
FARMAINDUSTRIA®' S COMMENTS ON THE COMMISSION'S
PRELIMINARY REPORT ON THE PHARMACEUTICAL SECTOR INQUIRY

- CONFIDENTIAL -

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I. INTRODUCTION

1. The purpose of this document is to offer Farmaindustria®'s comments on the Commission's Preliminary Report on the Pharmaceutical Sector Inquiry ("the Report") in Case N° Comp/D2/39.514 (Commission Decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation N° 1/2003 [2008] OJ C59/06).
2. In the Introduction, the Report announces that "it does not seek to identify wrongdoing by individual companies or to reach any conclusion as to whether certain practices described in the report infringe EC competition law. It provides the Commission with a factual basis for deciding whether further action is needed" (page 5 and paragraph 366).
3. However, from the news published by the media following the press conference held on 28 November 2008, it transpires that much more needs to be done to help the Commission achieve that goal. Hence, the purpose of these comments is not to criticize the data set forth in the Report but to provide additional views that may help the Commission get the factual basis right and ensure that the final version of the Report is not perceived by the media as pointing to any wrongdoing or illegal practices. In our respectful opinion, the Report's failure to achieve the goal announced on page 5 has been due in part to the unfortunate headline chosen to present the Report ("Preliminary Report on Pharmaceutical Sector Inquiry highlights costs of pharma companies' delaying tactics"). This headline, which no doubt caught the media's attention, does not quite fit in with the goal announced by the Report in its Introduction.
4. Our comments will be divided into two main parts. In the first part, we will offer Farmaindustria®'s points of views on some of the general findings discussed in the Report. In the second part, we will address aspects that are specifically related to the Spanish market, such as the advertisement mentioned on page 285.

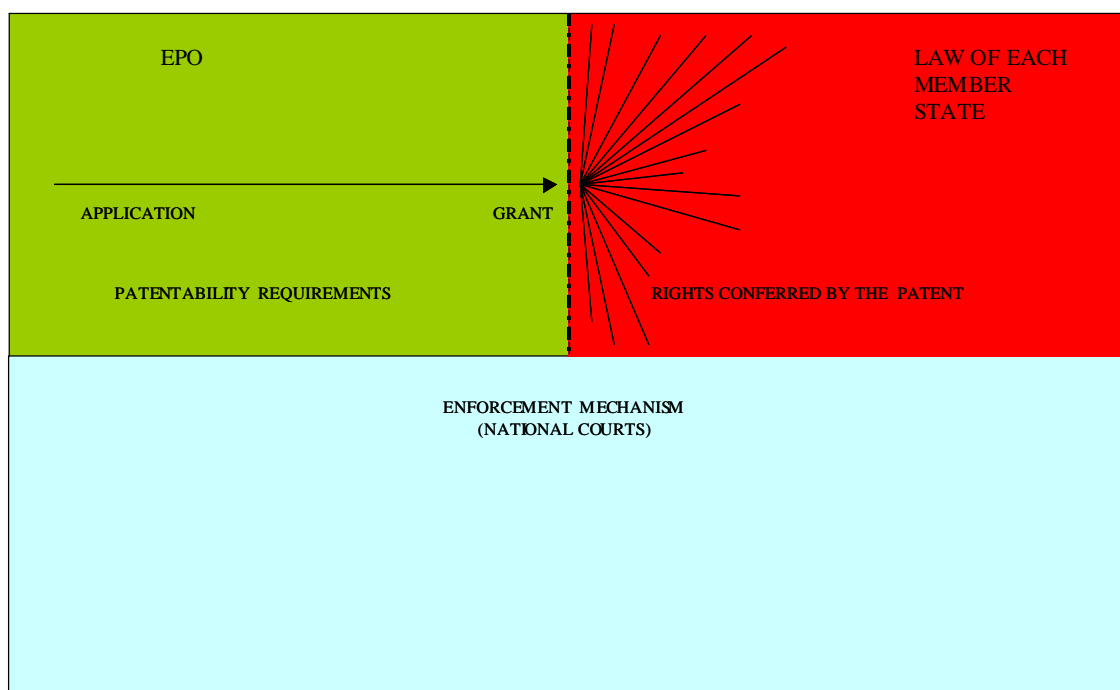
II. COMMENTS ON THE MAIN FINDINGS OF THE REPORT

- 2.1 Introduction: the analysis of fundamental additional aspects not covered by the Report would help the Commission have a wider view of the factors that constrain the launch of new pharmaceutical products in the EC
5. The main findings of the Report are based on two factual premises: (i) Both generic and innovative products reach the market later than one would normally expect (this is what the Commission identifies as a "delay"); (ii) the delay would not be a natural consequence of a complex mixture of legal, commercial, economic, scientific and technical factors, but the direct consequence of one factor: the alleged "delaying" tactics deliberately used by originator companies. The Report even assigns a specific figure to the cost allegedly caused by such delay: "Had the entry been immediate following loss of exclusivity instead of delayed, this expenditure could still have been more than 5 % or €3 billion" (paragraph 186).

6. As we will justify below, to confirm whether or not these two premises rest on solid grounds, account should be taken of fundamental aspects that have not been covered by the Report, such as:
 - (a) The Regulatory Framework of each Member State regarding patent protection: The Report only deals with the process whereby patents are granted (Section 2.1.4) and stresses that there is no single enforcement mechanism (Sections 2.1.3 and 2.1.6), but fails to examine thoroughly the laws of each Member State on patent protection, which have clearly a bearing on the time scales involved in the launch of new generics in each country. This has led the Report not to take into account the fact that until relatively recently, launch on day 1 after patent expiry was legally impossible, or that in some Member States products have had a shorter term of protection (due to the lack of Supplementary Protection Certificates), which might explain why in such countries patentees have defended their exclusivity more vigorously;
 - (b) The efforts deployed by DG TRADE before international fora such as the World Trade Organization ("WTO") against countries which allowed the launch of generics on day 1 after patent expiry: As explained below, the fact that the average time for generics to enter the market after loss of exclusivity is about seven months is not only the natural consequence of the Member State's legal regime on patent protection, but also a result that has been vigorously supported by DG TRADE before international fora such as the WTO to allow originator companies to amortise the investments made in the development of new products;
 - (c) The legislative proposals of the Commission aimed at introducing the so-called "Bolar provision" into the patent laws of Member States: A careful analysis of the legislative history of Directive 2004/27, which exempted so-called "preparatory acts" from the realm of patent infringement as of 31 October 2005 onwards, would help DG COMPETITION to see that the entry of generics has been more influenced by the prohibition of said "preparatory acts" during five of the eight years covered by the Report than by delaying tactics allegedly used by originator companies.
 - (d) The commercial strategy of generic companies: In our respectful opinion, a fundamental flaw of the Report is that it is based on information gathered from the premises of originator companies only. As explained on page 24 of the Report, most of the inspections took place at originator companies only. This has resulted in a rather one-sided stream of information that has prevented the Report from portraying wider, more objective findings.
 - (e) Scientific data explaining the reasons which have contributed to the decline of new launches: A complete assessment of the real reasons that explain the decline in the stream of launches of innovative medicines over the last decade would require examining the vast amount of scientific literature on this subject. This analysis is absent from the Report.
7. In the following Sections 2.2 to 2.6 we will address these five topics which, as

mentioned, are not covered by the Report. In Sections 2.7 to 2.12 we will deal with additional topics that are covered but which, in our opinion, need further reflection and data to get the factual basis right.

- 2.2 The Regulatory Framework of each Member State regarding patent protection:
8. The Report departs from the premise that "patents are key in the pharmaceutical sector, as they allow companies to recoup their own often very considerable investments and to be rewarded for their innovative efforts" (page 5 and 86 et sequitur). The central role of patents prompts the Commission to analyse:
 - a. The process whereby patents are granted and, in particular, the grant procedure before the European Patent Office ("EPO");
 - b. The enforcement mechanisms, which leads the Commission to note the absence of a unified and specialised patent judiciary in Europe (page 6).
 9. However, there is a third pillar which is even more important for an objective description of the legal factors which constrain the launch of new pharmaceutical medicines: the laws on patent protection of each Member State.
 10. As the table below illustrates, the European Patent Convention ("EPC") only regulates the procedure whereby patents are granted. However, once the European patent has been granted, in the absence of a single Community patent, the rights conferred by the patent depend on the law of each Member State (Article 2.2 of the EPC). This is the space depicted in red, which the Report has failed to consider:



11. Hence, a complete account of the legal framework that has constrained the launch of new medicines during the period under investigation would require an analysis of aspects such as whether or not the launch of a new medicine on day 1 after patent expiry was legal under the patent laws of each Member State.
12. No doubt such an analysis would be a mammoth task. Fortunately, this work was already conducted by the Commission (DG TRADE) in the context of a case heard before the Dispute Settlement Body ("DSB") of the WTO, which will be briefly discussed further on. At this point it will suffice to highlight that the Commission confirmed for the panel established by the WTO that under the patent laws of the Member States it was not legal to launch a generic on day 1 after patent expiry. To illustrate this, we set out below a transcription of the Commission's response (Annex 5 of the panel's report) where it highlighted that neither Community Law nor the patent laws of its Member States had a "Regulatory Approval Exception" or "Bolar Provision" allowing so-called "preparatory acts" (i.e. use of the invention prior to the expiry date for the purpose of obtaining marketing approval):

Reply from the EC

1. The EC/MS have pointed out under point 24 of their oral statement to the first meeting of the Panel that "[...] all industrialised countries which have been mentioned by Canada in its first written submission [...] all these countries have a system of patent term extension [...]." This has been fully confirmed by the replies by the third parties. The more complete picture appears to be this:

United States: patent term extension **and** regulatory review/approval-type exception;

Japan: patent term extension **and** regulatory review/approval-type exception;

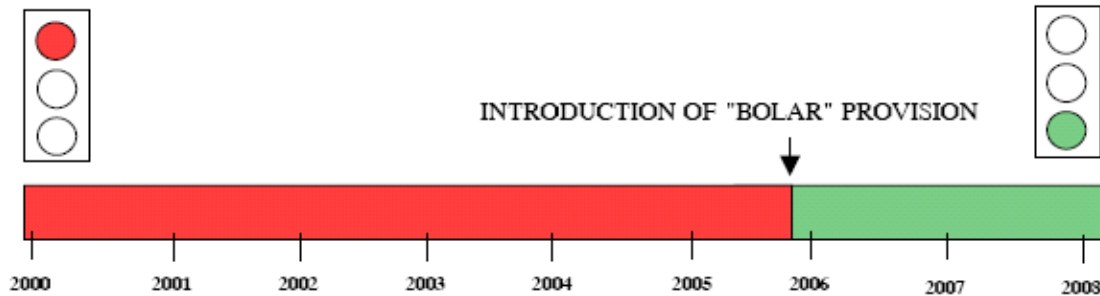
Australia: patent term extension **and** regulatory review/approval exception;

Switzerland: special protection certificate **without** regulatory review/approval exception;

EC/MS: special protection certificate **without** regulatory review/approval exception;

Canada: no patent term extension, but regulatory review/approval and manufacturing and stockpiling exception.

13. As the drawing below illustrates, this legal framework did not change until 31 October 2005, the date when Member States were due to implement Directive 2004/27, which introduced the so-called "Bolar Provision," as we will discuss later on.
14. Hopefully, this information will help the Commission to fine-tune comments such as the one found in paragraph 213 of the Report: "Once the period of protection of the invention has expired, anyone may use the invention commercially without the authorisation of the original patent holder." As the following drawing illustrates, this has been so from 31 October 2005, but this was not the legal position during the first five years (2000-2005) covered by the Report:



15. In conclusion, during five (2000-2005) of the eight years (2000-2007) covered by the Report, one could not expect generics to be launched on day 1 after patent expiry (which is the assumption on which the entire Report is based) simply because it was prohibited by the patent laws of the Member States, which the Report does not consider.
- 2.3 As the Commission (DG TRADE) has rightly highlighted in other contexts, post-patent windfall protection was a natural consequence caused by the prohibition of so-called "preparatory acts"
16. The core message that the media reported to citizens throughout the Community after the Commission's Press Release of 28 November 2008 is that originator companies have stolen €3 billion from national health systems over the eight-year period investigated. This accusation was based on the fact that generics do not normally enter the market on day 1 after the patent expires. Rather, the Report observes that "the average time to entry is about 12 months in absolute terms, whereas it is about seven months in weighted value terms" (paragraph 165).
17. To help the Commission put the time scales involved in the launch of generics after patent expiry in the right context, it is necessary to note that the very fact (post-patent "natural" market exclusivity extensions) that DG COMP appeared to reproach in the Press Conference held on 28 November 2008 has been vigorously vindicated by DG TRADE as a legitimate part of innovators' R&D amortisation process. In short:
 - a. DG COMP is accusing innovators of having caused national health systems to lose €3 billion because they enjoy an average 7-month "natural" post-patent market exclusivity extension.
 - b. DG TRADE has defended until relatively recently that innovators should enjoy an average 24-month "natural" post-patent market exclusivity extension to allow them to recoup their R&D investments.
18. On 19 December 1997, the Commission (DG TRADE), acting on behalf of the EC and each Member State, filed a complaint against Canada before the DSB of the WTO, denouncing that the "Bolar Provision" approved by Canada was contrary to the TRIPS Agreement. By allowing generic companies to conduct so-called "preparatory

acts" before the expiry date of the patent, the practical consequence of that provision was to reduce by approximately two years the term to amortise the invention.

19. The DSB formed a panel which issued a report on the case on 17 March 2000, from which the following statement may be extracted to illustrate the position defended by the Commission:

"4.7 The European Communities and their member States, in support of their claims, also provided advance information on the economic losses suffered by their pharmaceutical industry from the effects of Sections 55.2(1) and 55.2(2) of the Patent Act together with the Manufacturing and Storage of Patented Medicines Regulations. The European research-based pharmaceutical industry (EFPIA) had conducted an analysis of its alleged losses suffered in Canada, which exceeded the amount of C\$ 100 million per year. This analysis was based on the conservative assumption that, while the operation of the provisions referred to above would allow copy manufacturers to market the product immediately upon patent expiry, in the absence of these provisions [i.e. the Bolar provision] effective marketing would only be possible two years after patent term expiry at the earliest" (WTO, WT/DS114/R, paragraph 4.7)

20. The panel report went on to note that:

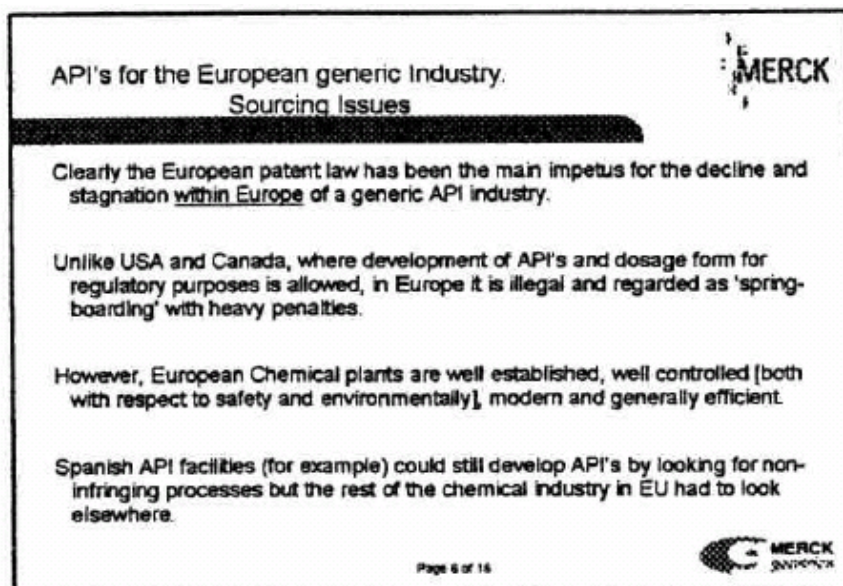
"[...] as was apparent from their submission, it was that windfall period of protection that the European Communities and their member states asserted here". (WTO, WT/DS114/R, paragraph 4.14, iii).

21. Although the complaint was not totally successful, the relevant point in the context of the Commission (DG COMP)'s Report on the pharmaceutical sector enquiry is that in its submissions, the Commission (DG TRADE) emphasised that under the laws of the Member States this windfall period of protection was the natural consequence derived from the prohibition from carrying out "preparatory acts" before patent expiry (see paragraph 12 above). As mentioned above, the submissions made by the Commission (DG TRADE) in that case prove an important fact that the Report has failed to consider: the contents of the patent laws of Member States.

22. In conclusion, the position taken by the Commission itself (DG TRADE) in international fora such as the WTO show that post-patent exclusivity extensions have not been the result of an abuse of the patent system, but a legitimate tool vigorously defended by the Commission (DG TRADE) aimed at allowing originator companies to recoup their R&D investments.

- 2.4 The legislative proposals of the Commission aimed at introducing the so-called "Bolar provision" into the patent laws of Member States further confirm that the delays identified in the Report were the natural consequence of the Member States' patent protection regimes

23. During the last decade, the Commission has delved into an internal debate that led it to revisit its position. This process resulted in the introduction of the "Bolar Provision" in Directive 2004/27, which member states had the obligation to implement no later than 31 October 2005. However, bearing in mind the deadline to implement the "Bolar Provision", most likely its introduction will not have had a significant impact on the practice followed by generic companies during the period investigated (2000-2007).
24. In fact, in April 2004 the EGA gave a Press Release urging Member States to implement the "Bolar Provision" as soon as possible so that preparatory acts could start before patents' expiry dates.¹ Obviously, if in the middle of the period covered by the Report the EGA was pressing Member States to accelerate the introduction of the "Bolar Provision" was because preparatory acts were prohibited before, as the Commission (DG TRADE) highlighted in the case discussed above.
25. On 21 and 22 February 2005 a conference was held in Rome, which included sessions co-chaired by EGA's director general.² Dr Howard Rosenberg, speaking as "Group IP and API Strategy Director" of Merck Generics, the company that the Report identifies as the EC's fifth largest generic company,³ showed the following slide:



26. The Commission may wish to include this slide in the final version of the Report, since it is highly illustrative of the legal framework then in force. As the IP Advisor of Merck Generics highlighted in February 2005, the legal position before 31 October 2005 was that:

¹ See El Global, 5-11 April 2004, "La EGA solicita una rápida inclusión de la disposición Bolar en la UE" ("EGA requests a quick introduction of the Bolar provision in the EU").

² Farmaindustria® would be delighted to forward a copy of the programme to the Commission.

³ See the ranking in paragraph 73 where Mylan, the company that has acquired Merck Generics since then, is ranked 5th.

"Unlike USA and Canada, where development of APIs and dosage form for regulatory purposes is allowed, in Europe it is illegal and regarded as «spring-boarding» with heavy penalties"

27. In conclusion, taking into account that during approximately $\frac{3}{4}$ of the period covered by the Report the patent laws of Member States prohibited preparatory acts and that, therefore, generics could not be launched until a significant period of time had passed after patent expiry, there is nothing surprising or reproachable in the finding that "for a sample of medicines under investigation which had lost exclusivity in 2000 to 2007 the average time to enter after loss of exclusivity was about seven months on a weighted average basis, whereas also for the most valuable medicines it took about four months" (pages 5-6). In fact, what such findings would prove is that in many instances the patent laws of Member States were not respected.
- 2.5 A complete account of the dynamics of the pharmaceutical market would require a thorough analysis of the commercial strategies followed by generic companies
28. As announced in the Introduction, a fundamental flaw of the Report is that it is based on information gathered from one side only, that is, from originator companies. An analysis of the commercial strategies followed by generic companies would have discarded the scenario of "perfect" competition that underpins the findings of the Report.⁴
29. In particular, it would have shed further light on why some generics are launched earlier in certain jurisdictions than in others (when they are launched in such other jurisdictions at all), the factors that affect the price of generics, the different state incentives for generics, how generic companies litigate in cases where they have obtained legal opinions warning them of the risks of infringement in markets where the risk of damages is low, how they speculate by hoping for judicial errors in clear-cut cases where they know that they infringe, and the like. This would have allowed the Report to add in paragraph 69 that, in many instances, the attempts of generic companies to launch before patent expiry is due to the fact that in some jurisdictions the low amount of damages awarded in even clear cases of patent infringement acts as an incentive to infringe.
30. All one can find in the Report in relation to the strategies of generic companies are vague and isolated sentences such as "consultation of EPO public databases reveals that many of the generic companies questioned in the inquiry were increasingly more active in filing applications for patents over the period 2000 to 2007" (paragraph 364). The complete lack of analysis of the generic-to-generic competition has resulted in a rather one-sided stream of information, which has prevented the Report from reaching more objective findings.

⁴ In this regard, the London School of Economics has highlighted that more efficient generic-to-generic competition would bring significant savings (as high as 44 %).

- 2.6 In the Report there is a dearth of data regarding scientific factors explaining the reasons that have led to the decline of new launches
31. The progressive decline in the stream of new launches has not only caught the Commission's attention, but also the attention of the scientific community. Some of the factors identified as having a bearing on this include the increasing safety thresholds applied by health authorities. This has made it more difficult to obtain marketing approval for new drugs and, in some cases, it has caused some important blockbusters to be withdrawn from the market.⁵
32. An analysis of scientific data produced by independent research centres such as the Tufts Center for the Study of Drug Development would further confirm that the delays identified in the Report are caused by factors other than the alleged delaying tactics, such as the increase of R&D costs in the pharmaceutical sector.⁶
- 2.7 The Report lacks a comparison between the number of patent applications filed in the pharmaceutical sector and in other comparable industry sectors
33. The Report notes that "the increase in A61K* doubled between 2000 and 2007, corresponding to an average 10.2 % increase per annum compared to 4.9 % for all sectors. In organic chemistry the number of applications rose by 61 %, corresponding to an average increase per annum"(paragraph 336). These data allow the Commission to conclude that filing a massive number of patent applications appears to be another of the tools found in what the Report labels the originator companies' "tool-box" (see paragraph 369).
34. To help correct this mistaken impression, we would ask the Commission to take into account the following facts:
- a. The relevant comparison is not between the pharmaceutical sector and the average number of applications for all sectors, but between the pharmaceutical sector and other sectors, which like the former, are "among the higher investors in R&D in the EU" (see footnote 14 of paragraph 36 of the report).
 - b. If the comparison is made with the telecommunications sector, for example, the suggestion that the pharmaceutical sector might be abusing the system fades away.
 - c. The fact that more patent applications have been filed in A61K* than in organic chemistry, for example, is the logical consequence of the technical progress made by originator companies in developing new formulations that improve the way existing active ingredients (those protected by patents in the

⁵ The example of Lipobay® is highly illustrative of the difficulties encountered by originator companies in overcoming the increasing risk / benefit thresholds applied by health authorities across the board.

⁶ OCDE, Pharmaceutical Pricing Policies in a Global Market, Paris, 2008, p. 56.

organic chemistry category) are administered to patients.⁷

35. In addition, to avoid confusion, it would be advisable to clarify further the distinction between "primary" and "secondary" patents (see, for example, paragraph 342). These terms may convey to the uninformed reader the mistaken impression that the distinction relates to "important" and "unimportant" patents. The reality is that the term "primary" or "basic" patent is normally used in the industry to designate the first patents relating to a compound (i.e. an "organic chemistry" patent protecting the active ingredient and/or its salts as such, and / or processes to make it), whereas the term "secondary" patent normally designates patents which protect further developments such as formulations.⁸
36. "Secondary" patents are as important as "primary" patents. Like the latter, they are subject to stringent examination procedures. There are examples of active ingredients that were unable to reach the market until a formulation protected by a "secondary" patent was invented. Also, the cumulative effect of numerous relatively small incremental innovations may bring significant economic benefits.⁹ To question the value of "secondary" patents would lead to the stagnation of technological progress in the field of pharmaceutical formulations and would portray as irrelevant the invaluable work of numerous scientists who every day invent new formulations that improve patients' quality of life.
37. As with any other patent, these patents are filed as soon as the circumstances make it advisable and, in any event, as soon as the company is capable of doing so. Otherwise, a competitor could take the lead or a disclosure could jeopardise the novelty of the invention. As the citation transcribed in paragraph 384 illustrates, the purpose of these patents is "maximizing patent term through innovation." Contrary to what transpires from the context where this citation is used in the Report, obtaining these patents, no matter how many, is legitimate, as long as they meet the patentability requirements.
38. The fact that some formulation patents may be more vulnerable to validity attacks than the patent which protects the active ingredient, which is trite, may not be used to question the value of this type of patents. Otherwise, our Universities would have to shut down their formulation departments.
39. Finally, counting one patent which designates 5 Member States (paragraph 340) as 5 patents, and making reference to an INN allegedly protected by 1,300 patents counted in this way (paragraph 349) may be useful to catch the media's attention, but does not help enhance the objectivity of the Report.

⁷ It must be noted that 67% of the new chemical entities developed during the period 1975-2002 that entailed therapeutic benefits were developed from known chemical structures. See BARRAL, P.E., "28 Ans de Résultats de la Recherche Pharmaceutique dans le Monde 1975-2002", IRDES, Paris, 2004.

⁸ This is correctly explained in footnote 223 of paragraph 375, which the average reader is unlikely to read.

⁹ NATIONAL RESEARCH COUNCIL, "Prospectus for National Knowledge Assessment", National Academy Press, Washington, D.C., 1996.

- 2.8 The Commission's failure to examine the laws of the Member States influencing the patent protection regime distorts the reliability of the statistics on number of cases won / lost
40. The findings of Section 2.1.4.2 ("Procedural Enforcement of Patent Rights") are distorted by the Commission's failure to examine the laws of the Member States on patent protection.
41. Also, such statistics say nothing about the strength of the more than 99 % of patents which were not subject to litigation. For obvious reasons, in Member States with specialised Courts, generic companies only challenge patents, or defend themselves, in cases where they feel they may have high prospects of success.
42. In addition, one may not extract conclusions from these data unless they are compared with percentages of wins / losses in other fields of litigation. One may only suggest that a specific percentage of wins / losses (for example, the 62 / 38% mentioned in paragraph 502) could indicate an improper use of litigation if it deviates significantly from the percentage of wins / losses in other fields. The difficulty of making such a comparison does not allow one to circumvent the comparison and draw unsubstantiated conclusions. The same comment applies to the percentage of oppositions upheld by the EPO mentioned in paragraph 569. For example, in Spain only 9% of all civil liability claims are upheld. If the 38% of successful patent actions is compared with the 9% of successful civil liability actions, it would result that the percentage of wins in the pharmaceutical sector is almost four times higher than one would expect.
43. On the other hand, the suggestion that originator companies make an improper use of the patent system and, in particular, patent litigation, because they "only" win approximately 40% of the cases (51% of the cases that they initiate, see paragraph 504) fails to consider basic corporate due diligence standards. In any industry sector a company director would be sacked for not protecting the company's most important assets through litigation after being advised that the prospects of success were as high as nearly 40%.
44. In addition, to help the Commission have a better understanding of the difficulty of envisaging the outcome of patent litigation, it would be of help to consider further factors such as the highly technical nature of the debate, the ideological and/or chauvinistic biases of Court experts in some countries, and the overall environment surrounding patent enforcement. The fact that, as mentioned on page 10 of the Report, the same case may be decided differently by highly competent Courts in different jurisdictions (or even within the same country) illustrates the difficulty of foreseeing the outcome of a specific case in advance.
45. On another note, since the Report has only considered final judgments, judgments from countries where litigation ends at the second instance, such as the United Kingdom, are over-represented with respect to judgments from countries where

litigation does not end at the second instance. This has given a disproportionate weight to Judgments from the United Kingdom, where generic companies win many cases. It is not coincidence that, as mentioned in paragraph 476, in that jurisdiction 65% of the cases are initiated by generic companies.

46. Considering only final Judgments has caused the Report to portray a sample of cases which is not representative of the total number of cases decided during the period covered by the Report. In particular, cases from the United Kingdom, a jurisdiction with many cases (71) and where, as mentioned, generic companies win many cases, are over-represented. They are over-represented for the simple reason that the Court of Appeal hardly ever gives leave to file a further appeal before the House of Lords. In contrast, cases from another jurisdiction with a similar number of cases, such as Spain (70 cases), where generic companies win less cases, are under-represented for the simple reason that the Courts of Appeal hardly ever deny leave to file a further appeal before the Supreme Court.
47. In practice, this means that the outcome of many of the 70 cases heard before Spanish Courts will not have been considered in the Report because an appeal is pending before the Supreme Court. In contrast, the outcome of virtually all the 71 cases heard before the United Kingdom will have been considered because no appeal is pending before the House of Lords and, therefore, the decisions in those cases are final.
48. Although the Report mentions that "companies were asked to report on the outcome of patent litigation in all final judgments (*res iudicata*)" (paragraph 499), such statement is incomplete, since companies were also required to report on the outcome of cases where a final judgment has not yet been rendered. Therefore, the Commission has all the necessary information to complete the Report to avoid the distorting factor discussed.
49. To help the Commission correct at least some of these flaws, we propose that the final version of the Report should give details on the following important facts:
 - a. How does the percentage of wins / losses compare with the respective percentages of wins / losses in other fields of litigation?
 - b. What percentage of cases won by originator / generic companies are subject to appeal before the Supreme Court of each Member State?
 - c. Which party prevailed in the cases where an appeal was pending before the Supreme Court of each Member State?
50. In any event, the statistics mentioned in the Report do not support the proposition that originator companies might be abusing the legitimate right to litigate. As the Report points out "Litigation concerning the 20 most litigated INNs accounted for the vast majority of all patent litigation in the EU (80%)" (paragraph 482). There does not appear to be anything wrong in a company defending its most important assets.

- 2.9 The Report confuses "disputes" with "consultations"
51. Another fundamental flaw of the Report is that it confuses "disputes" with "consultations." On page 18 the following definition of "dispute" is offered: "«Dispute» is understood as every exchange of views between two companies where, in particular, the actual or potential infringement, non-infringement or invalidity of one or several patents concerning a specific INN* or R&D pole* has been raised, which, however, did not (yet) end in litigation*."
52. Since no source is cited, this definition has been presumably crafted ad hoc for the purposes of the Report. The use of this odd definition leads the Report to state that "data provided shows that nearly all disputes (91%) were initiated by an originator company, whilst generic companies launched only 9% of all disputes" (paragraph 447). The Report goes on to highlight that "in contrast, only about 9% of all reported were started by a generic company" (paragraph 450).
53. Such statements may lead to very serious confusions and misinterpretations because what the Report defines on page 18 is not a "dispute" but a "consultation."¹⁰ As the Permanent Court of International Justice clarified in the "Mavrommattis case, a dispute is "a disagreement on a point of law or fact, a conflict of legal views or of interests between two persons."¹¹
54. When an originator company is peacefully enjoying its patent rights and a third party decides to launch a product that may interfere with the scope of protection of those rights, the party that prompts the "turbatio" (i.e. controversy) is not the patent owner, but the third party.
55. Confronted with a potential threat to its patent rights, the patentee may react with "consultations", that is, with a communication addressed to the third party drawing its attention to the patent's existence and, eventually, asking the third party to discontinue the activities that have prompted the dispute (see paragraph 449).
56. In addition, the Commission's failure to consider the Member States' patent laws has caused the Report not to take into account the fact that in some Member States such "consultations" are mandated by Law (more on this in paragraph 77 of these comments).
57. Therefore, presenting situations where originator companies have simply started "consultations" (in many cases complying with a Law requirement) in response to disputes prompted by generic companies as having initiated 91% of the "disputes" (paragraph 447) is another of the elements of the Report that needs serious correction.

¹⁰ See ZEMANEK, K., "On Consultations", in MEDINA, M. et altri, Pensamiento Jurídico y Sociedad Internacional: Libro Homenaje al Profesor D. Antonio Truyol Serra, Madrid, 1986, p. 1247.

¹¹ Mavrommattis Palestine Concessions (Greece v. United Kingdom), 1924 P.C.I.J. (Ser. A), No. 2, at p. 11 (30 August).

- 2.10 The uninformed reader may misinterpret the amount of investment made in relation to R&D and marketing activities
58. To help the Commission prevent the uninformed reader from misinterpreting the investment made in R&D and marketing activities, we would suggest that the final version of the Report should clarify that, whereas marketing investment must be incurred in each and every one of the countries where the company is present, this is not usually the case for R&D investment.
59. Suggesting that a company that invested, say, €1,000 million in R&D in one country, and € 12 million in marketing activities in each of the 100 countries where it is present, "[...] spent more money on marketing than on R&D" (as the Report notes in paragraphs 57 and 769) does not appear to be the most objective way of reporting the investment made in each activity. In addition, the OCDE has recently noted that "although [...] investment in pharmaceutical R&D accounts for only about 16 % of global sales revenue, the economic cost of financing this investment is greater in that proceeds from the investment are accrued years after the investment. Estimates of the economic cost of R&D investment range from about 30 to 40 % of sales (OFT, 2007)".¹²
- 2.11 "Second generation" products
60. Another of the kits that the Commission identifies in originator company's alleged delaying tool-box are "second generation" products. The Report notes that "several generic companies and their industry associations and consumer associations have strongly criticised life cycle strategies leading to second generation products. They refer to this practice as «evergreening» and have raised concerns about their effects. They claim that some of the new products show little if any innovation and limited if any additional benefits, and that they serve primarily to retain the revenue streams of the first generation product" (paragraph 830). Quite surprisingly, the Spanish association of generic companies (AESEG) has put as an example of this a delayed release formulation that the Spanish Government has excluded from the price reference system for five years because it considers that it constitutes an advantageous innovation.
61. The generic companies' criticism of second and third generation patents ignores the fact that once the first generation (or "basic" patent) has expired, any competitor is free to use the matter that has fallen into the public domain. Suggesting that competitors should also be free to copy improvements protected by "second" and "third" generation patents would lead to the stagnation of technological progress in the pharmaceutical sector.
62. There is nothing to criticise about second and third generation patents, as they are key to the further improvement of the quality of the life of the Community's patients.

¹² OCDE, Pharmaceutical Pricing Policies in a Global Market, Paris, 2008, p. 187.

Trying to invent improved formulations of known active ingredients is not only an ethical obligation but also a legal right. Generic companies are free to make use of this legal right, although they find it easier and cheaper to copy someone else's inventions. If generic companies were to invest in the R&D of new formulations, they would be rewarded with a patent, exactly like originator companies.

63. And some generic companies do so. Whereas EGA has quoted, for example, controlled-release formulation patents as an intolerable example of "evergreening" practices, an objective international organisation such as UNCTAD has highlighted the controlled-release formulation patents developed by Ranbaxy Laboratories as an example of the type of high added-value research-based products that may be developed in emerging markets (See UNCTAD, Investment and technology policies for competitiveness: review of successful country experiences, 2003). Hence, we see that the same thing (a controlled-release formulation patent) is regarded as yet another kit in the devil's tool-box or as an example to the world of the angel's R&D achievements, depending on whether one uses EGA's or UNCTAD's perspective. For the final version of the Report to give an objective account of facts, it would be advisable to take everybody's views on board, and not only those of EGA.

2.12 Dependent patents

64. The Report points out in paragraph 986 that "the sector inquiry identified a total of more than 1,100 instances, across the 27 EU Member States, where patents of one originator company may be infringed by the INNs, R&D programmes and/or patents of another originator company."
65. So what? So-called "dependent" patents, which protect inventions that one may not use without obtaining a licence over a prior patent that otherwise would be infringed are as old as the patent system.¹³
66. Reporting that many R&D programmes converge is stating the obvious, since the natural objective of all pharmaceutical companies is to try to devise solutions (i.e. inventions) for problems (i.e. diseases) which have not yet been solved or for which more satisfactory solutions are needed. There are of course interferences, which in the vast majority of cases the companies solve in good faith applying the solution required by the aforementioned laws: a licence.¹⁴
67. In relation to the fact that "in more than one third of these cases, initial indications are that an originator company entered into litigation against another competing originator company over patents which did not in fact protect any of its activity in the market" (paragraph 1031), it should be noted that the patent laws that the Commission has not

¹³ See Patent Act of Venice of 19 March 1474 or, more recently, article 56 of the Spanish Patent Act.

¹⁴ See paragraph 996, noting that "out of the 99 reported cases of licence requests mentioned above, in 77 cases a licence was granted, and in four cases discussions were still ongoing."

examined have suitable mechanisms to sanction these practices.¹⁵

III. COMMENTS RELATING SPECIFICALLY TO SPAIN

68. In this second part we shall specifically address some facts that have a particular relationship with the Spanish market. For ease of reference, our comments shall follow the order of these facts as they appear in the Report.

Timing of entry in Spain (paragraph 167)

69. The Report notes in paragraph 167 that the average time for entry in Spain (among other Member States) exceeds half a year. This is the natural consequence of the fact that, as explained in Section 2.2 above, using a product covered by a patent before patent expiry was illegal prior to the introduction of the "Bolar provision".

70. The Court of Appeal of Barcelona (Section 15), the only Spanish Court specialising in intellectual property matters since 1993, confirmed this in its Judgments of 26 September 2002, 13 December of 2004 and 4 January of 2006.

Supplementary Protection Certificates (paragraph 245)

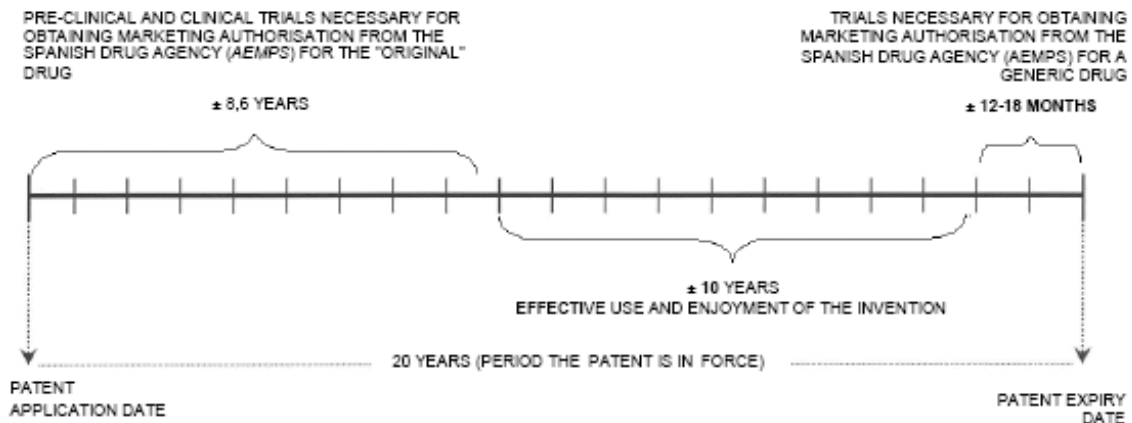
71. Unlike in most other European jurisdictions and, in particular, all other large pharmaceutical markets, where Supplementary Protection Certificates ("SPC") became available on 2 January 1993, SPCs were not introduced into Spain until 2 January 1998. Due to the size of the Spanish market (it is the EC's fourth largest market), this fact has significantly harmed the originator companies' ability to amortise their inventions in the EC.¹⁶

72. This has had dramatically unfair consequences, since only a handful of the products that are currently on the market are protected by SPC. For example, a Spanish innovator company protected its key invention with a patent that, for the aforementioned reasons, could not obtain a SPC. In contrast, when that company tried to enforce that patent against generic companies which had imported the product before the Bolar provision was introduced, the Courts rejected the claim on the grounds that such importations were covered by the so-called "experimental use exception." Therefore, as the following drawing illustrates, many companies have not been able to enjoy the supplementary protection¹⁷ sought by the Commission when it crafted Regulation 1768/92, and was not was able to enjoy the natural "windfall" extension defended by the Commission (DG TRADE) together with all Member States before the WTO's DSB either:

¹⁵ For example, in Spain, a patentee that is not making use of a patented invention is not entitled to apply for a preliminary injunction (Article 133 of the Spanish Patent Act). Also, any third party is entitled to obtain a "compulsory" licence (Article 86). In addition, when patent infringement is established, the patentee is only entitled to a notional royalty (Article 66). In practice, this has the same effect as a "compulsory" licence.

¹⁶ As the Report notes in paragraph 121, originator companies lose an average of 8.6 years from patent application filing to product launch.

¹⁷ The purpose of the "supplementary protection" is to compensate originator companies part of the time lost completing the tests and requirements necessary to obtain marketing approval.



73. It is worth remembering that Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a Supplementary Protection Certificate for Medicinal Products¹⁸ estimated the period of "adequate effective protection" to be 15 years.¹⁹ In conclusion, for the final version of the Report to give a fair account of the legal factors that have constrained the activities of originator companies during 2000-2007, it should mention that during 2000-2007 in the 4th largest EC market, originator companies have enjoyed only 2/3 of the "adequate effective protection" sought by Council Regulation (EEC) No 1768/92.

Data protection (paragraph 265, footnote 163)

74. According to Circular 3/1997 from the General Directorate on Pharmacy, the data exclusivity period vis-à-vis applications filed by generic companies is ten years.
75. However, the regulatory framework is not crystal clear. This legal uncertainty is another of the factors which have curtailed the originator companies' ability to amortise their R&D investments.

Number of "disputes" in Spain (paragraph 439)

76. In paragraph 439 the Report makes reference to 133 disputes in Spain. As mentioned in paragraph 51 above, the figure does not correspond to "disputes" but to "consultations."
77. To help the Commission clarify that such consultations, far from being part of the originator companies' "tool-box", are required by Law, as mentioned in Section 2.2 above it would be advisable for the Commission to make a careful review of the patent laws of each and every Member State. In the case of Spain, we would draw the Commission's attention to Article 64 of Law 11/1986, of 20 March, on Patents (the "Patent Act"):

¹⁸ O.J. L 182, 2 July 1992, p. 1.

¹⁹ See 8th Recital of Council Regulation (EEC) No 1768/92.

- " 1. Whosoever, without the consent of the patent holder, manufactures or imports objects protected by it or uses the process patented shall be obliged in any case to answer for loss and damage caused.
2. All those performing any other act of exploitation of the object protected by the patent shall only be obliged to indemnify for loss and damage caused if they have been warned by the holder of the patent, suitably identified, of its existence, and of its infringement, with the request that they cease in the same, or if guilt or negligence were involved in their acts."
78. Since many generic companies market generics manufactured and / or imported by other companies, in most cases originator companies are obliged to hold such consultations.
79. The same applies to wholesalers. In paragraph 798 the Commission notes that "Germany, the Netherlands and Spain are especially prone to approaches by originator companies to wholesalers to draw their attention to their patents. Most of the approaches reported were made in the form of warning letters sent by originator companies or their legal advisers." Since wholesalers neither manufacture medicaments nor import them, the patentee would only be able to claim damages against them if a warning letter were sent. This is a legal requirement that should be mentioned in the final version of the Report to prevent the uninformed reader from considering that companies send warning letters just for the sake of sending them.
80. Likewise, under article 127 of the Patent Act, before filing a declaratory non-infringement action, the complainant has the obligation to hold consultations with the patentee.
81. Thus, the fact that 133 consultations have been held during the period covered by the Report simply shows that both originator companies and generic companies have complied with these legal requirements. To avoid confusion, this is another important point that should be clarified in the final version of the Report.

Number of litigation "cases" in Spain (paragraph 473)

82. The Report notes in paragraphs 473 and 474 that Spain is the country with the third highest number of cases (70), after Germany and the United Kingdom. This is what one could expect, taking into account that Spain is the fourth largest market examined.
83. In addition, the high number of cases in Spain is due to two additional factors:
84. First, the fact that "product" claims were not accepted until 7 October 1992 caused most patents enforced during the period covered by the Report to have "process" claims only. It is widely known that in disputes around "process" claim patents there are many more grey areas than in disputes around "product" claims. It is from grey areas where litigation normally arises.

85. Second, the traditional prudence of Spanish Courts with regard to damages has made it very difficult for originator companies to obtain any significant damage award. This has prompted generic companies to take risks in Spain that would not have been taken in jurisdictions where it is easier to obtain damage awards. It is expected that the implementation of Directive 2004/48, crafted by the Commission to dissuade infringers, will put Spain on an equal footing with regard to damages to other large markets such as the United Kingdom and Germany.

Contacts with Marketing Authorisation (paragraph 713) and Pricing and Reimbursement Bodies (paragraph 753)

86. The number of contacts with Market Authorisation (34) and Price and Reimbursement Bodies (17) reported, respectively, in paragraphs 713 and 753, must be read in the context of the difficulties faced by originator companies to obtain a preliminary injunction before the generic is ready for launch.
87. In the case of patent protected products, originator companies have a legitimate interest in obtaining a preliminary injunction before the generic is launch. Otherwise, the mechanics of the price reference system would definitively jeopardise the patentee's ability to amortise its invention, even if it prevails in the main proceedings.
88. Due to the difficulty in obtaining preliminary injunctions in the three countries mentioned in paragraph 713 (the Netherlands, Spain and Portugal), it is not surprising that patentees use all available means to try to protect their ability to amortise their R&D investments.
89. It is also not surprising that in Portugal alone there are more than 50 Court cases (paragraph 725) bearing in mind that, as the Report notes, during 2000-2007 the Portuguese Courts did not order even one preliminary injunction. The Report's implied suggestion in the sense that companies confronted with the impossibility of obtaining preliminary injunctions should simply give away their most important company assets (i.e. patents and the ability to amortise them) is difficult to reconcile with the goals announced in the Recitals of Directive 2004/48 and Regulation 1768/92.
90. In any event, as the Report notes in paragraph 743 "the data gathered does not establish causality between the interventions and the fact of obtaining the marketing authorisation at a later date than expected."

Information campaigns (paragraphs 792-794)

91. No doubt, one of the most unfortunate parts of the Report is the paragraphs dealing with the advertising campaign carried out by Farmaindustria® to stress the importance of trademarks in the pharmaceutical sector.
92. The advertisement is mentioned in the context of the "information campaigns" that the Report portrays as yet another of the kits that the investigation has found in the "tool-

box" used by originator companies and their associations to deliberately delay the entry of generics.

93. As will be shown below, the statements made in the Report in relation to this campaign are based on an error of fact and an error of law.
94. The error of fact is to assume that only the products marketed by originator companies bear commercial trademarks and that, therefore, the campaign only covered such products. This is factually wrong.
95. The confusion may have been caused by the fact that original products are often called "branded products", in contrast to generics, which are often called "me-too products." However, the reality is that in Spain both products marketed by originator companies and products marketed by generic companies may bear trademarks. As a consequence, the effect of Farmaindustria®'s campaign cannot be to convey the message that "generic products are not of good pharmaceutical quality and are less effective" (paragraph 792).
96. The purpose of the campaign was to highlight that trademarks are as important in the pharmaceutical sector as in any other industry sector, if not more. In particular, the campaign was prompted by article 85 of Law 29/2006, of 26 July, colloquially known as the "new Medicines Law", which establishes that when a doctor simply prescribes an active ingredient, the pharmacist shall give the medicament with the lowest price and, if the prices are equal, the generic. This is clear discrimination that we would like to draw to the Commission's attention too, since it distorts the fairness and equality of the playing field in the pharmaceutical sector in Spain.
97. The practical effect of this provision was to deprive an entire industrial sector (the pharmaceutical sector) of the valuable functions of trademarks. Farmaindustria®'s campaign is totally in tune with the tireless efforts deployed by the EC institutions to enhance and protect the invaluable functions of trademarks in all industry sectors.²⁰
98. Doctors, pharmacists and patients have the right to know, for example, if the origin of the product is a company with an irreproachable regulatory track record or a company that has encountered difficulties with regulatory authorities.²¹ Longstanding compliance with stringent regulatory requirements forms part of the goodwill that a trademark seeks to protect. Without trademarks, pharmaceutical companies would have no incentive to streamline their manufacturing practices to the benefit of patients.
99. It is ironic that the Commission has perceived this advertising campaign as an attack against generic products bearing in mind that one of the pharmaceutical companies that may suffer most from article 85 of the new Medicines Law is the company that

²⁰ Most notably, Council Directive 89/104/EEC of 21 December 1988, Council Regulation (EC) No 40/94, of 20 December 1993, and Directive 2004/48.

²¹ For example, in September 2008 the U.S. Federal Drug Administration ("FDA") banned the importation of 30 generic medicaments manufactured by Ranbaxy Laboratories.

over the period covered by the Report has supplied the medicament that the Report identifies as the top selling generic in paragraph 76.

100. The error of law is to suggest that there might be something wrong with this campaign, when the campaign is irreproachable from a legal point of view. If there is anything wrong, the Report should explicitly mention what this is. And if there is not anything wrong, then the campaign should be eliminated from the Report altogether.
101. If, as announced in the Introduction of the Report (page 5), it "does not seek to identify wrongdoing [...]," we trust that the Commission will eliminate this advertising campaign from the final version of the Report. The inclusion of the campaign in a document meant to report the alleged "delaying tactics" of originator companies would be clearly denigratory and it would implicitly convey a message that the Report fails to substantiate.

IV. CONCLUSIONS

102. Although the goal of the Report was not to identify wrongdoing or to reach any conclusion as to whether the practices described infringe EC competition law, but to provide the Commission with a factual basis for deciding whether further action is needed, the news published by the media after the Press Conference held on 28 November 2008 proves that a lot needs to be done to help the Commission achieve that goal.
103. Farmaindustria® would be grateful if the Commission would kindly consider the comments offered in this document within such context. The purpose of our comments is not to express our disagreement with points of the Report which may be subject to different interpretations but to provide additional data that may help the Commission get the factual basis right.
104. As explained above, if the final version of the Report were to consider thoroughly the patent protection regime of all Member States and take into account the fact that until the "Bolar Provision" was implemented (31 October 2005), so-called preparatory acts were contrary to patent law, the suggestion that the entry of generics seven months after patent expiry may be due to hypothetical delaying tactics devised by originator companies would fade away. Such a suggestion is at odds with the positions defended by the Commission itself (DG TRADE) in important international fora such as the WTO.
105. Also, a closer look at the patent protection regime of each Member State would show that in many cases, what the Report presents as yet another kit in the originators' "tool-box" aimed at delaying the entry of generics are actions that are mandated by law (such as sending warning letters to companies which conduct acts other than manufacturing or importing a patented product). In this regard, it would be desirable for the final version of the Report to clarify the confusion between "dispute" and "consultations". For the reasons explained above, from a technical perspective one may not state that the purpose of sending a warning letter is to prompt a dispute.

Warning letters are aimed at holding consultations which, in many instances, help the parties determine whether or not there is a dispute and delimit the boundaries of the dispute, as the case may be.

106. In addition, for the final version of the Report to give a more objective account of the legal factors that have constrained the activities of originator companies during 2000-2007, it would help to mention that during 2000-2007 in the 4th largest EC market (i.e. Spain), originator companies have enjoyed only 2/3 of the "adequate effective protection" sought by Council Regulation (EEC) No 1768/92.
107. In conclusion, the additional data shed in these comments plus the data obtained in the course of the further analysis suggested in this document would most likely indicate that the alleged "delaying tactics" reported are, in some instances, the natural result of patent protection regimes (lack of "Bolar provision" until 31 October 2005, mandatory warning letters, etc.) and, in other instances, legitimate practices that are common to all high technology industries on which the EC relies for R&D, employment and innovation.

31 January 2009

Farmaindustria®