

Oxera submission to the European Commission sector inquiry on pharmaceuticals

January 30th 2009

Oxera is pleased to respond to the public consultation on the European Commission's Preliminary Report of the Pharmaceutical Sector Inquiry.¹ Oxera considers that this sector inquiry will play an important role in shaping the future of the pharmaceutical industry in Europe, and has the potential to lead to significant changes in how the patent and competition law regimes operate in Europe.

In its report, the Commission has covered many of the issues which are central to the economics of the pharmaceutical industry, including the length of the patents which are granted, the costs of R&D, and the risks of failure of promising new compounds. The interactions between these issues and competition policy cause tensions. In particular, the patent system and the competition policy system have obvious and direct conflicts—whereas competition policy is designed to ensure that, as much as is possible, the market is fully competitive, the patent system allocates monopoly power in exchange for innovation.

To provide a reward for innovation and incentives for future research (and consequently, to increase dynamic efficiency), the patent system in the EU allows for patents which can last up to 20 years (regardless of the product being protected).² Once a pharmaceutical product is off-patent, generic competitors can launch replica products using the same active ingredients. Given that the generic companies do not need to undertake all the investigation and testing phases, these versions are usually sold at a discount to the original, branded, product. An important aspect of the industry recognised by the Commission is that a substantial proportion of the turnover of both branded and generic companies is generated from a few 'blockbuster' drugs which achieve very high sales.

Many of the points made in the analysis below come down to a single issue—the Commission does not appear to have yet adequately specified the counterfactuals against which it is assessing behaviour in the pharmaceutical sector. In several places throughout the Preliminary Report, the Commission notes that there have been delays in entry by

¹ European Commission (2008), 'Pharmaceutical Sector Inquiry: Preliminary Report', November 28th, p. 86.

² This may be extended in certain circumstances by up to five years through the use of supplementary protection certificates.

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generic producers, sets out a range of behaviours undertaken by originator companies which may have the effect of impeding entry, and then implicitly appears to ascribe all of the delays to these behaviours. However (if this is the Commission's intention, as it is not made explicit), such an approach will overstate the impact of anti-competitive behaviour, as any delays that are due to other features will also be ascribed to the assumed anti-competitive conduct of originator firms.

1 Potential causes of delayed generic entry

At the heart of the Commission's investigation lies a concern over whether agreements between originator and generic producers, such as settlements in patent disputes, have blocked or led to delays in market entry. The Commission found that generic entry occurred, on average, seven months after a product had gone off-patent, although, for the products with the highest sales in the Commission's dataset, generic entry occurred somewhat more quickly (on average four months after patent expiry).³

The Commission also found that there were significant variations between the Member States in the speed of entry of generics. For example, the average time from patent expiry to entry was less than three months in the UK, Denmark and Finland, while it was more than one year in Luxembourg, Greece and Spain. This may indicate that there are certain regulatory or market-related factors at the national level that are increasing the length of delays in entry.

Originator companies are reported to have designed and implemented what the Commission terms a 'tool box' of strategies aimed at reducing further market entry from generic producers. The Commission states that this tool box includes a number of practices: strategic patenting, patent litigation, patent settlements, interventions before national regulatory authorities, and life-cycle strategies for follow-on products.⁴

However, there are a number of reasons why entry may be delayed, even in the absence of strategic behaviour. Implicitly, the Commission is claiming that the counterfactual is immediate entry, but unless the various factors identified below are all irrelevant, this will not be the correct counterfactual.⁵ It would greatly assist the rigour of the Commission's analysis if the Commission were to set out in detail what it believes the appropriate counterfactual to be, and then determine potential consumer gains against this benchmark.

Patient switching costs. There may be perceived switching costs for some patients, making generic entry less profitable and so acting as a barrier to entry by generic producers. For example, if a drug is for a chronic condition (and is therefore taken over a long period of time), patients may be reluctant to change from their existing branded prescription to a generic prescription when there is generic entry. For such drugs, it could therefore take some time for generic producers to become profitable, as they may gain market share slowly.⁶

Impacts of regulatory authorisation. Regulatory constraints can lead to delayed entry. The Preliminary Report specifies that there are particular problems in obtaining marketing

³ European Commission (2008), 'Pharmaceutical Sector Inquiry: Preliminary Report', Fact Sheet: 'Prices, Time to Generic Entry and Consumer Savings'.

⁴ A follow-on product is a second generation of a product, improved in some way but offering the same basic active ingredient.

⁵ For example, see European Commission (2008), 'Pharmaceutical Sector Inquiry: Preliminary Report', Fact Sheet: 'Prices, Time to Generic Entry and Consumer Savings', page 3, where the Commission calculates €3 billion of additional savings if generic entry had been immediate.

⁶ This factor will depend on prescribing practices and the way in which reimbursement systems operate. In particular, if there is generic prescribing, the decision on the drug provided to the patient falls to the dispenser (usually a pharmacist).

authorisations in a few countries which have especially heavy workloads (Germany, the UK, the Netherlands and Denmark), with delays of more than one year in some cases even in beginning to consider a product.

Reimbursement systems. The Preliminary Report found that some countries' reimbursement systems impose conditions that are stricter than those for marketing authorisations. Thus, even when marketing authorisation has been granted, there may be further regulatory barriers to overcome before a pharmaceutical can be dispensed, creating additional delays in entry.

Lack of interest. It is instructive that it is for the highest-selling (and therefore presumably most profitable) drugs that entry occurs the most quickly. Therefore the incentives for generic producers to enter as quickly as possible, and the speed of entry observed, would broadly appear to be aligned. Consequently, on the basis of the evidence produced by the Commission so far, it seems plausible that, for some drugs, slow entry is because the generic producers have other priorities in terms of which generics they should attempt to launch.

Marketing authorisation procedures for generic entry. As noted by stakeholders in the Preliminary Report, patents granted by the European Patent Office (EPO) have to be transformed into a bundle of national patents, which are enforced in each Member State separately, in order to win marketing authorisation. There is usually more than one patent on a product. Trying to obtain market entry for a generic product can therefore be very costly and time-consuming.⁷ Moreover, companies, industry associations and agencies reported bottlenecks in the marketing authorisation procedures, which could lead to delays and administrative burdens.⁸

No unified judiciary. Generic producers who responded to the Preliminary Report highlighted that the courts of different Member States often take divergent views on the validity or scope of the same European patent.⁹ There are also conflicting conclusions on the validity of a patent resulting from the EPO's opposition and appeal procedures, and from national courts. A rapid uniform binding ruling on the validity of a patent throughout Europe could lower the costs for generic producers. The slow process in many Member States causes further delays in market entry because of patent disputes; the lack of a unified judiciary would be expected to increase the average time for generic entry even in the absence of any anti-competitive conduct.

The above factors raise questions as to what the appropriate counterfactual is when assessing the impact of alleged anti-competitive practices on speed of entry. Setting out an appropriate counterfactual would enable a fuller understanding of the extent to which delays in entry are caused by the behaviour of originator companies, and what proportion of delays are due to other factors.

2 Practices identified by the Commission which require further analysis

The Commission in its Preliminary Report describes a significant number of practices that it considers may inhibit generic entry to the benefit of originator companies, forming what the Commission terms a 'tool box'. Despite the Commission having presented considerable

⁷ European Commission (2008), 'Pharmaceutical Sector Inquiry: Preliminary Report', November 28th, p. 86.

⁸ Ibid., p. 389.

⁹ Ibid., p. 15.

detail regarding many of these practices, some of them require considerable further analysis before they can be considered to be robust findings.

Strategic patenting. One of the Commission's findings is that originator companies file multiple patent applications for the same medicine ('patent clustering'). It found that, for some drugs, a large number of patent applications were filed at a very late stage of the product life cycle, predominantly for blockbuster medicines.¹⁰ However, and in a similar fashion to many of the concerns not thus far addressed by the Commission set out in section 1, it is unclear how the Commission has determined what the counterfactual competitive structure for patent applications is. There does not appear to be detailed analysis of whether there are factors other than anti-competitive behaviour that can explain the pattern of patent applications for drugs where many patents are applied for towards the expiry date of the initial patents. Nevertheless, the Commission argues that patent clustering may create uncertainty for generic producers in terms of when they can enter the market without infringing one of the patents of the originator companies.

Patent litigation. The Commission also identified the initiation of litigation as a possible tool to delay or block generic entry. The Commission found more than 700 reported cases of patent litigation involving generic producers, on average lasting nearly three years; 62% of all such litigations were won by generic producers. Again, it is important to compare the number and outcome of reported litigation cases with an appropriate counterfactual. That is, what would be the likely number of cases (in both absolute terms and in the proportion won by generic producers) in a well-functioning market? The Commission does not yet appear to have settled on the level at which such a benchmark should be set. Given that the counterfactual proportion of cases won by generic producers appears unlikely to be zero, without such a benchmark it is impossible to address the extent to which patent litigation is actually a problem. Once again, this concern over the Commission's report arises from the lack of consideration of an appropriate competitive benchmark against which behaviour can be judged.

Furthermore, to the extent that there are delays in entry caused by patent litigation (whether anti-competitive or non-strategic), it appears that one of the main ways in which entry could be accelerated would be to reduce the length of time which it takes to obtain patent rulings in the various European jurisdictions. The Commission does not appear to have addressed this aspect (although exerting any active control over this lies outside its jurisdiction).

Patent settlement. The Commission identified more than 200 settlement agreements to resolve patent disputes or opposition between 2000 and 2007. A large proportion of those agreements involved a value transfer from the originator to the generic producer in the form of a direct payment, a licence, a distribution agreement or a 'side deal'. The marketing of generic producers' drugs was restricted in 48% of cases. More than 10% of the settlement agreements involved 'reverse payments' from the patent holder to generic producers where the latter agreed not to enter the market. Oxera welcomes the Commission addressing the issue of patent settlements and will be interested to see the analysis on which types of settlement it considers pro-competitive and which anti-competitive.

National proceedings. The Commission identified that when generic companies apply for marketing authorisation or pricing and reimbursement status for their products, originator companies often intervened in national procedures.¹¹ The majority of these proceedings were won by the generic producers—of 23 concluded interventions based on concerns around

¹⁰ European Commission (2008), 'Pharmaceutical Sector Inquiry: Preliminary Report', Fact Sheet: 'Originator–Generic Competition'.

¹¹ <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/1829&format=HTML&aged=0&language=EN&guiLanguage=en>.

data exclusivity, for example, all were won by the generic producer in question. Again, as with elements of the tool box referred to above, the Commission does not appear to have identified what the level of such interventions would have been in the absence of any anti-competitive behaviour. Furthermore, it may be that such behaviour could in any case have been addressed by the regulatory system—for example, speeding up consideration of such complaints, or splitting patent issues from marketing authorisations.

Life-cycle strategies for follow-on products. In 40% of the cases investigated for the purpose of the sector inquiry, originator producers launched follow-on products prior to patent expiry. The Commission stated that the launch of such products could reduce switching to generic brands.¹² This strategy would reduce the market share of generics only if customers preferred follow-on medicines to generic brands despite the higher prices, or if patients and doctors were price insensitive. However, the launch of follow-on products may create uncertainty around the demand for a (non-identical) generic product, and so deter entry. The question for the Commission and other regulators would be how to trade off this possible effect against the potential that the follow-on products may offer considerable improvements over earlier products. Where a follow-on product does offer such benefits, its introduction seems unlikely to be primarily strategic—indeed, if there is uncertainty over the precise benefits which will be offered by a follow-on product at the time of launch then, even in a fully competitive market, there would be expected to be some follow-on products with minimal benefits for patients. As with previous areas, the Commission therefore needs to define an appropriate counterfactual for the number of follow-on products which would be expected to be launched (and when) in a competitive market.

3 Impact of generic entry on average prices

The Preliminary Report finds that generic producers initially set their prices on average 25% lower than the originators' prices before patent expiry. Over time the prices of generic products drop to a level 40% lower than the (pre-entry) price of the originator drug.¹³ However, the Commission does not appear to have considered whether prices for generic brands are themselves set at a competitive level.

Analysing this question starts from the basic observation that the underlying average costs for generic products would be expected to be significantly lower than for patented products. The intuition behind this is that generic producers' overall R&D expenditure is much lower than for originator companies, consisting largely of R&D for biosimilar drugs.¹⁴

Moreover, a significant part of generic producers' turnover is generated from medicines equivalent to blockbuster products whose patents have expired, implying that the risks of launch are considerably lower than for originator producers, since there is limited underlying demand risk for the product. There are also no (or limited) costs incurred from unsuccessful R&D, as it has already been determined that the compound being researched is safe and effective. Marketing expenditure constitutes the largest share of generic producers' costs.¹⁵ All this suggests that the market for generics has some of the characteristics of a commodity market with predictable demand, where the expected risk—and consequently level of return in a competitive market—are smaller than for originator companies. It is thus reasonable to expect a significant drop in prices for generic brands.

¹² European Commission (2008), 'Pharmaceutical Sector Inquiry: Preliminary Report', November 28th, p. 311.

¹³ Ibid., p. 78.

¹⁴ 'Biosimilar' is defined as a product that has been approved by the relevant marketing authorisation agency as being comparable to a particular biopharmaceutical. See European Commission (2008), 'Pharmaceutical Sector Inquiry: Preliminary Report', November 28th, p. 42.

¹⁵ Ibid., p. 43. No data is provided on what proportion of generic companies' costs is marketing-related.

The Preliminary Report shows that there are large variations in the price reductions after generic entry between Member States. For example, in Sweden, prices were reduced by more than 50% after the first year after patent expiry, while prices for generic and originator brands were almost identical in the Netherlands two years after patent expiry. Against this background, it may be necessary to investigate the underlying reason why those price reductions after generic entry vary within the EU, as they may illuminate structural characteristics of the market, particularly around how successfully any purchasing power is marshalled by individuals, insurance companies, hospitals or the state. The Commission has given little consideration to this topic in its Preliminary Report. In addition, it has not yet assessed what it would consider to be an appropriate price level for generic drugs against which to benchmark the observed price reductions, given that their cost structure is very different to that of originator products.

4 Conclusion

Oxera welcomes the European Commission's Preliminary Report into the pharmaceutical sector. However, at this stage it has a number of omissions, which Oxera considers would be useful to explore for the final report. The most significant of these, which recurs throughout the report, is the lack of an appropriately defined counterfactual. In the absence of any counterfactual, it cannot be determined whether the market features identified by the Commission are the result of anti-competitive behaviour, or instead are features that would be expected to be observed in a market without any strategic behaviour.

Furthermore, a number of the problems raised by the Commission would appear to be able to be addressed via changes to the behaviour of Member States' regimes, whether in terms of the speed of the court system, the method of determining whether a drug is suitable for reimbursement, or ensuring consistency between different jurisdictions. Solving these problems would have the potential both to reduce the potential for gaming of the patent and product authorisation system, and to accelerate entry of drugs into the market even where no strategic behaviour is present.