
**RESPONSE TO DG COMPETITION PHARMACEUTICAL SECTOR INQUIRY
PRELIMINARY REPORT**

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INTRODUCTION

Norton Rose LLP welcomes the opportunity to provide comments on the preliminary findings of DG Competition's Pharmaceutical Sector Inquiry (**Preliminary Report**) presented on 28 November 2008.

Norton Rose Group is an international legal practice, with offices in major business and financial centres in Europe, Asia and the Middle East. Our pharmaceutical and biotechnology practice marries together expertise from a range of specialist areas including corporate finance, regulatory and competition, intellectual property and litigation. We have gained sector-specific knowledge of the pharmaceutical industry in advising clients in their interactions with the European Commission (**Commission**), National Authorities and Courts. However, this submission does not necessarily represent the position of any individual client of Norton Rose LLP.

In our response, we voice concerns with certain aspects of the Preliminary Report. We have also made suggestions of ways to improve innovation in the sector. Finally, we have highlighted areas where we believe the Commission should take the opportunity to clarify certain matters, in order to minimise legal uncertainty.

EXECUTIVE SUMMARY

The Commission's stated objectives in carrying out the Sector Inquiry were to determine the reasons for certain malfunctions which it had observed on the market for pharmaceuticals. The Commission was concerned by two main aspects of the pharmaceutical market namely:

- the delayed market entry of generic medicines following the loss of exclusivity; and
- the decline of innovative medicines reaching the market.

The Preliminary Report sought to link the use of patent strategies by originator pharmaceutical companies with the delayed market entry of generics. While we note that the Commission's findings as set out in the Preliminary Report are factual, we find it unhelpful that the document appears to cast doubt on the legal and legitimate use of patent protection by originator companies, without offering any insight as to whether the practices identified do in fact infringe competition law. We have particular concerns that the tone of the Preliminary Report in relation to settlement agreements may contribute to legal uncertainty in this area. We look forward to clarification of this area when the final report is published.

While DG Competition has a role to play in safeguarding competition on the market for pharmaceuticals, we remain convinced that, where shortcomings with the existing intellectual property system are identified, these are best addressed through specific legislation in this field.

On the question of the cause of the apparent decline of innovation in the pharmaceutical sector, we welcome the recognition by the Commission that the regulatory framework and, in particular, disparities across Member States, delays the entry onto the market of new products. In our view, a robust intellectual property system is vital to ensure continued innovation in this industry.

Finally, we note the absence of any detailed consideration of competition among generic companies in the Preliminary Report. In our view, without such an examination, any conclusions on the functioning of the market and suggestions to improve its functioning are necessarily limited.

1 General considerations

1.1 Particular features of the pharmaceutical industry

- 1.1.1 Any analysis of the pharmaceutical sector must recognize the distinctive economic and regulatory features of this market, which distinguish it from more conventional ones.
- 1.1.2 The pharmaceutical sector is a high technology and knowledge intensive industry, in which Intellectual Property Rights (**IPRs**) play a crucial role. Large multinational pharmaceutical companies, who have made a significant contribution to the health of EU citizens over the past 50 years, account for the majority of research and development (**R&D**) investment in the healthcare sector and hold the majority of patents for the most important prescription drugs.
- 1.1.3 The vital R&D work carried out by originator companies is funded primarily from the profits flowing from the exploitation of exclusive IPRs. The time-frame for product development in the pharmaceutical sector is very long and there are high risks relating to the discovery of new drugs. In this context, the protection and income generated by IPRs are fundamental incentives to innovation, which ultimately lead to the placing on the market of new products. Strong IPR protection is the only way to ensure that pharmaceutical companies can recoup R&D expenditure and continue to innovate. In this way, competition law and IPRs are complementary to one another, promoting innovation for the benefit of consumers.
- 1.1.4 Any intervention by DG Competition in the pharmaceutical sector requires extra care when dealing with IPRs, due to the vital role patents play as incentives for innovation. On this issue, we recall the findings of the Economic and Advisory Group for Competition Policy, which, in the context of advising DG Competition in its Article 82 EC's review, expressed concerns about any interference by competition authorities with IPRs. They observed that the granting of market power through patent protection is expressly intended to reward innovative efforts and noted that interfering with these rights *a posteriori* could remove pharmaceutical companies' incentives to innovate.¹
- 1.1.5 The pharmaceutical market is highly regulated and legislation in this sector is very fragmented across the EU's 27 Member States. This lack of harmonisation means that Member States still enjoy a wide margin of discretion in relation to patent protection, marketing authorisation procedures as well as pricing and reimbursement issues, which influence both the demand and the supply side of the industry.

¹ Report by the EAGCP, "An Economic Approach to Article 82", July 2005 at p. 44.

1.2 Scope of the Commission's review

- 1.2.1 Under Article 17 of Regulation 1/2003², the Commission can conduct inquiries in a specific sector whenever distortions or restrictions of competition might exist. The Commission is only authorised to gather information with the objective of effectively enforcing Articles 81 and 82 EC and it does not have jurisdiction to assess the regulatory framework of the market. However, in a sector as highly regulated as the pharmaceutical one, the failure to examine the effect of the regulatory framework on the behaviour of originators risks overstating the role that such companies play in the delayed entry of generic products on the market.
- 1.2.2 Further, we find it disappointing that the Commission did not use the opportunity presented by the Sector Inquiry to consider the workings of the pharmaceutical industry as a whole. In particular, the absence of any analysis in the Preliminary Report of the influence of competition among generics companies on the price of generic medicines, and of the impact of parallel trade on the industry inevitably means that the Preliminary Report does not offer a full picture. Without this, it is not possible to understand fully the cause of any alleged market malfunctions.

1.3 Market Structure

- 1.3.1 Any intervention by DG Competition in the pharmaceutical sector must take into account the unique structure of the market and in particular the regulatory limitations on the free working of competition.
- 1.3.2 The pharmaceutical market is characterised by very specific features, which make market definition difficult. Contrary to other sectors, the final consumer does not choose the product he or she consumes and will generally not pay the entire price of the product. National pricing and/or reimbursement bodies are charged with fixing the price of drugs and public and/or private insurance will pay the whole or part of this price. Additionally, doctors and pharmacists also play a role in determining which medicine should be taken by patients.
- 1.3.3 Supply, price and expenditure are controlled by Member States based on non-harmonised procedures. The EU has adopted guiding principles for good practice for implementing pricing and reimbursement policies, which have left the door open for Member States to regulate this sector freely.³ There have been frequent amendments to national legislation.
- 1.3.4 On the supply side, Member States can not only fix the price of medicine, but can also influence the quantity of medicines sold by pharmaceutical companies e.g. by limiting the marketing investments of the company or limiting the amount of sold medicines to be reimbursed. On the demand side, the same influence can be observed. Member States can reduce the final price to be paid by patients through insurance systems, as well as by supporting the substitution of originators' medicines by generic products. Member States

² Council Regulation 1/2003/EC of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, [2003] OJ L 1/1.

³ Guiding principles for good practices implementing a pricing and reimbursement policy adopted by the Pricing and Reimbursement Working Group of the Pharmaceutical Forum, DG Health and Consumers.

are also able to influence the sales of products through for instance, mechanisms encouraging the consumption of parallel imported drugs.

- 1.3.5 As a result, the pharmaceutical sector is not exposed to the law of supply and demand in the same way as other industries. Member States' regulatory powers distort competition on the pharmaceutical market, therefore, a cautious approach should be adopted when applying EC Competition rules to this sector.

2 Innovation

2.1 Competition on innovation

- 2.1.1 The Preliminary Report focuses on the two main commercial actors in the development of medicines, namely:

- originator companies, generally multinational companies, which make the vast majority of R&D investments, and hold the majority of IPRs; and
- generic companies, mainly SMEs, which account for a very minor part of R&D investment in the market and produce mostly off-patent generic medicines.

Whereas generic companies have the opportunity to compete on conventional grounds such as price, originator companies compete vigorously with one another on innovation.

- 2.1.2 There are clear incentives for originator companies continually to innovate and any delays in the development and commercialisation of new medicines will directly impact their profits. As such, there is no commercial interest for originator companies to decrease their R&D efforts. Far from impeding innovation, it is only by continually innovating that originator companies can continue to compete on the market.

2.2 Obstacles and incentives for innovation

- 2.2.1 As the Commission found in the Preliminary Report, originator companies spend a significant amount, approximately 17%, of their budgets on R&D.⁴ However, despite this massive investment, only a limited number of drugs ever receive marketing approval, and amongst these new medicines, only a very few are commercially successful.

- 2.2.2 The development of a new medicine is a lengthy, complex, expensive and very high risk undertaking, with very high failure rates. It is only because of the exclusive rights and protection afforded by IPRs that originator companies are able to carry out lengthy and very expensive investments to discover new medicines. Despite the lengthy period of patent protection, the reality of placing new medicines on the market means that originator companies enjoy only a relatively short exclusivity period in which they can recoup their costs. As such, the duration and the strength of patent protection at the national level or at the EC level should be determined in order to:

⁴ European Commission, Pharmaceutical Sector Inquiry Preliminary Report, 28 November 2008, section B.1.1, para. 55.

- allow originator companies to recoup research investments and reward the high risks taken; but also
- compensate the disadvantage of delays and costs arising from national market authorisation procedures and pricing and reimbursement systems; and
- ensure that patent exclusivity enjoyed on blockbuster products is long enough to allow R&D investment by originator companies in less popular drugs.

2.2.3 We agree with the Commission that the creation of a Community patent, as well as a unified patent judiciary could bring about significant cost and efficiency savings as well as further incentives to innovate.⁵

3 Patent protection

3.1 Patent applications and patent strategies

3.1.1 During the lifetime of a medicinal product, originator companies will create valuable processes and improvements to the original medicinal product. These improvements can often be of great benefit to the patient population. By way of example, improvements in formulation such as sustained release formulations can significantly improve a patient's quality of life by making the dosing regime a simple once a day regime. Where these improvements comprise innovation, companies will often, quite rightly, seek patent protection for them. Such secondary and follow-on patents are essential tools with which originators protect their discoveries and enable them to recoup investment costs and to prevent potential free riding by competitors. Many major scientific discoveries have resulted from exactly this kind of incremental innovation.

3.1.2 The conditions for obtaining secondary or follow-on patents are identical to those for obtaining first patents. These patents will only be granted where originator companies can demonstrate that the invention they are seeking to protect is new, involves an inventive step and is susceptible to industrial application.

3.1.3 It is settled case law that the holding of a patent portfolio, even by a company with market power, does not in itself constitute an abuse of dominant position. According to the judgment in *Tetra Pak II*, a very active patent policy is lawful in itself.⁶

3.1.4 One of the key concerns identified by the Commission in its Preliminary Report was the misuse of patent rights by originator companies. The Preliminary Report casts doubts over the legitimate use of a so-called toolbox of practices by originator companies, such as patent clusters and divisional patents.⁷ It was suggested that these practices may be a factor in the delayed entry of generic products onto the market.⁸ However, this possibility seems to be contradicted by the Preliminary Report's findings. In fact, the Commission found that

⁵ European Commission, Pharmaceutical Sector Inquiry Preliminary Report, 28 November 2008, section D.1.1, paras. 1087 and 1088.

⁶ Case C-333/94 P, *Tetra Pak International SA v. Commission*, [1996] ECR I-5951.

⁷ European Commission, Pharmaceutical Sector Inquiry Preliminary Report, 28 November 2008, section C.2.1.

⁸ European Commission, Pharmaceutical Sector Inquiry Preliminary Report, 28 November 2008, section C.2.7.4, summary.

originator companies use so-called life cycle tools most intensively for the best-selling medicines⁹, but the figures in the Preliminary Report show that the generic versions of these best-selling medicines enjoys the fastest average market entry time.¹⁰ These figures in fact show that there is no direct link between the use of life cycle tools and the delayed market entry for generic companies.

- 3.1.5 In addition, the Commission appears to take the view that the filing of numerous patent applications around one product signals an increase of “weak” patents.¹¹ Inevitably some patents will be stronger than others. However, if the invention which is the subject of the patent gets over the threshold of patentability, there should be no reason why a patent should not be granted.
- 3.1.6 Not to be forgotten in this, is the fundamental ‘deal’ that is struck between the patentee and the state granting the patent: namely, that in return for the opportunity of obtaining a patent the patentee publishes its invention to the world. The benefit to society of this deal should not be understated.
- 3.1.7 The assessment of the validity of a patent is the prerogative of national/supra-national patent offices and national courts. As such, questions concerning the quality of IPR’s and the conditions under which IPRs are to be granted should be dealt with by these bodies. We believe that any weaknesses identified in the patent system should be addressed through reform of existing patent legislation. The absence of a single EU-wide patent, in particular the lack of a clear and uniform regulatory framework, is costly and time-consuming for all industry stakeholders. Therefore, we welcome the Commission’s intention to pursue the introduction of a Community patent.
- 3.1.8 As the case law of the European Court of Justice demonstrates, competition law has a role to play here only in very limited circumstances. Therefore, we question the extent to which DG Competition’s enforcement powers under antitrust legislation can tackle the market concerns identified in the Preliminary Report.

3.2 AstraZeneca case

- 3.2.1 *AstraZeneca* is the only antitrust case to date in which the Commission has sanctioned the misuse of the patent system by a company enjoying a dominant position in the pharmaceutical sector.¹² This decision is currently under appeal.
- 3.2.2 The European Court of Justice had previously considered whether the refusal of a dominant company to licence IPRs could constitute an abuse of dominant position. Taking into account the serious influence of IPR protection on innovation, the European Court of Justice

⁹ European Commission, Pharmaceutical Sector Inquiry Preliminary Report, 28 November 2008, section C.2.7.2, para. 904.

¹⁰ European Commission, Pharmaceutical Sector Inquiry Preliminary Report, 28 November 2008, section B.1.3, figure 13.

¹¹ European Commission, Pharmaceutical Sector Inquiry Preliminary Report, 28 November 2008, section C.2.1, para. 393.

¹² Case COMP/37.507, *AstraZeneca*, [2006] OJ L332/24.

carefully stated that dominant companies could be compelled to licence their IPRs only under exceptional circumstances.¹³ Such a refusal is only considered as abusive if:

- it prevents the development of the secondary market to the detriment of consumers;
- it cannot be justified by objective considerations; and
- it is capable of eliminating all competition on the market.

3.2.3 This view, adopted by the European Court of Justice in the *IMS Health* case, was subsequently used by the Commission in the *AstraZeneca* case. Here though the question was whether the obtaining of IPRs constituted an abuse under Article 82 EC.

3.2.4 Ultimately, AstraZeneca was sanctioned for seeking unlawful protection to which it was not entitled. According to the Commission's decision, for the behaviour to constitute an abuse, there must be evidence that the company knew it had no valid claim for IPR protection and provided misleading information with the objective of obtaining it. This approach could be compared to the practice of the United States authorities, which generally require a fraudulent component in order to sanction the misuse of patent protection.

3.2.5 According to the United States Supreme Court case law, there will be an abuse of dominant position where a dominant originator company intends to enforce a patent obtained by a knowing and deliberate fraud (fraudulent misrepresentation or a fraudulent omission) on the United States Patent and Trademark Office.¹⁴

3.2.6 Only in very restrictive circumstances, where there is clear evidence of a dominant company's intention to mislead or misreport should Article 82 EC be used to sanction the use of IPRs. In our view, this approach constitutes an appropriate assessment of the misuse of patent legislation. Indeed, it seems proportionate only to sanction fraudulent behaviour as this avoids creating uncertainty regarding the use of lawful patent protection. If patent applications are based on accurate data and the originator company does not seek to enjoy a protection to which it is not entitled under the applicable rules, the exploitation by that company of its legitimately obtained IPRs should not be threatened by EC competition law.

4 Patent remedies

4.1 Litigation

4.1.1 On the issue of patent litigation, the Preliminary Report finds that the vast majority of litigated disputes were initiated by originator companies, most often invoking their primary patents.¹⁵ In this respect, it should be recalled that access to justice is a fundamental right

¹³ Case C-241/91 P and C-242/91, *RTE and ITP / Commission*, [1995] ECR I-743, Case C-7/97, *Bronner*, [1998] ECR I-7791, Case C-418/01, *IMS health v. NDC Health*, [2004] ECR I-5039.

¹⁴ *Walker Process Equipment, Inc. v. Food Machinery Corp.*, 382 U. S. 172 (1965).

¹⁵ European Commission, *Pharmaceutical Sector Inquiry Preliminary Report*, 28 November 2008, section C.2.2, paras. 447 and 453.

according to the general principles of EC law and that companies, even those which enjoy a dominant position, have a fundamental right to protect their IPRs through the court system.

4.1.2 The question of vexatious litigation was dealt with by the European Court of First Instance in the *ITT Promedia v. Commission* case.¹⁶ Here, the Court established that it is only in wholly exceptional circumstances that the raising of legal proceedings by a dominant undertaking is capable of constituting an abuse of a dominant position. Under the test established by the Court, two cumulative conditions must be fulfilled for the raising of court proceedings to be considered abusive:

- the action cannot be reasonably considered as an attempt to establish the rights of the undertaking concerned, but is only designed to harass the opposing party; and
- the action is conceived within the framework of a plan the goal of which is to eliminate a competitor.

4.1.3 Concerning excessive litigation, the Preliminary Report found that litigation was very often initiated in many different Member States across the EU with respect to the same medicine.¹⁷ In this regard, we point out that companies who wish to litigate IPRs in the EU are obliged to initiate proceedings across many different Member States as a result of the fact that there is no Community wide patent and so patents must be litigated separately in the courts of each Member State. The validity of national patents must also be challenged nationally, except in the limited case of European patents challenged at the European Patent Office within the limited 'opposition period' of nine months from grant. This is costly and time-consuming for all stakeholders. There is also the risk that litigation before multiple national courts can lead to diverging national decisions, resulting in legal uncertainty. These difficulties could be resolved through the introduction of a Community patent and the establishment of a single EU judiciary for patent matters.

4.2 Settlement Agreements

4.2.1 The uncertainty and high costs of litigation provide a compelling justification for the use of settlements for both originator and generic companies. Indeed, under a number of Member State jurisdictions, parties to court proceedings are actively encouraged to settle disputes and may even face costs for failure to do so. In the Preliminary Report, the Commission acknowledges that patent settlement agreements between originator and generic companies can lead to early generic entry onto the market.¹⁸ To this we would add that settlement discussions can also provide an opportunity for companies to identify areas where they can work together and to take advantages of opportunities which might not previously have been apparent.

4.2.2 As a general observation, we note that the terms of any settlement agreement will inevitably be highly fact-specific and for that reason any attempt by DG Competition to impose prescriptive rules, or to exclude automatically certain settlements terms seems, in our opinion, inappropriate. Therefore, we support the Commission in taking a case-by-case

¹⁶ Case T-111/96, *ITT Promedia / Commission*, [1998] ECR II-2937.

¹⁷ European Commission, Pharmaceutical Sector Inquiry Preliminary Report, 28 November 2008, section C.2.2.

¹⁸ European Commission, Pharmaceutical Sector Inquiry Preliminary Report, 28 November 2008, section C.2.4.

approach which should carefully consider the characteristic of the industry in assessing such settlement agreements.

Reverse payment agreements

- 4.2.3 According to the Preliminary Report, reverse-payments in settlement agreements limit the market entry of generic medicines, by providing for payments by originators to generic companies.¹⁹
- 4.2.4 In the United States these agreements and their implications for the operation of competition law have been the subject of scrutiny by the courts and antitrust authorities, as well as the subject of a growing body of academic literature for many years. The question of their legitimacy remains however, highly controversial. The FTC and the United States Department of Justice have conflicting views on the lawfulness of such agreements. No clear guidance can therefore be drawn from the US experience.
- 4.2.5 The questions surrounding reverse payment agreements are highly complex. There are a wide variety of ways in which settlement agreements may be structured and the forms which reverse payments may take. On this basis, and in the absence of any clear view on the competitiveness of these types of payments, there should be no *per se* presumption against the lawfulness of reverse payment settlements in the EU. As stated above, we do not think that competition authorities are best placed to evaluate the strength of IPRs. Any attempt to second guess the outcome of court proceedings is likely to lead to significant uncertainty regarding the use of settlement agreements, which will in turn weaken patent protection.

License agreements

- 4.2.6 Patent settlements may include license agreements, which can take many forms e.g. exclusive or non-exclusive, cross-licensing agreements, pools, agreements not to license to third parties or agreements to license jointly. Licensing agreements allow licensees early access to new medicines, whilst the licensor is able to generate revenues which can then be invested in further R&D. License agreements disseminate new technology, bring new competitors to the market and increase rewards for innovation. The effects of licensing are generally pro-competitive and overall, beneficial to consumer welfare.
- 4.2.7 In settlement agreements which include the granting of a license to generic companies, the parties usually agree to withdraw all litigation claims and undertake not to initiate new litigation concerning the same subject matter in the future (so-called non-challenge clauses). While this issue was not specifically addressed in the Preliminary Report, such clauses have previously been a source of concern for the Commission and the European Court of Justice. The Commission took the view that non-challenge clauses in the context of settlement agreements were generally not caught by Article 81(1) EC since they are inherent in such agreements. Conversely, the European Court of Justice rejected this argument, holding

¹⁹ European Commission, Pharmaceutical Sector Inquiry Preliminary Report, 28 November 2008, section C.2.7, para. 894.

that, depending on the legal and economic context, a non-challenge clause may restrict competition within the meaning of Article 81(1) EC.²⁰

4.2.8 We understand the Court's concerns about the potential anticompetitive effects of non-challenge clauses. Nonetheless, we think that the Commission should continue to assess the effect of such clauses taking into consideration the specific features of settlement agreements. Patent settlements aim at replacing uncertainty with certainty, and as such, these agreements are pro-competitive. Since non-challenge clauses represent the essence of a settlement agreement, they have to be seen as necessary restraints and, as a result should fall outside the scope of Article 81 EC.

4.2.9 We believe there is merit in drawing on the example of the Technology Transfer Block Exemption Regulation²¹ where non-challenge clauses are treated as an excluded restriction in cases where there is no right of the licensee to terminate the license. We believe that the Commission should follow this invariably permissive approach in relation to non-challenge clause in settlement agreements. We urge the Commission to clarify this position in its final report to avoid continued legal uncertainty in this area.

5 Regulatory issues

5.1 Discrepancies across Member States

5.1.1 Although the scope of sector inquiry is limited under Regulation 1/2003, we are disappointed that the Commission excluded the influence of Member State regulation from its assessment of the pharmaceutical market. The different pricing policies across the 27 Member States tends to preclude meaningful price competition for originators/generics. The fragmentation of national prices and reimbursement procedures create delays and uncertainties, particularly for originator companies.

5.1.2 Added to this is another factor causing delays, namely, the issue of delays in payment by national health care systems to pharmaceutical companies. According to the *Fenin* jurisprudence²², bodies or organisations (including ministries) which run national health systems do not act as undertakings in their dealings with suppliers, and therefore are not subject to competition rules. This means that pharmaceutical companies cannot rely on competition rules to enforce their rights with particular reference to systematic delays in payment by these bodies.

5.2 National marketing authorisations

5.2.1 The Preliminary Report highlighted the high costs and delays in market entry stemming from the regulatory framework, in particular due to the national marketing authorisation procedure.²³ The current system offers two routes to marketing authorisation: one

²⁰ Case C-65/86, *Bayer AG v. Süllhöfer*, [1988] ECR 5249.

²¹ Commission Regulation 772/2004/EC of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements, [2004] OJ L123/11.

²² Case C-205/03 P, *Federación Española de Empresas de Tecnología Sanitaria (FENIN) v. Commission*, [2006] ECR I-6295.

²³ European Commission, Pharmaceutical Sector Inquiry Preliminary Report, 28 November 2008, section D.2.1 and D.2.3.

centralised before the European Medicines Agency, the other decentralised before national authorities. This lack of harmonisation and rationalisation gives rise to an unnecessary financial and administrative burden, which constitutes an obstacle to innovation. Accordingly, it is our view that this procedure should be made uniform across Member States and that periods for approval should be reduced.

5.2.2 The EU has acknowledged the prejudice caused by these delays and has, as a result, created the opportunity for originator companies to extend their basic patent protection by a maximum of five years.²⁴ The Supplementary Protection Certificate allows originator companies to be compensated for the time period during which, following the filing for a patent application for a new drug, they have to wait for the granting of marketing authorisation before launching this new product on the market. This mechanism, aimed at protecting patent exclusivity, explicitly recognises that patent protection significantly influences originator companies' incentives to innovate.

5.2.3 We are of the view that these existing procedures should be complemented by an in-depth amendment of marketing authorisation system in order to create an efficient and uniform procedure and to maximise innovation in the pharmaceutical industry.

6 Other relevant issues absent from the Preliminary Report

6.1 Competition between generic companies

Pricing issues

6.1.1 The entry of generic products onto the market is intended to benefit consumers by bringing down the price of medicines. As generic medicines are essentially commodities, one would expect to see vigorous price competition on the market between generic companies. The figures provided in the Preliminary Report show that, in most Member States, at the time of initial market entry, generic drugs are sold at a price 25% lower than that of the patented medicines and that over time, with increased market penetration by other generic manufacturers, this price drops to around 60% of the originator product.²⁵

6.1.2 Compared with originators, generic companies bear very little R&D costs, and manufacturing represents no more than 15% of the final product cost. We were therefore surprised that DG competition chose not to investigate the issue of price competition among generic companies in its Preliminary Report. The significance of such competition for the market and the Commission's failure to examine this area, focusing instead only on the behaviour of originator companies, means that any findings on the functioning of the market are necessarily limited.

6.2 Parallel trade

6.2.1 As the Commission aims at ensuring that safe, affordable, and innovative medicines are introduced on the market, it is disappointing that issues relating to parallel trade were

²⁴ Council Regulation 1768/92/EEC of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, [1992] OJ L182/1.

²⁵ European Commission, Pharmaceutical Sector Inquiry Preliminary Report, 28 November 2008, section B.1.3.2.1.

excluded from DG Competition's analysis of this sector. Parallel trade has a significant influence on the behaviour of pharmaceutical companies. The *Sot. Lélos kai Sia* case in September 2008²⁶, in which the European Court of Justice considered that pharmaceutical companies were entitled to protect their business and to restrict parallel trade if they received orders *out of the ordinary* in terms of quantity, has contributed to legal uncertainty in this area.

6.2.2 This legal uncertainty was reinforced by the adoption of the Commission's proposal for the pharmaceutical package, amending the conditions under which a product can be repackaged. In this context, it would have been instructive for the Commission to have included an in-depth investigation of the influence of parallel trade on the pharmaceutical market in its Preliminary Report. We look forward to future guidance in this area.

7 Contacts

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²⁶ Joined Cases C-468/06, C-469/06, C-470/06, C-471/06, C-472/06, C-473/06, C-474/06, C-475/06, C-476/06, C-477/06 and C-478/06, *Sot. Lélos kai Sia E.E* (not published yet).