Italian case *Pfizer/Ratiopharm*[1]

In January 2012 the Italian Competition authority (ICA) fined Pfizer for several abusive practices aimed at extending its patent rights for a certain medicine (the *Xalatan*), in order to delay the entry of generic drugs in the market.

As when the pharmaceutical *Xalatan* was developed, Pharmacia (then acquired by Pfizer) forgot to ask for the related patent term extension in Italy – *i.e.* the supplementary patent protection certificate (SPC) – Pfizer applied for a divisional patent descending from *Xalatan* before the EPO, in order to obtain and then enforce the relevant SPC. The divisional patent was validated only in Italy and the relevant SPC was granted. Furthermore, a pediatric extension was given. Once patent protection has been extended, Pfizer informed generic drugs producers of the extension and warned them against entering the market. Then, it filed complaints before courts against generic suppliers. It also pressured the Italian Medicines Agency not to authorize competitors to produce generic drugs.
According to the ICA, all these behaviors showed the existence of a complex strategy aimed at impeding the entry of generic drugs in the market.

The decision of the ICA has been annulled by the Lower Administrative Court, but has then been upheld by the Supreme Administrative Court.

Italian case *Roche/Novartis*[2]

In February 2014, the ICA fined Roche and Novartis for having executed an anti-competitive agreement aimed at unjustifiably disfavoring the use for a certain pathology of one of the medicine of such companies (*i.e.* the *Avastin*), which was significantly cheaper than the other medicine commercialized by such companies for the same pathology (*i.e.* the *Lucentis*). While the price of *Avastin* amounted to approx.. 80 euro, the price of *Lucentis* exceeded 900 euro. Also, such two medicines had equivalent effects for the afore-said pathology.

More specifically, pursuant to the agreement, the companies diffused information primarily to doctors and media aimed at raising public concerns on the safety of the cheaper medicine; also, the companies concertedly modified the summary on product characteristics of the cheaper medicine filed at the European Medicines Agency (for highlighting the risks deriving from the use of such medicine).

The Lower Administrative Court confirmed the decision of the ICA; the judgment of such Court has been appealed before the Supreme Administrative Court, which submitted to the European Court of Justice a reference for a preliminary ruling on several questions connected to the competition law assessment of the agreement at hand.

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[1] See the decision of the ICA no. 23194, dated January 11, 2012, case *A431 – Ratiopharm/Pfizer*, published in the Bulletin of the ICA no. 2/2012 (dated January 30, 2012), p. 5 et seq..
[2] See the decision of the ICA no. 24823, dated February 27, 2014, case *I760 – Roche-Novartis/Farmaci Avastin e Lucentis*, published in the Bulletin of the ICA no. 11/2014 (dated March 17, 2014), p. 78 et seq..