SPEECH

Georg de Bronett

EU competition policy and generic medicines

First EGA Legal Affairs Forum

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1. Introduction

Thank you for inviting me to address this forum. The topic assigned to me is “EU competition policy and generic medicines”. Before I address this key issue, I would first like to place it in a broader context.

2. The Lisbon context

A key priority of the Barroso Commission is to increase the competitiveness of the European economy, notably by strengthening the knowledge-based industries. This ambition forms part of the so-called Lisbon strategy. A mid-term review of this strategy is due in the spring.

So where do the pharmaceutical sector and competition policy enter into the Lisbon process?

Firstly, I can think of few industries which are more knowledge-based or potentially more significant to the EU’s future competitiveness than the pharmaceutical industry.

Secondly, competition policy is highly relevant as competitive markets provide incentives for companies to innovate, especially in knowledge-based industries such as pharmaceuticals.

Thirdly, the strategy aims to plug remaining holes in the internal market. As you know, there are still quite a few holes that need to be filled before we are able to speak of a genuine internal market in pharmaceuticals.

What can DG Competition do to speed up this process of integration? To use the language of contemporary international politics, DG Competition can and will employ both soft power and hard power.

3. Soft power: regulation and competition advocacy

The need to use soft power relates to the undisputed fact that the pharmaceutical sector in Europe is intensely regulated.

A pharmaceutical product remains closely regulated throughout its long life cycle.

- national and international patent law is crucial at the time of conception of the active substance – the core element in a medicine;

- EU pharmaceutical law comes very much into play in connection with the manufacturing and marketing of the final product;

- national rules influence pricing, reimbursement, wholesale and retail margins, as well as copayments by the final consumers.

While DG Competition's hard power – that is Articles 81 and 82 on anticompetitive agreements between companies and abuses by dominant companies of the Treaty - cannot normally be applied to state regulation, even if such regulation harms competition, DG Competition will try to use soft power – gentle or not-so-gentle persuasion - to push such regulation in a more competition-friendly direction. We call this activity competition advocacy. This can be a very effective way of solving unintended competition problems resulting from public regulation.

For example, DG Competition provided input to and assisted DG Enterprise in shaping the package of EU legislation that is the subject of several of the presentations at this conference.

An example of advocacy by DG Competition vis-à-vis the Member States concerns the liberal professions, including pharmacists, notaries, accountants, architects, engineers and even lawyers. This ongoing advocacy campaign was effectively launched by a report published by the Commission in February 2004.

4. Hard power: full applicability of competition rules to the pharmaceutical sector

This does not mean that there is no scope for the application of the arsenal of antitrust instruments provided by the Treaty to enforce its competition rules: Article 81 which prohibits anticompetitve agreements and concerted practices between companies, as well as decisions of associations of undertakings, and Article 82 which prohibits abuses by dominant companies.

On the contrary, if anything, the restrictions on competition that may result from the regulatory framework make it even more vital that DG Competition's Treaty-based hard power is applied to the residual competition on the market.

It is sometimes claimed that the special nature of the pharmaceutical sector means that competition law should not be applied to the sector in full.

As a matter of law, however, no limitation applies to the scope of competition law in the pharmaceutical sector.

There are no pharmaceutical opt-outs or other special rules in the context of Article 81 and Article 82 or the merger regulation.

The specificities of the pharmaceutical sector are obviously taken into account when the Commission assesses pharmaceutical cases. But this is no different from the approach in other sectors.

For example, in analysing pharmaceutical cases we have to take into account that the geographic markets are often national and not EU-wide. As I mentioned, we are still far from a genuine internal market in pharmaceuticals.

One important reason for this fragmented state of affairs is that prices and reimbursement for prescription medicines are highly influenced by public intervention.

5. Re-evaluation of DG Competition's approach to parallel trade cases

This fragmentation into distinct national geographic markets characterised by different price levels for the same products obviously creates incentives for arbitrage. This in turn creates incentives on the part of the manufacturers to impede such arbitrage.

It can safely be said that the Commission's own action in the pharmaceutical antitrust field has traditionally focused on assessing whether such impediments to parallel trade infringe Article 81 which prohibits agreements restricting trade between the Member States.

I will not enter into the details of this rather long line of Commission prohibition decisions and subsequent court judgments on parallel trade. Suffice it to say that whenever the Commission has prohibited one particular type of behaviour the industry has – in an increasingly sophisticated manner – adopted new ways of impeding parallel trade between Member States.

Most recently, through so-called supply quota systems. Following the judgment by the court of justice in the Bayer/Adalat case which the Commission lost, a number of manufacturers copied Bayer's supply quota system, effectively limiting the number of boxes they will supply to their wholesalers.

There is a whole range of supply quota arrangements. The supplies may be limited to domestic needs or past orders. Sometimes export wholesalers do not obtain supplies at all. The common feature is the manufacturers' claim that the quotas are unilateral and therefore not covered by the prohibition of anticompetitive agreements in Article 81 of the Treaty.

DG Competition is currently reflecting on its approach to this behaviour, in particular whether it is caught by Article 82 of the Treaty, which bans abuses by companies of their dominant position.

In this reflection process, DG Competition will have to take into account the pending judgment by the European Court of Justice on whether a supply quota system in Greece violates Article 82. In his recent, non-binding opinion, Advocate-General Jacobs says that it does not.

6. Misuses of government procedures to stifle competition

In addition, my staff have found that restrictions of competition in the pharmaceutical sector can arise not only from behaviour linked to buying and selling on the actual market.

In fact, in recent years my unit's work has increasingly been moving towards looking at how companies may misuse government procedures to prevent or delay market entry of generic versions of original medicines whose patent protection is about to expire.

I would in particular refer to two regulatory systems that very much determine the conditions of competition in the pharmaceutical sector: the patent system and the procedures for the authorisation of medicines.

7. US antitrust practice

In this work we have found inspiration and encouragement in US antitrust law and the Federal Trade Commission's recent enforcement practice.

For example, according to longstanding case law the acquisition of a patent obtained by fraudulent means before the patent office and the subsequent reliance on such a patent can violate US antitrust law.

Moreover, in recent years, the federal trade Commission has vigorously pursued misuse of the US system for authorisation of medicines.

Some cases have involved research-based companies filing false patent information to the federal drug administration. The filings have been scrupulously timed so as to significantly delay the authorisation of generic versions of a medicine whose patent protection is about to expire.

At potentially huge cost to consumers and insurers.

The former chairman of the FTC has described its action in the pharmaceutical sector as its most aggressive use of US antitrust law since the 1970s.

It appears that this work has borne fruit.

When looking at the experience we should bear in mind that there are some differences between the US and European regulatory contexts which makes it somewhat easier to foreclose generic competition in the US for a significant period of time.

Under US law, the first generic version of an original medicine authorised by the federal drug administration obtains six months market exclusivity in relation to competing generic versions. The research based company under threat can therefore focus its exclusionary efforts on one generic firm only. Such generic exclusivity does not exist in Europe.

Due to the absence of price control in the united states, generic market entry tends to result in particularly sharp falls in prices.

8. The AstraZeneca case

This brings us to the Commission's own abuse of government procedures case in the pharma sector. This is the AstraZeneca case where the Commission issued its preliminary findings – a so-called statement of objections – in July 2003.

Our preliminary findings are that AstraZeneca has abused – within the meaning of Article 82 - both the patent system and the system for authorising medicines to protect its anti-ulcer blockbuster Losec from generic competition when the patent began to expire from 1999 onwards. At that time annual sales of Losec amounted to 6 billion euros.

The Commission's first preliminary finding is that AstraZeneca filed misleading information to various patent offices in the EU and the EEA to obtain extra patent protection in the form of supplementary protection certificates for Losec with the aim of delaying market entry of generics.

The Commission's second provisional finding is that AstraZeneca surrendered its market authorisations for Losec in selected countries to prevent market entry of generic versions of Losec, and to prevent parallel trade in Losec.

I should stress that the AstraZeneca case is about the use and misuse of government procedures and not about the use of intellectual property rights.

In this sense the case is different from other important Article 82 cases, such as Magill and IMS, and the recent Microsoft case. These cases are about granting competitors access to property or information protected by IP rights.

There is not much more I can say about the AstraZeneca case at this stage. A statement of objections is a confidential document. The press release on the statement of objections can be found at the DG COMP website.

If you are interested in the FTC's numerous actions related to generic medicines I can refer you to the FTC website www.FTC.gov

9. Other potentially anticompetitive behaviour to exclude generic competition

Apart from the types of behaviour in the AstraZeneca case, my services have learnt about other forms of possibly anticompetitive behaviour, in particular aimed at excluding generic competition.

Two examples concern patenting, which is simply aimed at excluding competitors, as well as baseless litigation.

But we have also come across potentially anticompetitive practices involving generic companies.

For example payments from research based companies to their generic competitors to induce them to delay market entry.

In the US the FTC has in recent years taken enforcement action under US antitrust law against such agreements whereby research based companies have paid its main generic competitor to delay its market entry.

In Europe some national competition authorities have also examined allegations that generic firms have entered into anticompetitive agreements between themselves.

10. Competition policy rationale for generic competition

The competition policy rationale for protecting generic competition is that generic market entry normally entails immediate and significant cost savings for both consumers and taxpayers.

The Swedish media recently reported that the obligatory generic substitution at the pharmacy level introduced in 2002 has virtually halted the spiralling reimbursement costs. During the 1990s, reimbursement costs for medicines in Sweden increased by at least 10 per cent per year.

In addition, strong generic competition is likely to promote innovation in the pharmaceutical sector in the long term by pushing research based companies towards continual innovation.

This conclusion is supported by a comprehensive study on pharmaceutical innovation published in November last year by the economic consultant Charles River Associates. The report was commissioned by our colleagues in DG Enterprise.

Generic competition therefore fits nicely into the Lisbon goal of strengthening Europe's knowledge-based industries and thereby its global competitiveness.

However I should also emphasise that from a European competition policy perspective generic competition is not an end in itself. EU competition law is about protecting the competitive process, not competitors as such.

Allow me to put it even more crudely: if generic firms cannot successfully compete on the merits we have no power, and indeed no interest, in intervening in their favour.

11. A more comprehensive antitrust approach in the pharmaceutical sector

Finally, let me briefly outline the approach that I and my staff intend to pursue in the future.

As I have said, we are currently evaluating our approach in the field of parallel trade. In any case, we are likely to cast our net wider than in the past, covering not least the issue of generic market access on fair terms.

As part of this more comprehensive approach, we will closely monitor market and regulatory developments. Today's conference provides an excellent opportunity to this end.

We would be particularly interested to learn whether there are any aspects of the new pharmaceutical legislation at EU level which might be susceptible to misuse.

I will conclude by saying that competition enforcement in the pharmaceutical sector is a challenging task. This is a very dynamic industry where the regulatory and market context at national, community and international level is constantly changing.

We will do our best to keep up with this moving target.

Thank you for your attention