

## PAROXETINE INVESTIGATION – CE-9531/11

### Case closure summary in respect of the IVAX-GSK agreement

#### 1. SUMMARY OF WORK

- 1.1 The Office of Fair Trading ('OFT') commenced an investigation into a number of agreements in the pharmaceutical sector on 11 August 2011.<sup>1</sup> An element of the investigation related to whether an agreement between IVAX and GSK (the 'IVAX-GSK Agreement') breached the Chapter I prohibition of the Competition Act 1998 and/or Article 101 TFEU.
- 1.2 The OFT issued a Statement of Objections ('SO') to the following parties (together 'the Parties') on 19 April 2013:
- (a) GlaxoSmithKline plc, GlaxoSmithKline UK Limited, SmithKline Beecham Limited (formerly SmithKline Beecham plc) and Beecham Group plc (together referred to as 'GSK');
  - (b) Norton Healthcare Limited (which previously traded as IVAX Pharmaceuticals UK) and IVAX LLC (formerly IVAX Corporation) (together referred to as 'IVAX');
  - (c) Generics (UK) Limited and Merck KGaA (together referred to as 'GUK-Merck'); and
  - (d) Actavis UK Limited (formerly Alparma Limited), Xellia Pharmaceuticals ApS (formerly Alparma ApS) and Alparma LLC (formerly Alparma Inc) (together referred to as 'Alparma').
- 1.3 In the SO, the OFT notified the Parties that it proposed to find that:
- (a) the Parties had infringed the Chapter I prohibition;<sup>2</sup>

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<sup>1</sup> Responsibility for the Investigation passed to the CMA on 1 April 2014. From that date, the functions of the Competition Commission and the competition and certain consumer functions of the OFT were transferred to the CMA. The CMA was established under the Enterprise and Regulatory Reform Act 2013.

<sup>2</sup> The prohibition imposed by section 2(1) of the Competition Act 1998.

(b) GSK, IVAX and GUK-Merck had infringed Article 101 TFEU; and

(c) GSK had infringed the Chapter II prohibition.<sup>3</sup>

1.4 The CMA issued a Supplementary Statement of Objections ('SSO') to the Parties on 21 October 2014, making certain changes to the SO in particular in respect of the IVAX-GSK Agreement.<sup>4</sup>

1.5 Having considered representations made to the CMA by the Parties during the investigation, and having reconsidered the case in the round, the CMA issued the Proposed No Grounds For Action ('NGFA') Decision in respect of the IVAX-GSK Agreement on 30 June 2015. The CMA received representations from the Parties on the Proposed NGFA Decision in July 2015 and August 2015. The CMA issued the final NGFA Decision on 12 February 2016.

## **2. SUMMARY OF THE NGFA DECISION**

2.1 The CMA concluded that:

(a) The Vertical Agreements Exclusion Order<sup>5</sup> applied to the IVAX-GSK Agreement and consequently the Chapter I prohibition did not apply to that agreement. For the purposes of the agreement between GSK and IVAX as defined in the SSO, GSK and IVAX were operating at a different level of the production and distribution chain, and the agreement did not contain elements (such as an express restriction on entry by a potential competitor) which would deprive the agreement of the benefit of the exclusion.

(b) IVAX's and GSK's representations and the CMA's further analysis cast doubt on whether the IVAX-GSK Agreement had an anti-competitive object and/or effect during the period from 1 May 2004 (when the Modernisation Regulation became applicable) to 29 June 2004 (when the IVAX-GSK Agreement terminated), and consequently there were no longer grounds for reaching a finding in relation to the IVAX-GSK Agreement under Article 101 TFEU, in the period between 1 May 2004 and 29 June 2004. As regards its provisional finding in the SSO that the IVAX-GSK Agreement restricted competition by object, the CMA considered that: (i) on the balance of probabilities, the entry by the Apotex Parties<sup>6</sup> in December 2003 meant that the purpose of the continued payment of the promotional allowance after

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<sup>3</sup> The prohibition imposed by section 18(1) of the Competition Act 1998.

<sup>4</sup> For example, the CMA no longer considered that there had been an agreement between IVAX and GSK pursuant to which IVAX had agreed not to enter the market with paroxetine sourced independently of GSK. The IVAX-GSK Agreement was defined in the SSO as the supply agreement between IVAX and GSK dated 3 October 2001 (together with the side letter to that supply agreement, dated 3 October 2001).

<sup>5</sup> The Competition Act 1998 (Land and Vertical Agreements Exclusion) Order 2000, SI 2000/310.

<sup>6</sup> Apotex Europe Limited through its distributors Neolab Limited and Waymade Healthcare Plc.

this point was no longer to incentivise IVAX to defer its efforts to enter the market independently of GSK; and (ii) by May 2004, IVAX was no longer making product purchases from GSK and therefore was no longer receiving any value transfers in relation to the supply of a restricted volume of paroxetine. Following the Apotex Parties' market entry in December 2003, there were also no longer grounds for reaching a finding that the value transfers from GSK to IVAX had the likely effect of inducing IVAX to delay its efforts to enter the market independently of GSK, or assisting GSK in preserving the entry barriers faced by IVAX and other potential entrants, in the period between 1 May 2004 and 29 June 2004.

- 2.2 The CMA therefore decided to close its case in respect of the IVAX-GSK Agreement under the Chapter I prohibition and Article 101 TFEU on the basis that there were no longer grounds for action by the CMA in relation to that agreement.
- 2.3 Nonetheless, aspects of the evidence relating to the IVAX-GSK Agreement are relied on by the CMA in the separate decision it has reached in respect of each of the entities comprising GSK, GUK-Merck and Alparma (each as defined at paragraph 1.2 above), finding various infringements of the Chapter I prohibition (in respect of GSK, GUK-Merck and Alparma), Article 101 TFEU (in respect of GSK and GUK-Merck) and the Chapter II prohibition (in respect of GSK) and imposing financial penalties, as set out in that decision.<sup>7</sup>

### **3. CONCLUSION**

- 3.1 The CMA decided to close its case in relation to the IVAX-GSK Agreement under the Chapter I prohibition and Article 101 TFEU on the basis that there were no longer grounds for action.

**10 August 2016**

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<sup>7</sup> CMA infringement decision in *Paroxetine*, 12 February 2016.