The assessment of restrictions of competition by object in the ICA's decisional practice

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(*) *Disclaimer*: the views expressed in this presentation are those of the author and are not necessarily those of the AGCM.

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Introduction

- Restrictions by object and by effect: a dichotomy in the Treaty and in national competition law:
  - Art. 101 (1) TFEU (formerly art. 81 TEC, 85 EEC)
  - Art. 2 Law n. 287/90 (molded on art. 101 TFEU)
- Art. 1(4) of Italian competition law reads:
  - "*The provisions of this Title shall be interpreted in accordance with the principles of the European Community competition law*".
  - Duty to interpret national competition law provisions in line with EU competition law provisions.

Cartes Bancaires

- *Quid novi sub soli*?
  - certain types of coordination between undertakings reveal a sufficient degree of harm to competition that it may be found that there is no need to examine their effects (para. 49).
    - *Consten and Grunding*, *Société Technique Minière*
  - certain types of coordination between undertakings can be regarded, by their very nature, as being harmful to the proper functioning of normal competition (para. 50).
    - *T-Mobile Netherlands, Irish Beef, Allianz Hungaria*
  - it is established that certain collusive behavior, such as that leading to horizontal price-fixing by cartels, may be considered so likely to have negative effects, in particular on the price, quantity or quality of the goods and services, that it may be considered redundant, for the purposes of applying Article 81(1) EC, to prove that they have actual effects on the market (para. 51).
    - *Clair, Commission's Guidelines on the application of Article 81(3) of the Treaty*

Cartes Bancaires

- *Quid novi sub soli*?
  - Where the analysis of a type of coordination between undertakings does not reveal a sufficient degree of harm to competition, the effects of the coordination should, on the other hand, be considered and, for it to be caught by the prohibition, it is necessary to find that factors are present which show that competition has in fact been prevented, restricted or distorted to an appreciable extent (para. 52).
    - *T-Mobile Netherlands, GlaxoSmithKline, Allianz Hungaria*
  - **to determine whether an agreement between undertakings** or a decision by an association of undertakings reveals a sufficient degree of harm to competition that **it may be considered a restriction of competition 'by object**' within the meaning of Article 81(1) EC, regard must be had to the **content of its provisions, its objectives and the economic and legal context of which it forms a part**. When determining that context, it is also necessary to take into consideration the nature of the goods or services affected, as well as the real conditions of the functioning and structure of the market or markets in question (para 53).
    - *Société Technique Minière, GlaxoSmithKline, Allianz Hungaria*
  - **the concept of restriction of competition by 'object' must be interpreted 'restrictively'** (para. 58): the sole new aspect (restrictively does not mean a close list of restrictions of competition by object).

Post *Cartes Bancaires*

- C-373/16, ***Toshiba****:*
  - "*Thus, the Court has already held that market-sharing agreements constitute particularly serious breaches of the competition rules. The Court has also held that agreements which aim to share markets have, in themselves, an object restrictive of competition and fall within a category of agreements expressly prohibited by Article 101(1) TFEU, and that such an object cannot be justified by an analysis of the economic context of the anticompetitive conduct. In respect of such agreements, the analysis of the economic and legal context of which the practice forms part may thus be limited* ***to what is strictly necessary*** *in order to establish the existence of a restriction of competition by object.*" (para. 28 and 29);
- C-286/13, ***Dole*** (para. 120 et seq.);
- C-172/14, ***ING Pensii*** (para. 29 et seq.);
- C-345/14, ***SIA-Maxima Latvia*** (para. 15 et seq.);
- T-472/13, ***Lundbeck*** (para. 340 et seq.);
- C-469/15, ***FSL Holding*** (para. 101 et seq.);
- E-3/16, ***Ski Taxi*** (EFTA Court).

Post *Cartes Bancaires*

- *Carte Bancaires* has not set a higher standard for the appraisal of restriction of competition by object.
- In order to assess whether an agreement reveals a sufficient degree of harm to competition, it is necessary to examine:
  - ***The objectives of the agreement***
    - The wording but also the substance of what was agreed between the parties
    - Note that according to the case law an agreement can restrict competition by object even if it also pursues other legitimate aims (see C-209/07, *Beef Industry*)
  - ***The economic and legal context of the agreement***
    - nature of the goods or services affected, as well as the real conditions of the functioning and structure of the market
  - ***Role of parties' intention*** (helpful but not necessary)

Post Cartes Bancaires

- Apart from classic restrictions like price fixing, output limitations and sharing of markets and customers, there are other, more ambivalent situations, where a contextual analysis can either cast doubt on or confirm the anticompetitive object of an agreement.
- Please note that this cuts both ways:
  - A restraint that at first sight looks like a restriction by object may on closer examination turn out not to be a restriction at all. For example, the Court held that selective distribution systems for high-end products tend to reduce price competition. And yet, such arrangements can actually spur competition on factors other than price, especially on quality of service, etc. If so, they do not fall under Article 101(1).
  - Conversely, a restraint of which the anti-competitive nature had not been clearly determined in the past may yet turn out to have an anti-competitive object. An example would be reverse payment cases where the Commission recently took its first decision in Lundbeck (confirmed by the General Court).
- **We need to remember: restrictions by object are serious - but not necessarily obvious (see Roche/Novartis)!!**

Restrictions by object in the ICA's analysis

- Object qualification as a short-cut for competition analysis by competition authorities?
  - Filtering and prioritizing complaints and enforcement by competition authorities.
  - Limited public resources should be addressed to fight the most harmful restrictions of competition.
  - Should competition authorities deal only with restrictions by object and leave restrictions of competition by effect to courts (i.e. to private enforcement)?
    - No, it is part of competition law provisions so competition authorities shall analyze effects when required by law.
- Do competition authorities shy away from effect analysis as it is «too difficult»?
  - No, indeed the ICA has sometimes performed effect analysis in object cases, <u>even if not required by the legal standard</u>, see e.g.:
    - Vending case (cartel)
    - Roche/Novartis case

By object cases dealt by the ICA after *Cartes Bancaires*

- ***Cartels***:
  - *Bid rigging*: cover bids, bid suppression, bid rotations (I/782, I/785 removal of asbestos, I/792 school cleaning, I/759 refurbishment of trains, I/792 therapeutic administration of oxygen, I/744 insurance of public local transport vehicles)
  - *Price fixing, market sharing and customer allocation* (I/783 automatic distribution, I/777 mortgage interest rates, I/793 cement, I/772 concrete, I/789 top models, I/742 reinforcing steel bars)
- ***Others***:
  - I/760 Roche/Novartis
  - I/761 Services for the maintenance of the tlc network
  - I/790 Diritti TV Lega calcio (Italian football league TV broadcasting rights)
  - Liberal professions (codes of ethics): restrictions on pricing and advertising introduced or enforced by the professional associations after the introduction of liberalization measures (I/748 lawyers and I/738 medical doctors, I/747-749-750-751 notaries)

The Vending cartel

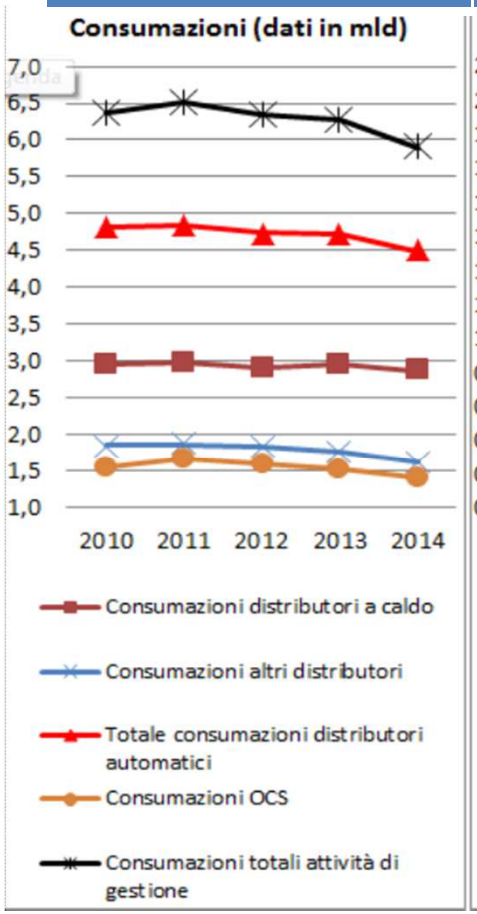
- Cartel amongst the major players active in the Italian market for the distribution of food and beverages (hot and cold) via automatic and semi-automatic vending machines.
- Overwhelming evidence of anticompetitive conducts (price fixing, market sharing, customer allocation, bid rigging, etc.):
  - clear-cut by object case;
  - investigation started from a compliant lodged by a competitor attaching a recorded conversation occurred with the call center of one of the cartelists;
  - documents found during dawn-raids left no doubt about the collusion;
  - fines imposed on the cartelists: 100 millions euros.

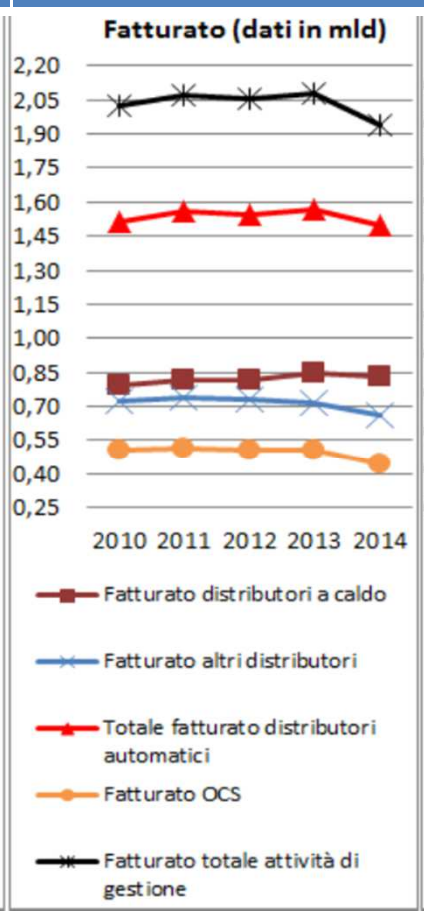
The Vending cartel

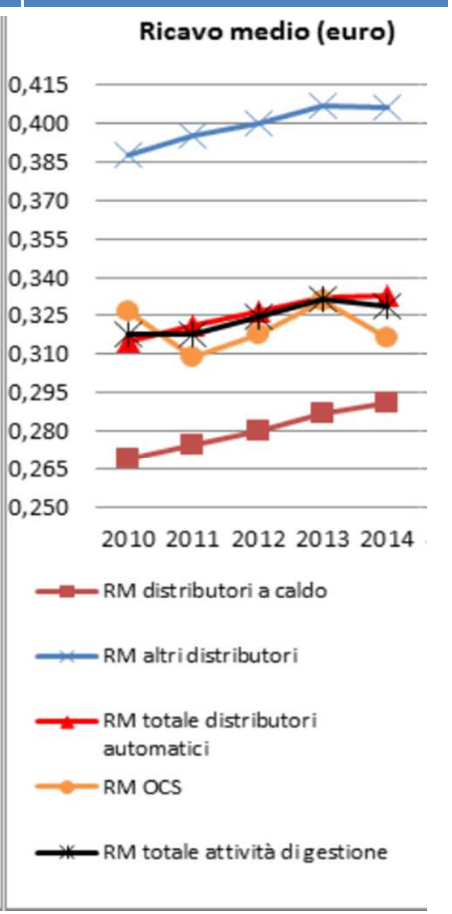
- However effect analysis added on the top of the object analysis (***even if not necessary***):
  - Effects analysis showed that notwithstanding the reduction in the consumption of products distributed via vending machines (due to the economic crisis), the turnover of the undertakings taking part to the cartel remained stable and their market shares actually increased as well as their average revenue per consumption.

The Vending cartel

Consumption	Turnover	Average revenue







The Vending cartel

- Moreover the ICA estimated the effects of the cartel on prices due to the price coordination occured amongst the undertakings to pass on VAT increase (from 4 to 10%) to all their customers (note this is not an estimation of the damages whose assessment is up to the courts, but of the impact of the practice on the market!).
  - It was estimated that prices raised around 9-10% for coffee a bit less for other products.
- More and more attention to economic evidence in the course of the administrative procedure before the competition authority by the undertakings, in particular where effect analysis is involved!! Why?
- Remember: Directive 2014/104 on actions for antitrust damages
  - Art. 9: "*Member States shall ensure that an infringement of competition law found by a final decision of a national competition authority or by a review court is deemed to be irrefutably established for the purposes of an action for damages brought before their national courts under Article 101 or 102 TFEU or under national competition law*" (binding effect of NCAs final decisions).

Roche/Novartis

- **Roche/Novartis - The case in a nutshell**
  - On February 2014 the ICA fined Roche and Novartis groups for an illicit agreement, pursuant to art. 101 of the TFEU, also taking into account its effects on Italian National Healthcare System (NHS) expenditures and general efficiency.
  - The relevant market was the Italian one of the medicines used for curing some severe and widespread eye diseases (especially wAMD), with an estimated value of € 100 million (year 2012).
  - The fines imposed were respectively € 92 million (Novartis group) and € 90,5 million (Roche group).
  - The assessment of the ICA has been upheld by the first-degree administrative court (see TAR Lazio, no. 12168 of 5 November 2014). Further appeal has been lodged before the Council of State (and a preliminary ruling is pending before the CJEU C-179/16).

THE PRODUCTS

Avastin (bevacizumab) ROCHE

- anti-VEGF drug developed by Genentech, part of Roche Group
- marketed worldwide by Roche, excluding US (1999 general licensing agreement with Genentech)
- market entry: 2004 (US), 2005 (EU)
- registered use: treatment of some forms of metastatic cancer

Lucentis (ranibizumab) NOVARTIS

- anti-VEGF drug developed by Genentech, part of Roche Group
- marketed worldwide by Novartis, excluding US (2003 licensing agreement with Genentech)
- market entry: 2006 (US), 2007 (EU)
- registered use: treatment of wAMD

THE PRODUCTS

Avastin (bevacizumab)	**Lucentis (ranibizumab)**
• off-label use: treatment of wAMD and other ophthalmic diseases	
• inserted by WHO in the Essential Medicines List (since ed. 2013) for the treatment of wAMD	• rejected by the WHO Essential Medicines List (ed. 2015)
• covered by NHS since 2007 (also) for off-label ophthalmic use (List 648)	• covered by NHS since 2008
• cost (calculated per eye injection obtained by splitting the vial): € 15-80	• price (per vial/eye injection): € 1,700 (lowered to € 900 since 2013)

Roche/Novartis

- Due to the independent development of ophthalmic off-label uses of Avastin, this drug became a competitor of Lucentis – against the will of both Roche and Novartis.
- According to their separate licensing agreements with Genentech, Roche and Novartis expected to sell the two products on two different markets, both taking economic advantages from the sales of Lucentis.
- In the ICA's view, Roche and Novartis colluded for keeping Avastin out of the ophthalmic sector in order to protect Lucentis sales:
  - HOW: artificial product differentiation
  - WHEN: at least since June 2011

Roche/Novartis

- **The strategy:**
  - Novartis actively pursued the goal of «generating and communicating Avastin safety concerns»:
    - funding and support to research activities oriented by the company;
    - sabotage of independent comparative studies (CATT & IVAN) proving that Avastin and Lucentis are similar under efficacy profiles
  - Roche requested the EMA to modify Avastin's SmPC in order to obtain an «extra-wording» related to its ophthalmic risks.
  - EMA did not grant what requested by Roche (modification of SmPC §4.8). Rather, it modified SmPc §4.4, and, after his CHMP stated that «*no evidence can be provided that bevacizumab is systemically more unsafe than ranibizumab and vice-versa*», further adopted a class warning related to all anti-VEGF drugs (Lucentis included).
  - Coordinated activities by the Italian branches related to the threat of legal reforms.

Roche/Novartis

The evidence:

In the ICA's view, internal documents of Roche and Novartis prove that:

- Roche and Novartis shared views on Avastin product differentiation:
  - «*Please, where are we with the activities of "differentiation" of the two products? What about the change of the [SmPC]? In May we should have some regulatory intervention, is this correct*?» (email by CEO of Roche to CEO of Novartis).
- Pharmacovigilance issues related to ophthalmic use of Avastin were, at best, debatable. In the ICA's view, Roche is not interested in solving real dangers, but rather in leveraging all available data for raising concerns:
  - *«To say if 20 cases [of adverse reactions] are few or many is difficult because the problem is that we do not know the population exposed, so we do not have the incidence data. It is therefore difficult to calculate the benefit/risk ratio, but nevertheless a proactive approach towards the authorities has already been made by Roche when we distributed a [DHCP] two years ago in order to warn the Italian ophthalmologists about the dangers associated with the use of bevacizumab against [wAMD*]» (e-mail sent on March 10, 2012, by the Drug Safety Manager of Roche Italy to his CEO).

Roche/Novartis

- Novartis was kept informed by Roche about the modification procedure of Avastin SmPC and explicitly requested Roche to act towards prescribing doctors:
  - «*Novartis requires us a proactive communication that emphasizes ethical and professional risks of ophthalmologists who use the drug off-label […] I share in principle the request of Novartis*» (e-mail sent on September 19, 2012, by the Medical Director of Roche Italy to the company's top management);
  - «*As a follow up to our discussion of today […] our Medical Director will send you the documentation and information you required. I would very much appreciate if you could also ask to your Medical director to get in touch with [Medical Director], as she has tried several times without success. [He/she] will obviously try again, due to the urgency of the situation*» (e-mail sent on September 12, 2012, by the CEO of Novartis Italy to the CEO of Roche Italy, referring to an Italian law proposal related to a liberalization of Avastin off-label uses).

Roche/Novartis

- **Licensing agreements:**

Both Roche and Novartis market their product on the basis of a licensing agreement entered with Genentech:

- vertical vs. horizontal relationships: the ICA's case refers only and plainly to horizontal agreements among direct (albeit against their own will) competitors:
  - Genentech has not been condemned nor held liable of anything illegal by the ICA
- coordinated efforts to «"differentiate"» products are beyond the legitimate contents of licensing contracts, e.g. field-of-use restrictions
  - Roche and Novartis acted jointly in order to influence the behaviors of independent third-parties (namely, prescribing doctors/NHS)
- evidence (dating back to 2007) show that Novartis internal legal offices did not consider sufficient what established by the licensing agreement in order to protect Lucentis from sales of Avastin related to off-label uses:
  - «*There is little we can do to stop Avastin off label use under our contract with Genentech […] Since Avastin is not our product, there is little we can do from a contractual position*» (e-mail sent on April 18, 2007, by an in-house lawyer of Novartis to the head of legal department of Novartis Italy).

Roche/Novartis

- **Conclusion on the restriction of competition**:
  - The agreement between Roche and Novartis had as its object the restriction of competition, aiming at preventing the use of the cheaper product:
    - Put in its legal and economic context the "differentiation strategy" carried out by Roche and Novartis reveled its anticompetitive nature, i.e. a market sharing agreement aimed at avoiding the cannibalization of Lucentis' market by the off-label use of Avastin.
    - Economic logic: joint maximization of profits given the economic relationships between Roche and Novartis:
      - Roche, via Genetech (its biotech subsidiary) receives fees and royalties from Novartis for the sales of Lucentis; thus Roche does have an interest that Lucentis performs well on the market and that its sales are not eroded by Avastin's off-label use.
      - Novartis holds a relevant share of Roche (around 33%)
    - Remember:
      - in order to be qualified as a restriction by object a market conduct does not need to have already been qualified as a restriction by object: the analysis of the objectives pursued as well as of the legal and economic context in which the market conduct occur can reveal a sufficient degree of harm to competition

Roche/Novartis

- ***Conclusion on the restriction of competition:***
  - The agreement has been implemented
  - The agreement did produce anti-competitive effects, estimated by the ICA in terms of extra-costs borne by the NHS due to product's switch (from Avastin to Lucentis) and of denied treatments for patients:
    - at least € 45 million of extra-costs (year 2012 only);
    - according to the Italian Ophthalmic Society the extra-costs due to the product switch impeded the NHS to provide cures to 100.000 patients.

Roche/Novartis

- ***Opinion of AG in C-179/16 - Roche Novartis (selected quotes)**:*
  - In order to establish whether particular collusive conduct is in the nature of a restriction by object, 'regard must be had … to the content of its provisions, the objectives it seeks to attain and the economic and legal context of which it forms a part'. That context also includes 'the nature of the goods or services affected, as well as the real conditions of the functioning and structure of the market or markets in question'. (para. 147)
  - In particular, this individual, detailed examination makes it possible to 'understand the economic function and the real significance' of the coordination at issue. It also makes it possible to check whether there is a plausible alternative explanation for the coordination other than the pursuit an anticompetitive aim. (para. 148)
  - I would add that, although the concept of restriction by object must be interpreted narrowly, it is not limited to the forms of collusion expressly listed in Article 101(1) TFEU. **The atypical or novel form of a particular instance of collusion does not prevent the Court from concluding, after an individual, detailed examination, that that collusion, in itself, reveals a sufficient degree of harm to competition. (**para. 150)

Roche/Novartis

- ***Opinion of the AG in C-179/16 - Roche/Novartis (selected quotes)**:*
  - **To my mind, the concerted communication of misleading allegations of the lesser safety of one medicinal product compared to another is, by its very nature, harmful to the proper functioning of normal competition, so much so that an examination of its effects on competition is not necessary.** (para. 151)
  - where an examination of the content of the allegations in question reveals that they are misleading, the concerted communication of those allegations impairs the quality of the information available on the market and, consequently, adversely affects the decision-making process of those who create the demand for the two products concerned. Such concerted communication is, in itself, likely to reduce, if not suppress, demand for the first product to the advantage of the second. (para. 152)

Roche/Novartis

***Opinion of the AG in C-179/16 - Roche/Novartis (selected quotes)**:*

- **Next, the objective of the concerted dissemination of misleading allegations of the lesser safety of one medicinal product by comparison with another is necessarily the exclusion of the first medicine to the advantage of the second, or at the very least a reduction in the demand for the first medicine. Given the misleading nature of such allegations, there can be no plausible alternative explanation for such collusion, in particular, one relating to the pursuit of legitimate aims concerning the transparency of the information available in the market and the protection of public health.** (para 163)
- If it is the case that the collusion at issue also pursued certain additional objectives unrelated to the restriction of competition, those may be taken into account only in the context of the possible application of Article 101(3) TFEU. (para 164)

Thank you for your attention!

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