



30 January 2009

Commissioner Kroes  
Directorate General  
Competition European Commission  
B1049 Brussels  
Belgium

Dear *Commissioner Kroes*

I am writing on behalf of the UK Bioindustry Association (BIA) in response to the invitation issued by DG Competition for the views of interested stakeholders about the preliminary findings of the pharmaceutical sector enquiry. I previously wrote to you on 20 October 2008 with observations on the sector enquiry.

The BIA anticipates that DG Competition will receive many submissions from the stakeholders in response to the Preliminary Report. The following observations therefore are not intended to be comprehensive but to highlight particular aspects of the Preliminary Report that are of concern to the membership of the BIA.

As I explained in my letter of 20 October 2008, the BIA is the trade association for innovative enterprises in the UK bioscience sector, representing over 300 members. The majority of the BIA membership are SMEs that have a very high research expenditure as a proportion of revenue and are absolutely reliant on strong, enforceable patent rights to attract continued investment. The BIA notes that the sector inquiry was prompted in large part by a concern that there has been a decline in innovation. BIA members are a vital source of innovative research and any measures that impair their ability to protect the fruits of that research will, we believe, have a markedly detrimental effect on their ability to contribute to that innovation.

The climate for SMEs in this sector is difficult at present, with companies finding it hard to attract the necessary investment for their continued research activities. Any increasing restriction on patenting for SME biotechnology companies will only increase their vulnerability. At the same time, there is an increasing reliance on research originating in the biotech sector to identify the next generation of innovative medicines. The BIA believes therefore that biotechnology in healthcare holds great promise for benefiting patients in Europe.

The Commission notes in its report that more than a third of all new medicines in the pharmaceutical sector are acquired from third parties. The biotechnology industry is the major source of innovative developments for the pharmaceutical industry. The research is expensive and companies often run at a loss for considerable periods while developing new products. The large pharmaceutical companies are often key to the

development and launch of products from the biotechnology sector in that they have the resources to conduct the costly clinical trials and other testing and development. In order to secure these resources, through funding, licensing or sale of technology, it is crucial that biotechnology companies have strong intellectual property rights.

Against this background, the BIA is concerned that in carrying out the Pharmaceuticals Sector Enquiry the Commission should fully appreciate the fundamental importance of patents to the innovative biotechnology industry. The BIA is concerned that in its efforts to identify instances of anti-competitive behaviour in the pharma sector, the Commission may form negative views of legitimate patenting activity which is necessary to foster growth and innovation across the healthcare sector, including biotechnology companies involved in healthcare research.

The comments below follow the order of topics in the Executive Summary to the Preliminary Report.

### **Market Features of the Pharmaceutical Sector**

The member companies of the BIA are "originator" companies as defined in the Preliminary Report. However, they are typically very much smaller than the originator pharmaceutical companies with which the Preliminary Report appears mostly concerned. In many instances they are smaller than generic pharmaceutical companies. They are inherently more vulnerable to the negative impact of an unfavourable intellectual property regime.

The Preliminary Report states that in the period 2000 to 2007 originator companies spent on average 17% of their turnover from prescription medicines on R&D worldwide. For companies in the healthcare biotechnology sector, approximately 40% of revenue is spent on research and development and for the most vulnerable SME's in this sector the proportion of revenue spent on R&D may be much higher.<sup>1</sup> It is this extremely high proportional research spend that drives innovation in the biotechnology industry.

### **Impact of Generic Entry**

The Preliminary Report highlights the time gap between the date on which medicines lose exclusivity and the date of first generic entry. This is stated to be about seven months on a weighted average basis or about four months for the most valuable medicines. It is stated that savings from generic entry could have been €3 billion or more if generic entry had taken place "without delay".

The BIA agrees with the Commission that the prompt entry of generic medicines after loss of exclusivity (both patent protection and data/marketing exclusivity) is to be welcomed and is in the public interest. The BIA is not however aware of any instance

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<sup>1</sup> Ernst & Young Beyond Borders Global Biotechnology Report 2008

where generic entry has been delayed after exclusivity has been lost as a result of anti-competitive practices. Indeed, it is difficult to see how this could be the case given that there is no legal right that an originator company may enforce after the period of exclusivity has expired. It may therefore be that the issue is with national authorities, either through marketing approval or pricing and reimbursement mechanisms or other factors relating to individual national markets for generic medicines that have led to the delay. Indeed this is a problem the generics companies recognise. In addition for most of the period covered by the Preliminary Report, generic companies could not file for product approval under the abridged procedure until the period of data exclusivity had expired, making delay in entering the market inevitable. New rules on the distinction between data exclusivity and marketing exclusivity may assist. The BIA therefore recommends that in formulating its final report, the Commission investigates these effects.

### **Patent Filing and Patent Enforcement Strategies**

The Preliminary Report refers to a commonly applied strategy in the pharma industry of filing numerous patents for the same medicine. This is a strategy that is common in other industries (for example electronics and telecommunications) where there may be hundreds of patents relating to any one piece of equipment. The BIA does not consider that this is in itself an abuse of the patent system. Such filings may be quite legitimate and represent genuine ongoing research and development work being carried out to improve a medicinal product. Examples include the development of new methods of manufacture which are more efficient for producing the compound (particularly in areas such as biotechnology where manufacturing is not straightforward). In addition, innovative research may lead to the development of improved dosage forms, methods of administration and innovative combination therapies that have a dramatic effect on the efficacy of a compound. Research may also result in the identification of new indications for a therapeutic compound, further increasing its benefit to patients. The BIA does not believe there is any reason why further protection for such research should be denied to the innovator company that may have invested extremely large sums in generating the improvements outlined above.

The Preliminary Report also refers to the practice of filing divisional patent applications. This is a well recognised and quite legitimate practice before the EPO. In appropriate cases, it can allow for the early grant of a patent relating to certain aspects of a research programme while allowing time for other aspects of the research, for which protection is sought, to be examined by the EPO in more detail.

The BIA notes the observation in the Preliminary Report that enforcement of patent rights in court is generally legitimate. As observed in my previous letter, it is only through court proceedings that legal rights granted after substantive examination in the EPO or national patent offices can be enforced. Given the central importance of patent protection to biotechnology companies, it is not surprising that they seek to defend their patent positions robustly. However, as I stated in my previous letter, the BIA is not

aware of any instance where the enforcement by a biotechnology company of its patent rights has been considered vexatious.

### **Use of patent related exchanges and litigation**

The Preliminary Report refers to the large number of patent litigation cases between originator and generic companies. The BIA does not consider that this is surprising in itself. The pharma industry is unique in that it is so starkly divided into two sectors – companies that bear all the risk and expense of innovation and rely on legal protection to recoup investment and other companies that perform little or no research and rely on copying the innovated products once legal protection has lapsed. It is inevitable that legal disputes will arise that test the limits of the protection afforded to the innovator companies. The BIA does not believe that this points to anti-competitive behaviour. Rather, it is a signal of robust competition between innovators and generic companies that are continually exploring ways to enter the market at the earliest opportunity. There is often a race among generic companies to be the first to launch and this can cause increased litigation as there may be infringement concerns in relation to multiple companies simultaneously or they may themselves start to “clear the way”.

Further, litigation in multiple jurisdictions is an inevitable result of the current legal framework. The Commission notes that both generic and originator companies want a simpler centralised system.

It is observed in the preliminary report that the majority of court cases (though only a small majority at 54%) were initiated by originator companies but that generic companies won approximately 60% of cases in which final judgment was given. The fact that the majority of cases are originated by innovator companies is hardly surprising – they have their investment to protect. It is generally the originator companies that own patents, so more likely that they will bring proceedings. The report also notes that the originator companies are, unsurprisingly, concerned with protecting their IP while the generics are more concerned with costs. As the industry develops, it is likely that this will change as generic companies increasingly develop their own intellectual property.

As to the success rate for originator patentees, in the experience of the practitioners of the BIA’s Intellectual Property Advisory Committee, a success rate of approximately 40% for a patentee in court proceedings is not unusual in any industry sector. The cases that reach courts are often not straightforward and may go either way – patent litigation is complex. It is also the cases that are finely balanced and where there is a reasonable doubt as to the outcome which are most likely to end up in a full trial. It does not appear from the Preliminary Report that a comparison was made with success rates for patentees in the pharmaceutical field compared with other industry sectors. It is recommended that this is looked into by the Commission before any final conclusions are reached.

The BIA recognises that product patents are more frequently upheld than secondary patents on formulations, second medical use and the like. However, the strength or

otherwise of any given patent can only be tested in full court proceedings. The preliminary report suggests that secondary patents are inappropriately sought and enforced. However, that does not necessarily follow from the figures presented. It is generally easier to challenge a secondary patent than a primary one as once patent protection is lost on the product itself, many more companies will research in the area. As a result there is a wider pool of prior art documents which may be relevant to developments such as new dosage forms (and not confined to the specific products) which may be available to invalidate or narrow the patent.

BIA would be concerned at any approach that sought to deny or restrict patenting activity to whole categories of development inventions on the basis of a blanket assessment that they are not worthy of protection. The BIA believes that this could severely restrict continuing research into improved formulations, methods of administration, combination therapies and research into new indications and patient groups as highlighted above. The value of such continuing research is well recognised in for example the extra protection afforded to drugs with a paediatric extension.

The BIA welcomes the observations by the Commission about the desirability of a Community Patent and single European Patents Court. This would have the potential for saving costs of patenting and patent litigation in Europe and eliminate the issue of conflicting final judgments. However, the BIA believes that for a Community Patent to be of benefit there must be a sensible language regime and the patent must be affordable for SME's. The court system must have experienced judges and a procedure that allows for speedy and affordable determination of both issues of infringement and of validity.

### **Opposition and Appeals**

The BIA shares the concern of the Commission that the duration of opposition proceedings before the EPO is too long. There are many reasons for this, mainly involving the internal procedures of the EPO. If the EPO opposition procedure could be streamlined, this would undoubtedly be desirable as it would lead to earlier clarification of patent rights. The BIA would welcome any dialogue between the Commission and the EPO as to how oppositions could be made faster

It is stated in the Preliminary Report that generic companies "prevailed" in approximately 75% of EPO oppositions during 2000 to 2007 either by achieving the revocation of the patent or by having its scope restricted. In this regard, it is quite common in EPO proceedings for amendments to be made to the patent claims that may reduce their scope. This does not however mean that the Opponent has "prevailed" in the sense of achieving freedom to operate. The BIA therefore believes that the statistic given in the preliminary report gives a misleading impression of the success rate of the Opponents.

### **Settlements and other Agreements**

The BIA is concerned at the approach taken in the Preliminary Report to settlement. In patent litigation as in any other area of civil disputes, there are strong public policy reasons for the parties to settle their differences rather than incur the cost, delay and uncertainty of full court proceedings. Indeed, in the UK at least the rules of civil procedure contain many provisions to encourage settlement before trial.

The Report refers to settlement agreements where the generic company's ability to market its medicine is restricted. The BIA does not see this as necessarily an abuse of the system. Such settlements typically reflect an assessment by the parties of the relative strengths of their positions. As proceedings develop, it may become apparent to a generic company that its attack on the originator's patent is weak and likely to fail. In such circumstances, the generic company may prefer to settle the dispute and agree to respect the originator's patent rights rather than incurring further legal costs on a case which is unlikely to succeed. Similarly, to a settlement where licensing or distribution deals are agreed is not necessarily anti-competitive – each agreement must be assessed on its own merits and its full commercial and legal context for such a judgment to be made. A settlement that allows a generic to come onto the market on agreed terms will be more procompetitive than a dispute that ends in a court decision under which a generic company is enjoined from selling its product at all.

### **Competition between Originator Companies**

In the biotechnology field, there are a number of “hot spots” where companies are pursuing competing programmes of research in particular technical fields. Any individual company's programmes of research will lead to patent filings as research progresses. In a “hot spot” there will be multiple filings by numerous parties. Given the uncertain nature of biotechnology research, it will not be clear to the company (perhaps for many years) whether any given patent filed will cover an ultimately successful commercial product. A biotechnology company may therefore have many patents in its portfolio that are not specifically directed to a commercial product but which do represent genuine innovative research leads. The BIA does not believe that these can be termed “defensive” patents. The BIA is concerned at the negative comments in the Preliminary Report directed at broad patent claims. In appropriate instances, broad patent claims will be entirely justified and correspond to the contribution that a patentee has made to the art. In biotechnology, there has been a history of groundbreaking inventions that open up whole new technical fields. There has also been development of platform technologies such as phage display technology (for developing humanised antibodies) and DNA microarray technology (for analysing gene expression) that have general application. The patent system has legal mechanisms for weeding out patents where the breadth of protection sought does not correspond to the technical advance made. Broad patents which are unjustified can be struck down while those that do correspond to the technical advance are unobjectionable.

As to litigation between originating companies, again it is inevitable where companies have overlapping research interests and overlapping patent positions that there is a potential for legal disputes. These disputes tend to break out in areas where competition

is at its fiercest. Settlements may involve cross-licensing of competing technologies but this generally has the effect of increasing the freedom to operate of the competing companies and not anti-competitive.

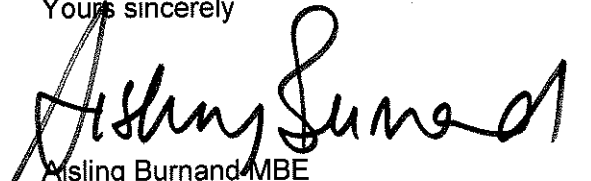
## Conclusions

The BIA and its member companies are following the progress of the Commission's sector enquiry with great interest but also with concern, given the far reaching negative comments which have been made by the Commission in presenting the Preliminary Report. It appears that the sector enquiry is focusing particularly on the practices of traditional large originator pharmaceutical companies and generics companies marketing small molecule drugs. However, biotechnology companies active in the healthcare industry are an increasingly important driver of healthcare innovation.

The ability to apply for and (if granted) enforce patents provides essential incentives for innovation in the biotechnology field, as elsewhere. The BIA believes that innovation has flourished in large part because of the protections offered by patents. Reducing the ability of originator companies (whether SME biotechnology companies or large pharmaceutical companies) to protect the fruits of their extensive - and expensive - research threatens to be counter-productive at a time when the Commission is already concerned about an apparent decline in the rate of innovation. Many of these patents are generated in the biotechnology industry. BIA members are continually striving to innovate and provide new and improved medicines. The availability of patent protection for new and inventive contributions is a key element of the system that enables BIA members to take the very substantial risks inherent in (and attract the very substantial investment required for) this activity and protects the position of the biotechnology companies (and other SMEs) against larger pharmaceutical companies. To reduce innovators' ability to obtain or enforce patents in the pharmaceutical sector would, we believe, be counter-productive.

The BIA encourages the Commission to take into account the particular characteristics of healthcare biotechnology companies in reaching its final conclusion. The BIA remains committed to providing the Commission with support and assistance if needed. If you have any questions arising from the points made in this letter or my earlier letter of 20 October 2008, please do not hesitate to contact me.

Yours sincerely



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