

Competition in Pharmaceuticals: the challenges ahead post AstraZeneca ⁽¹⁾

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1. Introduction

Traditionally, the Commission's anti-trust enforcement activity in the pharmaceutical sector has focused on removing private obstacles to parallel trade in pharmaceuticals within the Single Market. In the summer of 2005, however, the Commission adopted its first abuse of dominance decision in that sector ⁽²⁾. Since then, much has been happening in terms of anti-trust enforcement activity in pharmaceuticals at Community level. The time has come to take stock of the most recent developments post *AstraZeneca*, and to take a glimpse at some of the challenges ahead.

In the area of health care, the European Union ("EU") shares competence with its Member States who are responsible for the organisation and delivery of health services and medical care within their territories ⁽³⁾. In particular, this means that national pricing and re-imbursement rules for pharmaceuticals are not harmonised within the Single Market. Nevertheless, in carrying out their responsibilities, Member States and health care stakeholders such as national health services and pharmaceutical companies are bound to respect the EC Treaty rules on free competition and the free movement of goods and services within the internal market.

This is where the Community comes in notably the European Commission ("the Commission"). The Commission is responsible for ensuring compliance with these EC Treaty freedoms. The Commission's activities in this area are focused on two pillars: first enforcement action, and second advocacy. In this respect, the Community is no different from its other major trading partners such as the United States and Canada.

2. Enforcement action: A two pronged approach

Since *AstraZeneca*, the focus of competition policy enforcement action in pharmaceuticals in the EU has been twofold. First, there is the traditional focus on intra-brand competition, by going after barriers to parallel trade in pharmaceuticals within the Single Market. Second, the adoption of the *AstraZeneca* case has heralded a new era in the Commission's enforcement activities in pharmaceuticals aimed at promoting inter-brand competition by spurring on innovation between pharmaceutical producers and by increasing price competition stemming from generic entry after patent expiry.

(a) Intra-brand competition

On intra-brand competition, we are faced with two types of conduct by pharmaceutical companies to impede parallel trade within the Community. First, there are the so-called dual pricing schemes where companies seek to apply differential pricing depending on the destination of their supplies within the Community, thereby reducing the scope for arbitrage. Second, there are the so-called supply quota systems where companies restrict the quantities they supply wholesalers in each national market to meet local demand alone thereby reducing the quantities available for parallel exports.

Regarding dual pricing schemes, the Commission's decision in the *Glaxo Wellcome* case ⁽⁴⁾, condemned GSK's dual pricing scheme in Spain as contrary to Article 81(1) of EC Treaty and refused to grant an exemption under Article 81(3) of the

⁽¹⁾ The content of this article does not necessarily reflect the official position of the European Communities. Responsibility for the information and views expressed lies entirely with the author.

⁽²⁾ COMP/37.507 — Generics/Astra Zeneca, 15.06.2005. See also, "*AstraZeneca*: the first abuse case in the pharmaceutical sector." EC Competition Policy Newsletter, Number 3 — Autumn 2005, page 54.

⁽³⁾ See Article 152(5) EC Treaty.

⁽⁴⁾ Cases: IV/36.957/F3 *Glaxo Wellcome* (notification), IV/36.997/F3 *Aseprofar and Fedifar* (complaint), IV/37.121/F3 *Spain Pharma* (complaint), IV/37.138/F3 BAI (complaint), IV/37.380/F3 *EAEP* (complaint), 8 May 2001, OJ [2001] L 302/1.

EC Treaty. The Commission's approach is predicated by two principles⁽⁵⁾:

- The Single Market in pharmaceuticals requires the unhindered free movement of products — private companies cannot erect barriers to undermine this without distorting intra-brand competition.
- The efficiency claims advanced by the research based pharmaceutical industry is unsubstantiated — i.e. there is no evidence that partitioning the common market would spur on global investment in inter-brand innovation.

On 27 September 2006, the Court of First Instance ("CFI") delivered its long awaited judgment in the *GlaxoSmithKline* case⁽⁶⁾, partially annulling the Commission's decision in the *Glaxo Wellcome* case. The GSK case is currently pending on appeal before the European Court of Justice ("ECJ"). It was appealed by all parties including the Commission in December 2006. Such multiple appeals may be expected to arouse judicial interest and consequently receive its fair share of scrutiny by the ECJ⁽⁷⁾.

Regarding supply quota systems, on 21 November 2006, the Athens Appeals Court (AAC) referred a number of questions in several civil cases pending before it, brought by Greek wholesalers against GSK, to the ECJ, the so-called *Syfait II* preliminary reference⁽⁸⁾. The questions referred are more or less identical to those referred to the ECJ by the Greek competition authority in the *Syfait I* case⁽⁹⁾.

In essence, the AAC is asking the ECJ to rule on whether the refusal of a dominant undertaking to meet fully the orders sent to it by pharmaceutical wholesalers, an association of pharmacies and

an association of warehousing pharmaceutical products, due to its intention to limit their export activity and, thereby, the harm caused to it by parallel trade, constitutes *per se* an abuse within the meaning of Article 82 EC Treaty⁽¹⁰⁾. The AAC asks *inter alia* if such refusal to supply may be an abuse even when parallel trade is particularly profitable for the wholesalers due to price difference, resulting from Member State intervention, that is to say where pure conditions of competition do not prevail in the pharmaceuticals market.

The Commission intervened before the ECJ in the *Syfait I* case and may be expected to do the same in the *Syfait II* preliminary reference. In his Opinion in the *Syfait I* case, Advocate General Jacobs summarised the Commission's position as follows:⁽¹¹⁾

"... a restriction of supply is abusive unless the dominant undertaking can point to an appropriate and sufficiently substantial objective justification for its conduct. ... [none] of the factors identified by the Greek Competition Commission could be relevant for the purpose of such a justification."

The European Commission supports its conclusion partly on the basis of the anti-competitive character of the conduct in question. A dominant undertaking is understood to abuse its position when it refuses to supply its goods and services with the aim of limiting or excluding actual or potential competitors from a given market and of reinforcing its position on that market. Given that any attempt by a producer to restrict supply in order to limit parallel trade is usually motivated by a concern to restrict intra-brand competition on the market of import, such a restriction is normally to be regarded as abusive. Partly, also, the Commission relies upon the market-partitioning object of the conduct at issue. The Court has consistently interpreted Articles 81 and 82 EC as prohibiting conduct aimed at dividing the common market."

Thus, in the last months of 2006, the ECJ was seized of two cases on parallel imports: one involving the applicability of Article 81 of the EC Treaty to dual pricing schemes and the other invoking the applicability of Article 82 of the EC Treaty to supply quota systems. Such timing means that the long standing debate on whether parallel trade in pharmaceuticals affects innovation or is pro-competitive and an important factor in market integration, is now firmly before the ECJ.

⁽⁵⁾ On the pros and cons of parallel trade from an economic perspective, see in particular, "Parallel imports and price controls" by Gene M. Grossman and Edwin L.-C. Lai, CEPR Discussion Paper No. 5779, August 2006; "The economic impact of parallel imports of pharmaceuticals" by Ulrika Enemark, Kjeld Møller Pedersen, Jan Sørensen, June 2006, CAST and University of Southern Denmark; and "Pharmaceutical parallel trade in Europe: stakeholder and competition effects" by Panos Kanavos and Joan Costa-Font, Economic Policy October 2005 pp. 751-798.

⁽⁶⁾ Case T-168/01 *GlaxoSmithKline v Commission*, judgment of 27 September 2006. For commentary on the judgment see "Parallel Exports in the Pharmaceuticals Sector: Take Nothing For Granted", Richard Eccles, [2007] ECLR 134.

⁽⁷⁾ See Case C-501/06 P before the ECJ.

⁽⁸⁾ See Cases C-468-478 *Sot. Lelos kai Sia EE & Others v GlaxoSmithKline*, OJ [2007] C20/03-13.

⁽⁹⁾ See Case C-53/03 *Syfait & Others v Glaxosmithkline*, opinion of Advocate General Jacobs 28 October 2004 and judgment of the ECJ of 31 May 2005.

⁽¹⁰⁾ See further "An analysis of the application of Article 82 EC to supply-restrictions in the pharmaceutical sector", September 2005, EAEPC.

⁽¹¹⁾ See Case C-53/03 *Syfait & Others v Glaxosmithkline*, opinion of Advocate General Jacobs 28 October 2004, paragraphs 49 and 50.

(b) Inter-brand competition

As the much contested and long debated issues surrounding parallel trade in pharmaceuticals were making their way to the Community's highest judicial instance, the Commission's enforcement efforts have been focused on promoting inter-brand competition.

In 2005 the Commission adopted the *AstraZeneca* decision on inter-brand competition. AstraZeneca was fined for abusing its dominant position by misusing the Community rules for the grant of supplementary patent certificates and marketing authorisations to delay generic entry of its ulcer treatment drug Losec.

The *AstraZeneca* decision is currently under appeal to the CFI where the Commission is actively defending its decision and would naturally hope to prevail ⁽¹²⁾.

Since the adoption of the *AstraZeneca* decision, Commissioner Neelie Kroes explained to the European Parliament ("EP") in response to an oral question in the summer of 2006 ⁽¹³⁾, that the aim here is "to promote competition in innovation for patented medicines between the pharmaceutical producers, which has declined in Europe in the last decade, and to encourage inter-brand competition from generic substitutes after patent expiry". Commissioner Kroes emphasised that this should "in time, contribute to ensuring a wider choice of both patented and generic pharmaceutical products to European patients at affordable prices". Commissioner Kroes also stressed that the Commission will take due account "of the need for the industry to recover its research and development costs, given the industry's heavy dependence on innovation for its further competitiveness." Commissioner Kroes assured the EP that the Commission was "not circumspect about rigorously applying the anti-monopoly provisions in the pharmaceutical sector, for generic competition is an area which has suffered from under-enforcement in the past." Especially since, as Commissioner Kroes pointed out "the importance of the generic segment for the provision of affordable medicines in the enlarged Union cannot be ignored." Commissioner Kroes summed up that this was why "the Commission will give greater priority to competition in the generic sector in the immediate future."

In doing so, the Commission will likely continue to build on the experience gained from the adop-

tion of the *AstraZeneca* decision, and tackle various types of life cycle management strategies by research based pharmaceutical companies aimed at raising rivals' entry barriers, thereby dampening inter-brand competition. It may also be expected that current enforcement activities would contribute to the Lisbon Agenda by stimulating innovation in the pharmaceutical sector whilst delivering on cost-containment through generic competition.

3. The importance from a competition policy standpoint of inter-brand competition in pharmaceuticals

Commissioner Kroes' announced focus on enforcement action aimed at inter-brand competition reflects the importance of that topic from a competition policy — and from a broader economic policy — standpoint.

(a) The importance and specific features of the pharmaceutical sector

The pharmaceutical sector is a knowledge-based manufacturing industry and an important part of the health care sector. In the past decade, the health care sector has created millions of new jobs. It employs 10% of the active EU population. As life expectancy of EU citizens is steadily rising, the health-care related economy has a strong growth potential with the greying of Europe, and the increasing demand for medicinal products.

The industry is characterised by players of a different nature: a limited number of R&D based multinationals and an increasing number of niche innovative small and medium sized enterprises ("SMEs"), as well as generic producers which compete with medicinal products for which patent protection has expired. The industry has been undergoing a concentration process concerning mainly R&D based multinationals. However, a recent trend might have started with the multinational Novartis taking over the generic producer Hexal ⁽¹⁴⁾.

The research based pharmaceutical producers attempt to out compete each other on innovation, as demand for innovative products is relatively inelastic allowing for high prices. As patent term expiry approaches, companies are increasingly confronted with the prospect of competition from generic equivalents with significantly lower price levels, the race to innovate and migrate the patient population to the next generation medicinal products intensifies.

⁽¹²⁾ See Case T-321/05 *AstraZeneca AB & AstraZeneca plc v Commission*, 2005/C 271/47.

⁽¹³⁾ Commissioner Neelie Kroes' reply to Oral Question put by the honourable Member of the European Parliament Mr von Boguslaw Sonik, (H-0459/06).

⁽¹⁴⁾ See Case M.3751 *Novartis/Hexal*.

Focussing enforcement activities on inter-brand competition means dealing with elements exercising direct pressure on competitors' prices. Such action has the potential to yield significant welfare enhancing effects. This is all the more so in the EU-27, in view of the importance of the affordability of medicines for the EU-12.

Obstacles to the entry of innovative medicinal products and generics may pose competition problems for example when, in order to maintain its market power, a dominant undertaking strategically uses patent procedures. Such strategic use raise additional barriers to entry, for which little economic justification but for the maintenance of market power is likely to exist, and are often coupled with the dominant undertaking's effective threat of vexatious litigation. As a result, such behaviour often deny patients the use of better, more and cheaper medicinal products, because the incumbent's strategy aims at prolonging the product-life cycle of its product rather than competing with innovative new medicinal products and generics.

The risks that such behaviour cause to patients and to the economy is all the more acute, since the current cycle of the pharmaceutical industry is characterised by dwindling R&D pipelines coupled with increasing numbers of medicinal products approaching patent expiry.

(b) Competitiveness in the pharmaceutical sector

The Commission's selection of competition law enforcement priorities is only one aspect of the Commission's initiatives, aimed at enhancing the competitiveness of the EU pharmaceutical sector and at creating welfare benefits in Europe. By way of illustration, the Recommendations of the High Level Group on Innovation and Provision of Medicines (the so-called "G10 Medicines Group") *inter alia* identified that full competition should take place (through generics and for non-reimbursed medicines). The G10 Medicines Group Recommendations have led to an overreaching review of the EU's pharmaceutical legislation (the so-called "Pharmaceutical Review") managed by the Commission's Directorate-General Enterprise. The Pharmaceutical Review (2000-2004) aims to improve market access for innovative medicines and to deliver a competitive generic market. MEMO/05/186.

Work is currently on-going on the potential for convergence of national pricing and reimbursement schemes. This is taking place within the Pharmaceutical Forum (2005-2008), which is a collaborative effort between Directorate-General

Enterprise and Directorate-General Health and Consumer Protection. One of the aims of the Pharmaceutical Forum is to find alternative ways of controlling national health care expenditures including the option of letting manufacturers set the prices of new products, while negotiating appropriate safeguard mechanisms for Member States to contain expenditure in compliance with EU competition rules IP/06/1282. Competition law enforcement action that protects inter-brand competition between generics and patented drugs, such as the *AstraZeneca* decision, has the potential of contributing to important savings for national health care systems: for example, the introduction of generics can lead to the increased availability of more affordable alternatives to patented branded pharmaceutical products — usually in the region of 20-50%, but possibly up to 80%, cheaper.

Competition law enforcement has also a major contribution to make to promoting more innovation in pharmaceuticals. In the early 1990s, the European pharmaceutical industry was the leader in innovation on a world-wide scale. Today, the US pharmaceutical industry has become the leading inventor of new active ingredients. In particular, the EU-based R&D has been moving to the US at a time when the EU will be facing new challenges from India and China. A particular attention must thus be given to deterring behaviour that stifles innovation — such as abuses of dominance that fend off small, innovative SMEs. A stronger competitive constraint on "old" block-busters will also provide additional incentives to pharmaceutical companies to develop new products through efficient and timely R&D programmes rather than resting on their laurels, and focussing their energy on the preservation of the rents based on past R&D efforts.

4. The need for Community-wide collaboration and advocacy

Article 152(2) of the EC Treaty provides that:

"The Community shall encourage cooperation between the Member States in [public health] and, if necessary, lend support to their action. Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in [public health]. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination."

In the area of competition policy, since the entry into force of Regulation 1/2003 and the package for the modernisation of the Community's framework for the enforcement of Articles 81 and 82 of the EC Treaty, on 1 May 2004, a network of

proactive public enforcers made up of the national competition authorities (“NCAs”) of the Member States, otherwise known as European Competition Network (“ECN”) has been set up.

The ECN provides a framework for applying and developing the EC anti-trust rules. It does so through work-sharing and case-allocation between NCAs and the Commission; as well as through joint action and assistance in fact-findings and investigations. Just as importantly, it also promotes the exchange of information and sharing of experiences both in terms of cases and policy. By doing so it provides a forum to foster the development of a common competition culture within the ECN.

To enhance the effectiveness of the ECN, a number of Working Groups have been set up, some deal with horizontal issues such as leniency and abuse of dominance whilst others have a sectoral focus. In 2005 the ECN Pharmaceuticals Sub-group was established. It is made up of the NCAs of the Member States and the Commission.

The initiative was highly welcomed as it was anticipated that it would help all those concerned in learning from the experiences of the other members of the network. In time it is hoped that it will prove to be a valuable vehicle to support its members’ enforcement and advocacy efforts in the pharmaceutical sector. At the very least, it may be expected to foster a culture of finding common solutions to shared problems in the enforcement of the EC anti-trust rules in the pharmaceuticals sector. The purpose of the ECN Pharmaceuticals Sub-group is to harness the collective expertise of the ECN to deliver not only better and consistent competition enforcement throughout the EU, but also to assist the Member States in their own advocacy efforts aimed at injecting more competition into their respective health care sector.

Typically, this involves the reforming of the national regulatory framework for the provision of medical care, by introducing greater inter-play of market forces, based on patient/practitioner choice, value for money, the rational distribution of medicines and services and the availability of greater information on the different products and services. The ECN Pharmaceuticals Sub-group aims to harness this process by providing a focal point for the sharing of the different experiences, processes, tools and analytical frameworks applied throughout its Member States.

Such a coordinated approach is all the more important in public health where responsibility for the achievement of the primary objective of deliv-

ering “*high level of human health protection*”⁽¹⁵⁾ for Europe’s citizens is split not only between the Community institutions and its Member States, but necessitates that orchestration of different Community and national policy areas of which competition policy forms one part.

In such circumstances, competition enforcement action alone constitutes a partial response to the competition policy challenges facing the Community in the pharmaceutical sector. To deal with these challenges in a credible and sustainable manner, attention must also be given to advocacy, policy screening and reflection initiatives aimed at delivering an analytical framework for promoting an environment for the rational and efficient allocation of resources in the pharmaceutical sector, based on informed consumer choice and transparency.

The ECN Pharmaceuticals Sub-group provides an important vehicle for the dissemination of such analytical tools thus empowering its members in turn to harness the efficiency gains and associated cost savings that may be derived from the injection of greater competition in the delivery of pharmaceuticals to European patients.

5. Conclusion

It would seem that interesting times lie ahead in terms of competition policy enforcement and advocacy in the pharmaceutical sector.

At the very least, the Commission’s past focus on intra-brand competition may be expected to be complemented by a more nuanced multi-faceted approach aimed at inter-brand competition to deliver enhanced consumer welfare in medicines to patients throughout the EU.

The greater emphasis placed on advocating competition based market led solutions to the address challenges facing the EU in delivering innovative yet affordable pharmaceuticals to European patients may in time be expected to empower the EU to reap dividends in this area.

However, doing so will require steady and sustained efforts from all those concerned within the EU to work together and stay the course.

⁽¹⁵⁾ See Article 152(1) EC Treaty.