Final report of the hearing officer in the case COMP/A/37.507 — AstraZeneca

(pursuant to Articles 15 and 16 of Commission Decision 2001/462/EC, ECSC of 23 May 2001 on the terms of reference of hearing officers in certain competition proceedings — OJ L 162, 19.6.2001, p. 21)

(2006/C 291/03)

The draft decision in the abovementioned case gives rise to the following observations:

The investigation was initiated subsequent to a joint complaint lodged on 12 May 1999 by the company Generics (UK) Ltd and the company Scandinavian Pharmaceuticals Generics AB (both referred to hereinafter as 'Generics' or 'the complainant') under Article 82 EC and Article 54 EEA against the pharmaceutical companies Astra AB (currently AstraZeneca AB) and AstraZeneca Plc (both referred to hereinafter as 'AstraZeneca') ([1]) pursuant to Article 3 of Council Regulation No 17/62 ([2]).

The case concerns abuses by AstraZeneca of government procedures aimed at excluding generic firms and parallel traders from competing against AstraZeneca's product 'Losec'. The abuses consisted in the misuse of the patent system by knowingly making misrepresentations to patent offices with a view to extending the basic patent protection for Losec as well as in the misuse of the system for authorising the marketing of medicines by deregistering the original capsule version of Losec in selected countries with a view to preventing the authorisation of generic versions of Losec as well as excluding parallel trade.

A Statement of Objections was sent to AstraZeneca on 29 July 2003 in accordance with Article 2 of Regulation No 2842/98 ([3]). At the same time, AstraZeneca was provided with a list of the documents on the Commission file together with copies of accessible documents from that list in the form of two CD-Roms.

AstraZeneca submitted a joint reply on 3 December 2003 (date of receipt) and requested an oral hearing pursuant to Article 5 of Commission Regulation (EC) No 2842/98.

I should mention, with regard to their right to access to file, that AstraZeneca took the view that the Commission services were obliged to take notes of their meetings with the complainant and that these notes should have been placed on the file. DG Competition stated that in the final decision they would rely exclusively on the written submissions that the complainant made in connection with the meetings in question. They considered that they were under no obligation to draft notes of these meetings unless such notes would be used as evidence in the final decision. I consider that this point of view is supported by the case-law of the Court of First Instance (joined cases T-191/98 and T-212/98 to T-214/98 — *Atlantic Container Line,* paragraphs 377, 386, 394-395). On the basis of this case-law, notes that the Commission may — or may not — make of meetings with the complainant constitute internal documents which do not in principle have to be disclosed, unless the Commission relies on them in the final decision.

The complainant was provided with a non-confidential version of the Statement of Objections on 7 November 2003 and with a non-confidential version of AstraZeneca's reply on 8 January 2004. The complainant submitted comments on the Statement of Objections on 16 December 2003, which were transmitted to AstraZeneca.

With a view to enabling two former employees of AstraZeneca to attend the oral hearing, the setting up of the hearing was somewhat delayed. It took place on 16 and 17 February 2004. AstraZeneca and Generics were both represented. Both before and after the oral hearing, on 9 March 2004, AstraZeneca submitted new information, in particular with a view to further responding to matters raised at the oral hearing.

([1]) With effect from 6 April 1999, Astra AB merged with Zeneca Group Plc to form the United Kingdom company AstraZeneca Plc.

([2]) Regulation No 17 of the Council of 6 February 1962, First Regulation implementing Articles 85 and 86 of the EC Treaty (OJ L 13, 21.2.1962, p. 204)

([3]) Regulation No 2842/98/EEC of the Commission of 22 December 1998 on the hearing of parties in certain proceedings under Article 85 and 86 of the EC Treaty (OJ L 354, 30.12.1998, pp. 18-21).

By letter of 23 November 2004 the Commission then afforded AstraZeneca the opportunity to comment on a number of factual elements and considerations not explicitly mentioned in the Statement of Objections to which the Commission could refer in the final decision against AstraZeneca ('letter of facts'). Upon request, I extended the delay for commenting on this letter of facts to 13 January 2005. Furthermore, I ensured that AstraZeneca was provided with all additional non-confidential documents that had been placed on the Commission's case file subsequent to the issuance of the Statement of Objections. AstraZeneca provided its observations on the letter of facts by letter of 21 January 2005.

It is my opinion that the draft decision only contains objections in respect of which the parties have been afforded the opportunity of making known their views.

In the light of the above, I consider that the rights to be heard of all participants to the procedure have been respected in this case.

Brussels, 31 May 2005

Serge DURANDE