

THE INTERNATIONAL CONFERENCE ON INTELLECTUAL PROPERTY AND COMPETITION IN THE PHARMACEUTICAL INDUSTRY, ITALIAN COMPETITION AUTHORITY, 19 AND 20 MARCH 2015, ROME

Giovanni Napolitano¹, Renato Ferrandi²

On March 19 and 20, 2015, the Italian Competition Authority and the World Intellectual Property Organization (WIPO) jointly organized an “International Conference on Intellectual Property and Competition in the Pharmaceutical Industry”, held in the premises of the Italian Competition Authority in Rome.

The objective of the Conference was to bring together representatives of competition agencies, regulators, institutions (both from mature and emerging economies) dealing with intellectual property issues, as well as representatives of the industry, to foster a high level discussion on various aspects concerning the interface between protection of intellectual property, antitrust enforcement and regulation. The speakers presented their own perspectives on that interface and their views on possible options to enhance access to medicines at reasonable prices while fostering product development and preserving the IP rights

necessary to protect the results of R&D activities.

Intellectual property (IP) law and enforcement represent an important incentive for industries that rely on the protection of their inventions to reap the benefits of their investments. Competition ensures that the fruits of those inventions are then offered to consumers at the lowest possible price. The pharmaceutical industry is one of the sectors where IP benefits encourage further research and product development. In recent years, the pharmaceutical industry has been involved in several antitrust enforcement cases that have also attracted media attention because of their social and health policy implications. The Actavis case in the United States, the Avastin and Xalatan cases in Italy, the investigations concerning Schering-Plough and Sanofi in France as well as the initiatives taken by the European Commission (starting with the 2009 Sector Inquiry on the Pharmaceutical Industry) show an increasing focus of competition authorities on drug-related conducts at the crossroad between antitrust and IP. Some of the competition investigations have addressed the issue of regulatory loopholes that may favour anticompetitive conducts while

¹ World Intellectual Property Organization.

² Italian Competition Authority.

complying with the letter of statutes and regulations.

The Conference provided an opportunity on the one hand, to compare different national experiences in IP-related competition enforcement in the pharmaceutical sector and, on the other hand, to discuss possible policy and regulatory options with a view to addressing some of the frictions between IP and competition and preventing potential antitrust infringements.

The keynote speaker of the Conference was Damien Geradin, Professor of Competition Law and Economics at Tilburg University (the Netherlands) and at George Mason University School of Law (Washington, DC). The presentation underlined the main issues and case law concerning the IP/Competition interface in the pharmaceutical industry. Prof. Gerardin argued that originator companies play a major role in developing life-saving drugs but, like all other companies, have to comply with competition rules. Hence, the challenge for competition authorities is to enforce competition rules while maintaining originator companies' incentives to invest. In his view, this can be done by: i) avoiding to excessively focus on short-term allocative and productive efficiencies, since dynamic efficiencies are key in innovative industries; adopting clear standards to analyze firms' conduct; treating pharmaceutical companies like undertakings in other sectors because the fact that drug purchases are funded by social security systems is not a relevant factor in the analysis.

Three plenary sessions were dedicated respectively to: a) the experience of Competition Authorities from the BRICS

Countries, b) the viewpoint of European and National IP and healthcare organizations (including WIPO, EPO and WHO) and c) the perspective of industry associations (including the European Federation of Pharmaceuticals Industries and Associations as well as the International Generic Pharmaceutical Alliance).

The first plenary session was an opportunity to gather a deeper understanding of how competition authorities (particularly in the BRICS Countries) intend to apply their respective enforcement powers when IP-related investigations are carried out. The Chinese representative outlined the draft guidelines on IP and Competition which will be implemented soon, whereas the representative of the Indian Competition Commission presented their case law concerning mainly distribution issues and pharmaceutical merger remedies. South Africa underlined the importance to strike a balance between the protection of IP rights and a thorough enforcement of competition rules and mentioned licensing and price levels as their main concerns for accessible medicines. Brazil referred to their extensive record in competition enforcement in the pharmaceutical sector, including the recent "sham litigation" case concerning the company Eli Lilly. Russia described their policy toward IP and competition and briefly outlined the work of a working group on the pharmaceutical industry where other European competition agencies participate as well.

In the second plenary session, the representative of WIPO presented its understanding of the interplay between IP and competition, both aiming at encouraging

differentiation and market dynamics. Achieving a correct balance between regulation, IP and competition enforcement, particularly in the heavily regulated pharmaceutical sector, may be very difficult and the purpose of the Conference was in fact to bring together the different players and stakeholders, to discuss their different perspectives and to provide a platform for future discussions and sharing of experiences. The speaker from the European Patent Office recalled the 2009 Sector Enquiry of the European Commission and underlined the regulatory changes that, also thanks to the EPO, have since then taken place, such as the accelerated patent opposition mechanism and third party observations while patent filing procedures are still pending. The delegate from the World Health Organization highlighted the importance of competition to drive prices down in the pharmaceutical industry as well as the role played by WHO's essential medicines list which promotes the diffusion of effective drugs at reasonable prices, particularly in less developed countries. He also underlined the need for stricter patentability standard to avoid opportunistic "evergreening" of patent rights. Finally, the speaker from the Italian Medicine Agency stressed the importance of limiting the cost of public healthcare while promoting the development of innovative and cheaper drugs. Such a policy includes the possibility to allow an early access to new drugs that may have not yet been commercialized in Italy and those that are still undergoing clinical trials.

The session with industry representatives was an opportunity to understand their viewpoints which would sometimes differ such as in the

case of pharmaceutical companies and generic producers.

Finally, a technical Workshop enabled sector specialists to have a more informal exchange of views on specific topics. The Workshop was structured into parallel break-out sessions, dedicated to life cycle management (de-registering, product switching, supplementary/complementary protections certificates), litigation issues (pay-for-delay/reverse payments/sham litigation) and product distribution and merger issues in the pharmaceutical and healthcare markets.