

**Seventh United Nations Conference to review the UN Set on  
Competition Policy**

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Roundtable on:

***Role of Competition in the Pharmaceutical Sector and  
its Benefits for Consumers***

**Statement**

**By**

**Italy**

## **Outline of the speech of**

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**SUMMARY: 1. The interplay between Patent Law and Competition Law in the Pharmaceutical sector. 2. The Italian Competition activity. 3. Conclusions: towards a pro-competitive Patent system in time of crisis.**

**1. The interplay between Patent Law and Competition Law in the Pharmaceutical sector.**

The role of Intellectual Property Rights and among them of Patent Rights is crucial in our economies, especially in the pharmaceutical sector;

Dealing with the interplay between IP Law and Competition Law, public and private enforcers of antitrust law have to strike the balance between the innovation goal and the competition policy.

They ought to distinguish between the use and the abuse of Patent Rights: only the second one is relevant in the enforcement of antitrust rules.

## **2. The activity of the Italian Competition Authority in the pharmaceutical sector.**

In the last three years the Italian Competition Authority (ICA) has been very active in the pharmaceutical sector, in its advocacy activity as well in the enforcement intervention.

In the first ICA delivered a recommendation to Agenzia Italiana del Farmaco (AIFA), the Italian Regulatory Authority to realize an authorization system that could make easier generic drugs access to the market and hinder anticompetitive strategies by originators.

## **3. Advocacy activity by the Italian Competition Authority**

The Italian Competition Authority issued in 2014 a recommendation (AS1137 – *Recommendation addressed to the Parliament with regard to the annual law on market and competition*, which is currently under discussion) aimed at the achievement of an enhanced level of liberalisation in the pharmaceutical sector.

More in particular, one of the primary objectives of the recommendation at stake is to overtake the current legislative framework which limits the number of active pharmacies in Italy and doesn't allow a rational and satisfying territorial allocation of them based on demand and on patients' need. Moreover the Authority in its document suggested to favour an increase in competition on price and quality

among pharmacies, allowing owners to accumulate more licenses and open more stores.

With regard to pharmaceutical patents, the ICA put forward a proposal of a ban on patent linkage to make generic drugs access to the market easier. The aim of such proposal is to allow the registration of generic drugs in the list of reimbursable medications before the expiry date of originator's patents, as issuing authorizations to market drugs takes a while and eventual litigation among originator and generic makers can artificially delay generics entry. In the same framework the recommendation suggested to foster the sale of low-cost and generic drugs. In order to achieve such goal the ICA proposed to (i) turn the existing maximum threshold of pharmacies into a minimum threshold, (ii) abolish the existing maximum threshold of 4 licenses that can be owned by a single person, (iii) abolish the legislative provision which makes the registration of generic drugs in the list of reimbursable medication contingent upon the expiration of the original patent or the Supplementary Protection Certificates, (iv) to reform the existing legislative bonus system for the supply chain, introducing a system based on the payment by the State of a lump sum for each medicine sold which is independent from the price.

In its enforcement activity ICA has adopted landmark decisions in the field.

**Italian Competition Authority – Decision n. 23194, 11/01/2012,  
Ratiopharm/Pfizer**

In January 2012 the Italian Competition Authority (“ICA”) fined Pfizer for regulatory gaming practices concerning Xalatan. Pfizer had engaged in these practices in order to delay the entry of generic drugs in the market.

### THE PHARMA PATENTS HISTORY

In 1989 Pharmacia, a Swedish pharmaceutical company, applied for a compound patent covering the active ingredient “Latanoprost” (the base of Xalatan). In 1994 it obtained the European patent (EP0364417). Moreover, Pharmacia applied for and then obtained SPCs (Supplementary Protection Certificates) in some European countries, in order to extend the patent protection as a compensation for the time period necessary to obtain marketing authorizations. This application was not filed in Italy, Greece and Luxembourg.

As Pharmacia was then acquired by Pfizer, and as in the meantime the deadline for applying for SPCs in Italy passed, Pfizer applied for a divisional patent descending from “Xalatan”, aiming at obtaining and then enforcing a related SPC. The extension was given in 2009, so the patent was valid until 2011. Furthermore, a pediatric extension was given, extending patent protection until 2012.

## THE CONDUCTS

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 (“AIFA”) not to authorize competitors to produce generic drugs. These information and litigation had the effect of delaying generic drugs’ development and production.

In the meantime, the EPO revoked Pfizer’s divisional patent. Pfizer appealed the EPO’s ruling, and in the end the EPO upheld Pfizer’s patent.

## THE ICA DECISION

According to the ICA, all these behaviours show the existence of a complex strategy aimed at impeding the entrance of generic drugs in the market.

In particular, the ICA considers this strategy was composed by the following elements:

- The application for the divisional patent.
- The validating of the divisional patent only in Italy, in order to apply for SPC protection.
- The request to the Italian Medicines Agency in order to hinder the issuing of authorizations to the generic suppliers.

- Information to generic suppliers in order to warn them not to enter the market prior to the patent expiry.
- Abusive litigation against generic suppliers.
- Applying for subsequent pediatric extension.

It must be considered that the application for the divisional patent was not made because of the existence of a new product to be launched, but just in order to be able to ask for a SPC that could extend patent duration from 2009 to 2011. This is evident also because the application was filed only in countries where Pharmacia forgot to apply for SPCs. This underlines the exclusionary intent, and in particular the purpose of delaying the entry of generic drugs competing with Xalatan in the market.

Pfizer strategy created, according to the ICA, uncertainty about the possibility for competitors to enter the market, making it more difficult.

Pfizer's conduct was considered an abuse of dominance, although the firm had used lawful instruments to obtain the extension of patent. ICA followed the Astrazeneca doctrine, but its reasoning goes further than that of the Commission, as the basis for the reasoning in Astrazeneca was that the company provided misleading information to patent authorities.

In this case, instead, there are no misleading information provided, and it must be taken in consideration that only lawful proceedings were used by Pfizer. However, the ICA considered that Pfizer has misused administrative

proceedings and litigation, also because EPO proceedings are generally not subject to vigorous reviews and that third parties only have a limited role, as stated in the EU Commission pharmaceutical sector inquiry too.

## THE JUDICIARY

The Tribunale Amministrativo del Lazio (TAR Lazio), the Regional Administrative Court annulled ICA's decision "*on the ground that Pfizer's conduct did not go beyond the protection of its legal rights and legitimate interests*". In this case, according to the Court, Pfizer "*conducts should have had an exclusionary intent in the light of a quid pluris added to the mere sum of lawful behaviours*". This *quid pluris* was not demonstrated by the ICA.

In the end, the Consiglio di Stato ( CdS), Council of State overturned the First Instance Court's judgment, and upheld the original decision of the ICA. The Council of State considered that the lawfulness of the applications for patents is not relevant. According to the Council of State, ICA's decision did not take in consideration the compatibility of Pfizer's conducts with patent law, but their compatibility with competition law. Moreover, abuse of dominance, as abuse of right in a broader sense, does not require unlawful behaviours. On the contrary, it needs the existence of rights that are misused, i.e. rights whose exercise is formally lawful, but factually breaches the law.



## WHEN THE GOVERNMENT IS THE CONSUMER

In its judgment, the Council of State deemed Pfizer's conducts as *"characterized by a clear and persistent anti-competitive intent and aimed at delaying the marketing of generic drugs, even with considerable damage to the national health service "*,

Following the verdict, the Italian Ministry of Health filed a damages action against Pfizer Italia S.r.l, Pfizer Health A.B. e Pfizer Inc., aimed at getting a compensation for the patrimonial and not patrimonial losses suffered by the National Health Service due to the abuse of dominant position put in place by the American pharmaceutical group.

The damage has been estimated by the Italian Government at 14 million euro.

The compensatory judgment is currently pending.

### **Italian Antitrust Authority, Decision 27 February 2014,**

#### **Roche-Novartis**

The decision concerns an horizontal agreement between Roche and Novartis, as licensees of the patents related to the drugs called "Avastin" and "Lucentis". The agreement restricted competition by sharing the market of

drugs used to combat sight problems such as age-related macular degeneration.

## THE PHARMA PATENTS HISTORY

Genentech, a subsidiary of Roche, invented and patented both these drugs

Avastin, produced by Roche, is a drug which is used on-label for some cancer treatments. However, it can be used in order to treat macular degeneration, and to this extent it was used off-label in Italy.

Lucentis, produced by Novartis, is a drug specifically addressed to the treatment of macular degeneration, and it is much more expensive than Avastin<sup>1</sup>.

Being the owner of these patents (which should expire in 2018, with a CCP extension to 2022 for Lucentis and to 2019 for Avastin)<sup>2</sup>, Genentech entered in a license agreement with Roche, according to whom Roche has the right to commercialize Avastin outside the United States. Genentech has also a license and collaboration agreement with Novartis, according to whom Novartis can

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<sup>1</sup> In the decision of ICA it is reported that, at the time it was issued, one injection of Avastin costed € 81,64 under safety standards and € 15,29 without these standards. One injection of Lucentis, instead, costed € 902 when ex factory and € 1489 as the retail price.

<sup>2</sup> Lucentis: request number MI2007B021920, application date 03/04/1998, issue number 0000973804, issue date 27/12/06. Avastin: request number MI2005B024272, application date 03/04/1998, issue number 0001325932, issue date 20/04/05.

commercialize Lucentis outside the United States in return for royalties and other compensations.

As a consequence of this, in the US both Avastin and Lucentis were marketed by Genentech, so their differentiation, though it was made for economic purposes, from an antitrust perspective may be labeled as an unilateral conduct. In the rest of the world, Avastin and Lucentis were marketed on license by two different companies, and their differentiation could easily lead to competition concerns.

## THE CONDUCTS

Before Lucentis was marketed in Italy, Avastin was the only drug available for macular degeneration treatments, so it was prescribed off-label by the doctors. As Lucentis arrived on the market, it began to substitute Avastin, with an increase of related costs for the Italian National Health Service (“NHS”). Italian Medicines Agency (AIFA) forbade the off-label use of Avastin, according to existing legislation<sup>3</sup>. Although the Italian government tried to keep Avastin accessible, it did not succeed in this.

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<sup>3</sup> The existing legislation states that the off-label use of a drug is possible only when there are no suitable on-label drugs available on the market. A doctor who prescribes an off-label drug instead of the existing on-label one bears the liability in case of diseases deriving from the off-label use.

In the meantime, as both Novartis and Roche shared a stake in Lucentis, they colluded in order to artificially differentiate the two products, affirming Avastin was not secure and strongly promoting the use of Lucentis, much more expensive than the former. Furthermore, the two companies raised uncertainty and emphasized Avastin's danger when used off-label, in order to persuade doctors not to prescribe it. Moreover, Roche and Novartis acted in concert to debase the result of independent comparative research on the usability of the two drugs. These researches considered that Avastin and Lucentis were equivalent under a safety profile.

Another part of the companies' strategy was the attempt to modify the *Summary of Product Characteristics* inserted in the *European Public Assessment Report* for Avastin, aimed at obtaining an "*extra-wording*" related to the drug's ophthalmic risks (however, they did not succeed in this).

The whole strategy was aimed at hindering the possible authorization of Avastin off-label use, as many organizations and politicians were reconsidering the issue. Indeed, the increase of costs to Italian National Health Service was leading to a restriction for the patients to afford the treatment for macular degeneration and other similar diseases.

It must be noticed also that Roche, during the antitrust proceedings, maintained that it was bound to communicate to the medicines authorities the risks of ophthalmic off-label uses of Avastin detected by its own pharmacovigilance activities; the ICA considered this conduct as part of the

illicit collusion, based upon a distorted use of legitimate prerogatives and aimed at artificially differentiating Avastin from Lucentis on the basis of safety issues.

## THE ICA'S DECISION

In the end, the ICA ascertained both the anticompetitive object of the agreement and its effects, which entailed a consistent increase of costs for NHS, as said above. According to the nature of the agreement and to the importance of the concerned firms and the context (the pharmaceutical market) where the anticompetitive behavior had its effects, the Italian Competition Authority fined each of the two companies for an amount of 90 million €.

## THE JUDICIARY

The first degree Court of Appeal (*Tribunale Amministrativo Regionale – TAR – Lazio*) has confirmed Italian Antitrust Authority's decision the 2nd December 2014 with the judgment n. 12168/2014.

Furthermore, the World Health Organization has recently rejected the request by Novartis to include Lucentis among essential ophthalmologic drugs,

precisely because the new list already includes Avastin, considered effective and safe, as well as cheaper.

## WHEN THE GOVERNMENT IS THE CONSUMER

The Italian Government (National Health Service) has also issued a damages action before the Court, and claimed for more than 1.2 billion €.

The action is aimed at getting a compensation for the patrimonial and not patrimonial losses suffered by the National Health Service due to the cartel put in place by the two companies.

The damage has been estimated by the Italian Government at about 1.2 billion euro (about 45 million in 2012, 540 million in 2013 and 615 million in 2014).

The compensatory judgment is currently pending.

Furthermore, following the ICA's decision, Italian Medicines Agency granted the Ministry's request to reinsert Avastin among the medicines reimbursed by the National Health Service.

### **3. Conclusions: towards a pro-competitive pharma patent system in time of crisis.**

In the Italian Health Care system the costs of drugs are in a large measure reimbursed to patients: as a consequence the Government is a consumer on the pharmaceutical market. In this framework the right of individual consumers to have access to health care, as a Human Right is concerned;

Both Intellectual Property protection and Competition enforcement drive innovation: however the abuse of Intellectual Property Rights forbid both competition and innovation and violates Human Rights. The issue is a specially crucial one in time of crises.