

Bundesverband der
Pharmazeutischen
Industrie e.V.

BPI

Leben ist Vielfalt

Rue du Commerce 31
1000 Brussels
Belgium
www.bpi.de

Telephone: +32 2 5 00 89 61
Telefax: +32 2 5 00 89 68
Email: anatz@bpi.de

Date: 30.01.2009

The Pharmaceutical Sector Inquiry of the European Commission

- Preliminary Report -

Comments of the German Pharmaceutical Industry Association

I. Introduction

1. With over 50 years of experience in drug research, development, authorisation, manufacture and marketing, *Bundesverband der Pharmazeutischen Industrie e. V.* (BPI – German Pharmaceutical Industry Association) covers the wide range of pharmaceutical industry activities at national and international levels. The membership of BPI includes over 260 enterprises with some 72,000 staff: Classic pharmaceutical companies, businesses from biotechnology, phytopharmacy and homeopathy/ anthroposophy as well as pharma service providers. BPI represents both innovative pharma- and biotech-companies and companies with a small generic product portfolio. The diversified structure of BPI is also reflected by the fact that multinational companies as well as small and medium-sized enterprises are members of the association. The pharmaceutical industry employs some 643.000 staff in the 27 EU-Member States. BPI therefore represents more than 11% of staff working in the pharmaceutical industry in the European Union.

2. BPI welcomes the opportunity to contribute to the examination of competition and innovation in the pharmaceutical sector, a crucial sector to the health and welfare of European citizens and a leading player in Europe's innovative economy. The pharmaceutical industry also plays an important role in order to achieve the goals set by the Lisbon Agenda¹. The role of pharmaceutical companies especially in terms of research and development of innovative pharmaceuticals and for cost-savings for social security systems therefore deserves special consideration.
3. BPI appreciates the Commission's work to put together the preliminary report and welcomes the opportunity to comment on the report. However, BPI especially would like to point to some regulatory factors that inhibit the creation of a proper competition structure, which we feel could have deserved more consideration in the preliminary report. We welcome the fact that regulatory aspects of the pharmaceutical market are described in detail and that the contributions of stakeholders are displayed in the report. Nevertheless, we regret that the Commission does not draw broader conclusions on regulatory aspects for this important issue at this stage and we hope that those will be included in the final report.
4. BPI would like to highlight that it is primarily due to the fact that the "easy" targets for drugs are already exploited to a great extent. The scientific progress makes drugs more potent and specific, side effects can be studied in more detail and the R&D process is becoming more and more complex. Due to these reasons less new chemical entities (NCEs) reach the market.
5. Secondly it is due to regulatory hurdles that less NCEs have reached the market in the last years. It has to be pointed out that an analysis of competition and the impact on healthcare budgets is impossible without considering the impact of EU and EU Member State regulation. The Commission only looks at how the industry allegedly uses these rules to

¹ "The European Council on 21 March 2003 concluded: At Lisbon three years ago the EU set itself the strategic goal of building the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and greater social cohesion. The European pharmaceutical industry can make a major contribution to this goal."; "The sector's positive contribution to the trade balance in the European Union, the provision of highly skilled jobs, its contribution to public health and development of new environmentally friendly technologies will play a large role in meeting the Lisbon challenge of sustainable development.", European Commission: Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions - A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action, COM (2003)383 final, 1.7.2003, p. 4, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2668:FIN:DE:PDF>.

undermine competition, but not at how these rules undermine competition themselves². Especially the lack of effectiveness in marketing authorisation procedures, the lack of reward on innovation for incremental research and the specific structure of the pharmaceutical market with its inherent price regulations are responsible for the identified problems.

II. General remarks on the preliminary report and innovation

6. BPI wants to underline the general consensus that pharmaceutical innovation is wanted and indeed much needed to improve the possibilities to treat many diseases, which so far cannot be cured or treated adequately. The complexity of biological systems such as the human organism is huge and therefore it is – despite of enormous scientific advances in recent years – still extremely difficult to predict the efficacy and safety of drug candidates, many of which fail during the development process of new pharmaceuticals. This fact is behind the very long development process of new drugs and creates enormous financial risks for pharmaceutical companies who embark on discovering and developing new drugs. BPI therefore stresses the fact, that there is only one incentive that keeps pharmaceutical R&D alive in Europe: the financial rewards of new drugs on the market, which are protected by strong patents. To keep this incentive strong is of utmost importance for society as a whole, for patients, for pharmaceutical companies active in R&D and for generics companies as well, who are dependent on a steady stream of drugs, coming off patent.
7. Given these facts BPI wants to put some of the preliminary findings of the sector inquiry into perspective. The report states that in an ideal world with instant market access of generic drugs directly after patent expiry an additional amount of EUR 3.0 billion could have been saved during the eight year period between 2000 and 2007, corresponding to yearly savings of EUR 375 million. The report states further that the drug market in the EU has a yearly volume of approximately EUR 138 billion on the manufacturing level and EUR 214 billion at the pharmacy level. Potential savings of EUR 375 million per year correspond to

² European Commission, DG Competition: *Pharmaceutical Sector Inquiry – Preliminary Report*, 28 November, para. 206.; the report states: “The rules governing these areas set the framework in which the companies operate. They therefore determine the conditions for competition.”

0.27% on the manufacturing and 0.175% on the pharmacy level. On a per capita level this corresponds to potential savings of 75 ct per year or 6.25 ct per month. In some Member States it can be problematic – even when stringent measures are implemented – to reach immediate market access after patent expiry, given the complex regulatory hurdles which ensure efficacy, safety and quality on the one hand and price regulation procedures on the other³. Thus, achievable savings might be considerably smaller as stated above because the assumption that immediate market access in all Member States at the same time is not realistic.

8. In this respect, the Commission might want to take a closer look to the fact that especially in smaller Member States (such as Greece and Luxemburg) market access for generics is delayed while it is relatively fast in several larger Member States (such as UK and Germany)⁴. In addition to the different market entry levels among Member States, this fact shows that the regulatory circumstances prevent immediate market access and not the “toolbox” measures by companies. If the “toolbox” were the sole cause or even the major cause of delayed generic entry, then we would expect the delays to be the same in all Member States.
9. BPI therefore underlines the need of a balanced approach: to keep strong incentives for pharmaceutical R&D in place to help patients and in the long run the generics industry itself is much more important than the realization of relatively small savings compared to the total pharmaceutical market. Collateral damage to the innovation system and innovation incentives must be avoided under all circumstances as the primary aim of any action implemented by the European Union as a result of the sector inquiry.
10. Special attention should therefore be placed on implementing strong incentives for incremental research. The risks of stepwise innovations can be much better calculated and in many cases a long chain of step innovations is responsible for huge advances in therapeutic options. Incremental research should therefore be rewarded, even if those stepwise improvements of known substances or already available medicinal products cannot be effectively protected by the current patenting systems. Such innovations – which

³ The differences between Member States are shown in figure 14 of the *Preliminary Report*. However, the fact that in some Member States under immediate market access is possible is shown by the example of the active substance simvastatin below.

⁴ European Commission, DG Competition: *Pharmaceutical Sector Inquiry – Preliminary Report*, 28 November, para. 167.

are especially a domain of medium-sized enterprises – could be supported by a Community patent if it decreases the costs of patenting and provides for EU-wide and effective market exclusivity. However, additional need for better regulatory data protection in cases of incremental research is evident.

11. As was rightly pointed out by the Commission, the three main sources of regulation are patent, marketing authorisation and pricing and reimbursement rules. BPI stresses that these rules are mainly responsible for the time that elapses before a product actually enters the market. This holds true both for generic products, as well as for innovative pharmaceuticals. In many member states market access is for example delayed by extensive price-regulation procedures which prevent an imminent market access.

III. Regulatory hurdles in the patent system

A- The lack of a unified Community patent as a source of uncertainty and delays

12. Research activity is closely linked to the given market and legal environment. That includes many a factor from a variety of areas such as the industry sector, funding, the opportunities for partnership, the level of education and therefore the recruitment of specialists. However, a key factor for innovation is the legal framework. In order to motivate companies to allocate their resources to a certain region, country or association of states, there have to be reliable mechanisms in place to ensure an appropriate use and protection of an innovation.
13. The strength of patents should be enhanced and not reduced. Given the efforts of the European Union to further the role of intellectual property protection in international trade, each signal emitted by the EU is registered with high interest by its trading partners. If the EU conveys the impression of challenging the current legal instruments which protect intellectual property rights, instead of improving the current system by achieving the completion of the Community patent and a unified judiciary, this could be interpreted as an inconsistent signal. This holds true especially in those areas where an improvement of the standards of intellectual property rights protection would be in the very interest of the EU.

14. For the pharmaceutical industry, the lack of a Community patent constitutes an obstacle. Indeed, it forces a pharmaceutical company – if it wants to patent and thus protect its product – to patent the product either in the national context or via the European Patent Office (EPO). This means that if a company wants to protect its medicine in all 27 Member States, it might have to patent it at least 27 times using the national way. If it uses the procedure via the EPO, this “European patent” will become a bundle of national patents after the national validation procedure. The consequences of this system are considerable. In case that a number of four patents would be sufficient to protect a product, the total number of patents may well exceed 100 due to the necessity of undergoing 27 patenting procedures. This fact has to be taken into account when examining the so-called phenomenon of “patent-clusters”. But most importantly, this regime creates legal uncertainties for originator and generic companies.
15. The development of a medicine with a new active ingredient can last over a decade and involves considerable costs and risks regarding the success of the development. The complexity of the legal system could discourage certain pharmaceutical companies, especially SMEs, to invest in new research projects. Indeed, the current legal situation is unsustainable because of its lack of clarity: due to the complexity of the patenting system pharmaceutical companies cannot operate without having to refer to expensive legal advice and litigation costs. If the system does not entirely prevent a company from launching a new product, it might still prevent it from distributing it in all Member States. As a consequence, access to medicines for patients differs throughout the EU Member States. Thus, differences in the national patent approval and litigation systems - and not the usage of a so-called “toolbox” - are the main reason for the discrepancies in market access for generics among Member States as shown in figure 14 of the preliminary report⁵.
16. When pharmaceutical companies use the opposition procedure at the EPO – a legal instrument at their disposition to protect their patent or to obtain legal clarity –, they have to wait far too long to obtain clarity. It is not the fact that companies use a legal instrument that they have at their disposition that delays the entry of competitors on the market. It is rather the EPO that does not propose a solution in an adequate space of time. The accusation that companies prolong the opposition procedure lacks any evidence. Apart from

⁵ European Commission, DG Competition: *Pharmaceutical Sector Inquiry – Preliminary Report*, 28 November, para. 167.

unconfirmed allegations no other proof is delivered⁶. Without wanting to accuse anyone of anything, the question arises, much rather, if the slow resolution of opposition procedures is not correlated with the administrative procedures within EPO given the fact that the time EPO needs to grant a patent is also considerable⁷.

17. BPI wants to emphasise that it is not any alleged misuse of legal rights but rather the regulatory framework in the domain of patents, which provides uncertainty and therefore causes delays.

B- The lack of a unified judiciary is postponing the market entry

18. The lack of a Community patent and the resulting fragmentation of the European patenting system has also consequences for the judiciary system which should enforce the rights granted by a patent. Different courts could take different views on the same European patent, resulting in contradicting judgements concerning the scope of validity. Even worse, it is possible that the conclusions drawn by the EPO following an opposition or appeal procedure are different from the conclusions of the national courts. Of course, these elements lead to legal uncertainty, with all the negative effects we have described above. The high costs which are generated by this system are affecting both originators and generic companies.
19. Sometimes, national courts even wait for the ruling of the EPO before taking a decision themselves⁸. This example shows best how considerably the fragmentation of the judiciary delays the entry of medicinal products on the market. Again this also supports our claim that it is the regulatory framework and not the questionable concept of misuse of legal possibilities that is responsible for delays in market entry.
20. BPI supports the creation of a unified judiciary in case the appropriate quality is assured. In our eyes it seems important that the panels of such a court are composed of both legally qualified judges and technically qualified judges with qualifications and experience in the

⁶ European Commission, DG Competition: *Pharmaceutical Sector Inquiry – Preliminary Report*, 28 November, para. 555.

⁷ See in this respect: European Commission, DG Competition: *Pharmaceutical Sector Inquiry – Preliminary Report*, 28 November, para. 227.

⁸ European Commission, DG Competition: *Pharmaceutical Sector Inquiry – Preliminary Report*, 28 November, para. 1090.

field of technology concerned. Indeed, in such a specialised sector as the pharmaceutical sector, it is of highest importance that the judgements are passed by judges who are not only experts in patent law, but who also possess in-depth knowledge about the pharmaceutical sector so as to accelerate the procedures.

IV. Regulatory data protection / exclusivity: imbalance for incremental innovations for established substances

21. Examples for incremental pharmaceutical innovations are manifold. Incremental innovations that should qualify for additional data protection are: new indication of established substances, improved safety, lower dosage and toxicity, fewer side effects, patient regimen compliance/convenience/benefits, tailor-made solutions, i.e. for children and the elderly, device linked dosage forms. Such sequential improvements contribute to an increased efficacy, including safety or/and stability, and also, often lead to better cost benefit ratios.
22. Regulatory data protection had been implemented in Member States before the decision of ECJ (Generics, case C-368/96 from December 3, 1998) for e.g. new indications, new dosages or new delivery systems irrespective whether the additional data was delivered for new or well-known active ingredients. Therefore experiences to implement this approach are available.
23. Negative implications without regulatory data protection: Without regulatory data protection companies are reluctant to invest in this research. Patients are deprived of properly studied new indications of established products. The result is an increased off label use of established medicinal products on basis of insufficiently substantiated clinical data.
24. Necessity for research in established products: Clinical statements concerning efficacy, which are not scientifically substantiated, cannot be accepted as valid evidence under directive 2001/83/EC. Therefore all new indications have to be substantiated with appropriate clinical trials. For instance for a new indication for a cancer medicinal product with the indication "breast cancer" new data resulting from appropriate clinical trials is needed to apply for the indication „uterine cancer“. In order to encourage pharmaceutical

companies to conduct these clinical trial to generate the potential of existing APIs for the benefit of the patient the appropriate regulatory incentives have to be set.

25. The potential of incremental research becomes evident when considering the following examples for new indications or new delivery systems already authorized:

Active ingredient	Established indications / delivery systems	New indications / new delivery system
Azelastin	Oral antihistaminic product	For application on the eye
Azithromycin	Antibiotic against infections of the upper respiratory tract	Prophylactic against infections of mycobacterium avium-intracellulare for HIV patients
Bisoprolol	Beta-blocking agent	Chronic cardiac insufficiency
Doxorubicin	Cytostatic	AIDS-related Kaposi's sarcoma
Flupirtin	Oral analgesic	For parental application
Lamivudin	Antiretroviral HIV-therapy	Chronic hepatitis B
Lansoprazol	Gastric ulcer	For combination in the eradication therapy of helicobacter pylori
Metronidazol	Oral antibiotic	For dermal application against rosacea

26. The US regulatory system already grants a three years exclusivity for significant changes in already approved medicinal products, such as a new use ("other significant changes" exclusivity). This period of exclusivity is granted for a medicinal product that contains an active moiety that has been previously approved, when the application contains reports of new clinical investigations (other than bioavailability studies). This is the case for example, for new indications, strength, dosage form, route of administration or other conditions of use. The respective US regulations in this case grant exclusivity if clinical investigations were essential for the approval of the application containing those changes. At the moment the EU system only allows one year protection, which is too short to grant an appropriate return on investment.
27. SMEs often depend on research and development of established products e.g. new indications, new doses or new delivery systems lacking patent protection. Indeed, SMEs are very often not in the financial situation to develop NCEs. An appropriate legal framework is therefore essential also to promote R&D activities for SMEs.
28. The orphan drug Regulation EC/141/2000 can be seen as a positive example. The regulatory measures in terms of 10 new years of data protection under 8 of the regulation have proven to be very efficient. The positive results of protection of new data for established active ingredients could serve as an example for incremental research which effectively encourages R&D by setting an appropriate framework. Since 2000, when the regulation came into force 50 orphan medicinal products have been approved. Part of the framework conditions are the possibilities to get a return on investment. The costs for clinical studies are the same, irrespectively whether the clinical trial is performed with a new or an already established active ingredient. Therefore a balanced system is needed which supports R&D in both: established and new products.

V. Regulatory obstacles in marketing authorisation procedures

29. In the European Union, different types of marketing authorisations exist: the national procedure, which subdivides into the mutual recognition procedure (MRP), the decentralised procedure (DCP) and purely national procedures, as well as the Community

- authorisation (Centralised Procedure - CP). Their common feature is that all these procedures take a considerable amount of time. In order to identify the specific characteristics they have to be examined individually.
30. According to EMEA, there is no decrease in the number of applications for marketing authorisation via the centralised procedure between 2000 and 2007. On the contrary, the number of applications and authorisations by EMEA is even growing as well as in certain Member States⁹. The question arises why fewer medicines are reaching the market even though there are more applications and grants of marketing authorisations via the centralised procedure in 2007 than in 2000. This can be a result of the changes in the Pharmaceutical legislation, which defines a mandatory use of the CP for several new product groups. In addition the CP is increasingly used by other companies, because the national procedures take too much time.
31. BPI wants to point out the aspect of time and duration with regards to the national marketing authorisation procedures, be it MRP, DCP or purely national. It seems that the national authorities do not have sufficient resources to meet the demands. Taking into account that the majority of national procedures take place in only four Member States, this situation does not come as a surprise. This of course creates an enormous backlog for the agencies in these Member States.
32. Therefore, these agencies are often “fully booked” several months in advance. As the preliminary report states, some of these agencies that were acting as Reference Member States in the DCP were not able to attribute a slot time for 2008 and 2009 by mid-2008¹⁰. When there is no slot system, the queue of applications can reach 725 requests.
33. As generic companies are the main users of the DCP, it is obvious that the market entry of these products is delayed. Such a situation is no longer tolerable. Of course, BPI supports the fact that innovation shall be rewarded by exclusive rights for patent holders. But BPI also supports the fact that once the patent duration has expired generic companies can enter the market without undue delays in order to create real competition. BPI therefore encourages the Member States to correspond to this situation by raising the number of their

⁹ European Commission, DG Competition: *Pharmaceutical Sector Inquiry – Preliminary Report*, 28 November, para. 252.

¹⁰ European Commission, DG Competition: *Pharmaceutical Sector Inquiry – Preliminary Report*, 28 November, para. 1125.

staff in their marketing authorisation agencies and/or to take measures to increase the efficiency of the authorisation process.

34. As to answer the question of why there is an increased number of applications for marketing authorisations but a decreased number of NCE in the market, in addition to the facts pointed to in number 4, we refer to the Commission's report. It states that "[...] the number of [marketing] authorisations granted increased (trend) over the period in some Member States as well as before EMEA [...]"¹¹. Put differently, the number of grants of marketing authorisations by EMEA, Germany and the Netherlands increased over the period 2000-2007. It did not decrease in Denmark or the United Kingdom¹². These are the four Member States in which the majority of DCPs are processed. This means that, although the number of marketing authorisations increased, much more medicinal products could have reached the market if especially the national agencies would have worked faster. A "decline in innovation measured by the number of novel medicines reaching the market, and instances of delayed market entry for generic medicines, as compared to what might be expected" can thus be explained by the regulatory framework or rather the lack of administrative efficiency.
35. For these reasons, BPI welcomes the Commission's announcement, that "the functioning of the network of EU medicines authorities requires re-thinking to improve its efficiency, minimise the regulatory burden it generates and thus speed up market access for medicines."¹³ This fact should also be a result of the sector inquiry.

VI. Regulatory obstacles by national pricing and reimbursement measures

36. Contrary to other markets, the market for pharmaceuticals is characterised by regulation on two levels: 1. on the marketing authorization level to guarantee quality, safety and efficacy and 2. on the reimbursement and pricing level to ensure adequate prices for social security

¹¹ European Commission, DG Competition: *Pharmaceutical Sector Inquiry – Preliminary Report*, 28 November, para. 252.

¹² European Commission, DG Competition: *Pharmaceutical Sector Inquiry – Preliminary Report*, 28 November, footnotes 139 and 140.

¹³ European Commission: *Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector*, 10 December 2008, COM(2008) 666 final, p. 5.

systems. The latter fact makes it hard to compare it to any other market. Public authority decisions on pricing and reimbursement therefore have to be taken into account when assessing competition in the industry.

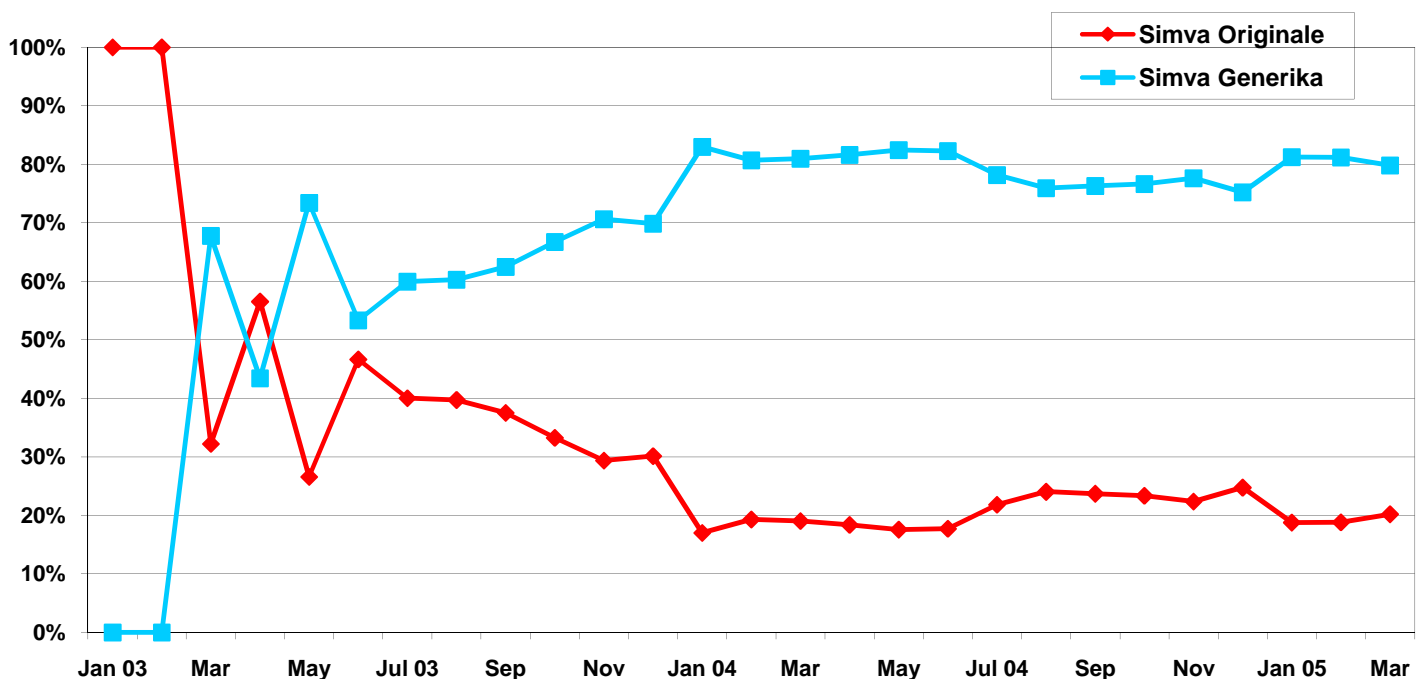
37. The report only briefly addresses the impact of national pricing and reimbursement on the launch of new NCEs. Member States are increasingly reluctant to fund the cost of developing new medicines if they feel that the benefits of these new medicines, when compared to existing medicines in the same class, are insufficient or when their budgetary constraints dictate otherwise. National pricing and reimbursement policies therefore have a strong impact on the research priorities of innovative companies and the numbers of new NCEs.
38. Innovative companies increasingly terminate research projects in Phase II and III before incurring the high costs of clinical trials when they feel that Member State buyers or social security systems will be unwilling to pay for such incremental innovation. There is an urgent need that the rules for these decisions by Member States or social security systems are transparent and fair; otherwise promising research projects might have to be terminated just because of the fact that the value of the innovation cannot be calculated adequately for example because social security systems do not reimburse for the medicinal product.
39. The effective application of the transparency directive 89/105/EC would be an important step to guarantee the procedural rights of pharmaceutical companies in national price control and reimbursement decisions. However, further instruments and an effective jurisprudence are necessary to ensure transparency.
40. In addition, the Commission's report fails to evaluate the impact of increased costs of clinical trials. Increased costs of trials may also make certain research projects uneconomic in combination with the impact of pricing and reimbursement and cost containment strategies.

VII. Timeline for generic entry in Germany (Examples: simvastatin and olanzapin)

41. One of the report's key findings is that market entry of generics might be delayed by various practices of pharmaceutical companies. For Germany, we have some difficulties to

see such delay in daily practice. In most cases generic competition for attractive substances already starts well before patent expiry by early entries of generic products on the basis of a license by the originator. In addition, on the very first day after patent expiration usually a multitude of generics become immediately available for sale in pharmacies and are being actively promoted by generic manufacturers and regulatory measures such as aut-idem substitution.

42. An example illustrating this experience is the patent expiration of simvastatin in the beginning of May 2003. As can be seen from attached table, early entries of generic simvastatin had already been launched in March 03, before more than 20 generic simvastatin products became available mid-May right after patent expiration. It is most interesting to see that generic simvastatin already gained market leadership over originator simvastatin before patent expiration, which was expanded with patent expiration and sustained over time. The example of simvastatin shows that generic entry is by any measure extremely fast at least in Germany if attractive active substances are concerned:



43. Another example for the functioning of generic entry in the German market is the active substance olanzapin: Although in late 2008 the Federal Court of Justice (BGH) had issued a landmark decision on the olanzapin patent invalidation proceeding overruling the invalidation of the patent by Federal Patent Court (BPatG), a variety of generic olanzapin products are on the market.

VIII. Conclusion

44. BPI would like to highlight that it is primarily due to regulatory hurdles that less new chemical entities (NCEs) have reached the market in the last years. It has to be pointed out that an analysis of competition and the impact on healthcare budgets is impossible without considering the impact of EU and EU Member State regulation.
45. BPI especially would like to point to the fact, that there is only one incentive that keeps pharmaceutical R&D alive in Europe: the financial rewards of new drugs on the market, which are protected by strong patents.
46. BPI thus underlines the need of a balanced approach: to keep strong incentives for pharmaceutical R&D in place to help patients is much more important than the realization of relatively small savings compared to the total pharmaceutical market. Collateral damage to the innovation system and innovation incentives must be avoided under all circumstances as the primary aim of any action implemented by the European Union as a result of the sector inquiry.
47. Special attention should therefore be placed on implementing strong incentives for incremental research. At the moment the EU system only allows one year protection, which is too short to grant an appropriate return on investment. The US regulatory system already grants a three years exclusivity for significant changes in already approved medicinal products, such as a new use ("other significant changes" exclusivity). The orphan drug Regulation EC/141/2000 can be seen as another positive example.
48. The Commission's criticism of the patenting of improvements to a product late in the original patent term disregards the importance of incremental improvements as a major source of innovation. These improvements provide real benefits to patients especially in

terms of new indications of known APIs, reduced side effects and improved dosage forms. The real benefit of existing APIs is often not discovered in clinical trials but through the broad usage by physicians after their release to market after testing them in numerous cases. It would be contrary to the competition rules' objective - in terms of increasing consumer welfare - to brandmark these innovations in general as "secondary patents" filed for sole commercial purposes.

49. Furthermore, we want to point out the fact that the sector inquiry only concentrates on the alleged blocking tactics of some companies. It does not provide any evidence of causality. The Report does not itself analyze causation, i.e a finding that the so-called "toolbox" caused the delay.
50. The Commission's report also fails to evaluate the impact of increased costs of clinical trials. The increased cost of trials may also make certain research projects uneconomic (in combination with the impact of pricing and reimbursement and cost containment strategies).
51. The strength of patents should be enhanced and not reduced. Given the efforts of the European Union to further the role of intellectual property protection in international trade, each signal emitted by the EU is registered with high interest by its trading partners.
52. BPI welcomes the Commission's announcement, that "the functioning of the network of EU medicines authorities requires re-thinking to improve its efficiency, minimise the regulatory burden it generates and thus speed up market access for medicines¹⁴." This fact should also be a result of the sector inquiry.
53. Another aspect which did not gain enough attention in the preliminary report is the role of SMEs for pharmaceutical innovation. The share of SMEs in the development of innovative pharmaceuticals is recognised only to a minor degree in public perception. It has to be pointed out, though, that the increase in licensing-in is often a consequence of the innovative achievements of small research entities. The European Commission should give special consideration to the question to what extent innovative pharmaceuticals result from inventions of SMEs. Multinational innovative pharmaceutical companies often ensure the

¹⁴ European Commission: *Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector*, 10 December 2008, COM(2008) 666 final, p. 5.

development of new products not only through their own laboratories but increasingly make use of external sources¹⁵. Collaboration in this respect should be increased.

54. BPI wants to emphasise that it is not any alleged misuse of legal rights but rather the regulatory framework in the domain of patents, which provides uncertainty and therefore causes delays. If the “toolbox” were the sole cause or even the major cause of delayed generic entry, then we would expect the delays to be the same in all Member States.

Brussels, 30.01.2009

Prof. Dr. Barbara Sickmüller
Deputy Director General

Dr. Norbert Gerbsch
Deputy Director General

Dr. Alexander Natz
Head of Brussels Office

¹⁵ See: The current Roland Berger study on the state of the global pharmaceutical industry which identifies expiring patents as the major threat to most of the innovative pharmaceutical companies (<http://www.presseportal.de/meldung/1223962>); according to the study, the following options could be used as a way out of this situation: concerning the question of the most efficient possibility to assure future innovation and a renewal of portfolio, there is a clear trend: 41 % of the multinational innovative pharmaceutical companies prefer the external purchase of innovations (in the sense of licensing-in or partnerships), 39 % prefer the acquisition of entire companies, especially in the biotech sector; only 20 % rely on in-house R&D to be the best source of future innovations.