: Number of litigations initiated by originator and generic companies in the EU by type of action (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(597) As might reasonably be expected, infringement actions represented by far the majority of legal actions initiated by originator companies (96%) with other actions accounting for the remaining 4%.[405] The picture is more varied when it comes to generic companies, where actions for annulment accounted for 67%, followed by declaratory actions for non-infringement (19%) and by joint actions for annulment and a declaration of non-infringement (9%). Other actions initiated by generic companies accounted for the remaining 5 %.[406]

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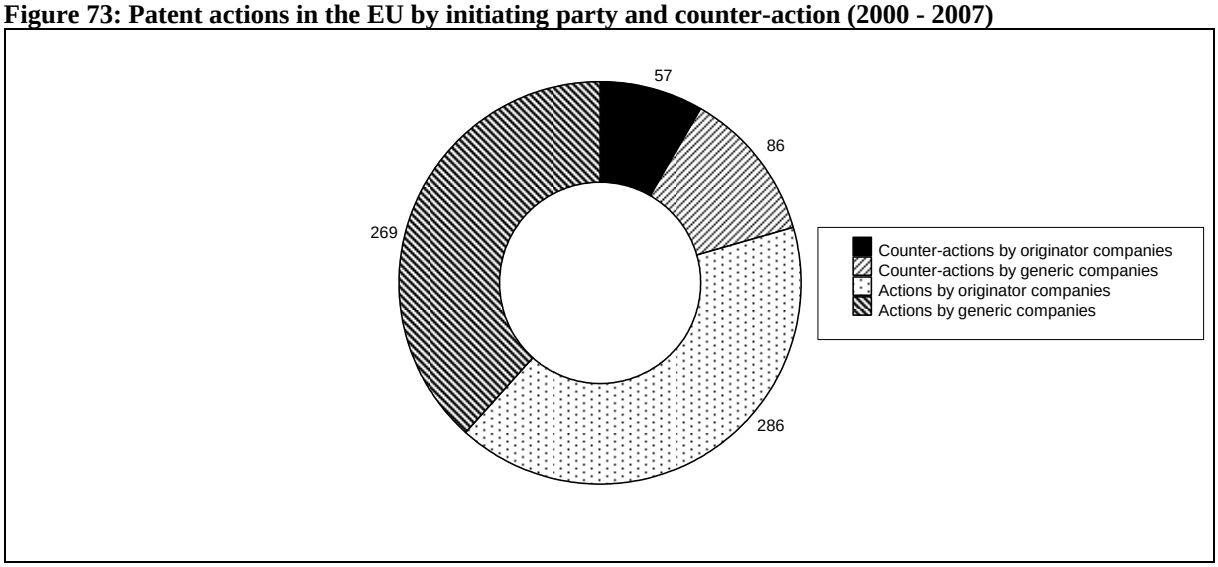
405 Respondent companies have indicated such other actions initiated by originator companies to cover, *inter alia*, actions for damages, etc.

406 Such other actions initiated by generic companies may be, amongst others, action for damages.

(598) Figure 73 illustrates the number of legal actions appearing under separate litigation reference numbers, which were reported as having been filed only by an originator company (without any subsequent counter-action by the defendant to appear under the same litigation reference number), only by a generic company or by both (initial action followed by a counter-action, both reported under the same litigation reference number).

Figure 73: Patent actions in the EU by initiating party and counter-action (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

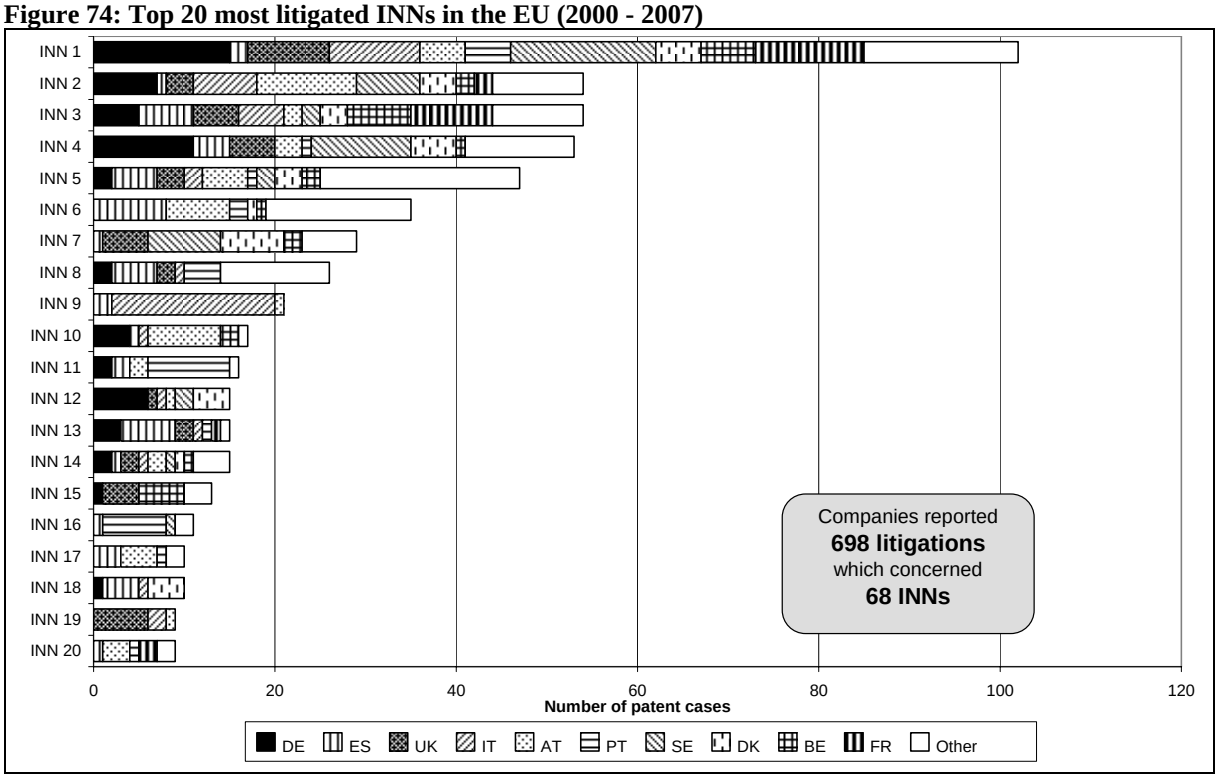
(599) Responses show that in 41% of all cases, a patent action was brought by an originator company without there being a counter-action filed by the generic company. In comparison, in nearly 39% of all reported litigations, the action initiated by a generic company was not followed by the launch of a counter-action by an originator company. In 12% of all cases, the patent action brought by an originator company was followed by the launch of a counter-action by a generic company. The cases where the action brought by a generic company was followed by a subsequent counter-action filed by an originator company represented 8% of the total.[407]

2.2.2.3. INNs Concerned by Patent Litigation

(600) Figure 74 provides an overview of the 20 INNs which were most often the object of litigation in the EU, as presented by EU Member State.

[407] The actions and the related counter-actions have been coupled on the basis of the litigation reference numbers provided by respondent companies, therefore, it cannot be excluded that the figures on counter-actions are underestimated due to the use of different litigation reference numbers.

Figure 74: Top 20 most litigated INNs in the EU (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(601) Litigation concerning the 20 most litigated INNs accounted for the vast majority of all patent litigation in the EU (80%). In addition, the top 20 INNs accounted for 29 % of all 68 INNs on which litigation was reported.

(602) The top six INNs were the object of nearly half (49%) of all reported litigations. By far the most litigated INN in the EU was INN 1 with 15% of all cases. The second to fifth most litigated INNs (INNs 2, 3, 4 and 5) were the focus of litigation in 7 to 8% of cases. The sixth most litigated INN (INN 6) was the object of litigation in 5% of cases. The remaining 14 INNs accounted for about 31% of all cases.

(603) The top three INNs in terms of intensiveness of litigation belong to INNs which were, on the major national markets during the period examined, both among the best-selling medicines (T50 list) and among the best-selling medicines which faced loss of exclusivity (E75 list).[408] Overall, all of the top 20 INNs belonged to at least one of the two aforementioned groups.

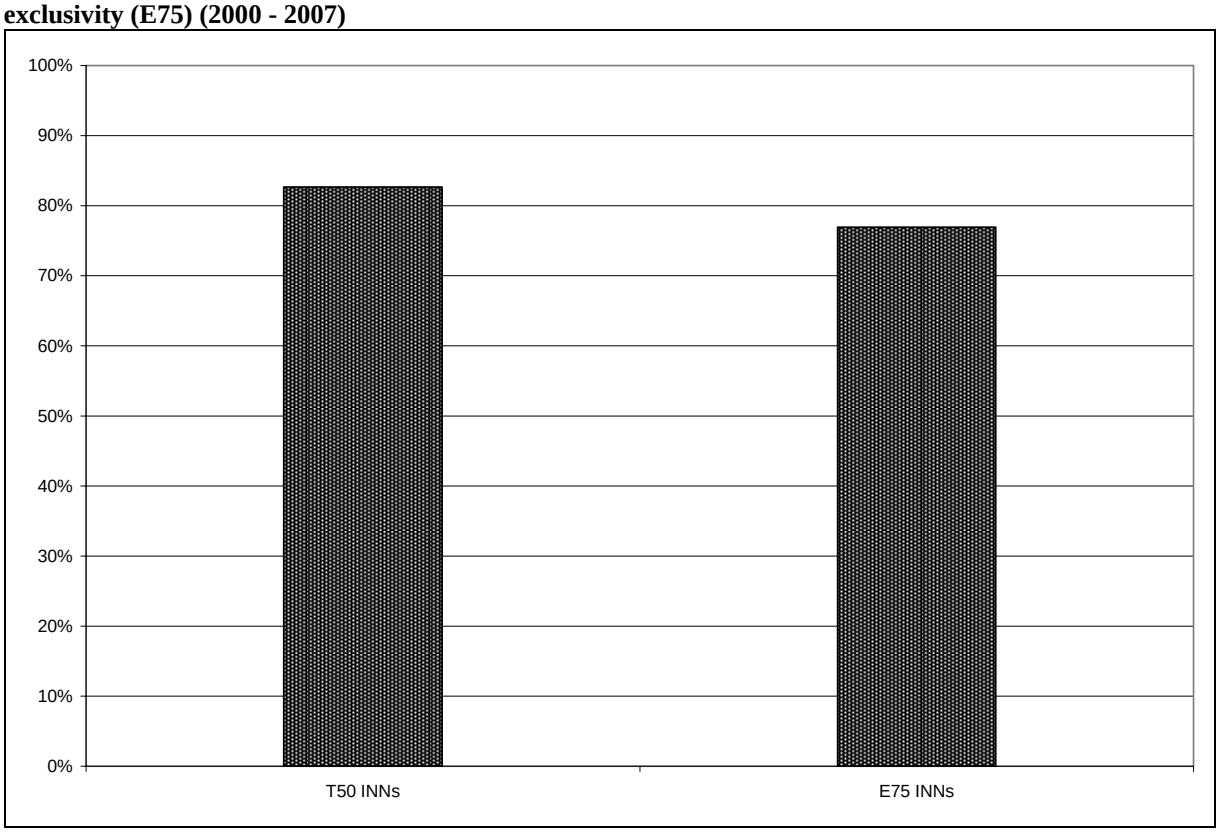
(604) All of the 20 most litigated INNs were the object of litigation in at least three Member States, whereas the top six INNs were litigated in at least five (and most often eight to

408 For more information on the T50 and the E75 lists, please refer to the Annex: Methodology (Annexes to Chapter A).

nine) Member States.[409] The reasons for which litigation on any given INN is initiated in a specific Member State appear to be case-specific.

(605) Figure 75 illustrates the percentage of all patent litigation cases, reported by respondent companies, which concerned the best-selling INNs (T50 list) and/or the INNs which faced loss of exclusivity in the period 2000 to 2007 (E75 list).[410]

Figure 75: Litigation concerning the best-selling INNs (T50)and the best-selling INNs which faced loss of exclusivity (E75) (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(606) Figure 75 shows that the vast majority (83%) of all reported cases concerned best-selling INNs (T50). Furthermore, more than three quarters of all cases (77%) concerned best-selling INNs which faced loss of exclusivity in the period examined (E75). These findings confirm the relevance of the sample of 219 INNs.

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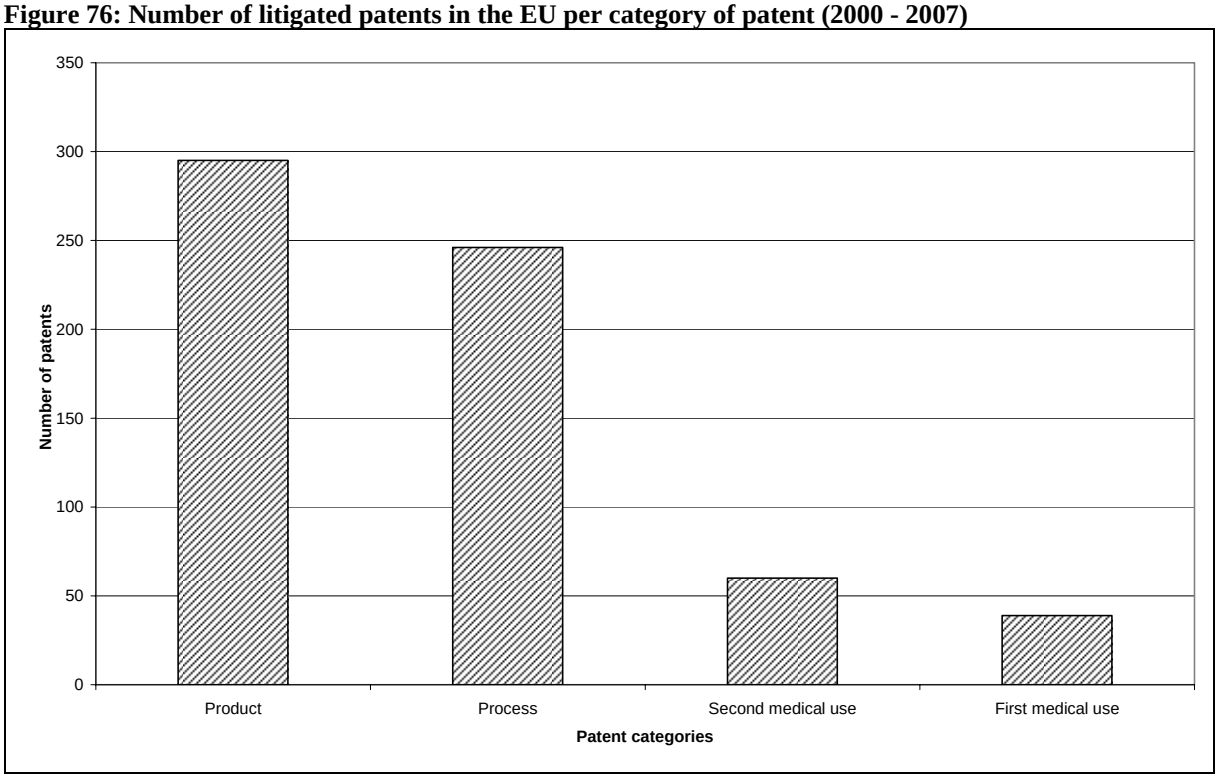
409 INN 1 was the subject of a substantial number of cases in Germany, Sweden, France, the United Kingdom and Italy (between 9% and 16% of all cases reported over INN 1 for each). An important number of cases concerning INN 2 were launched in Austria (20%), Germany, Italy and Sweden (13%). The highest number of litigations concerning INN 3 were examined by French and Belgian courts (17% and 13% respectively), followed by courts in Germany, Spain, Italy and the United Kingdom (9 to 11%).

410 For further details see footnote 408.

2.2.2.4. Categories and Types of Patents Concerned by Patent Litigation

(607) Figure 76 illustrates the number of patents per category of patent as litigated in courts across the EU in the period 2000 to 2007. Companies reported a total of 478 patents litigated across the EU for which patent categories were clearly specified.[411]

Figure 76: Number of litigated patents in the EU per category of patent (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(608) Responses show that a substantial number of litigated patents (62% or 295 out of 478 patents) fell into the category of product patents. Process patents were the second most litigated category of patents with 51% or 246 patents. In contrast, the percentage of litigated first and second medical use patents was substantially lower (8% (39) and 13% (60) of all patents, respectively).

(609) Figure 77 provides an overview of the types of patents (primary or secondary) which were most often the object of patent litigation.

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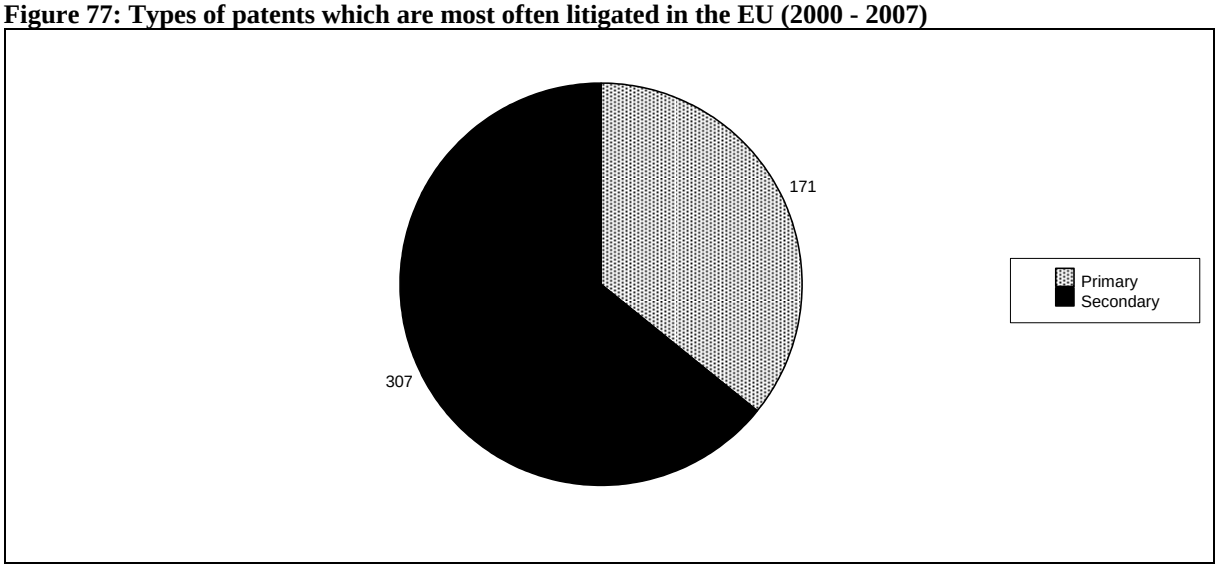
411 It should be noted that any given litigation may concern several patents. In addition, any given patent may fall under one or more different categories. Hence, due to multiple counting, the aggregate number of litigated patents across the four patent categories as listed in Figure 76 exceeds the total number of litigated patents reported by respondent companies (478). The number of patents falling in each of the four patent categories was calculated based on the national publication numbers, i.e. the instances of multiple occurrences of the same national patent were corrected to avoid double-counting. However, one patent may fall under more than one patent category, e.g. a patent that covers product and process claims will belong to both the product and the process category. In such cases, patents were allocated in their entirety to each of the relevant categories, i.e. the patent evoked in the above example would be added as one unit to the product bar and as one unit to the process bar.

Figure 77: Types of patents which are most often litigated in the EU (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(610) Figure 77 shows that secondary patents accounted for nearly two thirds of all litigated patents (64%). Primary patents made up the remaining 36%.[412]

(611) Results of the sector inquiry also show that originator companies initiated a higher number of cases concerning primary and secondary patents than generic companies (54% versus 46%).

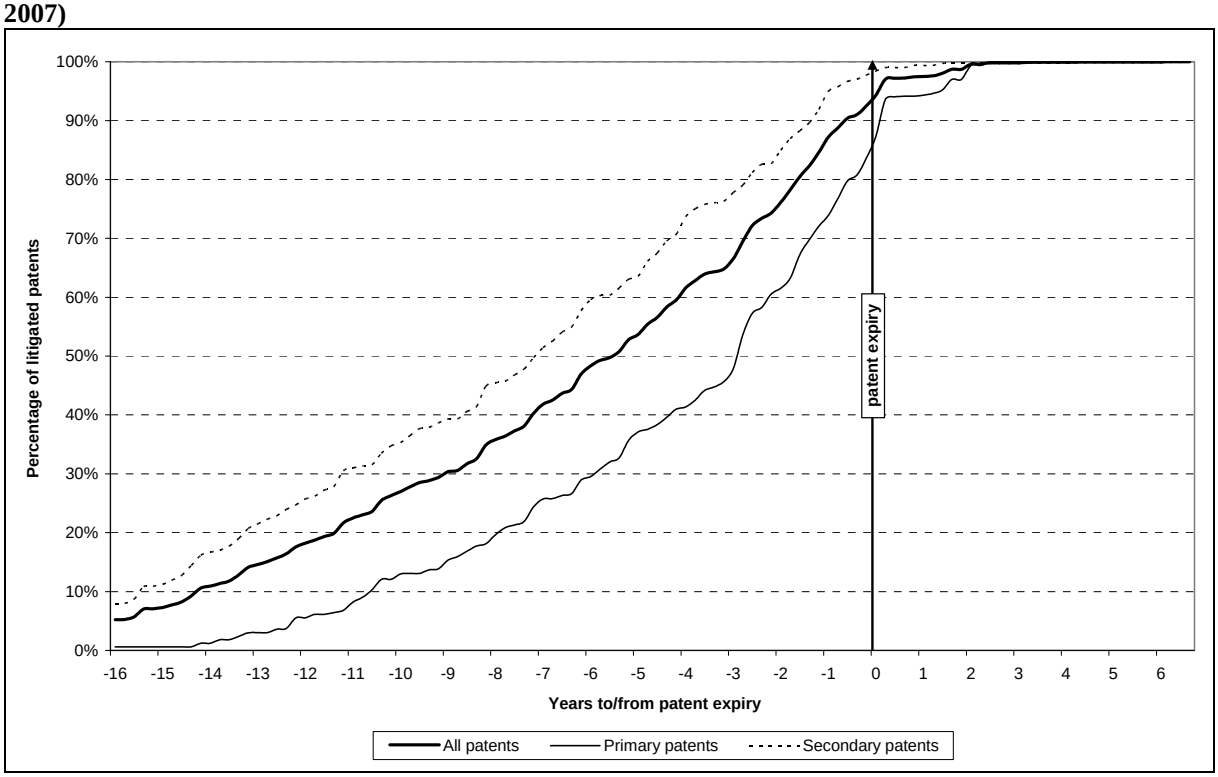
(612) In contrast to the data reported on disputes, which show that primary patents were the most frequent object of disputes in the EU (see Figure 66), responses indicate that it was secondary patents which were most often the object of litigation across the EU.

2.2.2.5. Patent Expiry Dates and the Start of Patent Litigation

(613) Figure 78 illustrates the relationship between the length of time until patent expiry and the date of initiation of litigation, distinguishing between primary, secondary and all patents in general. The vertical axis indicates the (cumulative) percentage of patents being the object of litigation as reported by respondent companies. The horizontal axis lists a given number of years before (16 years) and after (6 years) patent expiry. Each point in the curve relates to a single patent that was the object of litigation proceedings in the period 2000 to 2007. By way of illustration: 10% of primary patents concerned by litigation in that period had still 10.5 years or more to go until expiry. For secondary patents, the corresponding figure is 15.5 years.

412 The parties raised in litigation cases both primary and secondary patents at the same time in merely 52 cases or 7% of all patent cases reported by respondent companies.

Figure 78: Relationship between patent expiry dates and the start of patent litigation in the EU (2000 – 2007)



Source: Pharmaceutical Sector Inquiry

(614) The data provided show that patent litigation may begin shortly after grant. The cumulative number of litigated patents gradually increases as patent expiry approaches. This is true for all patents and the increasing dynamic of this process can be illustrated by the increasingly steep gradient of the curve as the patent expiry date approaches.

(615) However, the distribution of patent litigations over time reveals substantial differences between primary and secondary patents. The secondary patents curve is less convex than that of primary patents, which means that secondary patents are (a) more equally distributed over the relative period displayed in Figure 78 and (b) more likely to be litigated earlier in the process. As a consequence, the time before patent expiry is relatively longer. For primary patents the opposite is true.

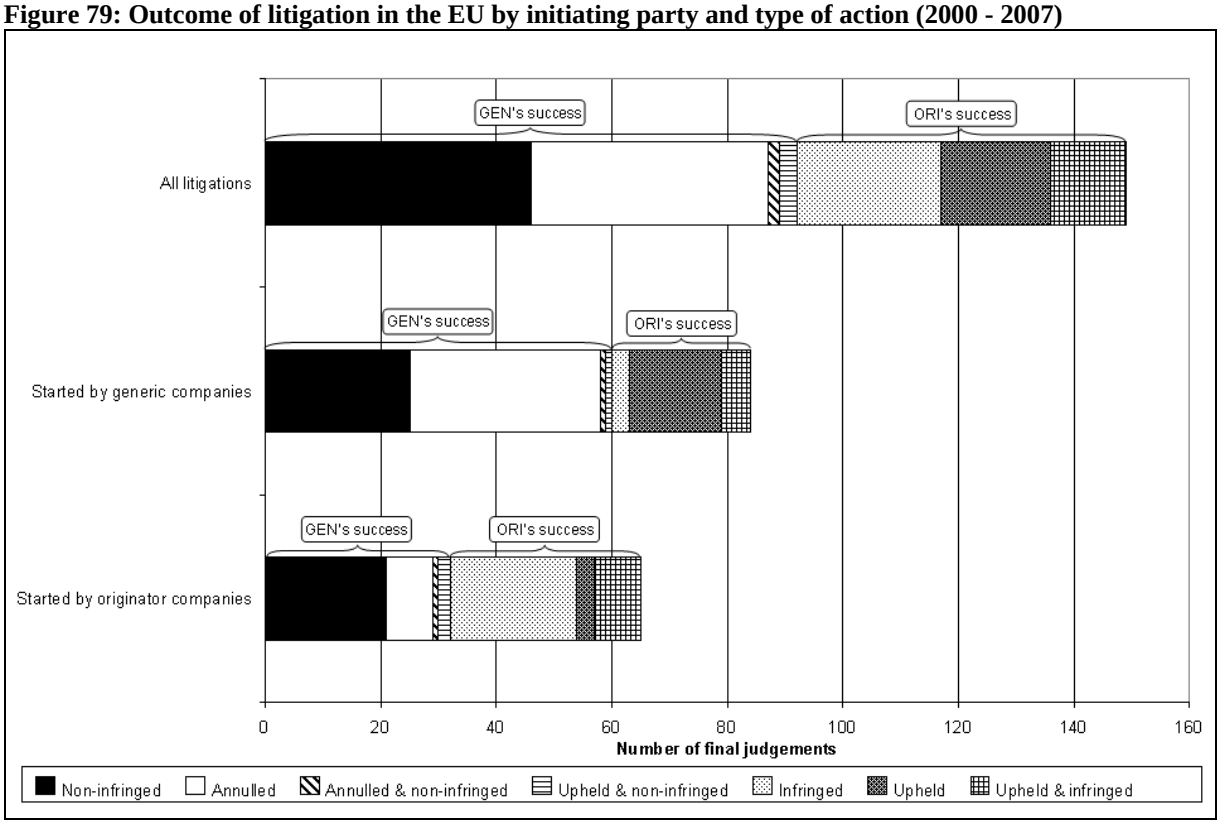
(616) For example, when the patents covered are those having ten years or more before expiry, the analysis shows that 13% of primary patents were the object of court proceedings versus 36% of secondary patents. Likewise, five years or more prior to patent expiry, 37% of primary patents and as much as 66% of secondary patents had already been litigated in court. Once the patents covered by the analysis include those having one or more years before expiry, the relative difference between primary and secondary patents narrows down with 77% of primary patents being the object of litigation versus 96% of secondary patents.

(617) At the date of patent expiry (year 0 in Figure 78), the difference between the two types of patents decreased considerably and was down to less than 6 percentage points. A limited number of cases relate to the situation where the date, on which litigation was initiated, falls after the patent expiry date. Those cases were specifically introduced by one of the litigating parties in order to seek damages (for example).

2.2.2.6. Outcome of the Main Action on the Merits

(618) Companies were asked to report on the outcome of patent litigation in all final judgements (*res iudicata*) in the period examined by indicating one of the following outcomes with regard to the litigated patent: (i) non-infringed; (ii) annulled; (iii) infringed; (iv) upheld and (v) other.[413] Figure 79 illustrates the final outcomes of all litigation reported and the final outcomes of litigation per initiating party (with the exception of final outcomes indicated as "other", where results could not be classified).[414]

Figure 79: Outcome of litigation in the EU by initiating party and type of action (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(619) As explained above, respondent companies reported 698 separate litigations. A final judgment was reported in 149 of the litigations, of which 84 were initiated by a generic company and 65 by an originator company. The remaining 549 cases were reported as being either settled (223 cases) or no final outcome was indicated, e.g. they were reported as pending (326 cases).

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413 The outcome involving the annulment of the patent and a declaration of non-infringement (which may be the result of litigation concerning two different patents or one patent covering several claims, some being annulled and the other declared non-infringed by the court) was subsequently added as some data reported by companies indicated such final outcome of litigation.

414 Such "other" final outcomes of litigation reported by respondent companies referred to, *inter alia*, settlement agreements.

(620) For the purposes of Figure 79, litigation outcomes were divided into two groups labelled "GEN's success" and "ORI's success" according to their likely market consequences allowing or forbidding market entry by a generic company. An outcome is considered a success, from the perspective of an originator company, if the final judgement does not allow generic entry prior to patent expiry. On the other hand, an outcome is considered successful for the generic competitor if the final judgement allows risk-free generic entry.

(621) Overall results show that generic companies won 62% of all patent litigations reported in which a final judgment was delivered (62%) whereas originator companies were successful in the remaining 38% of cases.[415]

(622) Furthermore, out of all litigation cases in which a final judgment was given on the issue of the validity of a given patent (78 cases), the court revoked the patent in 55% of cases (43) and upheld it in the remaining 45% (35).

(623) More specifically, generic companies won nearly three quarters of all patent cases they initiated (71%) and were unsuccessful in over one quarter of the cases they initiated (29%).[416]

(624) In comparison, originator companies were successful in slightly over half of the cases they initiated (51%) whilst they lost nearly half (49%).[417]

(625) As Figure 79 shows, generic companies won overall more than 60% of all patent litigations initiated in the EU from 2000 – 2007 in which a final judgment was given.[418] However, this outcome was achieved at the expense of the multiplication of

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[415] More precisely, the patent was annulled and declared non-infringed in 27.5% and 30.9% of all cases, respectively. The patent was upheld and declared not to be infringed in 2% of cases, and annulled and declared non-infringed in another 1.3%. In comparison, the patent was upheld and was declared infringed in 13% and 17% of all litigations, respectively. The court upheld the patent and found it infringed in another 8%.

[416] Courts annulled the patent and declared it not to be infringed in 39% and 30% of all litigations initiated by generic companies, respectively. The patent was upheld but found not to be infringed in nearly 1% of litigations, and annulled and declared non-infringed in another 1%. In comparison, the patent was upheld and declared infringed in 19% and nearly 4% of all cases, respectively. Court upheld the patent and declared it infringed in another 6% of cases.

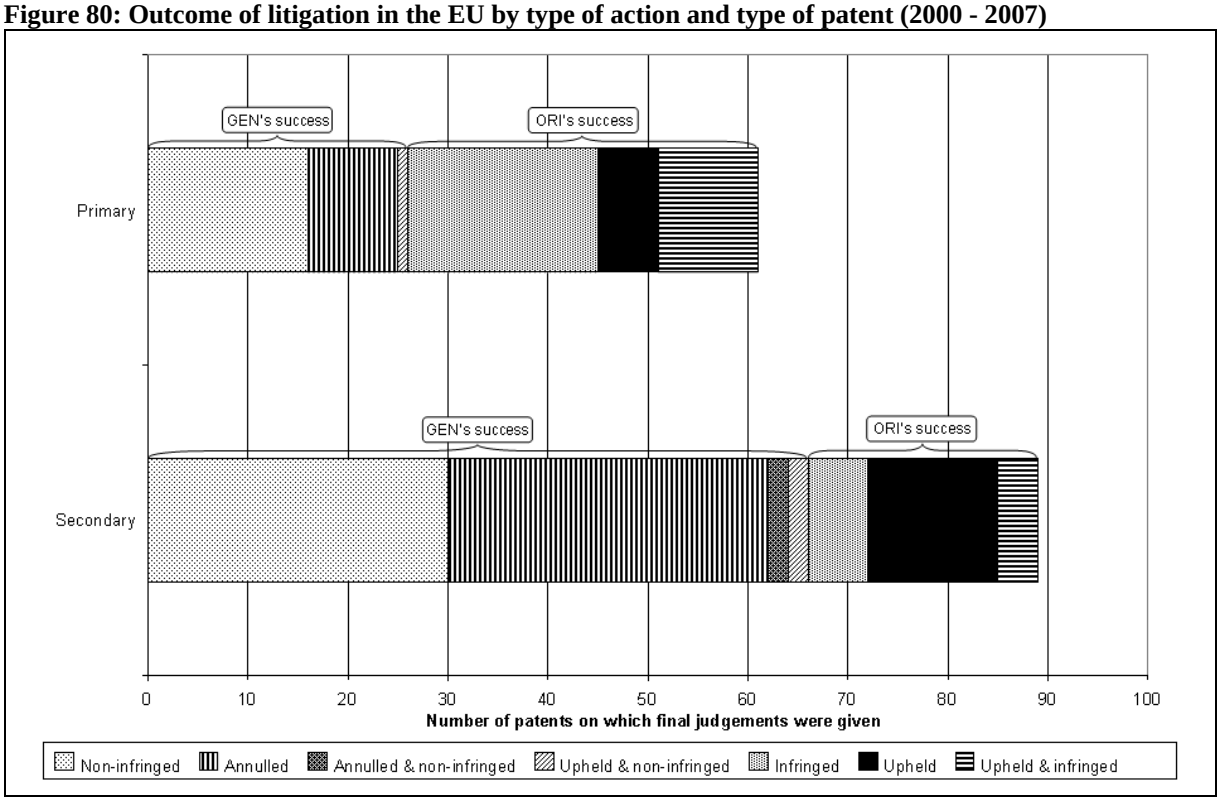
[417] Courts found a patent infringement and upheld the patent in over one third (34%) and 5% of all litigations initiated by originator companies, respectively. The patent was upheld and declared infringed in 12% of litigations. In comparison, in nearly one third of litigations (32%) initiated by the originator party the courts found the patent not to be infringed, and annulled in 12% of cases. The patent was upheld but found not to be infringed in 3% of cases, and was annulled and declared not to be infringed in another 1.5%.

[418] In the course of the public consultation, it has been argued that the sample of final judgements was biased due to the self-selection effect and that it was too small in order to be conclusive. However, it must be noted that even if only a limited number of cases reach final judgement, it is interesting to record their outcome as they can provide insights into the current situation. Furthermore, it must also be noted that the fact that certain patents have not been challenged in court does not necessarily provide certitude as to their ultimate solidity.

costly and often lengthy litigation before different national jurisdictions, thus entailing a significant burden and legal uncertainty for generic companies. In light of the above, the introduction of a Community patent, which could be challenged and enforced before a unified Community patent court, would significantly increase the legal certainty and efficiency of the European patent system.

(626) Figure 80 illustrates companies' responses as to the outcome of litigation in all final judgements by type of action and type of patent (primary or secondary) given from 2000 to 2007.[419]

Figure 80: Outcome of litigation in the EU by type of action and type of patent (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(627) As shown in Figure 80, originator companies won 57% of all cases concerning primary patents in which a final judgement was given, versus 43% for generic companies.[420]

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419 Figure 80 and Figure 81, contrary to Figure 79, are not based on a number of final judgements, but on a number of patents on which final judgements were given. The difference between the two methods relates to the situation in which a final judgement concerns more than one patent.

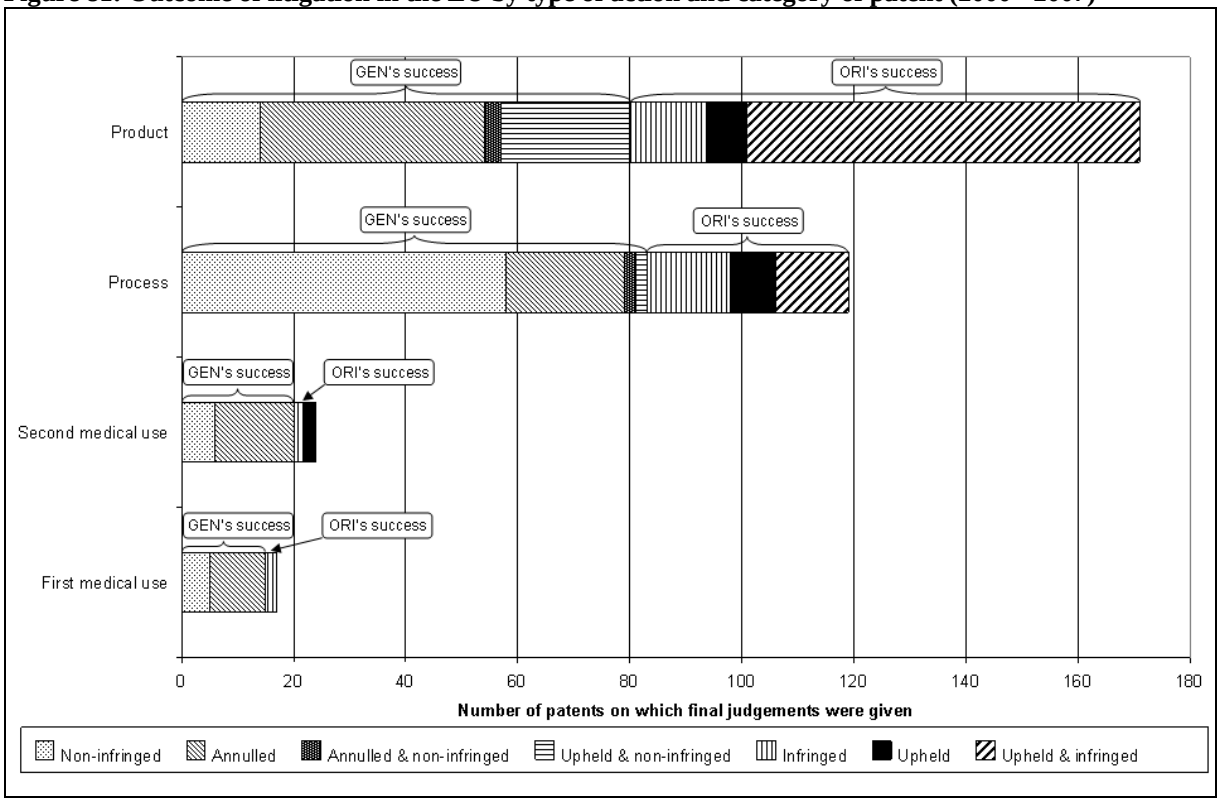
For more information on the patent and litigation strategies employed by originator companies see Chapter C.2.1

420 In particular, courts upheld the primary patent in 10% of all cases concerning primary patents, and upheld and declared the patent infringed in another 16%. The primary patent was declared infringed in 31% of cases. In comparison, the primary patent was found not to be infringed in 26% of cases concerning primary patents. It was annulled in 15% of cases and upheld but found not to be infringed in another 1.5%.

(628) The picture is different for secondary patents.[421] Generic companies won nearly three quarters (74%) of all cases concerning secondary patents in which a final judgement was given.[422] In contrast, originator companies were successful in over one quarter of litigations over secondary patents (26%). It should be recalled that secondary patents accounted for nearly two thirds (64%) of all litigated patents in the EU in the period 2000 – 2007 (see Figure 77).

(629) Figure 81 provides an overview of the outcome of litigation in all final judgements rendered in the period 2000 to 2007 shown by patent category.[423]

Figure 81: Outcome of litigation in the EU by type of action and category of patent (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(630) Responses show that, by and large, product patents were most often the object of litigation. Originator companies won a slight majority of cases with over 53% of final

421 Any comparison between primary and secondary patents can only be drawn insofar as it only concerns the primary and secondary patents that were brought up in litigation ending with a final judgment.

422 Secondary patents were annulled in over one third of all cases concerning secondary patents (36%) and were found not to be infringed in nearly 34% of cases. They were upheld but declared non-infringed, and annulled and found not to be infringed in 2% and 2% of cases. In contrast, secondary patents were upheld and declared infringed in 15 and 7% of cases, respectively.

423 It should be noted that a given litigation may concern one or several patents falling under one or more patent categories and, therefore, overlaps may occur in the number of cases ending with a final judgement presented on the figure above. For example, one final judgement may annul a patent which is classified as both process and product patent.

rulings, concerning product patents, being decided in their favour as against 47% for generic companies.[424]

(631) Process patents formed the second most litigated category of patents. More than two-thirds (nearly 70%) of all final judgments handed down on process patents were favourable to the generic litigant, with only 30% of final judgments being favourable to originator companies.[425]

(632) Generic companies were particularly successful in winning the vast majority of cases concerning second medical use patents (83%) with originator companies winning a merely 17% of cases.[426]

(633) Finally, generic companies were equally successful in challenging first medical use patents, with final judgments in their favour being given in the overwhelming majority of litigations (88% of all cases) compared to only 12% in favour of the originator party.[427]

(634) Hence, with the exception of product patents where originator companies were about as successful in litigation, generic companies won the overwhelming majority of cases concerning the other three categories of patents. Hence, it would appear that among litigated patents the strength of process patents, first medical use and second medical use patents is relatively more limited and their challenge before court more often yields favourable results for generic companies.[428]

(635) Figure 82 provides an overview of the average duration of litigation, in which a final judgement was given in the period 2000 to 2007, in a sample of 16 Member States, and lists the number of litigations per Member State.[429]

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424 More precisely, courts upheld the product patent and declared it infringed in 41% of all cases over product patents, found the patent infringed in 8% of cases and upheld it in 4%. In comparison, the product patent was annulled and/or declared non-infringed in 33% of all cases.

425 The process patent was found not to be infringed in 49% of cases, and was upheld but declared non-infringed in another 2%. It was annulled in nearly 18% of cases. In contrast, the process patent was upheld, found infringed and upheld and found infringed in nearly 7%, 13% and 11% of all cases concerning process patents, respectively.

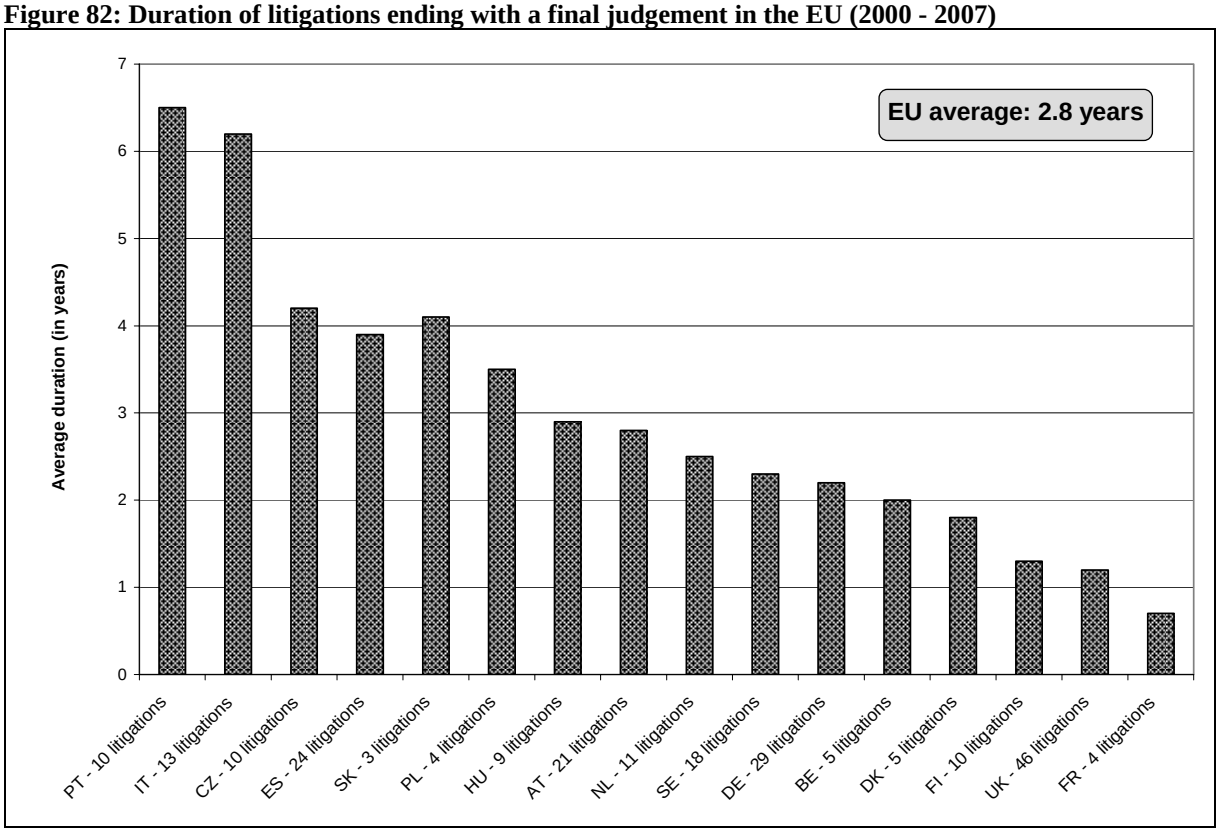
426 Second medical use patents were annulled in 58% of all cases concerning second medical use patents and declared non-infringed in another 25%. In comparison, they were upheld and found infringed each in 8.3% of cases.

427 First medical use patents were annulled and declared non-infringed in 59% and 29% of all cases, respectively. In comparison, first medical use patents were declared infringed in only 12% of cases.

428 For further information on originator companies' patent and litigation strategies see Chapter C.2.1.

429 It should be noted that litigation scenarios may vary with some cases involving one, and other two or three court instances and a varying degree of complexity of the subject matter.

Figure 82: Duration of litigations ending with a final judgement in the EU (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

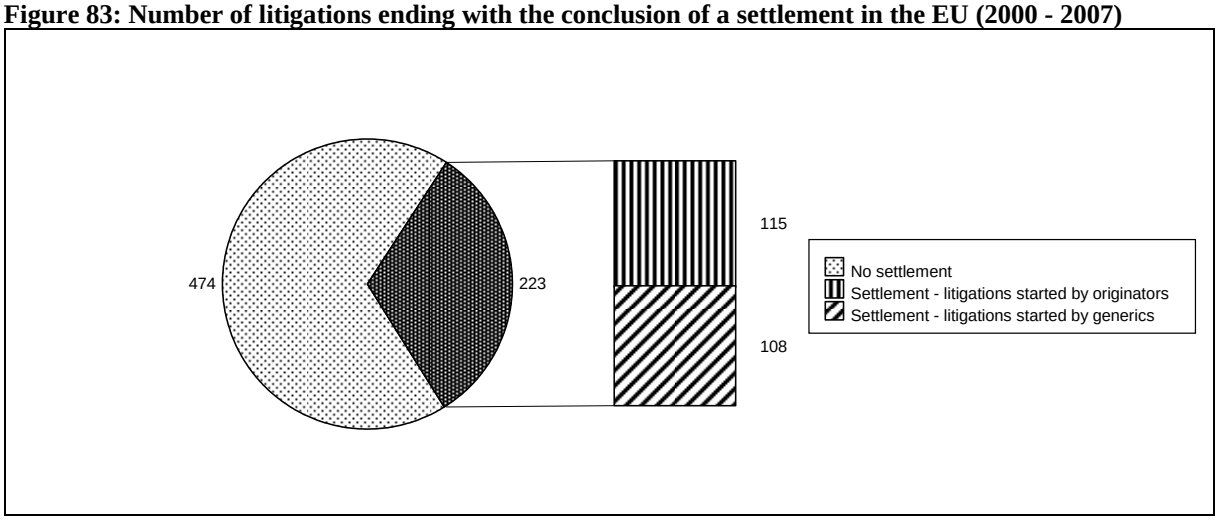
(636) Patent litigation in the EU took on average 2.8 years in the period examined. Figure 82 shows litigation before Portuguese and Italian courts was the lengthiest with an average duration of over six years. In the Czech Republic, the Slovak Republic, Spain, and Poland, litigation took on average between three and four years whilst in Hungary, Austria, the Netherlands, Sweden, Germany and Belgium, litigation had an average duration of two to three years.

(637) Patent litigation in Denmark, Finland and the United Kingdom took a significantly shorter time with an average duration of one to two years. Lastly, French courts were the most expeditious in examining patent litigation taking on average of less than a year (seven months) to pronounce a final judgement in the cases examined.

(638) Patent litigation in various Member States, following different procedural rules and with varying length of proceedings, enhances legal uncertainty for generic companies and the risk of divergent outcomes regarding the issue of the validity or the infringement of a given patent. In particular, litigation in some large EU Member States (such as Italy, Spain and Poland) significantly exceeded the EU average length of litigation of 2.8 years. The introduction of a single Community patent and a unified patent judiciary would significantly increase the efficiency of the European patent system by reducing legal uncertainly, litigation costs and resources used as well as shortening the delays incurred.

(639) Companies were asked to provide information on whether the patent litigation they initiated resulted in the conclusion of a settlement (see Figure 83 below).[430] Responses show that a settlement was the outcome of patent litigation in nearly a third of all reported litigations (32%).[431] Furthermore, out of all litigations which resulted in a settlement, 52% were initiated by an originator company and 48% by a generic company.

Figure 83: Number of litigations ending with the conclusion of a settlement in the EU (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

2.2.2.7. Interim Injunctions

(640) An important remedy for originator companies is the possibility of provisionally restraining the generic company from selling its products until the court decides on the merits of the case. Interim injunctions can be granted in order either to prevent an impending generic entry to the market or to provisionally forbid the marketing of a generic product which is already on the market. For interim relief to be granted, generally the originator company has to establish urgency, the risk of (irreparable) harm and minimum grounds for its main claim.[432] The grant of interim injunctions also

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430 For further information on settlement agreements between originator and generic companies see Chapter C.2.4.

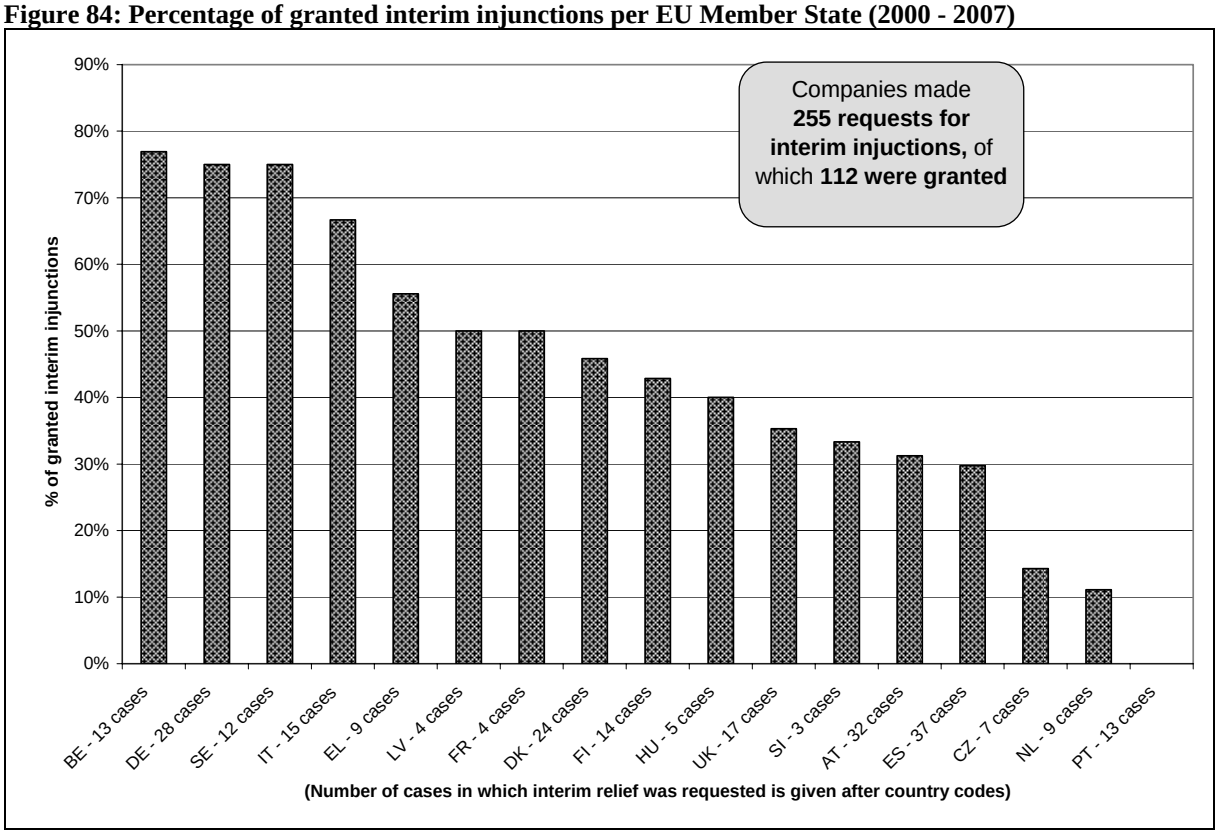
431 The aggregate number of settlements reported in the present section on patent-related exchanges and litigation between originator and generic companies (223 settlements resulting from litigation and 35 resulting from disputes) exceeds the total number of settlements as reported in the section on patent settlements (see Chapter C.2.4). This is explained by the different way in which settlement agreements were counted in the two sections. For the purpose of the present section, one settlement was counted in the case of each litigation ending with a settlement whilst in the context of the section on settlements (see Chapter C 2.4), many settlement agreements covered several litigations in several Member States. Hence, the figures provided in the two sections as such are not comparable.

432 Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157, 30.4.2004, pp.45-86, the "Enforcement Directive") harmonised Member States' legislation regarding the means of enforcing intellectual property rights. For more information see Chapter B.2.1.

entails risks for originator companies which may have to pay compensation to the generic company, whose product has been injuncted, in case the court ultimately invalidates the patent or finds the absence of infringement and revokes the interim injunctions. In the course of the public consultation, it has also been submitted that generic entry prior to patent expiry can have serious consequences for originator companies which may suffer irreversible commercial losses, in particular due to the decrease in price.

(641) Figure 84 provides an overview of the percentage of patent litigations in which interim injunctions were granted out of all litigations in which a request for interim relief was made, shown per EU Member State. Companies reported 255 requests for interim injunctions made by originator companies from 2000 - 2007, of which 112 (44%) were granted.

Figure 84: Percentage of granted interim injunctions per EU Member State (2000 - 2007)



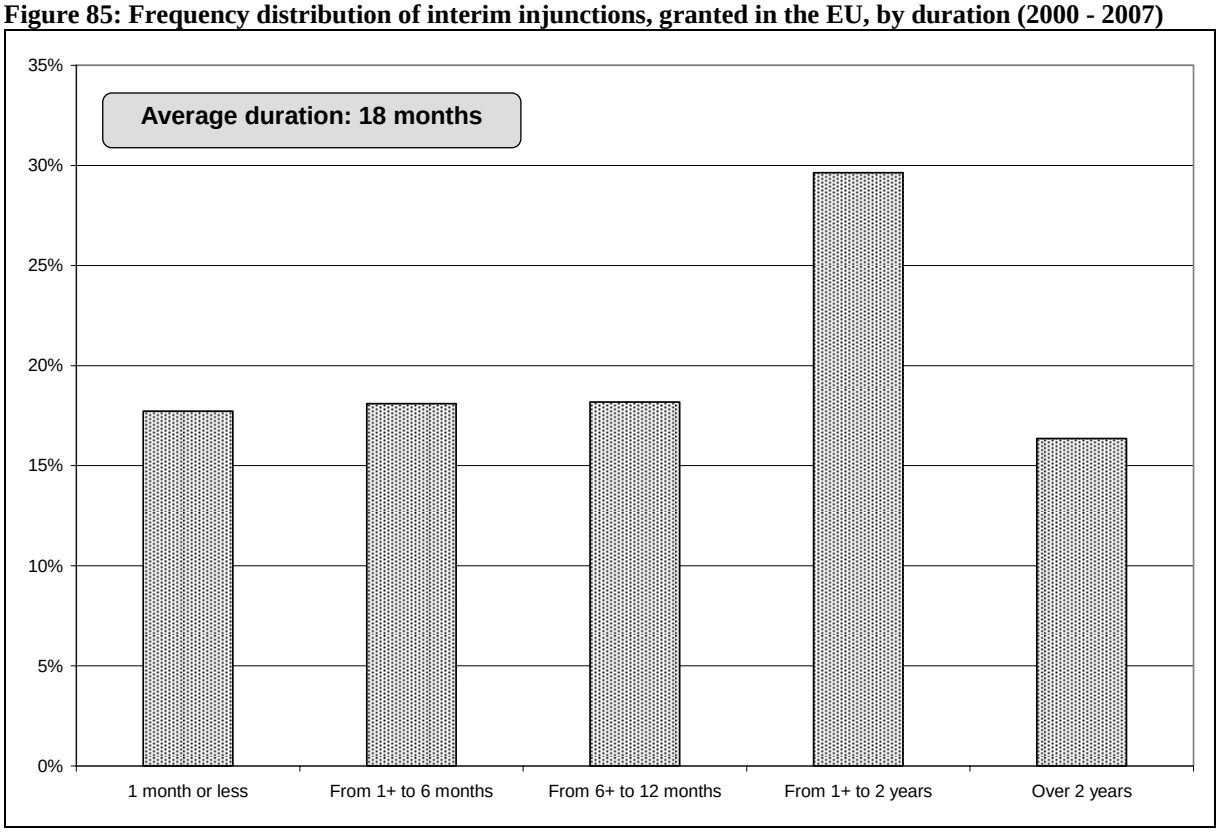
Source: Pharmaceutical Sector Inquiry

(642) Courts granted interim injunctions most frequently in Belgium, Germany and Sweden where injunctions were granted in three quarters of all cases in which interim relief was requested (75 – 77% of cases) and in two thirds in Italy (67%). Interim injunctions were granted in (over) half of all cases in Greece, Latvia and France. Courts in Denmark, Finland and Hungary granted interim relief in less than half of all cases (40 to 46%) whereas in the United Kingdom, Slovenia, Austria and Spain interim relief was granted in only one third of all cases (30 to 35%). Courts in the Netherlands, the Czech Republic and Portugal were the least inclined to grant interim injunctions with interim relief agreed in 14%, 11% and none, respectively, of all cases in which it was requested.

(643) The lack of a single Community patent and a unified patent judiciary result in a substantial burden for originator companies which need to file requests for interim injunctions in all the Member States where their patent rights are (about to be) infringed, without having any certainty as to the outcome of the request. Thus, it can happen that in a request for interim relief in the context of an (impending) infringement of the same INN, one national court may grant injunctions and another may not.

(644) Figure 85 provides an overview of the frequency distribution of interim injunctions granted by Member State courts from 2000 to 2007 in light of their duration.[433] The data have been used as reported by companies on interim injunctions granted in the framework of an initiated main action. Respondent companies were asked to provide the total period during which interim injunctions were granted by accumulating the duration of all interim injunctions granted in the course of a given patent case.

Figure 85: Frequency distribution of interim injunctions, granted in the EU, by duration (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(645) Data reported by companies show that interim injunctions were granted, on average, for a period of 18 months. A significant proportion of interim injunctions (46%) were granted for a period exceeding one year. More precisely, 30% of interim injunctions were granted for a period lasting between one and two years, and 16% were granted for a period exceeding two years.

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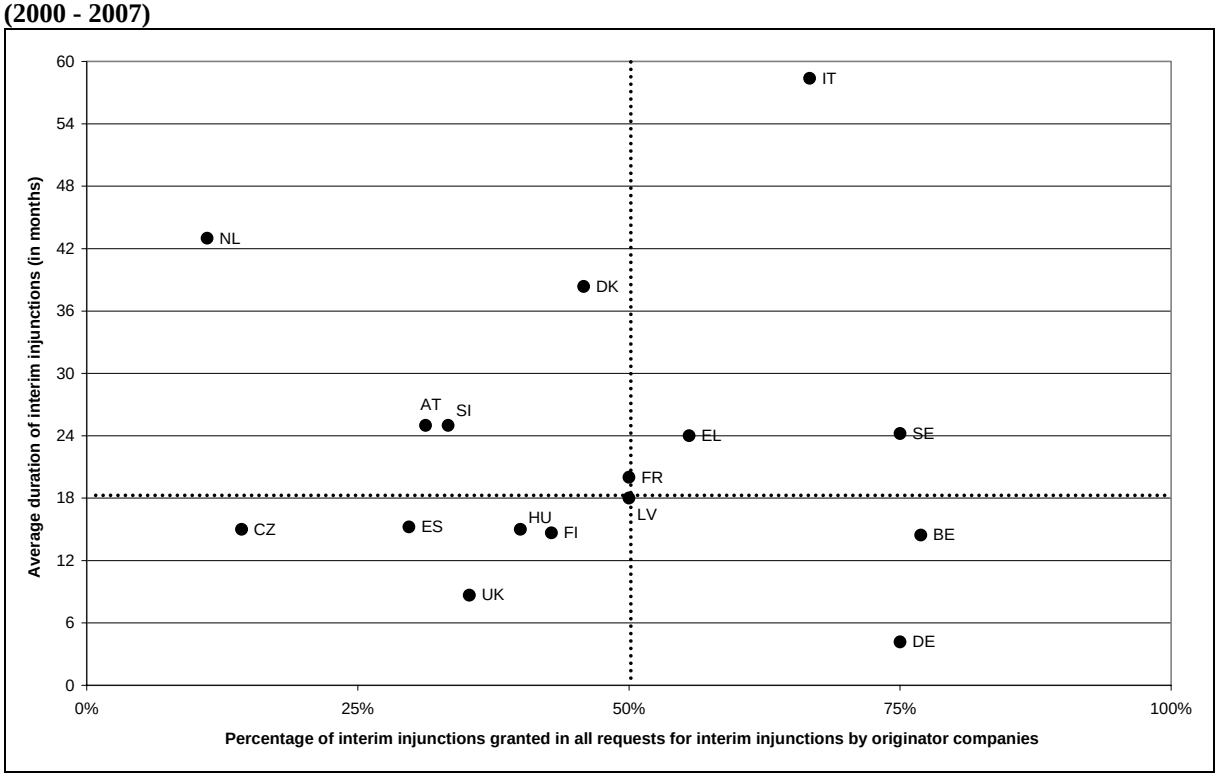
433 For the purpose of the present chapter, only requests for interim injunctions made in the framework of a main patent-related legal action have been taken into account.

(646) However, more than half of all interim injunctions granted in patent litigation in the EU (54%) did not exceed one year. Thus, 18% of interim injunctions were granted for a period of six to 12 months, another 18% for a period of one to six months, and nearly 18% were granted for a period not exceeding one month.

(647) Figure 86 shows the proportion of patent litigations in which interim injunctions were granted by EU Member State and the average duration in months of the interim injunctions reported.

Figure 86: Percentage of interim injunctions granted and their average duration per EU Member State (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

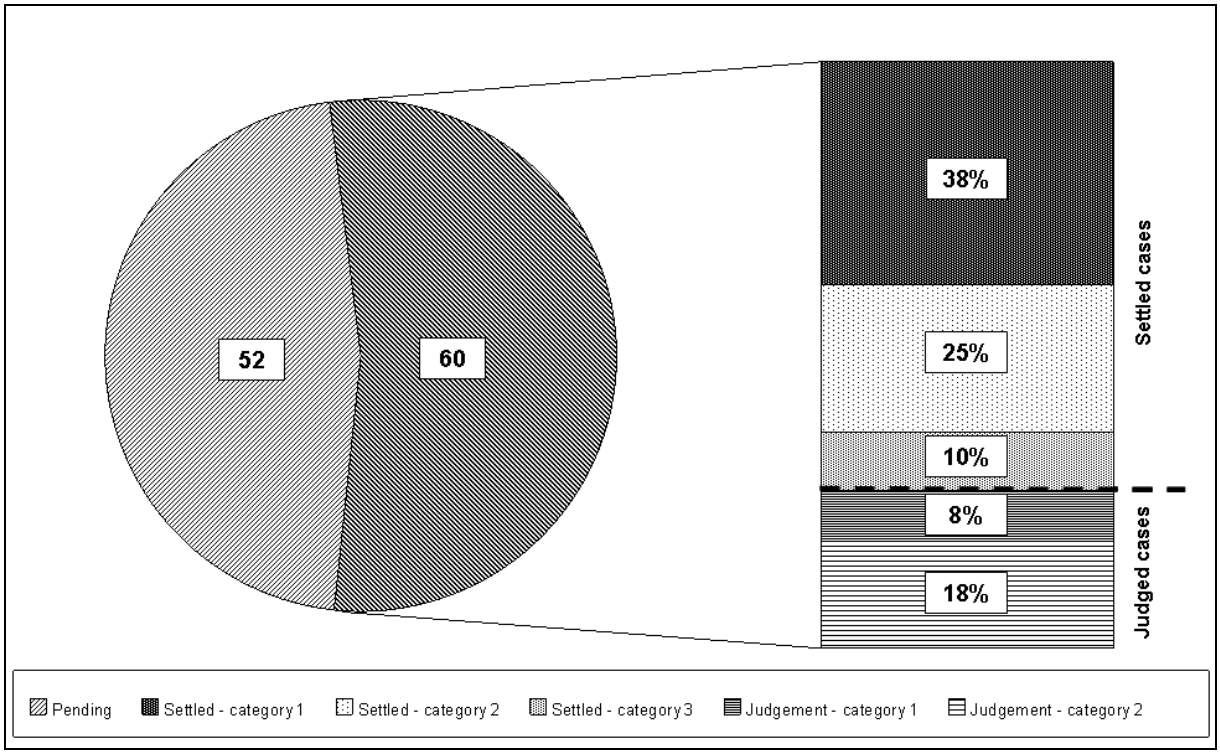
(648) Figure 86 divides Member States into four different groups according to (a) the average duration of interim injunctions, where a division was made between the Member States in which the interim injunctions were granted, on average, for less and for more than 18 months (which is the EU average), and (b) the proportion of litigations in which interim injunctions were granted, where a division was made between Member States having more or less than 50% of litigations in which interim injunctions were granted out of all litigations in which interim relief was requested.

(649) These divisions create four rectangular boxes (see the dotted lines in Figure 86) of which the lower left and the upper left rectangles are the most populated. The countries situated in the lower left rectangle are characterised by the relatively shorter duration of the interim injunctions granted (less than 18 months) and the lower percentage of litigations in which interim injunctions were granted (less than 50% of litigations: the rectangle includes the Czech Republic, the United Kingdom, Hungary, Finland and Spain). In the countries situated in the upper left rectangle, interim injunctions had a relatively longer average duration (more than 18 months) and were likewise granted in less than half of litigations (the Netherlands, Austria, Slovenia, and Denmark).

(650) In the lower right rectangle, which includes Belgium and Germany, interim injunctions were equally granted for an average duration of less than 18 months but the proportion of cases involving interim injunctions was relatively higher (more than 50% of cases). In the upper right rectangle, which includes Greece, Sweden and Italy, interim injunctions were granted for a higher average duration (more than 18 months) and in a higher proportion of cases (more than 50%). In Latvia and France,[434] interim injunctions were granted in 50% of all cases for an average duration of 18 and 20 months respectively.

(651) Figure 87 shows the outcome of patent litigation cases in which interim injunctions were granted as reported by respondent companies.

Figure 87: Outcome of cases in which interim injunctions were granted as reported by respondent companies



Source: Pharmaceutical Sector Inquiry

(652) Out of 112 cases in which interim injunctions were granted, in 60 cases respondent companies reported a formal closure by means of either settlement agreement (44) or final judgment (16). The remaining cases were reported to be pending. It concerned 52 cases.

434 The discrepancy between the data on the length of patent litigation in France and the duration of interim injunctions can be explained as follows. The data reported on interim injunctions granted in France concerned mostly ongoing patent cases for which no duration could be provided yet, whilst the data on the length of litigation in France relied on the limited number of cases ending with a final judgment which had been reported by respondent companies.

(653) With regard to the closed cases, their outcomes were further categorised according to the respective settlement provisions or judgements. Among the closed cases, the single largest category consists of 23 settlement agreements that provided for a value transfer from the originator to the generic company and/or allowed for generic entry before the end of the protection period as claimed in the litigation proceedings by originators. In Figure 87, these 23 settlements fall into the first category of settlements and represent 38% of all closed cases. Based on the terms of the settlement providing a value transfer to the generic companies involved in the litigation and/or their early entry, the outcome of these cases appear to be particularly favourable to the generic companies.

(654) The opposite cases, in which a value transfer took the direction from the generic to the originator company and/or generic entry was delayed until the end of the protection period as claimed in the litigation proceedings by originators, were allocated to the third category of settlements. They represent 10% of all final cases and should be counted as success for the originator companies. The second, middle category contains all other settlement agreements for which it was not possible to establish unequivocally whether a given settlement should belong to category 1 or 3. They represented 25% of all final cases.

(655) Figure 87 also provides a breakdown of 16 cases with interim injunctions that ended with final judgements. These cases were divided into two categories: (a) category 1, in which the generic company was successful and (b) category 2, in which the originator company obtained a favourable judgement in the main proceedings on substance. The former category contains five cases, while the latter eleven cases.[435]

(656) To sum up, the subsample of cases with interim injunctions shows two particular features, namely: a high ratio of settled cases (73%, i.e. 44 out of 60 cases, which are final) and a low ratio of judged final cases (27%, i.e. 16 out of 60 cases). Furthermore, it is interesting to note that in the subgroup of settled cases, there is a tendency to end litigation with the conditions that are favourable to generic companies (i.e. either allowing generic entry or a value transfer from the originator to the generic company). Even if this cannot be regarded to be a conclusive indication as to likely outcome of the respective court cases, this element needs to be borne in mind when interpreting a higher proportion of the cases with interim injunction won by originator companies (11 out of 16 cases).

(657) The overall picture is thus more nuanced than one would have expected from the cases in which interim injunctions, the most restrictive legal tool, were granted, taking into account that, when requesting interim injunctions, the applicant is usually required to show that he is likely to succeed in the main proceedings and to demonstrate urgency. Adding up the actual generic successes (8%) and the settled cases appearing to be particularly favourable to the generic companies (38%), it would seem that in almost a

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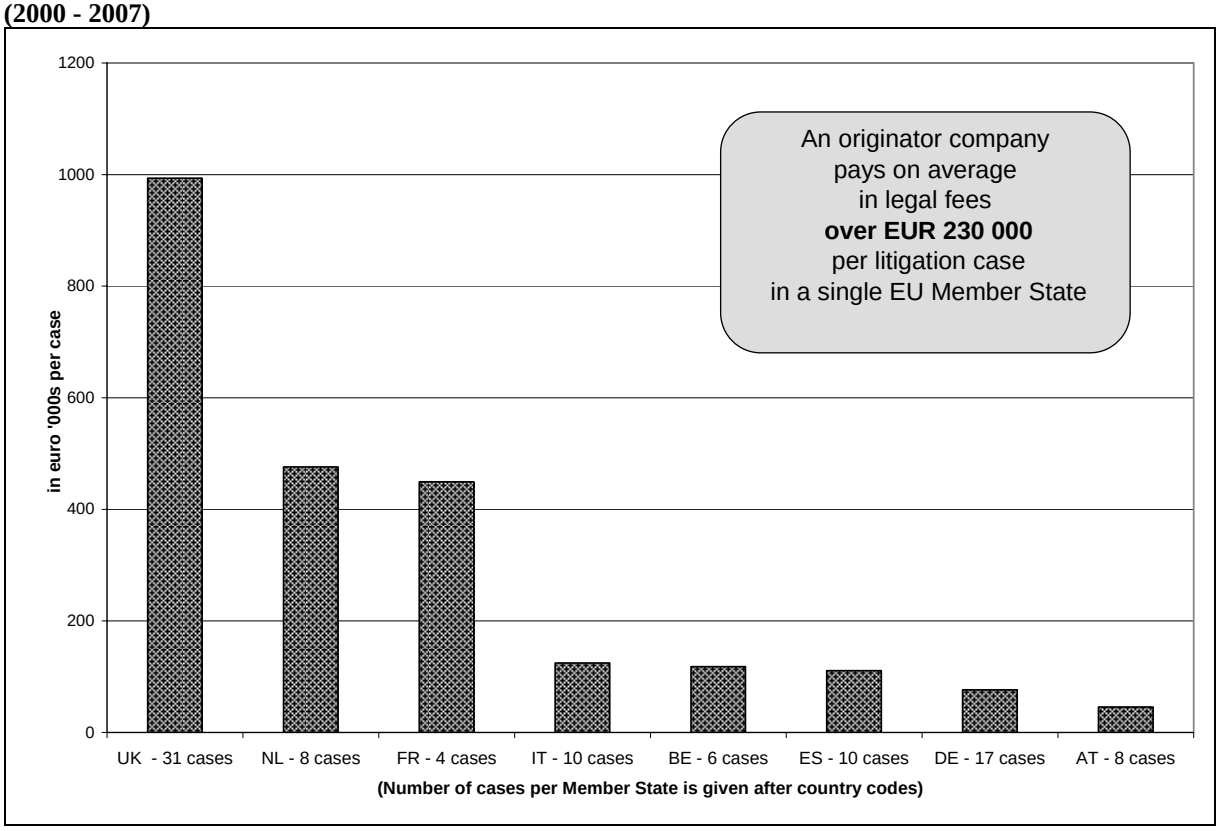
[435] The analysis of the outcome of the main proceeding on the merits in the sample under investigation is not intended to suggest that national legal systems should provide for a preliminary assessment of the likely outcome of the case before interim injunctions may be granted, which however is the case in a number of Member States.

half of the closed cases the grant of interim injunctions might not have been justified, whilst in another 25% of the cases that were settled the situation is unclear.

2.2.2.8. Cost of Fees for Legal Advice Incurred in Patent Litigation

(658) Companies were asked to report the total costs incurred for each litigation to which they were a party, including a break-down of lawyers' fees, man-hours used and other costs. The average legal fees [436] incurred by originator companies per litigation and per EU Member State are examined below (see Figure 88) by reason of their importance for the total cost of patent litigation. For the purpose of graphic presentation, the sample covers some of the largest Member States of the EU, on which more substantial amount of data was provided.

Figure 88: Average legal fees per litigation and per Member State as reported by originator companies (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(659) Responses show that originator companies paid, on average, € 230,000 in legal fees per case in a single Member State. Responses also show that legal fees incurred in patent litigation before UK courts were particularly high, with an average of € 993,000 per litigation. The second highest average legal fees (which were roughly half of those in the United Kingdom) were incurred in patent litigation in the Netherlands and

[436] For the purpose of the report, legal fees can be defined as the fees charged for advice by external lawyers in patent proceedings.

France (an average of € 476,000 and € 449,000 per litigation). In Italy, Belgium and Spain, legal fees in patent cases ranged between € 111,000 and € 124,000 on average. Finally, it was apparent that, on average, legal fees were lowest in Germany and Austria (€ 76,000 and € 46,000).[437]

(660) As to the total cost of pursuing patent litigation in the EU in the period 2000 to 2007, data reported by respondent companies show that, on a rough estimate, the total cost exceeded € 420 million.[438]

(661) As evidenced by companies' replies, legal fees incurred in multiple patent litigations in various EU Member States are very substantial. In addition to the high legal fees, litigation costs generally also include court fees, cost of experts, costs related to technical investigations and possibly appeal procedures, and translation costs required by litigation before different jurisdictions. Therefore, the cost of patent litigation in the EU could be substantially lower if the European patent system relied on a Community-wide patent, which could be challenged and enforced before a unified patent judiciary.

(662) According to a conservative estimate, around 30% of the litigation cases reported by respondents were duplicates of already pending proceedings in other national jurisdictions between the same parties.[439] This figure does not include those duplicates where an originator company was in litigation over the same medicine with different generic counterparties, which are considered independent from each other. The figure provides a rough indication as to potential savings in the pharmaceutical sector if only a unified patent judiciary was established.

2.2.2.9. Contradicting Decisions

(663) The data collected during the sector inquiry also allowed to analyse whether national courts reached contradicting decisions on the same underlying issues in patent litigations.[440] Such contradicting decisions are possible if a court in one Member State decides that the contested patent is valid, whilst a court in another Member State declares it invalid, or if a court in one Member State declares that the product launch of a generic version would infringe the patent rights of the originator company, whilst a

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437 It should be noted that litigation scenarios may differ with some cases involving several instances and a varying degree of complexity of the subject matter.

438 The total cost of litigation consists of legal fees, costs of own labour (i.e. man-hours spent by the company's employees on a given case) and other costs. The estimation is based on the figures made available in the framework of the sector inquiry and extrapolated for those litigation cases for which the requested information was not provided by respondent companies. Furthermore, the estimation takes into account the likely costs incurred by the counter-party to litigation.

439 For the importance of each litigation case for the present analysis, see footnote 403.

440 It should be noted that – legally speaking – the court cases pending in different Member States do not deal with the same subject matter as the geographic scope of the underlying patents is not identical.

court in another Member State finds that the patent would not be infringed by such action.

(664) Such contradicting rulings were found in a total of 16 cases out of the 149 final judgements reported in Figure 82, i.e. 11% of all cases. This is a significant finding since the existence of conflicting final judgements inevitably harms the legal certainty for the companies that are active in a given product on other EU markets.

Summary

Enforcing patent rights in court is legitimate and a fundamental right guaranteed by the European Convention on Human Rights: it is an effective means of ensuring that patents are respected. Like in any other industry the inquiry's findings show, however, that litigation can also be an efficient means of creating obstacles for generic companies, in particular for smaller ones. In certain instances originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants.

Taking into account the 219 molecules in the sample, originator and generic companies identified at least 1,300 patent-related out of court contacts and disputes concerning the launch of generic products in the period 2000 to 2007. The vast majority of disputes were initiated by the originator companies, which most often invoked their primary patents, e.g. by sending warning letters.

The number of patent litigation cases between originator and generic companies increased by a factor of four between 2000 and 2007. In total, 698 cases of patent litigation between originator companies and generic companies were reported in relation to the medicines investigated.

Of these, 223 cases were settled, and the courts rendered final judgements in 149 cases. The remaining 326 litigation cases were either pending or withdrawn. Whilst the originator companies initiated the majority of the cases, generic companies won 62% of the 149 cases. The average duration of the court proceedings was 2.8 years, but varied considerably between Member States, from just over six months to sometimes more than six years.

In contrast to the primary patents invoked in the pre-litigation phase, originator companies mainly invoked secondary patents during litigation.

In 30% of the cases litigation was initiated between the same parties in more than one Member State with respect to the same medicine. In 11% of the final judgments reported, two or more different courts in different EU Member States gave conflicting final judgments on the same issue of patent validity or infringement.

Originator companies asked for interim injunctions in 255 cases, and were granted such injunctions in 112 cases. The average duration of the interim injunctions granted was 18 months. In 46% of the cases in which injunctions were granted the subsequent court proceedings in the main case ended either with final judgments favourable to the generic company, or settlements which appear to be favourable to the generic company as they allowed early entry for the generic company and/or foresaw a value transfer to it. In addition there were a number of further patent settlements, for which a final classification (i.e. favourable to the generic or the originator company) was not possible.

The total cost of patent litigation in the EU relating to the 68 medicines on which litigation was reported for the period 2000 – 2007, is estimated to exceed € 420 million, of which a significant proportion could have been saved, if the cross-border duplication of cases linked to the absence of a Community patent and a specialised patent litigation system could have been avoided.

2.3. Oppositions and Appeals

(665) This section analyses oppositions and appeals filed by generic companies in respect of patents held by originator companies.

(666) The possibility of opposing an originator company's patent allows a generic company to seek legal clarification or remedy. At the end of the opposition procedure the patent-in-suit is either maintained (rejection of the opposition), revoked or amended.[441] Oppositions constitute a legal mechanism which enhances patent quality.

(667) In the previous chapter, the report analysed the litigation faced by generic companies, e.g. because originator companies invoke their patents against them. The opposition procedure is a way for generic companies to obtain verification of the validity and scope of an originator company's patent, which may be invoked in litigation.[442] If, in the opposition, this patent is proved to be invalid, it will be either revoked or its scope will be reduced. This may then allow the generic company to enter the market without facing the risk of infringing that patent. However, oppositions can only be launched within a certain period after the grant of a patent.[443]

(668) This section focuses on the opposition procedures before the European Patent Office (EPO). Appeals of EPO decisions on oppositions to the Boards of Appeal are also taken into account. National opposition procedures concerning national patents before the offices and bodies of the Member States are briefly considered.

(669) Opposition and appeal proceedings before the EPO are two separate and distinct procedures, the former being examined by the Opposition Divisions, the latter being examined by the Boards of Appeal. A similar separation of the two procedures is also seen in many national procedures. In other words, from a procedural point of view, both procedures are separate, as highlighted by the EPO in the context of the public consultation.

(670) While this procedural separation is acknowledged, one should bear in mind that one aspect of this inquiry, and the subject of the present section, is how to assess companies' use of patents in their commercial strategies, which can in principle delay the entry of other actors on the market. The time taken before a final decision has been issued in a case, whether this be after opposition only or after opposition with a subsequent appeal, was therefore considered to be of greater importance than a detailed description of the individual stage, since it is only after a final decision has been issued

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441 For further details see Chapter B.2.1.

442 In case a patent is challenged in front of a national court, parties in opposition may ask under certain circumstances to accelerate the opposition procedure. For further details see Chapter B.2.1. and D.1.

443 During the public consultation, it was underlined that third parties can already submit observations during the examination of a patent application (art. 115 EPC). This could in principle enhance the quality of granted patent as well as reduce the number of filed oppositions before the EPO. However, only few observations seem to be submitted at this early stage. For further details, see Chapter B.2.1. and D.1.

that competing companies have a clear idea of where patent protection lies. This means that, from the point of view of the competitive process, reaching a final decision as such, be it already in the opposition procedure or in the subsequent appeal, is of particular interest for the analysis undertaken in the present report. Hence, this section focuses on final outcomes in opposition and appeal procedures have been taken as a whole.[444]

(671) Regarding opposition and appeal procedures, it should be noted that decisions of the EPO (including the Boards of Appeal) are valid in all European Member States where a national patent has been validated. As long as the EPO (including the Boards of Appeal) does not reach a final revocation, national courts may still decide on the validity of a national patent which resulted from an EPO patent.[445] Nevertheless, some national courts regularly stay proceedings when an opposition procedure before EPO is pending, until the EPO has issued its decision. For further details on EPO and the appeal procedures, please refer to Chapter B.

(672) Before focussing on oppositions by generic companies against originator companies' patents, this section will first present data on oppositions in general, including oppositions by various types of opponents, e.g. other originator companies. More specifically, this general section provides information on the total number of oppositions by various types of opponents; a comparison between oppositions in pharmaceuticals and in all sectors; the INNs most opposed and the duration of opposition procedures. A brief overview of oppositions before the national offices and bodies of the Member States is also provided. Subsequently, a more detailed analysis is presented of all oppositions (including appeals), where generic companies opposed the patents of originator companies during the period 2000 – 2007.[446] The report presents the number of opposition procedures and opponents, and then goes on to examine the types of patents opposed. The section outlines the outcomes of the final opposition and appeal decisions. Finally, it looks into the cases where an originator company entered into a settlement with an opposing generic company.

2.3.1. General Information

2.3.1.1. Number of Opposition Procedures and Opponents

(673) In total, 170 opposition procedures against originator companies' patents were reported for the period 2000 - 2007. These opposition procedures concerned 73 distinct INNs

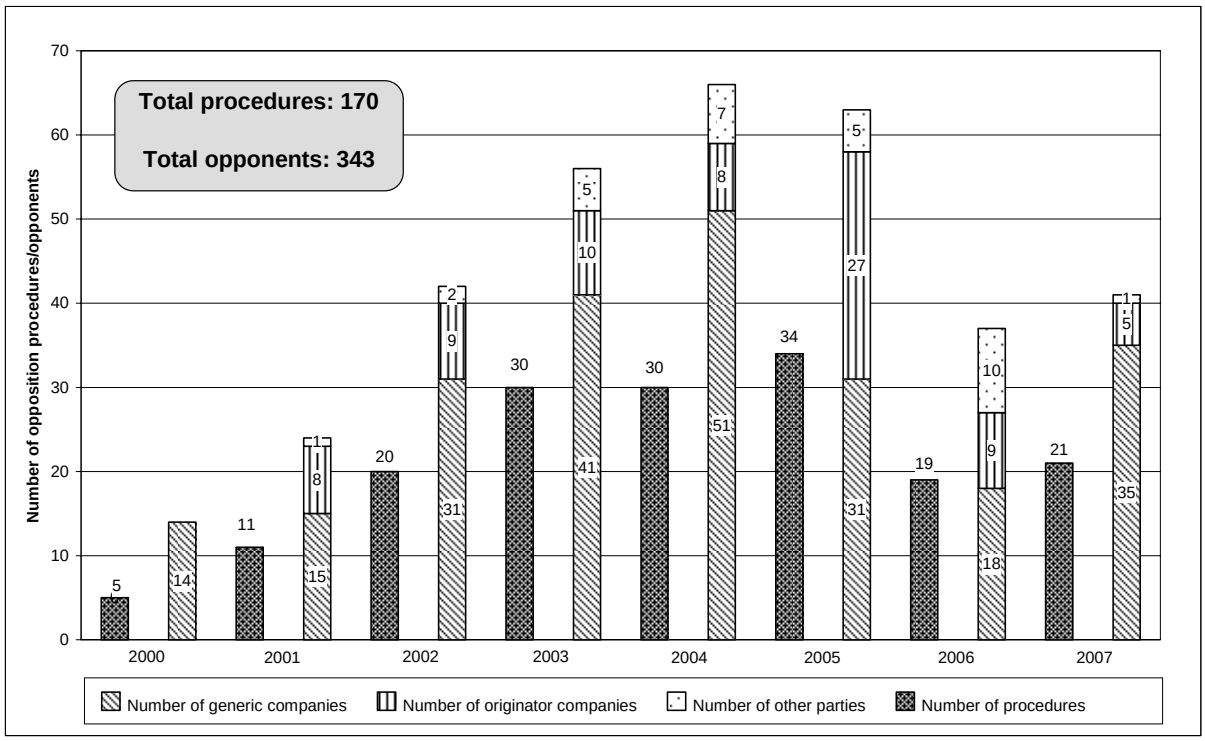
444 The approach proposed here was also suggested by EFPIA in the context of the public consultation.

445 Even if the validity and scope of an EPO patent was confirmed by the Opposition Divisions and the Boards of Appeal, its national validation can still be challenged before national courts.

446 For the analysis of opposition procedures, in which originator companies oppose the patent of other companies, see Chapter C.3.3

out of the 219 INNs for which information was gathered as part of the sector inquiry.[447] In these 170 opposition procedures, a total of 343 opponents were active.[448]

Figure 89: Number of opposition procedures before EPO and type of opponents per year (2000-2007)



Source: Pharmaceutical Sector Inquiry

(674) Figure 89 above presents the total number of opposition procedures and opponents broken down by year[449] for the period 2000 - 2007. There are two bars for each year. The first bar indicates the number of opposition procedures and, separately, the second bar shows the number of opponents (relating to these procedures).

(675) Opposition procedures increased from five procedures in 2000 to 21 in 2007. They reached a peak in the years 2003, 2004 and 2005 when 30, 30 and 34 procedures were reported, respectively. The number of opponents follows a similar pattern, reaching a peak of 56, 66 and 63 opponents in 2003, 2004 and 2005, respectively.

(676) In Figure 89, the annual total number of opponents is further divided up into generic companies, originator companies and other opponents. The category of other opponents also includes the so-called "straw men". A straw man is a party filing oppositions and/or appeals on behalf of other parties, whose identity must not be revealed. Straw men are often employed if the actual opposing party does not wish to be known by the party opposed. As one generic company explained in this context:

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447 For further information on the INNs most concerned, please see below Section C. 2.3.1.2.

448 The same companies may be involved in a number of opposition procedures.

449 The year refers to the start of the opposition procedure.

"[To disclose] the identity of the opponent in an EPO opposition procedure increases the risk that the applicant starts litigation actions against the generic companies."

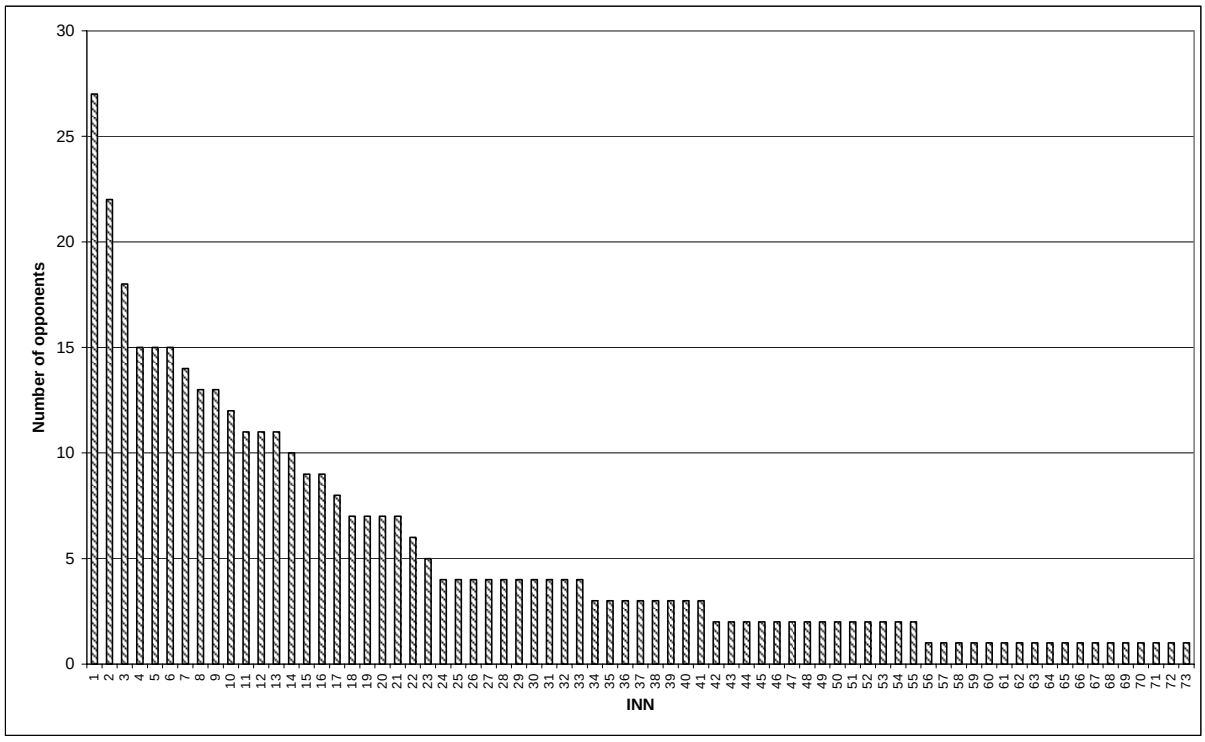
(677) Another generic company added:

"Straw man is a feature clearly to be maintained given the particularities of the patent system and the aggressivity of the originator companies."

2.3.1.2. INNs most Concerned

(678) As mentioned earlier, information was gathered on oppositions concerning 219 INNs. Patents regarding 73 INNs where concerned by opposition, with certain patents relating to these INNs attracting far more oppositions than others.

Figure 90: INNs by number of opponents before the EPO (2000-2007)



Source: Pharmaceutical Sector Inquiry

(679) Figure 90 above lists the number of opponents for any of the 73 INNs concerned by oppositions.[450] This figure indicates that in the period 2000 - 2007 the bulk of opponents concerned only a part of INNs. Further analysis showed that around one third of the INNs most concerned by oppositions belonged to the top 20 best selling INNs within the E75 list and around a quarter of them belonged the top twenty best selling INNs within the T50 list.

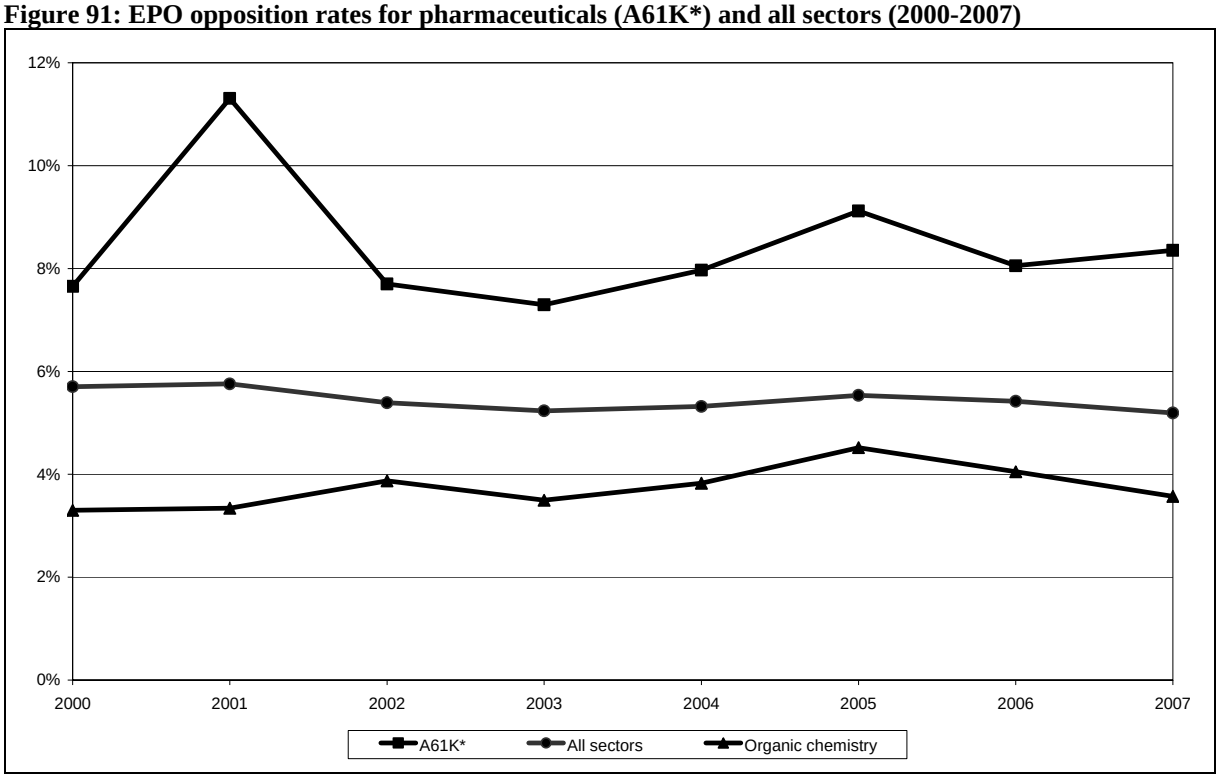
[450] An opponent involved in an opposition procedure concerning several INNs is counted as one opponent for each of the INNs.

2.3.1.3. Comparison between EPO Oppositions in Pharmaceuticals and in all Sectors

(680) For the purpose of the sector inquiry, it is also considered useful to compare the oppositions filed before the EPO in the pharmaceutical sector with the oppositions in organic chemistry as well as the ones filed in all sectors during the period 2000 – 2007, as provided by the EPO.

(681) Figure 91 illustrates that, in the period 2000 – 2007, the opposition rate (i.e. the number of oppositions filed per 100 granted patents) in the closest available proxy for pharmaceuticals (A61K*)[451] is consistently higher than the opposition rate in organic chemistry and all sectors taken together. In A61K* the opposition rate ranged from 7.3% to 11.3%, compared to organic chemistry where it ranged from 3.3% to 4.5% and all sectors where the opposition rate was between 5.2% and 5.8%.

Figure 91: EPO opposition rates for pharmaceuticals (A61K*) and all sectors (2000-2007)



Source: Pharmaceutical Sector Inquiry (based on data EPO)

2.3.1.4. Duration of Procedures (Oppositions and Appeals)

(682) The following section analyses the duration of procedures, taking into account all procedures which were reported as final, the earliest starting in 1999 and the latest ending in 2008.[452] The duration indicated contains procedures where Opposition

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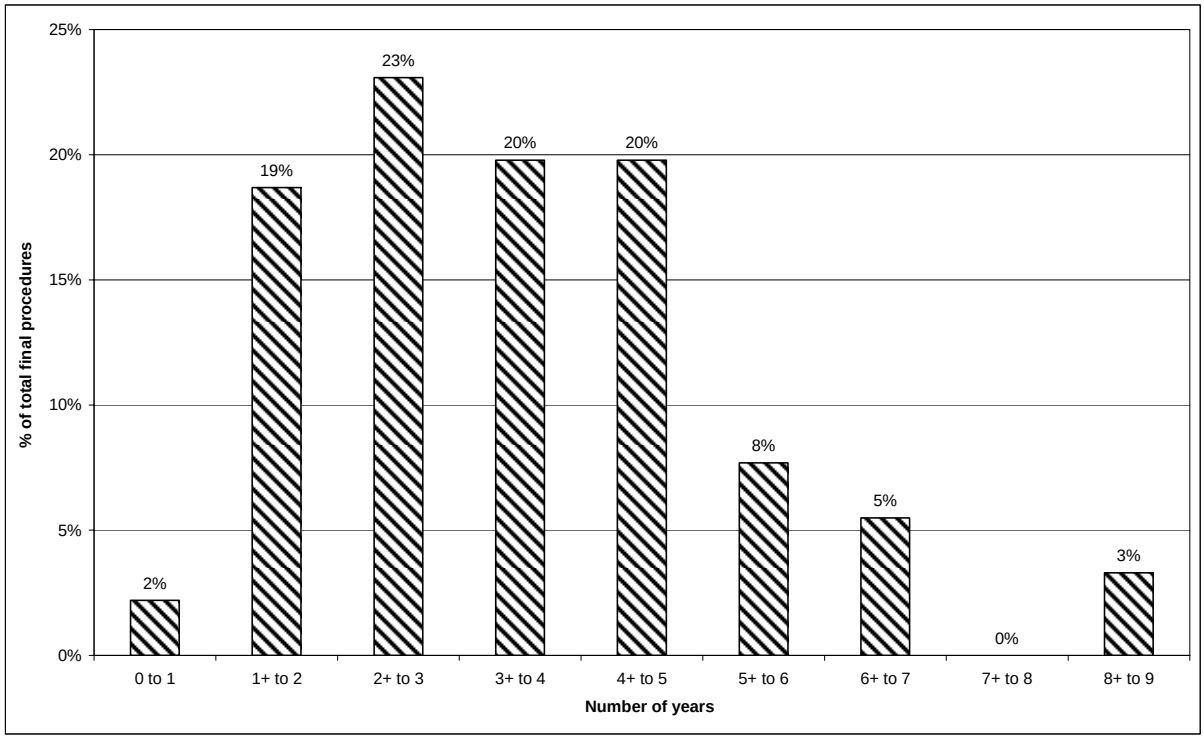
451 For further explanation on A61K*, see Chapter C.1.1.2.

452 In order to provide a better sample, the analysis of Figure 92 considers 91 opposition procedures (including appeals) in the extended period 1999 to 2008. Moreover, the duration is calculated from the

Divisions or Boards of Appeal have rendered final decisions (*res iudicata*). In other words, in this section the whole duration is measured which is on average necessary to receive a final decision on the validity and/or the scope of an EPO patent of an originator company.

Figure 92: Average duration to achieve final decision on validity and/or scope of EPO patents as percentage of the total (1999-2008)



Source: Pharmaceutical Sector Inquiry

(683) Figure 92 above shows the percentage of total final procedures lasting an average number of years. It can be seen that only approximately 21% of the opposition and appeal proceedings receive a final decision within two years. In most cases (approximately 79%), it takes more than two years to reach a final decision and, for some cases, it can take up to nine years in total before a final decision is reached. At the same time, the average duration of the opposition procedure was approximately 3.6 years from the initiation of the procedure until the final ruling (including in the sample final cases with and without appeal).[453] In this context, an originator company stated:

"It will often take many years to determine an opposition, given the pace at which the EPO and its appeal procedures operate."

starting date of the opposition procedure, it does not consider the nine months filing period for opposing a patent that reasonably prolongs the legal uncertainty of the patent validity.

453 It must be noted that the EPO strives to further improve its performance concerning the duration of opposition and appeal procedures.

(684) Some generic companies believe that originator companies whose EPO patents are opposed may, in some instances, prolong the opposition procedure.[454] Examples of statements from different generic companies include the following:

> *"In our experience the opposed originator company practically always tries to prolong both the EPO opposition and the appeal procedure."*

> *"The originator companies usually try to extend these procedures as long as they possibly can."*

> *"In cases where we filed an opposition to a European Patent granted to an originator company, we have experienced that the originator company prolonged the opposition procedure by requesting and obtaining a six-month extension of the time to reply to the opposition. This is however in accordance with the provisions of the EPC, that allow this extension request. We don't have a similar experience in appeal procedures."*

> *"[The effect of prolongation of procedures on our company is] the lack of commercial certainty, since the originator company may sue the opponent company for patent infringement before the national courts on the basis of patents that, in our view, have been improperly granted and, therefore, opposed."*

(685) A number of opposing originator companies indicated that in view of the duration of these procedures, they are obliged to have recourse to national courts in order to gain some legal certainty.[455] One company explained:

> *"[…] Therefore it can take up to 7 years or something more to get a final decision from the EPO. Some National Courts are particularly good at providing decisions quickly. […] National revocation action or actions may be filed in parallel to a European Opposition in key territories or territories where prompt decision may be expected. Some National Courts may stay any such actions until the final outcome of the European opposition is known, but many (for example UK and Belgium) will not if it appears that legal certainty is important and the proceedings at the EPO have some time still to run.*
>
> *Where a company has a particular product to launch in a particular jurisdiction it may prefer to launch national revocation proceedings because they are often determined (e.g. in the UK) inside 1 year."*

(686) Out of the 73 INNs concerned by opposition and the 78 INNs concerned by litigation in the period 2000 - 2007, 40 INNs were concerned by both opposition and litigation in that period.[456]

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[454] During the public consultation, it was claimed that patent holders request additional time in order to better respond to an opposition.

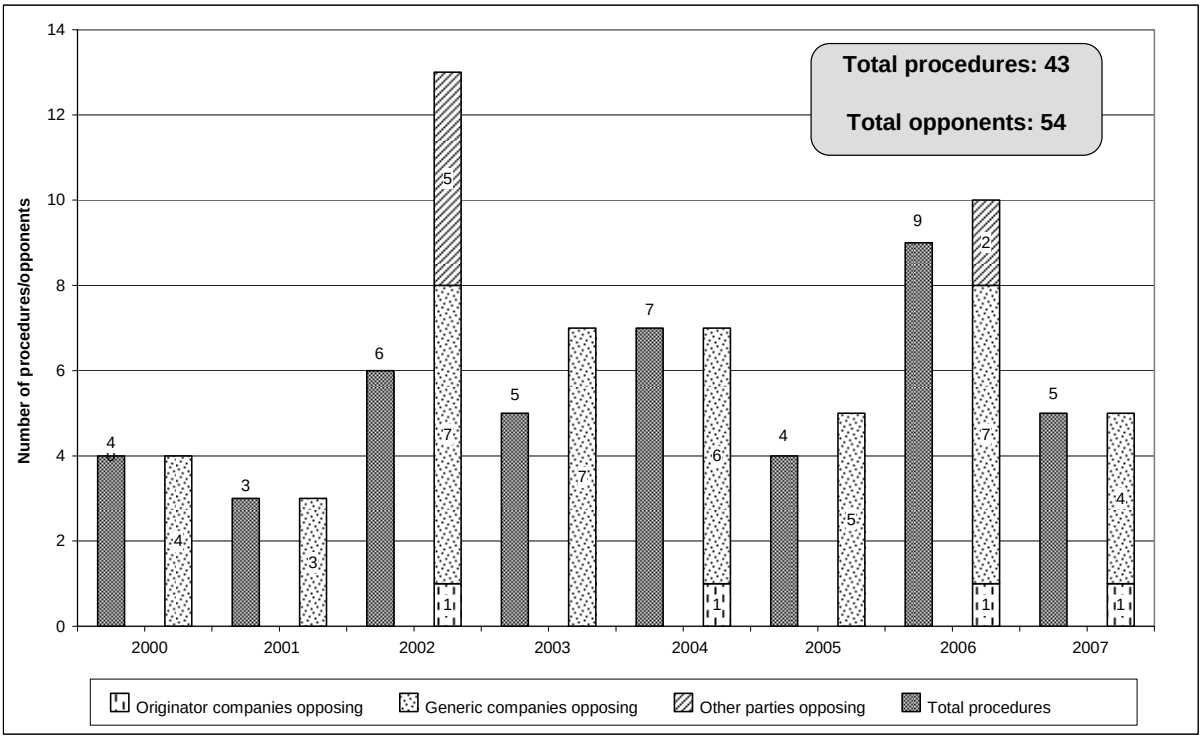
[455] See also footnote 442.

(687) It must be stressed that, unlike a decision of the EPO or the Board of Appeal which clarifies the patent situation for all designated contracting states, the judgments of national courts are only valid for the Member State in question. As shown above for generics,[457] this could, in principle, multiply the number of Member States where litigation must be carried out.

2.3.1.5. National Opposition Procedures

(688) For the sake of completeness, the report provides general data on national procedures before the offices and bodies of the Member States concerning the 219 INNs for which information was collected. However, it should be emphasised that the amount of information gathered on oppositions before the EPO (including appeal) was substantially greater than that on comparable national procedures. The information provided here on the number of national procedures in the period 2000 - 2007 gives a conservative estimate.

Figure 93: Number of national opposition procedures before offices and bodies of the Member States (2000-2007)



Source: Pharmaceutical Sector Inquiry

(689) Figure 93 above presents the total number of opponents and opposition procedures at national patent offices, broken down by year for the period 2000 - 2007. For each year,

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456 These findings do not intend to indicate that litigations in front of national courts and opposition procedures have the same nature and objectives.

457 For further details see Chapter C.2.2.

Figure 93 provides two bars. The first bar indicates the number of opposition procedures at national patent offices and, separately, the second bar shows the number of opponents (relating to these national procedures), broken down into generic companies, originator companies and other opponents.

(690) The number of national opposition procedures ranged from three in 2001 to nine in 2006. Compared to the number of opposition procedures before the EPO (see Figure 94), the number of national opposition procedures is substantially lower throughout the period. The number of opponents during the period was also considerably lower than for the EPO oppositions. It reached a peak of 13 in 2002, but otherwise remained fairly stable with between three and ten opponents per year.

2.3.2. Opposition and Appeal Procedures with Generic Companies as Opponents

(691) After the presentation of the general information on opposition procedures, the following section analyses opposition and appeal procedures before the EPO (including appeal) where a generic company opposed the patent of an originator company. The section starts by analysing the types of patents opposed and then goes on to examine the outcome of opposition and appeal procedures in further detail.

2.3.2.1. Number of Opposition Procedures, Opponents and Types of Patents Opposed

(692) A total of 109 opposition procedures in which generic companies opposed the patent of an originator company were reported in the period 2000 - 2007. Overall, generic companies acted as opponents on 236 occasions. These numbers further illustrate that, on average, there are at least two[458] generic companies opposing the originator patent in any given procedure.[459]

(693) Regarding the types of patents opposed, the sector inquiry shows that generic companies concentrate their oppositions on secondary patents.[460] Originator companies may be aware of this, as the following statement by an originator company illustrates:

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458 236/109 = 2.16.

459 However, this does not mean that in the 109 opposition procedures the patents of 109 different originator companies were opposed and that the 236 opponents were 236 different generic companies. In fact, one and the same generic company and originator company can be involved in a number of opposition procedures.

460 This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying interventions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

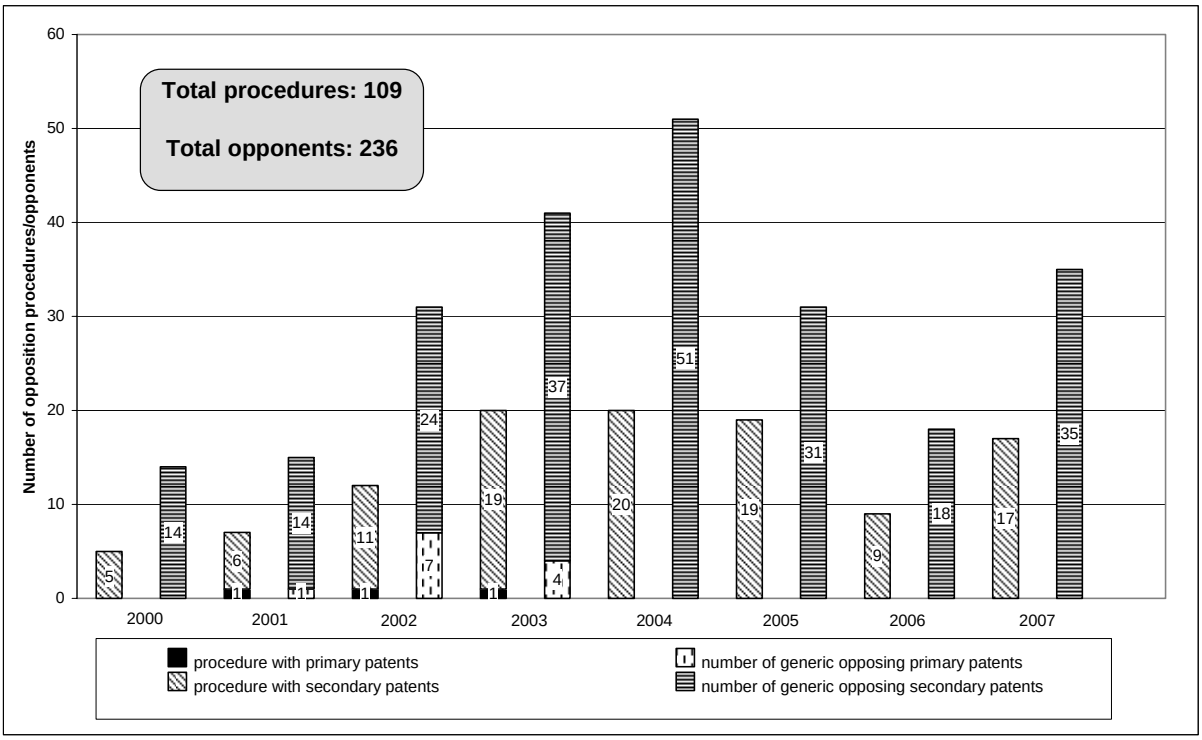
> *"Oppositions are more often filed against [our company's] secondary patents […] than patents that protect new compounds. […] [G]eneric companies do monitor when [our company's] patents are granted and then have the opportunity to (and in fact do) file oppositions."*

(694) Concerning opposition procedures, a generic company indicated:

> *"In the future we will use more the opposition procedure because many non-inventive patents are being approved which affect us due to the heavy abuse of the patent system."*

(695) Figure 94 below shows the total number of opposition procedures and opponents (generic companies) by year for the period 2000 - 2007. It provides two bars for each year, one relating to the number of procedures and the other relating to the number of opponents (relating to these procedures). Moreover, it distinguishes between opposition procedures related to primary and secondary patents of originator companies. It also distinguishes the opponents according to the same criterion. Figure 94 illustrates the fact that practically all opposition procedures (106 out of 109) concern secondary patents of originator companies. Such procedures peak in particular in the period from 2003 to 2005, where respectively 20, 20 and 19 opposition procedures against secondary patents were begun. Only in the years 2001 - 2003 were few primary patents opposed.

Figure 94: Number of opposition procedures before the EPO initiated by generic companies per primary/secondary type (2000-2007)



Source: Pharmaceutical Sector Inquiry

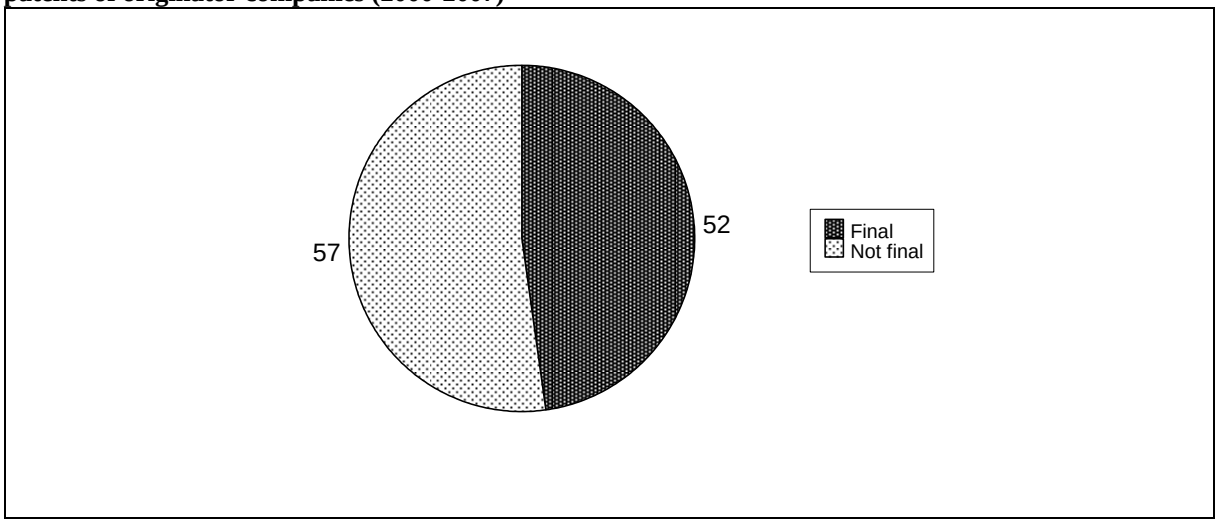
2.3.2.2. As indicated Analysis of the Outcomes of Final Opposition and Appeal Decisions

(696) This section analyses the final outcomes of opposition or appeal procedures (*res iudicata*). In principle, no further distinction between the two is made, as what is of interest here is the eventual fate of the originator company's patent.

(697) By Figure 95, a final decision was reached in 47.7% (52 out of 109) of the procedures initiated in the period 2000 - 2007. In the remaining 52.3% (57 out of 109) a decision is still outstanding. This can be partly explained by the very lengthy procedures, as mentioned previously.[461]

461 For further details see Subsection C.2.3.1.4.

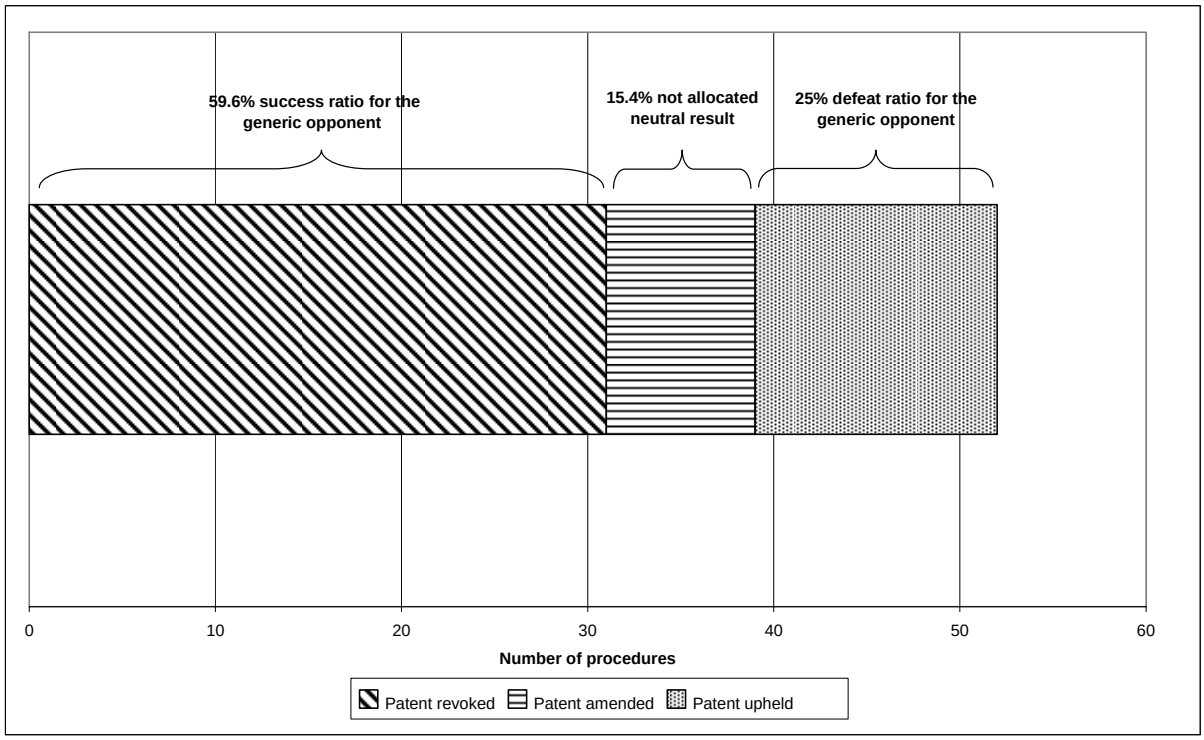
Figure 95: Final and pending opposition and appeal procedures involving generic companies against the patents of originator companies (2000-2007)



Source: Pharmaceutical Sector Inquiry

(698) Figure 96 reports the number of cases in which the originator companies' patents were revoked, amended or upheld by final decision. The following picture emerges: in 59.6% (31) of all final cases, the originator company's patent was revoked and in 15.4% (8) the patent was reduced in scope (reported as amended). Only in 25% (13) of the final cases, was the originator company's patent upheld. In the context of the public consultation, the EPO and other stakeholders pointed out that final outcomes resulting in amendments cannot clearly be identified as a success or defeat for either side involved in opposition and appeal procedures, therefore amendments are not allocated to either side.

Figure 96: Final outcomes of opposition and appeal procedures involving generic companies against the patents of originator companies (2000-2007)[462]



Source: Pharmaceutical Sector Inquiry

(699) From the above it is fair to conclude that, measured by final outcomes, generic companies won the vast majority of opposition and appeal procedures. Even if the final outcome resulting in amendments would hypothetically be counted as defeat for the generic companies, the picture that generic companies won the majority of cases would remain unaltered. Three of the final decisions related to (and revoked) a primary patent, whilst the remaining ones related to secondary patents.

2.3.2.3. Settlements

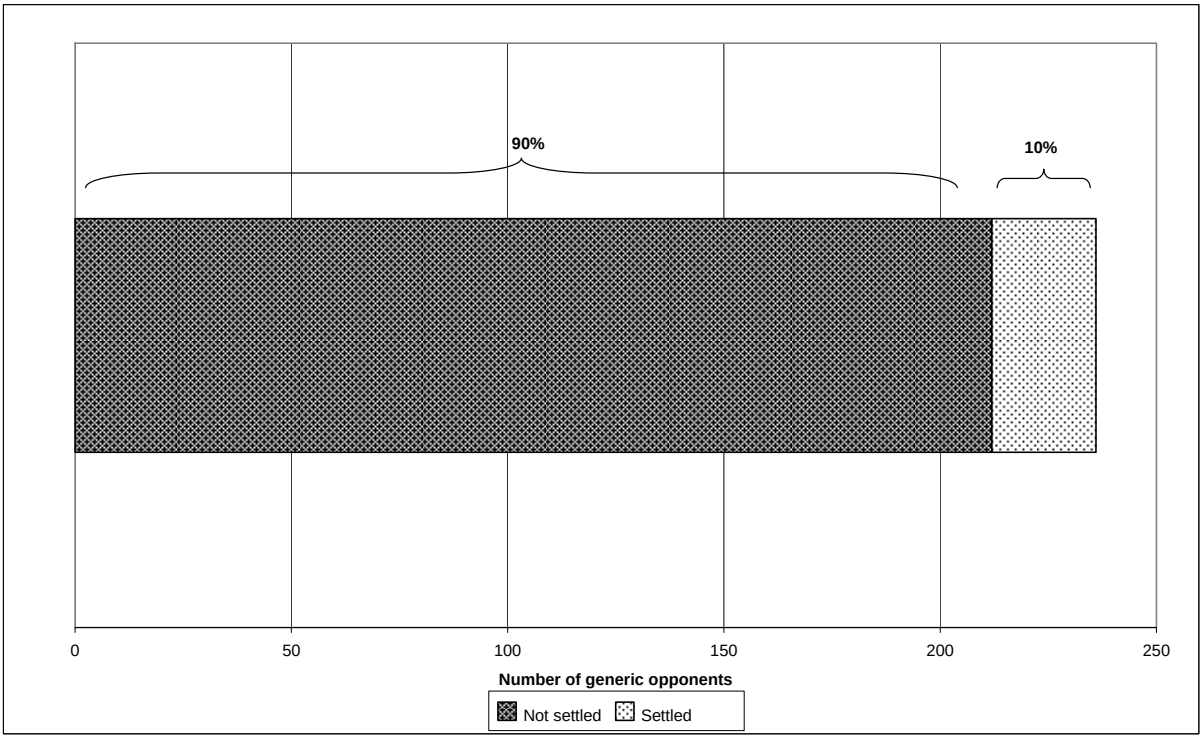
(700) The sector inquiry's documents show that settlements between originator and generic companies may also take place in the context of opposition procedures. As one originator company stated:

> *"In subsequent negotiations, [a generic company] consented to withdraw the opposition [against our patent] in consideration for the amendment and a narrowing down of the process claims of the patent."*

(701) Figure 97 shows that respondent originator companies settled with 24 of the 236 opposing parties (10%). These settlements concerned 13 different opposition procedures. The settlements are described in more detail in Section C.2.4.1.

462 Figure revised following update received from stakeholders.

Figure 97: Number of settlements with generic companies as opponents (2000-2007)



Source: Pharmaceutical Sector Inquiry

Summary

The sector inquiry confirms that the opposition rate (i.e. the number of oppositions filed per 100 granted patents) before the EPO is consistently higher for the pharmaceutical sector (about 8%) than it is in organic chemistry (about 4%) and across all sectors (overall EPO average: about 5%). Based on the information gathered, generic companies almost exclusively opposed secondary patents. In the cases where they opposed, generic companies prevailed in approximately 60% of final decisions rendered by the EPO (including the Boards of Appeal) in the period 2000 to 2007 and the scope of the originator patent was restricted in another 15% of the cases.

However, on average, it took more than two years to obtain approximately 80% of final decisions (including appeal procedures). Whilst it is acknowledged that opposition and appeal procedures – from a procedural point of view – are separate procedures, from a commercial perspective, the time until the final decision is taken – be it in opposition or appeal – is relevant. The duration of the procedures considerably limits the generic companies' ability to clarify the patent situation of potential generic products in a timely manner.