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The EC's Sector Inquiry on Pharmaceuticals

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On January 15, 2008, the European Commission initiated a sector inquiry on pharmaceuticals. This paper will briefly address three issues related to the inquiries:

1. First, what purpose do sector inquiries generally serve?
2. Second, what has sparked off the inquiry in the pharmaceuticals sector?
3. Third, what can we expect in light of previous experiences with other sector inquiries?

1. What Is the Purpose of Sector Inquiries?

According to Article 17 of EC Regulation 1/2003, the Commission can conduct sector inquiries “where the trend of trade, the rigidity of prices or other circumstances suggest that competition may be restricted or distorted within the common market” and in the course of such an inquiry, the Commission can make use of its traditional powers of investigation (i.e., with formal requests for information and surprise visits), to the extent “necessary for giving effect to Art. 81 and Art. 82 EC Treaty.”¹

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¹ This provision is not new. It essentially replaces the old Article 12 of Regulation 17/62.

However, in practice, the Commission has hardly undertaken any sector inquiry under the latter Regulation. The first (and in fact only) “serious” Commission inquiry under Article 12 of Regulation 17/62 was only launched in 1999 and it covered three segments of the telecommunications sector: leased lines, mobile roaming, and residential local loop, in that order, where “serious” means an inquiry that led the Commission to undertake concrete antitrust enforcement actions. In other words, not inquiries that essentially aimed at “soft” competition advocacy (e.g., liberal professions, although DG COMP does not list that inquiry amongst its sector inquiries).

Since the entry into force of Regulation 1/2003 on May 1, 2004, the Commission has already launched four comprehensive sector inquiries on the basis of Article 17. They concerned, respectively, energy, retail banking, and business insurance (June 2005) and now pharmaceuticals (January 2008). Why have sector inquiries become so fashionable?

We see two fundamental reasons for this. First, on May 1, 2004 the Commission buried its 40-year old, resource-intensive notification system that had allowed companies to request (and usually obtain) antitrust clearance for agreements which usually were anodyne or which were certainly presented as being anodyne. The abolition of this system freed human resources to invest in a more pro-active antitrust enforcement policy. Second, in the last decade we have witnessed an increasingly economic approach in the assessment of allegedly anticompetitive conduct.

The combination of these two factors explains, in my view, why the Commission decided to revive the sector inquiry tool that had been largely dormant since 1962. The ambition was two-fold:

1. to detect concrete enforcement cases that really mattered (i.e., where there was a clear theory of harm and where the Commission's intervention could make a difference in terms of consumer welfare); and
2. to deal with these cases on the basis of a solid understanding of the relevant markets.

As a consequence, sector inquiries have nowadays become the Commission's favored fact-finding tool outside the cartel area (where leniency applicants tend to be the Commission's prime source of inspiration).

The Commission's ultimate objective is to find prima facie evidence of anticompetitive practices in violation of Article 81 EC (agreements) or Article 82 EC (abuses), to open investigations against the individual companies involved in such infringements and, ultimately, to adopt formal prohibition decisions, with or without fines (Article 7 of Reg. 1/2003) or, in case the market is better served by a forward-looking remedy, to adopt commitment decisions (Article 9 of Reg. 1/2003).

2. What Has Sparked Off the Sector Inquiry for Pharmaceuticals?

There is a bit of a discrepancy between the public statements of Commissioner Kroes and the terms of the Decision initiating the inquiry. While the former are at times provocative, the latter are more informative and perhaps more worrying.

In the press release that announced the launch of the pharmaceuticals sector inquiry, Commissioner Kroes said:

Individuals and governments want a strong pharmaceuticals sector that delivers better products and value for money. But if innovative products are not being

produced, and cheaper generic alternatives to existing products are in some cases being delayed, then we need to find out why and, if necessary, take action.²

In her speech on the same day, the Commissioner noted—even more provocatively—that “patent protection has never been stronger, but the number of new pharmaceuticals coming to market is declining.”

In the decision initiating the inquiry, the Commission identifies upfront certain types of company conduct that could be found to infringe Articles 81 and 82. It refers to commercial practices that allegedly block “innovative and/or generic competition” and thus, in its view, limit consumer choice, reduce economic incentives to invest in research and development (R&D), and damage public and private health budgets.

The identification of specific types of company conduct, coupled with the fact that the sector inquiry was launched by surprise visits to a number of pharmaceutical companies sets this sector inquiry apart from its predecessors. Indeed, the decisions that initiated the two highest profile sector inquiries so far (i.e., energy and retail banking) did not contain such specific references to company conduct. Rather, they contained general statements about market fragmentation, entry barriers, high prices, and so forth. There was no explicit speculation about the causes, and even less a suggestion that specific types of company conduct were at the roots of these market imperfections. Quite logically, these sector inquiries started with formal requests for information to all important stakeholders in the sector, not with the most aggressive of antitrust detection tools (“dawn raids” to use jargon).

² Press Release IP/08/49, European Commission, Commission launches sector inquiry into pharmaceuticals with unannounced inspections (Jan. 16, 2008), *available at* <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/49&format=HTML&aged=0&language=EN&guiLanguage=en>.

In its decision initiating the pharmaceutical sector inquiry, the Commission describes three specific types of suspect commercial practices. The first two seem to refer to unilateral conduct that would have to be assessed under Article 82 whereas the third type of conduct seems—conceptually—to fall primarily within the scope of Article 81.

First, reference is made to the “use of patents . . . , for example, “*de facto* extended patent protection through unilateral conduct or agreements.” Although this could cover all sorts of company conduct related to patent acquisition or enforcement, this reference seems somewhat reminiscent of the *AstraZeneca* case.³ Second, vexatious litigation is mentioned. It is to be noted in this respect that the burden of demonstrating that such litigation is abusive (e.g., the *ITT-Promedia* case),⁴ is quite high for the Commission. Third, the Commission refers to “collusive agreements”. In this respect, Commissioner Kroes refers more in particular to settlement agreements in relation to patent disputes. This is the area where the U.S. Federal Trade Commission has shown pretty vigorous enforcement activity in this field.

3. What Can We Expect, in Light of Previous Sector Inquiries?

As said, the Commission’s powers in sector inquiries are identical to its powers when it opens investigations in enforcement cases based on Article 81 or 82 against individual companies. These powers consist primarily of sending formal requests for information to companies or their associations (Art. 18-1 of Reg. 1/2003) or in carrying out surprise inspections at the companies’ premises. When doing so, the Commission must guarantee due process (e.g., no self-incriminating questions, no use of attorney-

³ Commission Decision 2006/857/EC, Re: *AstraZeneca Plc*, 2006 O.J. (L 332) 24.

⁴ Case T-111/96, *ITT Promedia NV v. Commission*, 1998 E.C.R. II-2937.

client privileged documents, etc). The Commission can also send formal requests for information to national authorities—regulatory authorities as well as antitrust authorities (Art. 18-6 of Reg. 1/2003) and it can take statements from natural or legal persons who consent to be interviewed (Art. 19 of Reg. 1/2003).

In sector inquiries, there are typically a broad set of stakeholders on the market players' side as well as at the public authorities' side. With regards to the latter, it is easy to predict that DG COMP will keep a close and constant liaison with its national counterparts within the European Community (i.e., the national competition authorities with which it forms the European Competition Network) as well as with the U.S. authorities (in the context of the bilateral cooperation agreement between the United States and the European Community). Other national or international public authorities or agencies (e.g., those that grant patents, supplementary protection certificates, market authorizations, etc) will also be involved and are likely to receive requests for information. Last, in other sector inquiries we have seen how DG COMP “walked hand-in-hand” with other Commission departments that possess regulatory powers for the sector concerned. For pharmaceuticals, one would at least expect DG Markt, DG Entr and DG Sanco to be involved.

In all likelihood, the Commission will send out questionnaires in the coming weeks and months to the raided companies, to other pharmaceutical companies, to their associations, and all other private or public entities that it deems to be in a position to adduce relevant evidence or provide useful background.

Commissioner Kroes has announced that the Commission will issue an interim

report in the autumn of 2008. This interim report might or might not be preceded by an issues paper (as happened in the energy sector inquiry), although time seems to be very short to do so in the present case. Furthermore, the interim report might or might not be followed by a public hearing (as was the case in the retail banking sector inquiry). In any event, Commissioner Kroes would like to see a final report in the spring of 2009 (i.e., a couple of months before her mandate as Commissioner in charge of Competition expires).

What does past experience with other sector inquiries tell us about the possible outcomes?

Leaving aside the liberal professions, while this inquiry was essentially a “competition advocacy” effort to move towards less public regulation (because unregulated professions seemed to be more efficient), DG COMP’s other sector inquiries were active on two fronts:

- on the one hand, preparing the ground for case enforcement actions under Art. 81 or Art. 82 EC in individual cases; and
- on the other hand, providing support to regulatory initiatives launched by other Commission departments aimed at making the markets concerned more competitive.

Consider, for instance, the mobile roaming sector inquiry which led DG COMP to carry out dawn raids at the premises of nine mobile telephony operators located in the United Kingdom and Germany in July 2001 (i.e., seven months after it had issued a working document with its initial findings). In July 2004 and February 2005, it issued

statements of objections against some of these operators. In July 2007, it closed the cases—not because it had dropped its objections, but because a Council Regulation that addressed the issue of excessive charges by setting a cap on wholesale and retail roaming charges had entered into force in June 2007.

A common theme for the more recent sector inquiries on energy (specifically electricity and gas), retail banking (including payment systems), and business insurance is that DG COMP (and its Commissioner) teamed up with other Commission departments (and their Commissioners) to undertake joint regulatory and antitrust actions. The reason for this was that the sub-optimal functioning of markets in these sectors was found to be attributable, not just to unlawful company conduct under Articles 81 and 82, but also to “structural” or “technical” barriers to competition that could only be remedied by harmonization legislation. As in the telecoms case, we have witnessed the opening of antitrust investigations while the sector inquiry was ongoing (e.g., dawn raids at E.On, RWE, ENI, and Gaz de France in 2006). While the Commission stressed that these proceedings were not part of the sector inquiry, the issues raised in these proceedings fell squarely within the scope of the sector inquiry. Other Article 81 or 82 enforcement cases in the energy sector as well as in the retail banking sector had kicked-off before the launch of the sector inquiry, but were carried on during the sector inquiry (e.g., *Distrigaz* on the energy side and *MasterCard* on the retail banking side). Once again, while there was no formal link between the enforcement activity and the sector inquiry, the issues fell squarely within the scope of the inquiry.⁵ In *Distrigaz*, the case was settled in October

⁵ As is the similar case with long-term supply agreements in *Distrigaz* and interchange fees in *MasterCard*. See Press Release IP/07/1487, European Commission, Commission opens Belgian gas market

2007 (ten months after the Commission issued its final report in the sector inquiry). In *MasterCard*, the Commission took a prohibition decision with fines in December 2007 (almost a year after issuing its final report in the sector inquiry). Moreover, the theory of harm in the latter case is remarkably similar to the assessment (and the empirical evidence in support of that assessment) set forth in the final sector report.

What outcomes might we expect for pharmaceuticals?

As in previous instances, the inquiry's findings are meant to allow the Commission or national competition authorities to focus any future antitrust enforcement action on the cases that raise the most serious competition concerns.

For the market players concerned, the worst scenario is that this sector inquiry will lead to individual enforcement actions under Articles 81 or 82 that could result in prohibition decisions, possibly with fines (as in the *AstraZeneca* case). As a matter of fact, there are one or two cases in the pipeline—although it is unclear whether these will be pursued (it cannot be overlooked that the Commission learned from these cases that there was no point in singling out one or two companies, but that a broader look at things was warranted).

In another scenario, the Commission might conclude that it is better—from a public interest point of view—to close the enforcement cases under Articles 81 or 82 by accepting company commitments that address the concerns that have been identified in a

to competition (Oct. 11, 2007), *available at* <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/1487&format=HTML&aged=0&language=EN&guiLanguage=en>; and, Press Release IP/07/1959, European Commission, Commission prohibits MasterCard's intra-EEA Multilateral Interchange Fees (Dec. 12, 2007), *available at* <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/1959>.

statement of objections, where the Commission believes that the case is not suitable for fines.

Whether the sector inquiry will have an impact on the regulatory framework for pharmaceuticals is unclear at this stage. Given the focus on allegedly anticompetitive company conduct, one is inclined to answer this question in the negative. However, that begs the question whether the contemplated antitrust activity will not lead to ultra vires interference with the existing regulatory framework.