

## European Commission Pharmaceutical Sector Inquiry Preliminary Report

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### Submission to Public Consultation by Pfizer Inc., 30/01/2009

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Pfizer appreciates the opportunity provided by this public consultation to engage with the Commission and the wider public on the condition of the pharmaceuticals market. We are always pleased to discuss how to increase the competitiveness of the pharmaceutical sector to help secure the future supply of new, high quality medicines for European patients, as well as to sustain a healthy industrial and innovative base in Europe.

This consultation is equally welcome as it provides the opportunity to correct several elements of DG Competition's preliminary report that betray a misconception of the complex dynamics of the pharmaceutical sector and the nature of intellectual property rights, and which, were they to be reflected in policy, would inflict significant damage on the competitiveness of the industry in Europe and on the supply of new medicines to European patients.

Pfizer considers the submission made by EFPIA in response to this consultation to provide an excellent detailed analysis of the preliminary report's strengths and weaknesses. We fully support EFPIA's position and do not intend to duplicate their analysis. Our intention is to offer some further insights from a sectoral and societal perspective on the report's analysis and on the potential consequences of policies to which it appears to lend support. We believe that public engagement in this debate is vital in securing a more effective healthcare system in Europe.

Pfizer's comments on the preliminary report derive from four central observations which we intend to treat in order:

- I. The conclusions of the report are not substantiated by the data.
- II. The implications of the report's analysis frequently appear to contradict the stated aim of the inquiry.
- III. The report implicitly portrays as questionable the so-called 'toolbox' of practices which are perfectly lawful.
- IV. Changes to improve the functioning of the pharmaceuticals market need to avoid unbalancing the framework constructed and refined over many years.

#### I. Unsubstantiated conclusions

Pfizer is aware of the vast volume of information DG Competition has attempted to digest in the preparation of this preliminary report. Given the complexity of the sector and in light of the constrained time frame of the inquiry, it is unsurprising that the inquiry's analysis of this information has not always produced the clearest results. Nonetheless the report contains many interesting data and observations which could usefully serve to inform an open debate on how to improve the functioning of the sector. We therefore regret that the report downplays a full and balanced consideration of the data whilst highlighting conclusions which often appear unsubstantiated, unjustified or misleading. We consider this report to contain a number of significant analytical flaws which we would hope to see rectified in the final report:

Ø *The report simplifies or combines the available data to support its conclusions, in a way liable to mislead:* Firstly, the report portrays 'loss of exclusivity' as a clear and objective occurrence. The reality is different. Expiration of relevant patents does not always happen at the same time in different EU Member States, and it is not always evident when an originator is no longer entitled to exclusivity. This is why uncertainties exist which may lead to disagreement between originators and generics. In deriving its financial estimates the report effectively, and without justification, presupposes the question to be resolved in a particular direction – that which favors the generic.

Secondly, the report fails to distinguish between the expiry of a primary patent and the expiry of data exclusivity when calculating the time to generic entry. It is not infrequent in certain EU member states that data exclusivity either expires after the primary patent, or is the principal form of intellectual property protection in the absence of a primary product patent. A fair analysis needs to take account of the impact of this on realistic expectations as to the timing of generic entry. If anti-competitive behaviour is to be alleged, delays to entry should be demonstrably unrelated to the normal functioning of the patent and regulatory system. This confusing and misleading calculation underlies the report's claims as to potential savings to be made from swifter generic entry.

Thirdly, the report quotes the number of patents covering a product based on combined data for the EU-27 although these patents are necessarily duplicative. These figures are used to support allegations about the use of 'patent clusters' to block generic entry when originators seeking intellectual property protection in all EU markets have no choice but to file essentially the same patent in 27 separate jurisdictions. Duplication of patents across separate jurisdictions does not constitute a 'patent cluster'.

- Ø *The report relies on data pertaining to an extended time span to support its case, ignoring the most recent trends in a rapidly evolving market:* The report seems to be fighting yesterday's battles. The use of pooled data from 2000-2007 to derive the headline figures used in the report downplays trends in DG Competition's own data that show an improvement in market access by generics over this period. Again, this gives a misleading impression of the current and likely future status of the market and thus of the potential savings to European health systems of earlier generic entry. Contrary to the report's contention that innovator companies are successfully preventing generic entry, the evidence shows that European health systems are very successfully promoting generic entry and use.
- Ø *The report systematically ignores aspects of the evidence which point away from originator misconduct and towards other explanations:* The likelihood and the speed of generic entry into the market for a treatment is basically dependent on prices and volumes. The evidence presented in the report clearly supports the observation that generic entry occurs faster in more valuable markets than in less valuable ones. The report's failure to address the critical role of commercial factors in determining generic behavior, undermines the accuracy and validity of its conclusions.
- Ø *The report presents information out of context and downplays or omits important qualifications in order to support its argument:* DG Competition has throughout presented the available data so as to maximize the alleged cost of delayed generic entry as well as to discount the significant role that regulatory procedures and other influences extrinsic to the actions of innovators have on the timing of entry. The report makes frequent use of 'headline' figures such as the alleged €3bn potential savings and the case of 1300 patents for one product, whilst downplaying or omitting important qualifications necessary to avoid misinterpretation. The €3bn figure represents an alleged potential saving from immediate generic entry following loss of exclusivity over the eight years under investigation. It is nonetheless presented as a realizable saving for European health systems, although it is clear that immediate generic entry is not achievable in many circumstances, irrespective of the actions of originators. The figure of 1300 patents for one product is equally misleading, as explained above, but is often quoted without further explanation.

The report's selective use of quotations taken out of context is a further instance of this unscientific treatment of evidence.

Taken together these flaws combine to illustrate a weak argument. The report fails to demonstrate either that innovator conduct is primarily responsible for

delays in generic entry, or that innovators have acted unlawfully in seeking to defend their intellectual property.

## II. Contradictions between the report's stated aims and its analysis

While Pfizer does not doubt the sincerity of the Commission's desire to improve patients' access to effective medicines, we are concerned that elements of the report would in practice contradict this aim. For instance:

- Ø *On-patent competition and disparagement of incremental innovation:* At the same time as seeking to ensure competitive on-patent markets, the report criticizes incremental innovation. Incremental innovation – seeking to refine products to improve performance and/or to reduce costs – is not only a right of originator companies but results in more competitive on-patent and off-patent markets. These incremental improvements offer physicians and patients a choice of products (enhancing competition) and over time add up to significant overall improvements in treatment quality. Many chronic diseases (e.g. rheumatoid arthritis) require a broad range of therapeutic options – often the fruits of incremental innovation – to address the evolution of the disease in the long term. Frequently, moreover, significant numbers of patients do not respond to a particular treatment: their only hope of being successfully treated lies in alternative similar treatments in the same therapeutic class.

Incremental innovation has not been shown to impair generic entry to the market for the off-patent original – indeed the certainty of this entry, for the most valuable products, provides an additional incentive for originators to invest in improving their products.

- Ø *Maintaining that originators are stifling innovation while attacking Intellectual Property rights:* The report's analysis does not always support its acknowledgement that effective intellectual property protection is essential to innovation. Investments in pharmaceutical R&D are very costly and carry significant risk, with high rates of attrition during the development process – they are only undertaken if the present value of investment is estimated to exceed the significant potential downside. Any threat to the attainability or enforceability of intellectual property rights diminishes the present value of any future investments. The risk of early loss of exclusivity and any uncertainty in the legal framework are priced into investment decisions, effectively reducing the value and thus the effectiveness of a patent as a stimulus to innovation.
- Ø *On-patent competition and 'defensive' patenting:* DG Competition wishes to see healthy competition between patented medicines. Not only do the

data presented in the report not support the conclusion that competition between patented medicines is currently impaired, but interpreting some instances of patenting as 'defensive' and therefore anti-competitive would attack an intrinsic element of competition. Companies conducting research in a particular field will of course seek to protect any patentable discovery they make. They cannot predict with certainty at this stage whether patented discoveries will lead to commercialization.

Given that much early stage research is published and publicly accessible, the ability to patent discoveries is all the more vital. If firms are conducting research in the same field, it is inevitable that some of these patents will overlap with research being conducted by other companies. If patents overlap, the report shows that in most cases companies negotiate to license them. Imposing legal restrictions on this natural search for competitive advantage would only succeed in restricting investment in research for fear of being held to be acting anti-competitively, and would ultimately reduce competition.

Pfizer hopes that the final report will recognize that effective and enforceable intellectual property rights and vigorous competition to discover and patent new inventions are, far from constituting anti-competitive behavior, prerequisites of a healthy competitive pharmaceutical market. Any move to constrain the capability of innovators to secure or enforce intellectual property rights would result in lower inducements to entry and reduced competition.

### III. Implied criticism of legitimate business practices

It is regrettable that DG Competition seeks to portray legitimate business practices as an underhand 'toolbox' designed to distort the market. In truth, as in any competitive market, companies avail themselves of the framework established by law to seek to protect their interests. The framework is designed with this purpose in mind. It might just as well be argued that generic companies employ a 'toolbox' of strategies to challenge innovator patents and hasten market entry. A truly competitive market requires that generic companies challenge patents and that originators defend them. This gives the expert authorities set up for this purpose the opportunity to make a judgment on the validity and extent of protection. Society, which establishes the requisite legal and regulatory frameworks, is not helped by making recourse to these frameworks less accessible.

Each of the practices deemed by DG Competition to form part of the innovators' 'toolbox' has a perfectly legitimate use:

- Ø *'Patent clusters'*: DG Competition implies that the increase in number and sophistication of patents covering a product is only a strategy to prevent competition. This insinuation reflects a misunderstanding of the increasing complexity of drug development and administration. It is linked to the concept of a 'secondary patent', a simplification of a more complex reality. A number of different patent families can relate to a product, but vary significantly in content and scope of protection. It is often rightly pointed out that in any innovative sector 'eureka' moments are rare by comparison to the smaller innovative steps that constitute most innovation. Any analysis of the pharmaceutical industry should recognise that the discovery of a chemical or biologic with potentially therapeutic properties is only one element in the creation of new effective therapies. Once a particular chemical or biologic is discovered, many additional inventive steps are needed to create a viable medicine, and many more inventive steps remain before its possibilities are exhausted – it is common that a number of patent families are necessary to cover different aspects of the product. Each of these steps can and should be patented, if they are deemed by the European Patent Office (EPO) to represent a non-obvious improvement on prior art. Not all of these patents or patent families will necessarily cover a commercial aspect of the drug but they are a necessary feature of the R&D continuum leading to commercialization.

Furthermore, it is not surprising that in the continuing process of R&D related to a product, there will be some focus on that product later in its commercial life as additional experience with the product on the market is gained. Nor is it surprising that companies invest more money in additional research (and thus file more patents) on the most valuable products: these are the most effective products which patients and doctors want and health systems will buy.

Finally, once a primary patent expires, generic companies are typically able to replicate the original product or design around any 'secondary' patents (and for the most valuable medicines, often do so very quickly after primary patent expiration). Any refinement of the original product that has been created by the originator will only succeed commercially if doctors, patients and payers are convinced of its merits over the original (in an environment which increasingly favors generic prescribing or generic substitution).

- Ø *Litigation*: Litigation to protect patents granted by the EPO is a critical aspect of competition and a legitimate right of patent holders. If the EPO has granted a patent, it should not be considered 'vexatious' to request judgment from a competent court when infringement is suspected or the validity of a patent is challenged. Such litigation is common to all

technological sectors and singling out the pharmaceutical sector for criticism on this ground is unjustified.

Furthermore it is natural that infringement proceedings should be initiated by originator companies as the patent holders.

Finally, the granting of interim injunctions during the litigation process is to be expected given the reasonable presumption that a granted patent should be considered valid until proven otherwise. Generics companies have ample opportunity to seek judgment on the validity and scope of a patent before coming to the market and therefore cannot be surprised or unfairly prejudiced by an interim injunction being sought. To Pfizer's knowledge, courts in all jurisdictions take account of the merits of the case and balance of hardship when deciding whether to grant an injunction.

- ∅ *Opposition*: Pfizer agrees that an increase in the speed of handling patent opposition procedures would be desirable. This should not, however, come at the expense of a fair assessment of the merits of the patent, allowing each side in an opposition procedure sufficient opportunity to set out their case.
- ∅ *Settlements*: Settlements of litigation are in many cases the most efficient way to resolve these highly complex disagreements involving a high degree of uncertainty. Forcing litigants and already over-burdened courts to expend huge resources on litigation when a mutually acceptable settlement could be reached is inefficient, and would be detrimental to originators, generics, and society in general.
- ∅ *Patent linkage*: The report claims that any linkage between the regulatory procedure for assessing and granting abridged (generic) marketing authorizations on the one hand, and the patent protection status of the reference product on the other, is incompatible with EU law. However, EU law states that the abridged approval procedures shall be "without prejudice to the law relating to the protection of industrial and commercial property", which supports the position that the IP/patent status of the original product should not be overridden or damaged by the regulatory procedure<sup>1</sup>. There is therefore a real legal issue to be determined, which is particularly acute and important in countries where historically patent protection has been limited, and/or effective means of IP enforcement are lacking.

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<sup>1</sup> Article 10.1 of Directive 2001/83/EC, as amended

Furthermore, it is not Pfizer's experience that patent linkage arguments are raised with marketing authorization bodies in 'most' EU Member States. Such arguments have been applied only in a small number of countries, where legally merited and relevant according to the local legal and regulatory environment.

- Ø *Direct-to-Pharmacy (DTP) distribution*: Pfizer is surprised that the report portrays DTP distribution as potentially impairing market entry for generics. Originators and generic companies selling medicines directly to pharmacies is in the interests of patients who benefit from a shorter and more secure supply chain. Furthermore, DTP has recently been closely examined by the UK Office of Fair Trading and no basis was found for interfering with DTP systems being implemented by Pfizer and other companies.

In sum, the practices that comprise the so-called 'toolbox' are not only legal but entirely justified. The report presents no evidence of wrongdoing. Nor does it establish that eliminating or curtailing the use of these practices would benefit European consumers: the practices and processes which the report criticizes serve to balance the rights of originators and generics. Creating an artificial imbalance in their application would undermine the legal framework constructed over the years to serve the public interest. We hope that the final report will recognize the need for such a balance.

#### IV. Possibility of improvements

Pfizer believes that changes can and should be made to increase access, efficiency and value for patients, while advancing the Lisbon agenda to create growth and high quality jobs.

For instance, it could be beneficial to create progressively a more streamlined patent system in Europe that reduces costs and increases legal and commercial certainty.

Efficiency would also be improved by speeding up and requiring greater transparency in pricing and reimbursement decisions at Member State level – an aspect of the market that this report chooses to ignore, but which bears significant responsibility for delays in access to both originator and generic products. At the very least, Member States should be made to respect their obligations in this regard under the Transparency Directive of 21 December 1988 which requires decisions to be made within 180 days<sup>2</sup>.

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<sup>2</sup> Directive 89/105/EEC

It is nevertheless our firm conviction that potential changes must be developed with regard to the complex framework of regulatory structures and incentives that have been crafted over many years by the European institutions and Member States. The EU has long recognised the importance of the innovative pharmaceutical sector in Europe, and the fact that intellectual property is the main catalyst in furthering the development of new pharmaceutical products. The European institutions have, indeed, reinforced levels of protection here, e.g. via Supplementary Protection Certificates. At the same time, they have provided help to generic manufacturers, for instance by incorporating the 'Bolar' provision into EU law.

This framework has been constructed with the aim of balancing the social interest in cost effective medicines with the social interest in obtaining new products and a healthy and productive innovative technological sector in Europe. It is entirely correct that such a nuanced and important judgment should be made at appropriate length, and with necessary periodic refinement. Positive changes can be made to the system which will increase its efficiency without adversely altering the balance of incentives envisaged by legislators. Pfizer is however convinced that restraint should be exercised and care taken to assess the potential impact of actions which stand to affect this necessary balance designed to benefit European patients and societies.