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**COMPETITION AND PATENT LAW
IN THE PHARMACEUTICAL INDUSTRY:
CROSSING PATHS BETWEEN
THE EUROPEAN UNION AND THE UNITED STATES**

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ABSTRACT

The thesis addresses a topic that has been extensively debated in the competition law practice, namely its interface with the various paradigms of intellectual property rights. As this especially involves innovation-driven sectors, the research has focused on the interplay between competition policies and patent laws in the pharmaceutical industry, which calls into question a further level of human rights-based considerations when trying to strike a balance between the conflicting interests at stake.

The inquiry considers the outlined topic primarily from a European perspective, by carrying out a thorough analysis of case law and practice of both the European Union and Member States. However, given that the first theoretical studies and judicial decisions on these issues have actually emerged in the legal system of the United States, the relevant case law and literature is also taken into account in order to assess difference and similarities between the US and the EU approaches.

In the first chapter the scope and purpose of the thesis is presented. Then, the main features of the economic and regulatory framework underlying the pharmaceutical sector in the EU and the US are specifically dealt with in order to provide a general background for the subsequent assessment.

The second chapter addresses the relevant case law concerning the two main competition law infringements, restrictive agreements and abuses of dominance, as emerged from the practice in the EU, the US and the Member States (in particular, the UK and Italy).

The problematic issues arising from the analysed case law are then thoroughly assessed in the third chapter. Indeed, many questions emerge regarding the proper standard to structure the antitrust scrutiny in this patent-intensive sector, where pharmaceutical companies face high investments in research and development and try to put in place strategies aimed at extending the patent protection on their products.

Finally, some broader conclusions are drawn on the overall balancing between the various sets of rules that characterise the industry at issue, namely competition, patent systems and regulation.

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FOREWORD

Technologies are the drivers of the modern world. Many strategic industrial sectors are indeed developing by means of innovative tools that heavily rely on proprietary technologies and thus involve, to different extents, the various paradigms of intellectual property (IP). These exclusionary rights are increasingly becoming the substantial asset on which undertakings are measuring their market power. As a result, the protection of long-term incentives to innovate is a key aspect of the current economic policies at the global level.

Should competition law play a role in this context? One could reasonably argue that it is up to IP legislations to regulate the procurement and use of IPRs applied to these new technologies. But what if said legislation bodies are not be able to keep pace with innovation? Or what if companies should capitalise on their IPRs for purposes that fall outside the scope of legitimate business justifications? Competition law practice is therefore faced with a whole new set of challenges, which require the traditional legal standards of anticompetitive restraints to be accommodated within these technology-intensive industries.

From these and other similar questions stemmed the idea of focusing the research project on the particular perspective of competition policy interfacing with IP laws. More precisely, the chosen viewpoint is the relationship between competition and patent law in a specific IPRs-driven sector, which is the pharmaceutical industry. Here the above-mentioned technologies refer to a peculiar category of “products”, namely medicines and treatments, that further call into question human rights-based considerations such as the right to health and fair access to therapies.

With regard to the geographical scope of the thesis, the inquiry considers the outlined topic primarily from a European perspective, taking into account case law and practice of both the European Union and its Member States. However, as American scholars have actually paved the way towards a theoretical framework of the interface between antitrust and IPRs, and US courts have first assessed its practical consequences, a thorough review of the relevant case law from across the Atlantic is also carried out.

The thesis is structured as follows. The first chapter outlines its scope and purpose in order to set the overall scene and provide an introduction into the broader context of the patent-antitrust interface. Then, the remainder of the chapter addresses the main features of the economic and regulatory framework that underlie the pharmaceutical sector in both the EU and the US, paying particular attention to common approaches as well as divergences.

The second chapter discusses a selection of recent cases as emerged from the case law of antitrust enforcement authorities and courts. To this end, as already mentioned, the analysed decisions come from EU, US and national legal systems, thus presenting a wide range of examples from different perspectives.

In the third chapter the issues arising from the analysed cases are thoroughly assessed. In particular, the two fundamental categories of anticompetitive conducts as scrutinised in the decisions are addressed, as well as that resulting from the combination of restrictive agreements and abuse of dominance, which appears as a peculiar infringement within the pharmaceutical sector.

Finally, concluding remarks are proposed, more in general, as to the current balance between the overlapping sets of laws that characterise the industry in question, namely competition, patent systems and regulation.

Of course, the implications of such a complex subject matter spread far and wide, and the present work only aims at offering a few glimpses into the most compelling issues that antitrust practice has currently been tackling as regards its intersection with modern technologies. Indeed, the possibility of being constantly confronted with new challenges is also what makes such topics most interesting for scholars and practitioners alike, and inspires them to develop their research and work even further.

CHAPTER ONE

INTRODUCTION

The introductory chapter of the thesis will first present its scope and purpose, explaining the reasons that led the author to choose the main topics and to take into account a comparative perspective of the EU and the US legal systems and case law.

Preliminarily, the first part of the chapter will explore the broader topic of the debated nature of IPRs and their progressive integration into the human rights discourse, given their undeniable aims of protecting the interests of creators, inventors and artists, and contributing to the innovation and progress in society.

Following these considerations, the choice of a dynamic outlook into the manifold implications of IP regimes will be illustrated. Indeed, the work focuses on the complex legal questions surrounding the intersection between patent law and competition law: as is understandably very frequent in innovation-intensive sectors, undertakings capitalise on their legitimate IPRs to strengthen and expand their businesses, and this behaviour increasingly attracts antitrust scrutiny, which is faced with new issues that depart from the practice of other fields of action of competition policies. Among those sectors, a specific one will be further selected, which is the pharmaceutical industry. In this regard, the above-mentioned legal questions arising from the overlap between patent protection and antitrust need to strike an additional balance with the fundamental right to health that represents the cross-sectional aim of both bodies of law in this industry.

The second part of the chapter will then address two sets of preliminary considerations that make up a common background to which the following chapters refer. More precisely, both the economic and the regulatory framework that distinguish the pharmaceutical sector will be outlined, in order to provide a general overview of the most relevant notions and legal tools recurring in the case law analysis and then in the critical assessment.

1. SCOPE AND PURPOSE OF THE THESIS

1.1. A PECULIAR HUMAN RIGHT: INTELLECTUAL PROPERTY RIGHTS

In the general understanding of human rights, IPRs do not immediately come to mind when referring to a right possessing the common features of inalienability and universality that characterise such a notion. Nonetheless, they have been recognised at the international level within various catalogues of human rights, even though their formal acknowledgment has not always been supported by unanimous views on the issue. The choice of focusing on a right whose nature among the wider category of fundamental rights is still debated thus seems worthy of a more detailed inquiry.

Even in the first international legal instrument on human rights, namely the Universal Declaration of Human Rights¹ (hereinafter, also UDHR), a principle that recalls the concept of intellectual property is enshrined in its Art. 27(2). According to this provision, «[e]veryone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author». It is remarkable that already in 1948 the drafters of the Declaration considered it worth encompassing such a right among those that were universally recognised as human rights. At a first reading it appears that the literal formulation better adapts to the concept of copyright protection, but it may actually provide a human rights' basis for a broader framework of IPRs including industrial property. In fact, the reference to «scientific production» supports the claim that the right to protection of moral and material interests in intellectual creations also extends to individual inventions regulated for instance by patent laws².

¹ Resolution adopted by the United Nations General Assembly, 217A (III). *Universal Declaration on Human Rights*, 10 December 1948, A/Res/3/217A, available at www.un-documents.net. As is well known, the Declaration was conceived by its drafters as a common minimum standard of human rights protection for all nations of the world. Even though it has no binding force, it nonetheless collects rights and principles that are universally deemed to amount to customary international law.

² In the literature there is however no consensus on this broader interpretation: among those who support it, see P.K. YU, *Ten Common Questions About Intellectual Property and Human*

At the international level a further reference comes from the 1966 International Covenant on Economic, Social and Cultural Rights³ (hereinafter, also ICESCR), whose Art. 15(1)(c) resembles the above mentioned provision of the UDHR, laying down the right «[t]o benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author».

Even though it possesses binding force, the prescriptive extent of this provision is not immediately understandable and it was therefore interpreted by the Committee on Economic, Social and Cultural Rights in its General Comment No. 17⁴. The interpretative body of the Covenant first distinguished the human rights aspects related to the protection of interests in intellectual creations that fall within the guarantees of Art. 15(1)(c) from other legal entitlements recognized in IP systems, which are granted by national or international legislations and limited in both time and scope. Indeed, the fundamental right protected by the ICESCR aims at safeguarding «the personal link between authors and their creations and between peoples, communities, and other groups and their collective cultural heritage, as well as their basic material interests which are necessary to enable authors to enjoy an adequate standard of living», while IPRs «primarily protect business and corporate interests and investments»⁵.

Rights, in 23 *Georgia State University Law Review*, 2007, pp. 709-753, at pp. 721-726; among those commentators who do not share the view of patent protection to be grounded in fundamental concepts such as those of human rights, see for example R.C. DREYFUSS, *Patents and Human Rights: Where is the Paradox?*, in *New York University School of Law Legal and Economics Research Papers*, 2006, No. 38, available at <http://ssrn.com>.

³ Adopted and opened for signature, ratification and accession by the United Nations General Assembly resolution 2200A (XXI) of 16 December 1966, in *United Nations, Treaty Series*, vol. 993, p. 3 ff., available at <http://treaties.un.org>. It entered into force on 3 January 1976.

⁴ UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 17 (2005), The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author (article 15, paragraph 1(c), of the Covenant)*, 12 January 2006, E/C.12/GC/17, available at www.refworld.org.

⁵ UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 17 (2005)*, cited above, para. 2.

The General Comment then focused on the obligations imposed on State parties to guarantee the full realisation of the right at issue, which generally comprise obligations to respect, to protect and fulfil, and on the actions and omissions amounting to their violation. Finally, it acknowledged the relevant role also played by international organisations, institutions and other non-State actors in taking measures to contribute to the effective implementation of Art. 15(1)(c) of the ICESCR⁶.

The outlined international framework thus confirms a possible integration into the human rights discourse of rights that are an expression of interests pertaining to the broader concept of IPRs, and the consequential creation of possible synergies and even tensions between the two sets of rights. However, the different levels of protection between human rights-related aspects of IPRs and the national and international legal tools concerning IPRs must also be borne in mind, as clearly stated in the General Comment No. 17⁷.

Moving to the regional level, the European Convention on Human Rights (hereinafter, also ECHR) does not contain an express provision similar to Art. 27(2) of the UDHR or Art. 15(1)(c) of the ICESCR. Nonetheless, the European Court of Human Rights (hereinafter, also ECtHR) has recognised a formal reference for the protection of IPRs within the scope of Art. 1 of Protocol No. 1 to the ECHR that establishes the right to property, subject to limits and conditions in its exercise⁸.

⁶ In this regard the Comment expressly mentions United Nations agencies such as the World Intellectual Property Organization (WIPO), the Food and Agriculture Organization (FAO), the Education, Scientific and Cultural Organization (UNESCO) and the World Health Organization (WHO), as well as other international actors such as the World Trade Organization (WTO), which are all «called upon to intensify their efforts to take into account human rights principles and obligations in their work concerning the protection of moral and material benefits resulting from one's scientific, literary and artistic productions» (UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 17 (2005)*, cited above, paras. 55-57).

⁷ For further comments on the provisions of the UDHR and the ICESCR see M. SSENYONJO, *Economic, Social and Cultural Rights in International Law*, Oxford-Portland, 2016, pp. 640-642.

⁸ For the sake of completeness, Art. 1 of Protocol No. 1 («Protection of property») provides as follows: «[e]very natural or legal person is entitled to the peaceful enjoyment of his possessions.

The relevant case law is quite settled in this regard, as the first decision dates back to 1990. Namely, the European Commission of Human Rights delivered a decision on the admissibility of an application brought by Smith Kline and French Laboratories Ltd. against the Netherlands concerning the grant of a compulsory licence to a competing company in respect of a pharmaceutical patent held by the applicant⁹. The complaint alleged a breach of Art. 6, of Art. 1 of Protocol No. 1 and of Art. 13 of the ECHR, but the Commission declared the application admissible only with regard to the first and the last provisions. For the purposes of this inquiry, however, it is worth stressing that a patent granted by a national legislation (*i.e.*, under Dutch law) was deemed as «fall[ing] within the scope of the term “possessions” in Article 1 of Protocol No. 1 (P1-1)»¹⁰, even though no interference with the exclusive rights of the patentee was found in the case at hand. Other decisions followed this precedent and considered for instance copyrights¹¹, as well as patents again¹², to be included into a broader understanding of the right to property protected by the ECHR.

No one shall be deprived of his possessions except in the public interest and subject to the conditions provided for by law and by the general principles of international law. The preceding provisions shall not, however, in any way impair the right of a State to enforce such laws as it deems necessary to control the use of property in accordance with the general interest or to secure the payment of taxes or other contributions or penalties».

⁹ European Commission of Human Rights, decision of 4 October 1990, application no. 12633/87, *Smith Kline and French Laboratories v. the Netherlands*, CE:ECHR:1990:1004DEC001263387. The case law of both the European Commission and the Court of Human Rights referred to in the present work is available at <http://hudoc.echr.coe.int>.

¹⁰ *Ibid.*

¹¹ European Commission of Human Rights, decision of 14 January 1998, application no. 24563/94, *Aral, Tekin and Aral v. Turkey*, CE:ECHR:1998:0114DEC002456394, regarding a dispute related to commercial rights over artistic materials designed by the applicants.

¹² European Commission of Human Rights, decision of 9 September 1998, application no. 38817/97, *Lenzing AG v. United Kingdom*, CE:ECHR:1998:0909DEC003881797, concerning the application made by Lenzing in civil proceedings before the British courts in which it had sought to bring about changes in the national legal system for registering patents. Here the Commission held that there had been no violation of Art. 1 of Protocol No. 1 to the ECHR, since the applicant was given an opportunity to present its claims regarding the patent before a court having full juris-

The ECtHR, more recently, directly adjudicated a case concerning IPRs, precisely the application for registration of the «Budweiser» trademark in Portugal that was subject to litigation between the US company Anheuser-Busch Inc. (the brewer of *Budweiser* beer) and the rival Czech company Budejovicky Budvar. The latter opposed Anheuser-Busch's application citing its prior registration of an appellation of origin of «Budweiser Bier», which was filed pursuant to a 1968 agreement between Portugal and Czechoslovakia for the protection of indications of source, appellations of origin and other geographical and similar designations. A dispute ensued before the Portuguese courts, with the Supreme Court of Portugal ultimately ruling in favour of the Czech company. Consequently, Anheuser-Busch applied before the ECtHR alleging an infringement of its right to the peaceful enjoyment of its possessions protected by Art. 1 of Protocol No. 1 to the ECHR, and claiming the Supreme Court's decision amounted to an expropriation preventing the applicant from obtaining the registration of its trademark. The Second Section of the ECtHR heard the case and held that, while a trademark surely falls within the scope of the above-mentioned provision, «this is so only after final registration of the mark, in accordance with the rules in force in the State concerned»¹³. In the present case Anheuser-Busch was rather the holder of «a conditional right»¹⁴ that had been extinguished since it failed to meet the condition that it did not infringe third-party rights. Therefore, Art. 1 of Protocol No. 1 was not applicable and the rulings given by the Portuguese courts could not have consti-

diction over the subject matter. In relation to patents it is worth mentioning that in a previous instance, however, the European Commission of Human Rights held that an application for a patent that had been rejected by the competent national authority fell outside the protection granted by Art. 1 of Protocol No. 1, because the applicant company «was denied a protected intellectual property right but was not deprived of its existing property» (decision of 15 October 1993, application no. 19589/92, *British American Tobacco Ltd. v. the Netherlands*, para. 73; the full-text of the decision can be found in the subsequent Commission report of 19 May 1994, CE:ECHR:1994:0519REP001958992).

¹³ European Court of Human Rights (Second Section), judgment of 11 October 2005, application no. 73049/01, *Anheuser-Busch Inc. v. Portugal*, CE:ECHR:2005:1011JUD007304901, para. 52.

¹⁴ *Ibid.*, para. 50.

tuted an interference with the applicant's right. The US company later requested the referral of the case to the Grand Chamber of the Court, which delivered its final judgment on 11 January 2007¹⁵. With regard to the core issue of whether an application for registration of a trademark could fall within the meaning of «possessions» safeguarded by Art. 1 of Protocol No. 1, the Grand Chamber reached a different conclusion and stated that Anheuser-Busch actually «owned a set of proprietary rights – linked to its application for the registration of a trade mark – that were recognised under Portuguese law, even though they could be revoked under certain conditions»¹⁶. Having established that the legal position as applicant for trademark registration came within the scope of the provision in question, the Grand Chamber examined whether there had been interference with the applicant's right and established that the Portuguese Supreme Court's decision was not affected by elements of arbitrariness or unreasonableness. It thus affirmed that there had been no violation of Art. 1 of Protocol No. 1 in the case at hand.

From this brief review of ECtHR case law, a different approach to the debated interference between IPRs and human rights can be therefore inferred¹⁷, which needs to be distinguished from the protection provided by the international legal instruments mentioned at the beginning of this section. Indeed, within the ECHR framework, IPRs are regarded as fundamental rights, in contrast to the rights provided for in the UDHR and the ICESCR that have a narrower scope pertaining to the safeguarding of the moral and material interests of creators over their production, which has to be further implemented by State parties and international organ-

¹⁵ European Court of Human Rights (Grand Chamber), judgment of 11 January 2007, application no. 73049/01, *Anheuser-Busch Inc. v. Portugal*, CE:ECHR:2007:0111JUD007304901. For a comment on the case see, among others, K.D. BEITER, *The Right to Property and the Protection of Interests in Intellectual Property – A Human Rights Perspective on the European Court of Human Rights' Decision in Anheuser-Busch Inc. v. Portugal*, in *International Review of Intellectual Property and Competition Law*, 2008, pp. 714-721.

¹⁶ European Court of Human Rights (Grand Chamber), judgment of 11 January 2007, *Anheuser-Busch Inc. v. Portugal*, para. 78.

¹⁷ For a comprehensive analysis see L.R. HELFER, *The New Innovation Frontier? Intellectual Property and the European Court of Human Rights*, in 49 *Harvard International Law Journal*, 2008, pp. 1-52.

isations. Moreover, it must be taken into account that in these cases the applicants alleging an infringement of their right under Art. 1 of Protocol No. 1 were corporations, and not individuals. The broad subjective scope of the provision in question stems directly from its wording, which refers to «every natural or legal person». Still it is worth stressing it in this context where corporate IPRs may enjoy protection under the ECHR¹⁸.

IPRs have then found a definitive recognition in the human rights framework thanks to the EU Charter of Fundamental Rights, whose Art. 17(2) states that «[i]ntellectual property shall be protected». In spite of its plain wording, the interpretation of such a provision is rather controversial. The main argument used to support the separate mentioning of IP from the general right to property laid down by Art. 17(1) is the considerable expansion of EU law in this field, especially through secondary legislation¹⁹. The formulation of Art. 17(2) is however peculiar, as it departs from the standard of human rights provisions that are usually introduced with the words «everyone has the right to», and makes no reference to the limited nature of the right nor to any restrictions in its exercise, contrary to para. 1 and its counterpart in the ECHR. In this regard, the accompanying documents of the Charter have nonetheless specified that «[t]he guarantees laid down in paragraph 1 shall apply as appropriate to intellectual property»²⁰. The commentators have therefore argued for a limited impact of the provision at issue, which appears, at best, to «point out the *specificity* of IP in comparison to the general right to property»²¹.

¹⁸ This aspect has indeed raised some doubts as to its compatibility in a human rights framework: in this sense see P.K. YU, *Ten Common Questions*, cited above, pp. 728-730.

¹⁹ See, among others, EU Network of Independent Experts on Fundamental Rights, *Commentary of the Charter of Fundamental Rights of the European Union*, June 2006, pp. 168-169, available at <http://ec.europa.eu/justice/fundamental-rights>. For an overview of the relevant EU secondary legislation regarding IPRs in the pharmaceutical sector, see *infra*, in this Chapter, Section 2.2.1.

²⁰ *Explanations relating to the Charter of Fundamental Rights*, OJ C 303 of 14 December 2007, pp. 17-35, at p. 23.

²¹ C. GEIGER, *Intellectual Property Shall Be Protected?! – Article 17(2) of the Charter of Fundamental Rights of the European Union: a Mysterious Provision with an Unclear Scope*, in *Euro-*

In light of the above, some considerations can be made. Indeed, a progressive interaction between human rights and IPRs cannot be overlooked. While the two bodies of law still pursue different aims and develop within separate legislative frameworks, it is also true that IP (or, at least, some of its forms) does possess a human rights basis that needs to be taken into account, for example, when assessing the scope of a certain IPR, or determining the boundaries of its legitimate exercise. For these reasons, a «coexistence approach», as proposed at the international level²², seems a convincing theory in order to develop a mutually supportive relationship that promotes both innovation and access, and ultimately a general increase of human welfare²³. As will be explained later in this introductory chapter, this view is particularly appropriate to examine the complex issues arising from the exercise of patent protection within the pharmaceutical sector, which constitutes the material field of inquiry of this thesis.

pean Intellectual Property Review, 2009, pp. 113-117, at p. 116, who particularly criticises the «badly-drafted» provision as it could ultimately «contribute to amplifying the crisis of legitimacy that IP is currently facing across Europe» (at p. 117).

²² See, for example, the following reports drafted by the UN Economic and Social Council (ECOSOC), Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights: *Intellectual property rights and human rights. Report of the Secretary-General*, 14 June 2001, E/CN.4/Sub.2/2001/12; *The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights. Report of the High Commissioner*, 27 June 2001, E/CN.4/Sub.2/2001/13; *Intellectual property rights and human rights. Report of the Secretary-General*, 3 July 2001, E/CN.4/Sub.2/2001/12/Add.1, all available at <http://ap.ohchr.org>.

²³ It is not the only theory elaborated in this regard: the opposite approach viewing IPRs and human rights as being in fundamental conflict has also been proposed. On the issue see further L.R. HELFER, *Human Rights and Intellectual Property: Conflict or Coexistence?*, in 5 *Minnesota Intellectual Property Review*, 2003, pp. 47-61.

1.2. A DYNAMIC PERSPECTIVE:

THE INTERFACE BETWEEN COMPETITION AND PATENT LAW

The regulation of IPRs has not only undergone a development in its substantial aspects that spanned across several centuries, starting already in the Middle Ages, but has also extended its effects to many other legal fields, from civil to criminal law, from trade to international relations, as well as to economic policies. For the purposes of a scientific inquiry it thus seems particularly interesting to focus on one of those dynamic “interferences” of the IP regimes, namely that regarding patent law and competition law²⁴, for the reasons proposed below.

In the present technology-driven world, the importance of patent systems cannot be overstated. Patents have become essential assets for large-capitalised multinational corporations, as well as smaller undertakings and start-ups, yet their legal framework has not always been consistent with every development in the innovation process, especially with regard to certain industrial sectors such as technologies and life sciences. The existing legal tools are in fact faced with new patent-related issues (just to name a few: patent thickets, strategic patenting, patent

²⁴ This perspective has attracted much attention in both EU and US specialised literature. For example and without exhaustivity, the following works can be mentioned: V. KORAH, *The interface between intellectual property and antitrust: The European experience*, in 69 *Antitrust Law Journal*, 2002, pp. 801-839; G. GHIDINI, *Collisione? Integrazione? Appunti sulla intersection fra diritti di proprietà intellettuale e disciplina(e) della concorrenza*, in *Mercato concorrenza regole*, 2005, pp. 247-272; and by the same Author, *Innovation, Competition and Consumer Welfare in Intellectual Property Law*, Cheltenham-Northampton, 2010; H. HOVENKAMP, M.D. JANIS, M.A. LEMLEY, C.R. LESLIE, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law*, 2nd ed., Austin, 2010; S. ANDERMAN, H. SCHMIDT, *EU Competition Law and Intellectual Property Rights. The Regulation of Innovation*, 2nd ed., Oxford, 2011; G. CAGGIANO, G. MUSCOLO, M. TAVASSI (eds.), *Competition Law and Intellectual Property. A European Perspective*, Alphen aan den Rijn, 2012; and more recently M. TODINO, *Antitrust rules and Intellectual Property Rights in the EU and the US – Towards convergence?*, in *Italian Antitrust Review*, 2014, No. 2, pp. 25-40; H. HOVENKAMP, *Antitrust and the Patent System: A Reexamination*, in 76 *Ohio State Law Journal*, 2015, pp. 467-564; G. GHIDINI, *Profili evolutivi del diritto industriale*, Milano, 2015, especially pp. 411-487; A. DEVLIN, *Antitrust and Patent Law*, Oxford, 2016.

hold-ups) that have proven difficult to regulate. This phenomenon, together with the inherent tension between the exclusionary character of patents – which directly finds its basis in the above-mentioned recognition of the human rights nature of IPRs – and their concurrent aim to promote further innovation, has led to a progressive overlap with competition and market regulation policies. At first sight, these two sets of law appear to stand in stark contrast to one another, as one has in mind the patent paradigm’s goal to increase dynamic efficiency and the principle of static efficiency underlying a system of free and undistorted competition²⁵. From a more comprehensive point of view, there is however a concurrent background of social-welfare objectives that points towards a convergence between the two legal fields²⁶.

This framework of reconciliation should nevertheless not be overestimated to the extent that it can aid resolution to most of today’s questions arising from the patent/antitrust interface. It is true that the most pressing issues revolve around the continuous attempt to balance the conflicting souls of patent law and competition within the overarching aim of pursuing the highest level of consumer welfare and innovation. Yet, the answers to determine the boundaries of the two bodies of law are necessarily provisional and provided on a case-by-case basis.

Bearing in mind these general considerations, it is useful to examine in more detail the evolving trends developed among enforcement agencies and courts when called upon to rule on cases involving the intersection between patent law and antitrust. The overview considers the two most important competition law re-

²⁵ Quoting from the 1981 judgment delivered by the Court of Appeals for the Second Circuit in *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, at 1203, which summarizes the tension well: «[t]he conflict between the antitrust and patent laws arises in the methods they embrace that were designed to achieve reciprocal goals. While the antitrust laws proscribe unreasonable restraints of competition, the patent laws reward the inventor with a temporary monopoly that insulates him from competitive exploitation of his patented art». All US decisions cited in the present work are available at Westlaw database (www.westlaw.com).

²⁶ This common background is actually not limited to the patent system, but informs all IP paradigms.

gimes worldwide, namely the EU and the US legal systems, which also comprise the main viewpoints of the whole thesis.

The more traditional approach has moved along the patent-scope narrative, according to which any conduct falling within the scope of a patent's claims shall be immunised from antitrust scrutiny. In sum, it is a matter of ruling whether the challenged restraint lay within the patent grant or unlawfully sought to extend that scope. In the US system this doctrine already traces back to decisions from the first half of the XX century. One of those where the Supreme Court best expressed the theory, namely *Ethyl Gasoline* in 1940²⁷, it held that «[t]he patent law confers on the patentee a limited monopoly, the right or power to exclude all others from manufacturing, using or selling his invention. (...) The extent of that right is limited by the definition of his invention, as its boundaries are marked by the specifications and claims of the patent. (...) [The patentee] may grant licenses to make, use, or vend, restricted in point of space or time, or with any other restriction upon the exercise of the granted privilege, save only that, by attaching a condition to his license, he may not enlarge his monopoly, and thus acquire some other which the statute and the patent together did not give»²⁸.

This doctrine, however, seems to leave certain antitrust issues open: for instance, it could prove ambiguous in a context of vertical integration in which a patent-tying practice implemented in an internal production could remain well within the scope of the patent and thus lawful under a competition law perspective. Furthermore, it appears over-simplistic to the extent that the antitrust scrutiny would come down to a question pertaining only to patent law, rather than attempting an accommodation between the two sets of laws. As will be explained, the pa-

²⁷ *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436 (1940). The facts of the case referred to the gasoline market, where the system of licences on a gasoline-enhancer fluid granted by the patentee to the refiners was found to be in violation of the Sherman Act because it had «built up a combination capable of use, and actually used, as a means of controlling jobbers' prices and suppressing competition among them» (*ibid.*, at 457).

²⁸ *Ibid.*, at 456. In particular, in this case the licensing conditions granted by the patentee to the refiners were further used as a means to obtain a second monopoly, not covered by its patents, over the selling of the patented-fluid-infused gasoline by refiners to jobbers.

tent scope theory has indeed been rejected by the recent *Actavis* ruling of the US Supreme Court regarding restrictive agreements in the pharmaceutical industry, expressly stating that «patent and antitrust policies are *both relevant* in determining the “scope of the patent monopoly” – and consequently antitrust law immunity – that is conferred by a patent»²⁹.

Under the EU law framework, in which the IP/antitrust interface is a much more recent perspective, a different theoretical approach was initially set out. IPR statutes have been traditionally enacted by Member States and these laws could potentially run counter to the fundamental objectives of free movement of goods and undistorted competition within the EU internal market. When first assessing these issues, the Court of Justice has thus distinguished between the notions of existence and exercise of IPRs: the former was still regulated by national law, while the latter could amount to an infringement of EU law and be scrutinised under this perspective³⁰. It is easily understandable, however, that the existence of an IPR means little when considered separately from its exercise and, moreover, the practice has showed how anticompetitive restraints can result from contractual relations between IPRs’ holders and third parties, and more recently from conducts that regard the acquisition of the exclusionary right in itself³¹.

Indeed, EU case law has gradually shifted towards a position closer to the US patent-scope approach, as the aforementioned distinction between existence and

²⁹ *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), at 2231 (emphasis added). For a thorough analysis of this case and its implications, see *infra*, Chapter 2, Section 2.1.2.

³⁰ Among the first judgments dealing with this distinction see Court of Justice, judgment of 13 July 1966, joined cases 56 and 58/64, *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v. Commission of the European Economic Community*, EU:C:1966:41 (at p. 345 it was explained that the injunction refraining Consten to use the rights granted under national trade-mark law in order to hinder parallel imports «[did] not affect the grant of those rights but only limit[ed] their exercise to give effect to the prohibition under Art. 85(1)» of the EEC Treaty, now Art. 101(1) TFUE). All CJEU judgments referred to in the present work are available at <http://curia.europa.eu>.

³¹ For a clear assessment of these two perspectives see G. GHIDINI, *The Bride and the Groom. On the Intersection between Intellectual Property and Antitrust Law*, in G. CAGGIANO, G. MUSCOLO, M. TAVASSI (eds.), *Competition Law and Intellectual Property*, cited above, pp. 27-52.

exercise of an IPR also encompassed considerations regarding the specific subject matter of the right itself. A well-known decision that best illustrates this concept is *Windsurfing International*³² (1986), in which the Court of Justice examined the Commission's competence to evaluate the scope of a patent for the purposes of determining a restriction of competition in the context of a licensing agreement. More precisely, it was held that a contractual clause requiring «the licensee only to sell the patented product in conjunction with a product outside the scope of the patent [was] not indispensable to the exploitation of the patent»³³, and therefore was able to restrict competition under Art. 85(1) of the EEC Treaty (now Art. 101(1) TFEU).

The Court of Justice, however, later seemed to depart from the subject matter narrative when developing its case law regarding duties to licence imposed on an IPR holder³⁴. While under the US scope theory there were rarely cases of antitrust liability for a unilateral refusal to sell or licence a patent (or a copyright), under EU competition rules an obligation upon the incumbent to share its patented technologies with rivals has been affirmed in «exceptional circumstances». More precisely, in the *Magill* judgment³⁵ (1995) the refusal of an IPR holder to licence or supply an indispensable input to a competitor was held as an infringement of Art. 102 TFEU upon three conditions: (i) the competitor offered a new product for which there was a potential consumer demand, (ii) there was no objective justification for such refusal, and (iii) the incumbent reserved the secondary market for

³² Court of Justice, judgment of 25 February 1986, case 193/83, *Windsurfing International Inc. v. Commission of the European Communities*, EU:C:1986:75.

³³ *Ibid.*, para. 57.

³⁴ For a comprehensive comment on finding the right balance when applying competition rules to licensing agreements, see L. PEEPERKORN, *IP Licences and Competition Rules: Striking the Right Balance*, in *World Competition*, 2003, pp. 527-539.

³⁵ Court of Justice, judgment of 6 April 1995, joined cases C-241 P and C-242/91 P, *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v. Commission of the European Communities* (“*Magill*”), EU:C:1995:98. For a specific comment see, in the Italian literature, C.M. SARACINO, *Il caso IMS Health: proprietà intellettuale e diritto antitrust*, in *Rivista italiana di diritto pubblico comunitario*, 2005, pp. 676-695.

itself by excluding all competition in that market³⁶. The EU Court has further defined this exceptional-circumstances test in subsequent decisions³⁷, particularly recalling the need that the refusal excluded «any effective competition»³⁸ in the downstream market³⁹.

This trend therefore seems to point to an accommodation of IPRs within the EU competition law framework that acknowledges the contribution to innovation and economic welfare deriving from the legitimate exercise of such rights but, at the same time, limits them whenever they pose a threat to effective competition in a given market. In other words, it is up to competition rules (and not to patent laws) to define the boundaries between lawful exercise and exceptional circumstances⁴⁰.

³⁶ *Ibid.*, paras. 54-56.

³⁷ The following cases can be recalled in this regard: Court of Justice, judgment of 26 November 1988, case C-7/97, *Oscar Bronner GmbH & Co. KG v. Mediaprint Zeitungs- und Zeitschriftenverlag GmbH & Co. KG, Mediaprint Zeitungsvertriebsgesellschaft mbH & Co. KG and Mediaprint Anzeigengesellschaft mbH & Co. KG*, EU:C:1998:569; judgment of 29 April 2004, case C-418/01, *IMS Health GmbH & Co. OHG v. NDC Health GmbH & Co. KG*, EU:C:2004:257.

³⁸ Court of First Instance, judgment of 17 September 2007, case T-201/04, *Microsoft Corp. v. Commission of the European Communities*, EU:T:2007:289, para. 332.

³⁹ For an overview of this body of case law see, among others, J. KALLAUGHER, *Existence, Exercise and Exceptional Circumstances: The Limited Scope for a More Economic Approach to IP Issues under Article 102 TFEU*, in S. ANDERMAN, A. EZRACHI (eds.), *Intellectual Property and Competition Law. New Frontiers*, Oxford-New York, 2011, pp. 113-140; A. MUSELLI, *I diritti di proprietà intellettuale e l'abuso di posizione dominante – Rassegna delle decisioni comunitarie (1998-2010)*, in *Concorrenza e mercato*, 2012, pp. 425-445; A. EZRACHI, M. MAGGIOLINO, *European Competition Law, Compulsory Licensing and Innovation*, in *Journal of European Competition Law & Economics*, 2012, pp. 595-614; T.C. VINJE, A. VAN ROOIJEN, *The Relationship between Intellectual Property Rights and Competition Laws*, in N. WILKOF, S. BASHEER (eds.), *Overlapping Intellectual Property Rights*, Oxford, 2012, pp. 365-386; C. QUATTROCCHI, *Osservazioni circa l'applicazione della dottrina dell'essential facility al settore della proprietà intellettuale*, in AA.VV., *Studi in onore di Augusto Sinagra*, vol. IV, Roma, 2013, pp. 255-275.

⁴⁰ See S. ANDERMAN, *Overplaying the innovation card: The stronger intellectual property rights and competition law*, in P. DRAHOS, G. GHIDINI, H. ULLRICH (eds.), *Kritika: Essays on Intellectual Property*, vol. I, Cheltenham-Northampton, 2015, pp. 17-58, at pp. 30-31.

After analysing the state of play through case law pertaining specifically the pharmaceutical sector, in the final chapter it will be argued how the balance between patent laws and competition has currently been struck in both the EU and the US.

1.3. A SPECIFIC SECTOR: THE PHARMACEUTICAL INDUSTRY

The choice of a sector-specific perspective to further define the material scope of the present work has been made with the precise purpose of providing a practical viewpoint into the manifold contexts in which the patent/antitrust intersection has developed, especially in recent years.

Within the pharmaceutical industry, the tension outlined above between the characteristic principles of patent laws and competition policies is particularly common. On the one hand, innovation pushes towards the invention of new drugs requiring large investments and R&D activity, which the pharmaceutical companies are willing to make upon the condition of benefiting from strong patent protection. On the other hand, like all undertakings they have to comply with competition rules whose priority in this specific industry is to promote patients' welfare by ensuring access to therapy at reasonable prices and conditions⁴¹.

In addition, the pharmaceutical industry's features as a heavily regulated sector on both national and supranational levels⁴² have contributed to an increasingly intensive scrutiny into the exercise of patent rights under competition law para-

⁴¹ For a general assessment of the IP/antitrust implications in the pharmaceutical sector see, among others, S. PRIDDIS, S. CONSTANTINE, *The Pharmaceutical Sector, Intellectual Property Rights, and Competition Law in Europe*, in S. ANDERMAN, A. EZRACHI (eds.), *Intellectual Property and Competition Law*, cited above, pp. 241-275; M.A. CARRIER, *Competition law and enforcement in the pharmaceutical sector*, in A. EZRACHI (ed.), *Research Handbook on International Competition Law*, Cheltenham-Northampton, 2012, pp. 521-544; Á. GARCÍA VIDAL (dir.), *Patentes farmacéuticas y Derecho de la competencia*, Navarra, 2015; C. TESAURO, *La concorrenza nel settore farmaceutico*, in E.A. RAFFAELLI (ed.), *Antitrust fra diritto nazionale e diritto dell'Unione europea. XI Convegno*, Bruxelles, 2015, pp. 371-387; L. HANCHER, W. SAUTER, *A dose of competition: EU antitrust law in the pharmaceutical sector*, in *Journal of Antitrust Enforcement*, 2016, pp. 381-410; G. PITRUZZELLA, G. MUSCOLO (eds.), *Competition and Patent Law in the Pharmaceutical Sector: An International Perspective*, Alphen aan den Rijn, 2016. See also the results and the key findings of the 121st Meeting of the OECD Competition Committee held on 18-19 June 2014, in particular the Discussion on Competition and Generic Pharmaceutical where the invited experts were Prof. C.S. Hemphill and Mr. R. Subiotto, available at www.oecd.org.

⁴² See *infra*, in this Chapter, Section 2.2, for an overview of the sector-specific regulatory framework in the EU and the US legal systems.

digms. Judicial and enforcement authorities have in fact carried out competition law investigations concerning the possible exploitation of regulatory loopholes that amount to an anticompetitive conduct, even though it may formally appear consistent with the given legal framework. In this regard, conducts involving abuses of dominance as well as restrictive agreements pose challenging legal questions that are unique to the industry at issue, and, in some cases, are only beginning to be addressed. The second chapter of the thesis will thoroughly analyse and discuss the most relevant case law and practice that have emerged in the EU and the US legal systems.

More generally, in the pharmaceutical industry the interface between patent protection and antitrust is also faced with the concurring need to strike a balance with particularly sensitive interests, as the human right to health represents a common minimum standard underlying the whole sector. Indeed, the fundamental objectives of providing fair and affordable access to treatment as well as safe and effective medicines further qualify both the bodies of law at issue. This conflicting scenario has been subject to growing attention by the international community, especially on the account of the least-developed countries, which led to the adoption, within the WTO framework, of the Declaration on the TRIPS Agreement and Public Health on 14 November 2001 (also known as the «Doha Declaration»)⁴³. This legal instrument evidenced the intention of WTO members to support the implementation of the TRIPS Agreement in a way that is consistent with the principles of public health and access to medicines⁴⁴. In particular, it affirmed

⁴³ WTO, Ministerial Conference, Fourth Session (Doha, 9-14 November 2001), WT/MIN(01)/DEC/2, 20 November 2001.

⁴⁴ For further comments on the Declaration see, among others, F.M. ABBOTT, *The Doha Declaration on the TRIPS Agreement and Public Health: Lightning a Dark Corner at the WTO*, in *Journal of International Economic Law*, 2002, pp. 469-505; C.M. CORREA, *Implications of the Doha Declaration on the TRIPS agreement and Public Health*, June 2002, available at www.who.int. More in general on the issue see also J. SELLIN, *Access to Medicines. The interface between patents and human rights. Does one size fit all?*, Cambridge-Antwerp-Portland, 2014, pp. 225-289; B. CARAVITA DI TORITTO, *Balancing the Human Right to Health with the Competition Law and the Intellectual Property Regime*, in G. PITRUZZELLA, G. MUSCOLO (eds.), *Competition and Patent Law in the Pharmaceutical Sector*, cited above, pp. 53-66.

the right of WTO members to use the flexibility provided by the TRIPS Agreement for the specific purpose of guaranteeing the right to health. Among such flexibilities, the Declaration recalled the tools of compulsory licences⁴⁵, parallel imports⁴⁶ and exceptions to patent rights⁴⁷. As to its legal value, even though declarations are not specifically regulated in the WTO regime, it can be argued that it specified the scope of application of certain TRIPS provisions with regard to public health issues, and therefore has a similar effect to an authoritative interpretation of the Agreement.

The principles expressed in the Doha Declaration, moreover, appear to be well adjusted into the progressive integration of IPRs into the human rights discourse that has been previously contextualised. In particular, it constitutes a workable example of the mentioned coexistence approach between the two sets of rights, bringing together the contrasting aspects of innovation and access to knowledge towards the ultimate aim of promoting social and economic welfare within the specific area of public health.

For these reasons, the pharmaceutical industry sets itself a privileged framework in which the traditional paradigms of patent laws and competition are tested against new and evolving legal issues, thus offering a scientific challenge that is worth engaging in.

⁴⁵ Art. 5(b) of the Declaration states that «[e]ach Member has the right to grant compulsory licences and the freedom to determine the ground upon which such licences are granted», thus specifying the legal tool already provided for in Art. 31 of the TRIPS Agreement.

⁴⁶ Art. 5(d) of the Declaration refers to the possibility of authorising parallel imports of pharmaceutical products under the doctrine of exhaustion of rights pursuant to Art. 6 of the TRIPS Agreement, adding that «[e]ach Member [is] free to establish its own regime for such exhaustion without challenge».

⁴⁷ In this regard the reference is to Art. 30 of the TRIPS Agreement, according to which Members can enact limited exceptions to the exclusive rights conferred by a patent upon conditions that they «do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner». For an example that pertains specifically to the pharmaceutical sector, the so-called “Bolar exception” can be mentioned, which both the EU and the US legal systems have introduced: on this issue see *infra*, in this Chapter, Sections 2.2.1 and 2.2.2.

2. PRELIMINARY CONSIDERATIONS

2.1. ECONOMIC FRAMEWORK OF THE PHARMACEUTICAL INDUSTRY

Although this thesis examines the previously outlined interface between IP and antitrust in the pharmaceutical sector from a legal perspective, it seems however appropriate to consider some aspects that need to be taken into account also from an economic viewpoint. Indeed, as well known, competition law itself relies heavily on economic theories and studies in all of its policy areas (for instance to determine market structures, or substitutability between certain products, etc.). Regarding the industry at issue, the supply chain in particular presents certain features that characterises the supply and the demand side, respectively. In addition, the distribution channels as well play a relevant role within this market structure. A brief overview of these sector-specific features will thus be carried out.

Regarding the supply side, pharmaceutical undertakings are commonly divided into two categories: originators and generics. The former are R&D-based companies, which manufacture pioneer drugs starting from their development through research, tests and trials, obtaining patent protection and the necessary marketing authorisations, and finally placing them onto the market. These firms are typically large multinationals that act both at a global and a local level through various branches and subsidiaries. Some originators, however, take the form of smaller-sized businesses specialising in a narrower therapeutic area, which usually enter into licence or sale agreements with larger undertakings.

On the contrary, generic companies produce and sell medicinal products containing the same active pharmaceutical ingredient (API) as a patented drug after it has lost its exclusivity status. Generics are sold at a much lower price than the reference drug, thus promoting competitive dynamics between the two product versions and allowing lower expenditures for public healthcare budgets. The product development of generic products typically starts several years before the loss of exclusivity granted by patent or Supplementary Protection Certificates (SPCs), and in this timeframe potential anticompetitive conducts are subjected to close scrutiny by enforcement authorities and courts.

In between the supply and the demand sides, the pharmaceutical distribution chain has a number of relevant actors, namely wholesalers and pharmacies⁴⁸. More precisely, the first category of distributors acts between manufactures (both originators and generics) and pharmacies by delivering medicines within given geographical areas and ensuring certain amounts of stocks. In the EU legal system, wholesale distribution has been furthermore qualified as a public service, thus requiring the performance of the specific obligation to «ensure appropriate and continued supplies of (...) medicinal product[s] to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered»⁴⁹.

As to the demand side, a further categorisation that pertains exclusively to the sector in question is observed: it is in fact divided into patients, doctors, hospitals and (where provided) healthcare systems/insurers. The interrelationships among these actors is rather peculiar, in that a high level of information asymmetry is perceived between doctors, who prescribe the medicine, and patients, who are the

⁴⁸ A further category of actors, *i.e.* parallel traders, is active within the distribution chain, especially in the EU where the differential pricing create the conditions to profit from the purchase and resale of pharmaceutical products between low-price and high-price Member States. This aspect, however, falls partly outside the scope of the thesis, as it entails a different set of considerations referring to the regulation of public economic policies, and it will therefore not specifically discussed. For a comprehensive assessment see, among others, C. STOTHERS, *Parallel Trade in Europe*, Oxford, 2007; with particular regard to the pharmaceutical industry see L.G. GRIGORIADIS, *The Application of EU Competition Law in the Pharmaceutical Sector: The Case of Parallel Trade*, in *European Business Law Review*, 2014, pp. 141-201; K.R. BREKKE, T.H. HOLMÅS, O.R. STRAUME, *Price regulation and parallel imports of pharmaceuticals*, in *Journal of Public Economics*, 2015, pp. 92-105.

⁴⁹ Art. 81 of the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, *OJ L* 311 of 28 November 2001, pp. 67-128. On this aspect, see also Court of Justice, 16 September 2008, joined cases C-468 to C-478/06, *Sot. Lélos kai Sia EE and Others v. GlaxoSmithKline AEVE Farmakeftikon Proïonton, formerly Glaxowellcome AEVE*, EU:C:2008:504 (for a comment on the decision see for example S. BASTIANON, *Il caso Sot. Lélos kai Sia EE e il binomio diritto della concorrenza-importazioni parallele nel settore farmaceutico*, in *Il Diritto dell'Unione europea*, 2009, pp. 589-606).

actual consumer but whose role in choosing the product is minimal. Moreover, prescribing doctors are not the ones who actually bear the costs of the medicines, because the related expenses are placed upon private insurance providers or public healthcare systems (and, at times, upon patients themselves in the form of co-payments). This impacts directly on the degree of price elasticity since the doctors' prescribing behaviour tends to be insensitive to changes in the price of a given medicine.

The mentioned economic factors are therefore relevant for the analysis of case law and practice within the pharmaceutical sector, as well as its subsequent critical assessment, and, where appropriate, they will be further referred to in these specific contexts.

2.2. REGULATORY FRAMEWORK OF THE PHARMACEUTICAL INDUSTRY

2.2.1. IN THE EUROPEAN UNION

Within the EU institutional framework health policy in general is included among the shared competences between the EU and its Member States. More precisely, Art. 168(4)(c) TFEU⁵⁰ lists the circumstances in which the EU can exercise such competence, namely by means of legislative measures, adopted by the European Parliament and the Council, «setting high standards of quality and safety for medicinal products and devices for medical use». Besides these specific cases, healthcare is governed by domestic legislation and the EU exercises a supporting competence, particularly «encourag[ing] cooperation between the Member States to improve the complementarity of their health services in cross-border areas» as provided by Art. 168(2) TFEU.

Among the various aspects included in such broad competence the pharmaceutical sector, as already mentioned, is characterised by an extensive regulation at both supranational and national level⁵¹. In particular, there are two policy areas

⁵⁰ The now explicit competence set forth in said provision has its predecessors in Art. 129 of the EEC Treaty and Art. 152 of the EC Treaty, which both recognised an involvement of the Community in health-related matters. The major innovation of the current provision resides in the substantial expansion as to the range and definition of the EU competence in this field of law. See further S.L. GREER, T.K. HERVEY, J.P. MACKENBACK, M. MCKEE, *Health law and policy in the European Union*, in 381 *The Lancet*, 2013, pp. 1135-1144; M. GUY, W. SAUTER, *The History and Scope of EU Health Law and Policy*, in *CCP Working Papers*, January 2016, No. 16-2, available at <http://competitionpolicy.ac.uk>; in the Italian literature M. MIGLIAZZA, *Commento all'art. 168 TFUE*, in F. POCAR, M.C. BARUFFI (dir.), *Commentario breve ai Trattati dell'Unione europea*, 2^a ed., Padova, 2014, pp. 1039-1042.

⁵¹ For a comprehensive analysis and further references see, among others, L. HANCHER, *The EU pharmaceutical market: parameters and pathways*, in E. MOSSIALOS, G. PERMANAND, R. BAETEN, T.K. HERVEY (eds.), *Health systems in Europe: The role of European Union law and policy*, Cambridge, 2010, pp. 635-682; D. CURLEY, M.H.J. VAN DEN HORST, *Patents and Regularity Data Exclusivity for Medicinal Products*, in N. WILKOF, S. BASHEER (eds.), *Overlapping Intellectual Property Rights*, cited above, pp. 119-136; H. MISCHKE, E. KAMILANOVA, D. SCHNICHEL,

where these legal systems overlap, at least to some extent: the first one is patent protection and the second regards marketing authorisation (MA) procedures. Instead, pursuant to Art. 168(7) TFEU a third relevant policy area concerning distribution, pricing and reimbursement of drugs remains a matter of Member States' competence, in which the main actors are the respective national health systems (NHS).

With regard to patent laws in Europe, as is well known the relevant international legislation is provided by the 1973 European Patent Convention (EPC)⁵², which established the European Patent Organisation – whose bodies are the European Patent Office (EPO) and the Administrative Council – and set forth the substantive rules for granting a European patent⁵³. Once granted, the protection so conferred practically amounts to possessing a bundle of national patents that need to be validated in each State party and are subject to domestic enforcement proceedings. The term of extension of the European patent is twenty years from the date of filing the application (Art. 63 EPC), during which its holder is entitled to exclusive commercial exploitation of the patented invention.

Within the international legal framework, the filing of a European divisional application is further regulated (Art. 76 EPC). This is possible only as to subject matter that does not extend beyond the contents of the parent application to which the divisional refers, and, most commonly, such application is filed whenever the parent does not meet the requirement of unity of invention as provided in Art. 82 EPC. If the divisional application does satisfy these conditions, it is regarded as

Pharma, in J. FAULL, A. NIKPAY (eds.), *Faull & Nikpay: The EU Law of Competition*, 3rd ed., Oxford, 2014, pp. 1869-1876; M.I. MANLEY, M. VICKERS (eds.), *Navigating European Pharmaceutical Law. An Expert's Guide*, Oxford, 2015; S. SHORTHOSE (ed.), *Guide to EU Pharmaceutical Regulatory Law*, 6th ed., Alphen aan den Rijn, 2015.

⁵² The Convention entered into force in 1978 and the contracting States are now 38 (including all 28 EU Member States). Moreover, there are other States which have an extension (Bosnia and Herzegovina, Montenegro) or validation agreement (Morocco, Moldova) with the European Patent Office, although are not parties to the Convention. The complete list of contracting States and the official texts of the EPC are available at www.epo.org.

⁵³ Art. 52 EPC, in particular, recalls the basic requirements for the patentability of an invention, namely that it be new, involve an inventive step and be susceptible of industrial application.

having the same date of filing and priority date as the parent application, and the contracting States designated in the latter are deemed to be designated in the divisional as well.

The scope of application of EPC rules is of course general, thus also covering drugs and pharmaceutical products, but at the EU level, a sector-specific legislation closely related to the European patent system is provided. Indeed, Regulation (EC) No. 469/2009⁵⁴ envisages the legal tool of supplementary protection certificates (SPCs), which grant extended protection over the active ingredient of a medicine for a limited period of up to five years, so allowing a pharmaceutical company to recoup from the time and the significant investments required to bring the product onto the market. Despite the EU legal framework, SPCs are actually based on either a national patent or a European patent designating one or more contracting States, and therefore are granted and maintained by national patent offices.

In summary, according to Art. 3 of the Regulation an SPC can be granted in a Member State provided that the medicinal product is protected by a basic patent in force for which it has received a MA in that State, and no prior certificate has been issued for the same product. The application for an SPC shall be lodged in each Member State where such protection is sought within six months from the date on which a MA was granted in that State, and the duration of the certificate is calculated from the date of the first MA for the product granted anywhere in the EEA. Given the relevance of this piece of legislation on the competitive dynamics within the pharmaceutical industry, a substantial case law has developed with re-

⁵⁴ Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, *OJ L* 152 of 16 June 2009, pp. 1-10, which repealed Regulation (EEC) No. 1768/92, *OJ L* 182 of 2 July of 1992, p. 1-5. It is worth mentioning that this is not the only category of SPC regulated by EU legislation, as also a second one concerning plant protection products is provided for: see Regulation (EC) No. 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products, *OJ L* 198 of 8 August 1996, pp. 30-35. For a comprehensive analysis see for example T. GORAYA, *Supplementary Protection Certificates*, in S. SHORTHOSE (ed.), *Guide to EU Pharmaceutical Regulatory Law*, cited above, pp. 201-226.

gard to the interpretation of the Regulation's provisions⁵⁵, as well as to its implementation. This latter perspective will be particularly examined in the following chapter.

Moving to MA procedures, the general EU law provisions are laid down in the Directive 2001/83/EC⁵⁶ that requires the prior issue of such authorisation before placing any medicinal product on the market of a given Member State. In this regard, there are two possible routes that pharmaceutical companies may choose. On the one hand, the request for MA can be submitted to the competent national authority and then recognised in other EU Member States by means of the mutual recognition procedure (National Procedure), or it can be obtained in several Member States at the same time through a single application submitted to a national authority acting as a so-called Reference Member State (Decentralised Procedure)⁵⁷. On the other hand, a MA that is valid throughout the EU can be granted by submitting the application to the European Medicine Agency (EMA)⁵⁸ (Centralised Procedure)⁵⁹.

⁵⁵ For a more thorough assessment of the still-evolving case law see, recently, M. SCUFFI, *I certificati complementari di protezione: l'evoluzione della giurisprudenza sui termini di prolungamento brevettuale e l'ambito di protezione*, in *Rivista di Diritto Industriale*, 2015, I, pp. 5-17; C. GALLI, *Innovazione e concorrenza nella giurisprudenza UE in materia di SPC*, in *Il Diritto industriale*, 2016, pp. 111-124; F. PAPADOPOULOU, *Supplementary protection certificates: still a grey area?*, in *Journal of Intellectual Property Law & Practice*, 2016, pp. 372-381.

⁵⁶ Directive 2001/83/EC on the Community code relating to medicinal products for human use, cited above.

⁵⁷ This alternative procedure was introduced by the Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, *OJ L* 136 of 30 April 2004, pp. 34-57.

⁵⁸ The EMA is an agency of the EU whose main tasks consist in the scientific evaluation, supervision and safety monitoring of medicines used throughout the EU. For a comprehensive assessment on the role of decentralised agencies within the European institutional framework see, in the Italian literature, V. SALVATORE, *Commento all'art. 298 TFUE, Sezione 2. Agenzie e altri organismi UE*, in F. POCAR, M.C. BARUFFI (dir.), *Commentario breve ai Trattati dell'Unione europea*, 2^a ed., Padova, 2014, pp. 1431-1435; and by the same Author (ed.), *Le Agenzie dell'Unione europea. Profili istituzionali e tendenze evolutive*, Pavia, 2011 (in this volume, with particular regard to the EMA, E. PAVIONE, *Economia sociale di mercato e nuovi rapporti di partenariato pub-*

Within these national or EU procedures, an application for a MA may follow different patterns according to the nature and the scope of the data to be submitted, which consider the results of the expensive and time-consuming pharmacological, toxicological and clinical trials conducted by pharmaceutical companies during the drug development process. Besides an ordinary procedure that requires the submission of a full application, there are two alternatives, namely the abridged and the hybrid abridged procedure, which allow the applicant, upon certain conditions, to refer to data already included in a MA for a reference medicinal product⁶⁰. More precisely, the former is provided for a generic version of the product falling within the meaning given in Art. 10(2)(b) of the Directive 2001/83/EC⁶¹, whereas the latter is envisaged for a product that does not meet the criteria of biological equivalence to a reference drug and thus requires the submission of further data to support the MA application.

blico-privato: l'esperienza dell'iniziativa per le medicine innovative (IMI) e il coinvolgimento dell'Agenzia Europea per i Medicinali, pp. 193-212).

⁵⁹ This procedure finds a more specific legal framework in Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, *OJ L* 136 of 30 April 2004, p. 1-33.

⁶⁰ For the limited purposes of this inquiry, the provisions regarding reference biological products and biosimilars will not be taken into account.

⁶¹ According to said provision, a generic product is «a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines».

These abridged procedures are reasonably aimed at avoiding repetitions in the already costly clinical trials for drugs that are bioequivalent or at least present certain common features in relation to a reference medicine. At the same time, however, the originators companies must be rewarded as well for their investments in developing innovative treatments. The legislative balance between these conflicting interests has been struck in the form of «pharma-specific data protection rights»⁶² that regard the results of tests and trials submitted for the purposes of a MA procedure. Indeed, the Directive 2001/83/EC provides that an eight-year period of data exclusivity shall elapse before MA authorities can process an abridged application for a generic version of a drug. In other words, during such time only the originator that conducted the trials is allowed to apply for a MA, and to subsequently use it. Moreover, the same piece of legislation also grants an additional two to three-year protection before third parties that obtained a MA through an abridged application can bring their product onto the market⁶³.

Another feature of the MA system that needs to be taken into account is that said authorisation, in general, only relies on the basis of scientific criteria concerning the quality, safety and efficacy of the given drug⁶⁴, while the status of the patent protection for the originator reference product plays no role under this per-

⁶² The definition is proposed by H. MISCHÉ, E. KAMILANOVA, D. SCHNICHEL, *Pharma*, cited above, p. 1874.

⁶³ The relevant rules on data and marketing exclusivity are provided for in Art. 10(1) of the Directive 2001/83/EC. Considering the cumulative period of protection granted, they are commonly known as “8+2(+1)” (the additional year of marketing exclusivity specifically requires that during the first eight years the MA holder has obtained «an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies»: Art. 10(1), fourth subparagraph).

⁶⁴ See Arts. 126 of the Directive 2001/83/EC and 81 of Regulation (EC) No. 726/2004, providing that the grounds of refusal, suspension or revoking of a MA are only those set forth in the two legal instruments, among which the status of a patent is not included.

spective. Consequently, in the EU framework the so-called “patent linkage”⁶⁵ is not provided for in this context, as opposed to other regulatory systems.

As regards MA procedures, the so-called “Bolar provision”⁶⁶ or research exemption must also be mentioned. The term refers to Art. 10(6) of the Directive 2001/83/EC⁶⁷, under which generic manufacturers are exempted from infringement of patents or SPCs granted for medicinal products when conducting the necessary studies and trials with a view of obtaining MA for their drugs. This amounts to a safe harbour allowing them to carry out R&D while the reference product is still patent-protected and, thus, to apply for MA as soon as the period of data exclusivity has elapsed.

As to the pricing and reimbursement of drugs, as already mentioned, the legislative competence primarily lies with the Member States. In this regulatory context as well, national policies need to strike a complex balance between the objectives of ensuring fair access to treatments for the patients, granting incentives for originator companies and maintaining sustainable healthcare budgets. Moreover, the legislation enacted by Member States in this regard must comply with the provisions of the Directive 89/105/EC⁶⁸ (the so-called “Transparency Directive”),

⁶⁵ The notion comes from the practice of linking regulatory approval for a generic version of a drug to the patent status of the originator reference product. For an overall framework of linkage regulations see R.A. BOUCHARD ET AL., *Structure-Function Analysis of Global Pharmaceutical Linkage Regulations*, in 12 *Minnesota Journal of Law, Science & Technology*, 2011, pp. 391-457; with specific regard to the Italian legal system L. ARNAUDO, *Il patent linkage nel settore farmaceutico e nell’ordinamento italiano*, in *Mercato concorrenza regole*, 2014, pp. 355-364.

⁶⁶ The term “Bolar” comes from the judgment rendered by the US Court of Appeals for the Federal Circuit in the case *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984). The decision and the subsequent legislative amendments in the US legal systems are further discussed *infra*, in this Chapter, Section 2.2.2.

⁶⁷ Also this provision was not provided for in the original draft of said legal instruments, but was subsequently introduced by the Directive 2004/27/EC.

⁶⁸ Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems, *OJ L 40* of 11 February 1989, pp. 8-11. The European Commission later proposed to amend this piece of legislation in order to adapt its provisions to the evolving trends within the pharmaceutical sector (see Proposal for a Directive of the European

which sets forth certain requirements of transparency, objectivity and verifiability for pricing and reimbursement procedures. Since the present work mainly focuses on anticompetitive dynamics between undertakings within the pharmaceutical industry, an in-depth analysis regarding pricing and reimbursement procedures falls partly outside its scope⁶⁹. Nonetheless, some overall remarks on the main driving factors within this policy area are worth mentioning. Moreover, certain features of pricing and reimbursement systems implemented in specific Member States will be illustrated, where relevant, also in the case law analysis carried out in the following chapter.

In general, the price of a given drug is made up of different values, based primarily on the ex-factory price to which the margins for wholesalers, pharmacists and taxes are added to form the retail price level. The reimbursement then consists in the percentage of such a retail price that is paid by public healthcare systems, while the remaining part, known as co-payment, is charged to the patients and (if any) private supplementary insurance. Most EU Member States directly control the price of reimbursed medicines, while others have implemented systems where pharmaceutical companies are allowed to freely set their initial price levels. In this latter case, however, the price control is still indirectly exercised to the extent that drugs will benefit from reimbursement only up to a certain amount or on condition that the price is considered acceptable⁷⁰. Further elements to consider in this regard are the requirements and conditions imposed by domestic legislation on the demand side, namely on prescribing doctors and pharmacists, which affect the final decision towards a certain medicinal product (*e.g.* by imposing generic substi-

Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems, COM(2012) 84 final of 1 March 2012, available at <http://eur-lex.europa.eu>), but the proposal was withdrawn with the adoption of its 2015 Work Programme.

⁶⁹ For a thorough assessment see, among recent studies, A. BELLONI, D. MORGAN, V. PARIS, *Pharmaceutical Expenditures and Policies: Past Trends and Future Challenges*, in *OECD Health Working Papers*, 2016, No. 87, available at www.oecd-ilibrary.org.

⁷⁰ In particular, the EU countries that have adopted such a system of indirect control are Denmark, Germany and the United Kingdom.

tution unless there is a medical necessity for choosing a specific drug, or by rewarding prescribing behaviours whenever a certain budget or quota is respected).

The EU pharmaceutical industry, as outlined above in its main features, was subject to a comprehensive inquiry launched by the European Commission in January 2008⁷¹ and finalised on 8 July 2009⁷² (the Pharmaceutical Sector Inquiry, hereinafter also «Inquiry»). Its purpose was an assessment of the state of play as to competition in the industry at issue in response to some concerns expressed with regard to frequent delays in the entry of generic drugs into the market and an apparent decline of new medicines produced by originator companies.

The initiative fell within the wider EU policy objective of «providing European patients with safe, effective and affordable medicines, while at the same time creating a business environment that stimulates research, boosts valuable innovation and supports the competitiveness of the industry»⁷³. To pursue the evaluation, the Commission limited its scope to prescription medicines for human use, selecting 219 substances, and monitored the competitive behaviour of 43 originator companies and 27 generic manufacturers from 2000 to 2007. Both the subjective and the product scope allowed a reliable portion of the EU pharmaceutical market to be considered, given that the selected molecules accounted for 50% of the overall turnover of prescription drugs in 2007 and the selected companies represented 80% of the relevant turnover.

⁷¹ Commission decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation (EC) No. 1/2003, case No. COMP/D2/39.514, available at <http://ec.europa.eu/competition>.

⁷² Communication from the Commission, *Executive summary of the Pharmaceutical Sector Inquiry Report*, COM(2009) 351 final of 8 July 2009, accompanied by Technical annexes forming the Final Report of the Inquiry. It was also preceded by a Preliminary Report issued on 28 November 2008. All the mentioned documents are available at <http://ec.europa.eu/competition>. For a comment on the findings of the Inquiry see D. SCHNICHEL, S. SULE, *The Pharmaceutical Sector Inquiry and its Impact on Competition Law Enforcement*, in *Journal of European Competition Law & Practice*, 2010, pp. 93-11; D. STAUDER, S. ABEL, T. FRIEDE (Hrgs.), *Sektoruntersuchung Pharma der Europäischen Kommission – Kartellrechtliche Disziplinierung des Patentsystems?*, Köln, 2010.

⁷³ *Executive summary of the Pharmaceutical Sector Inquiry Report*, cited above, para. 1.

Briefly recalling the main findings of the Inquiry, the Commission divided them into issues arising from competition between originators and generics⁷⁴, and issues arising from competition between originators⁷⁵.

As to the former, the study focused on the dynamics that occur towards the end of the product life cycle, when the loss of the exclusivity granted by the patent is approaching and generic competitors are preparing to enter the market. To this end, a list of conducts implemented by pioneers in order to extend the breadth and duration of their patents was provided (so-called “tool-box” of instruments): the analysed practices referred to patent-filing strategies (*e.g.* patent clusters and voluntary divisional patent applications), patent-related litigation, oppositions and appeals before the EPO, patent settlements and other types of agreements, litigation in administrative proceedings for marketing authorisation or pricing and reimbursement of drugs, and life cycle strategies for second generation products (*i.e.* new therapeutic uses of products, or new formulations within the same indication). The data collected in this regard confirmed that these conducts contribute to a delayed generic entry into the market⁷⁶. Yet this finding appeared more of an assumption than an evidence-based inference, considering that the EU institution fell short of establishing a causal link between the possible anticompetitive behaviours of originators and the delay of generic entry⁷⁷. Moreover, the Commission seemed to overlook some of the features of the sector-specific legislative framework that play an actual role in this context.

As to competition between originators, the considered behaviours, such as defensive patent strategies, dispute settlements through licensing agreements or oth-

⁷⁴ *Ibid.*, para. 3.2.

⁷⁵ *Ibid.*, para. 3.3.

⁷⁶ On average, the generic entry was calculated after seven months once the originator lost its exclusivity on a certain medicine. For the highest selling products, the elapsed time reduced to four months (see *Executive summary of the Pharmaceutical Sector Inquiry Report*, cited above, para. 2.1.2).

⁷⁷ This point is particularly stressed by D. ROSENBERG, *A view of the research-based industry*, in D. STAUDER, S. ABEL, T. FRIEDE (Hrgs.), *Sektoruntersuchung Pharma der Europäischen Kommission*, cited above, pp. 51-72, at pp. 67-69.

er types of agreements, were found to have an impact on innovation and the difficulties in bringing new medicines into the market.

On the basis of this assessment, the EU antitrust enforcer reached its conclusions and proposed a number of initiatives that could be undertaken in the sector with the aim of creating a more competitive environment.

Preliminarily it underlined the necessary coexistence of IP laws and competition since both promote new developments and investments in R&D, but, at the same time, it reminded that the exercise of patent rights shall not be «immune from competition law intervention». In accordance with its main findings, the above-mentioned issues were identified as worthy of further scrutiny by the Commission and National Competition Authorities (NCAs).

Moreover, particular attention was paid to patent settlement agreements between pioneers and generic manufacturers. These conducts were in fact subject to a more focused monitoring, which so far has led to seven periodical Reports as follow-up to the Inquiry. In this context, the Commission introduced a categorisation of settlement agreements based on the combination of two elements: whether the agreement poses a limitation on generic entry, and whether a value transfer from the brand firm to the generic producer is envisaged. Three categories have thus been singled out: agreements not restricting generic entry into the market are characterised as A-type, while those posing such limitation (B-type category) are further subdivided into B.I settlements, which do not involve a value transfer from the originator to the generic, and B.II settlements, which do include this additional element.

The Commission has reaffirmed in its monitoring Reports that the B.II category is likely to attract the highest degree of antitrust scrutiny. However, any agreement would need to be evaluated on a case-by-case basis. The last one of these Reports, covering the period from January to December 2015, was published on 13 December 2016⁷⁸ and confirmed the general trend of a continued use of patent settlements in the European pharmaceutical sector. The total number of agree-

⁷⁸ All Reports on the Monitoring of Patent Settlements are available at <http://ec.europa.eu/competition>.

ments concluded throughout the mentioned period appears to have substantially increased as compared to the last year of monitoring, even though it did not exceed the peaks reached in previous years⁷⁹.

With regard to policy recommendations, in the Inquiry the EU institution confirmed its efforts towards the creation of a unified patent system and the adoption of the legal instruments related thereto, as well as streamlined marketing authorisation processes and improved pricing and reimbursement procedures. These aims, however, did not appear to be particularly innovative, as they have been already pointed out by the Commission in other instances⁸⁰.

The issues highlighted in the Inquiry, in particular concerning competition between originators and generics, are still much debated to this day. In fact, it was followed by an active antitrust enforcement that led to the opening of several investigations against pharmaceutical companies regarding alleged violations of Art. 101 and/or Art. 102 TFEU at both EU and national levels. In some cases the decisions have been appealed before the courts, thus providing for a further evaluation of the potential anticompetitive conducts. A thorough analysis and subsequent critical assessment of this body of case law will be carried out in the following chapters.

⁷⁹ More precisely, 125 settlements between originators and generics were concluded in 2015, compared to 76 in 2014, 146 in 2013, 183 in 2012, 120 in 2011, 89 in 2010 and 73 in 2009. In this regard it should be specified that the considerable increase of agreements in the years 2012-2013 was partly due to the enactment of a Portuguese law (No. 62/2011, published on 12 December 2011), under which any dispute on IPRs relating to pharmaceuticals shall be settled by mandatory arbitration.

⁸⁰ In relation to the improvement of the patent system see for example the Communication from the Commission to the European Parliament and the Council, *Enhancing the patent system in Europe*, COM(2007) 165 final of 3 April 2007; regarding the procedural framework for marketing drugs see, among others, the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector*, COM(2008) 666 of 10 December 2008. Both are available at <http://eur-lex.europa.eu>.

2.2.2. IN THE UNITED STATES

As opposed to the EU legal system, in the US a sector-specific regulatory framework for the pharmaceutical industry has been provided. The Drug Price Competition and Patent Term Restoration Act of 1984⁸¹ (best known as the Hatch-Waxman Act) represents the landmark piece of legislation in this area, passed by the Congress with the intention of increasing competition from generic drugs by streamlining their application process and favouring the incentives of challenging invalid patents.

On the one hand, the Act allows generics manufacturers to file an Abbreviated New Drug Application (hereinafter also ANDA) with the Food and Drug Administration (hereinafter also FDA) on the condition that they demonstrate the bioequivalence (*i.e.* the same active ingredients and performance) between the generic product and a patented drug already listed in the Approved Drug Products with Therapeutic Equivalence Evaluation (also known as the Orange Book)⁸².

On the other hand, the filing of an ANDA can be referred to the marketing of a generic either before or after the expiry of the relevant patents of the bioequivalent brand product. When a pre-expiration marketing is sought, the generic manufacturer is moreover required to certify that such patents are invalid or not in-

⁸¹ Public Law No. 98-417, Sept. 24, 1984, 98 Stat. 1585, which amended, among others, the Federal Food, Drug and Cosmetic Act (21 U.S. Code, Chapter 9 - FD&C Act) as regards to the procedures for new drugs applications. For an exhaustive comment of all the provisions introduced, see, among others, E.J. FLANNERY, P.B. HUTT, *Balancing Competition and Patent Protection in the Drug Industry: the Drug Price Competition and Patent Term Restoration Act of 1984*, in 40 *Food Drug Cosmetic Law Journal*, 1985, pp. 269-309; for a perspective on the future challenges and proposed amendments to the Act, see A.S. KESSELHEIM, J.J. DARROW, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, in 15 *Yale Journal of Health Policy, Law and Ethics*, 2015, pp. 293-347.

⁸² The listing of a new drug in the Orange Book and the consequent marketing approval comes at the end of a time-consuming and high-risk process, in which a brand company must submit a New Drug Application (NDA) to the FDA demonstrating the safety and effectiveness of its product through expensive clinical trials. For an overview of the requirements for the submission of such applications, see www.fda.gov.

fringed by the new drug. This, known as a «Paragraph-IV Certification», amounts to an actual infringement of the patents held by the brand firm and has precise consequences under the regime provided by the Hatch-Waxman Act. In fact, if the patent challenge is successful, and the generic producer was the first to have filed an ANDA with a Paragraph-IV Certification, it is entitled to a 180-day exclusivity right whereby the new generic drug and the originator product are the only competitors in the given market. The patent holder may nevertheless decide to bring a lawsuit against the generic manufacturer within 45 days from the receipt of notice of the Paragraph-IV Certification, thus automatically staying the ANDA proceedings for a maximum duration of 30 months.

To compensate the potential anticompetitive restraints that a strategic use of these two main features of the regulatory framework could bring about, Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003⁸³ introduced some amendments to the regime provided under the Hatch-Waxman Act.

As far as the 30-month stay is concerned, the 2003 rules place a limit of one stay per ANDA, which can only be referred to patents listed in the Orange Book before the filing of the application. Therefore, no additional 30-month stay could be triggered in relation to new patents concerning the same drug that an innovator may have listed and the generic company need to have filed an ANDA thereto.

Moreover, with regard to the 180-day exclusivity, the Medicare Act establishes a list of forfeiture events related to the failure of the first ANDA applicant with a Paragraph-IV Certification to get the new drug on the market. The purpose of this provision is thus to prevent the first generic manufacturer challenging the innovator's patents, to take advantage of its exclusivity right as a way of delaying competition⁸⁴.

⁸³ Public Law No. 108-173, Dec. 8, 2003, 117 Stat. 2066.

⁸⁴ See S.M. GREENE, *A Prescription for Change: How the Medicare Act Revises the Hatch-Waxman to Speed Market Entry of Generic Drugs*, in 30 *Journal of Corporation Law*, 2005, pp. 309-356, for a comment on the case law dealing with the abuse of the above-mentioned provisions and an evaluation of the amendments introduced by the 2003 rules.

The role played by settlements within this regulatory framework, especially before the expiration of the patents related to the brand product, can therefore be of great importance⁸⁵, as will be further discussed in the third chapter of the thesis⁸⁶. By settling the patent challenge with the first generic manufacturer to have filed an ANDA with a Paragraph-IV Certification, the innovator agrees to pay a large sum in exchange for withholding the generic entry into the market. Considering the mentioned 180-day exclusivity that follows from such an ANDA application, no other generic firm would be entitled to enter the market and a considerable anticompetitive harm would be caused.

Moreover, within the US regulatory framework, another aspect that is worth mentioning is the statutory research exemption rule (the so-called “safe harbour statute”) provided for in 35 U.S.C. § 271(e)(1)⁸⁷. Mirroring the already examined Bolar provision in the Directive 2001/83/EC, this rule was introduced by the Hatch-Waxman Act following the decision rendered by the Court of Appeals for the Federal Circuit in the case *Roche Products, Inc. v. Bolar Pharmaceutical Co*⁸⁸, where it was held that the legal framework at the time did not exempt the activities carried out for experimental purposes, and subsequent submission of testing data to a regulatory agency, from patent infringement. The aim of said amendment was therefore to allow a faster route to the market for generic prod-

⁸⁵ See extensively C.S. HEMPHILL, *Paying for delay: pharmaceutical patent settlement as a regulatory design problem*, in 81 *New York University Law Review*, 2006, pp. 101-167, at pp. 124-125.

⁸⁶ See *infra*, Chapter three, Sections 3.1 and 3.3.

⁸⁷ The rule, more precisely, reads as follows: «[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products».

⁸⁸ *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), cited above.

ucts that were equivalent to already approved drugs, in accordance with the general policy objectives of the Act itself⁸⁹.

⁸⁹ For a further analysis of the provisions, as well as its practical application, see for example A.C. SERVER, *Application of the Hatch-Waxman Act's Safe Harbor Provision Following Momenta*, in 13 *The John Marshall Review of Intellectual Property Law*, 2013, pp. 1-67.

CHAPTER TWO

CASE LAW ANALYSIS

SECTION ONE

CASE LAW ON RESTRICTIVE AGREEMENTS

Taking into account the findings of the 2009 Pharmaceutical Sector Inquiry, this section will discuss a selection of follow-up cases regarding practices between originator companies and generic producers, as well as between pioneers, that potentially infringe Art. 101 TFEU.

With regard to the former, the focus is set in particular on reverse payment settlement agreements, which have been dealt with by the European Commission in four probes (one is still pending) as a result of the above-mentioned findings of the Sector Inquiry in this specific context. One of the decisions issued by the EU institution has also been tested by the General Court, and thus the legal assessment acquires even more significance.

Then, a comparison with the landmark US Supreme Court ruling in the *Actavis* case is presented in order to assess differences and similarities of its approach with the legal reasoning of the EU institution.

This overview ends with an analysis of practice in Member States, namely that of the UK where reverse payment settlements have been investigated by the Competition and Markets Authority (hereinafter also CMA) in the *Paroxetine* case.

As to competition between originators, the analysis takes into account the practice of another Member State – Italy – regarding the dispute in which the Italian Competition Authority (hereinafter also ICA) opposed the brand companies Roche and Novartis.

2.1.1. IN THE EUROPEAN UNION

The Commission directed its antitrust scrutiny under Art. 101 TFEU towards reverse payment agreements concluded between originator companies and generic manufacturers. They form part of the most comprehensive category of patent settlements, which is subject to the follow-up monitoring activity of the EU enforcer as mentioned in the previous section. Their distinctive feature resides in the value transfer flowing from the brand producer to the generic as a form of compensation for delaying the entry into the market of the generic's competing product and settling the patent litigation between them. Therefore, these agreements qualify as «reversed» in the sense that the direction of the value transfer is opposite to the one that usually occurs when settling patent disputes. They are also known as «pay-for-delay» because of their effect of excluding generic competition from the given market for the time agreed upon¹. It should be noted, however, that such a definition of pay-for-delay agreements actually has a broader scope than the notion of reverse payment settlements, insofar as the former also applies where a value transfer in exchange for a delayed entry in the market takes place without being agreed upon in a patent dispute.

Furthermore, the value transfer at issue can take different forms depending on the terms of the agreement that the parties opt for: the basic scheme entails a direct cash payment from the patentee to the generic company, but there are also other types of value transfer such as distribution or licensing agreements, and side-deals on authorised generic drugs (hereinafter also AG) or co-promotion agreements. The manifold arrangements actually constitute an element that needs to be properly considered when assessing a potential infringement of Art. 101 TFEU, as the agreement needs to undergo a cost/benefit analysis whereby a proper transfer of value should be acknowledged only if «the cost to the payer appre-

¹ See L. ARNAUDO, *Dispute farmaceutiche e concorrenza: il caso Lundbeck*, in *Il Foro italiano*, 2015, IV, cc. 326-332.

ciably exceeds what they otherwise receive»². This view is also confirmed in the Commission's Inquiry, according to which the competition law evaluation requires an «in-depth analysis of the individual agreement» on the basis of the «factual, economic and legal background»³. However, as it will be further underlined, the EU watchdog has then distanced itself from this effects-based approach and rather applied in its decisions the stricter legal standard of a restriction of competition by object.

Lundbeck case.

The first Commission decision on this matter was issued on 19 June 2013 in the *Lundbeck* case⁴. The agreements entered into between 2002 and 2003 by the involved pharmaceutical companies (Lundbeck, Alpharma, Merck, Arrow and Ranbaxy) were found to infringe Art. 101 TFEU (and Art. 53 of the EEA Agreement, which has the same scope), and the drugmakers were consequently fined.

The factual background of the case refers to the blockbuster antidepressant drug citalopram, which the Denmark-based company Lundbeck marketed in the EEA under the brand names «Celexa» and «Cipramil». The originator held both

² P. TREACY, S. LAWRENCE, *Intellectual Property Rights and Out of Court Settlements*, in S. ANDERMAN, A. EZRACHI (eds.), *Intellectual Property and Competition Law. New Frontiers*, Oxford-New York, 2011, pp. 277-302, at p. 290.

³ *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, para. 1530, available at <http://ec.europa.eu/competition>.

⁴ Commission decision of 19 June 2013, case AT.39926, *Lundbeck*, published on 19 January 2015, available at <http://ec.europa.eu/competition>; see also the press release IP/13/563, available at <http://europa.eu/rapid>. For further comments on the case see A. GIANNACCARI, «Pay for delay» nel settore farmaceutico: il caso Lundbeck, in *Mercato concorrenza regole*, 2014, pp. 561-570; L. ARNAUDO, *Dispute farmaceutiche e concorrenza*, cited above; A. ZULLI, A. ROBERT, C. BURTON, P. BOGAERT, *The Commission's Lundbeck Decision: A Compass to Navigate between Scylla and Charybdis?*, in *Intellectual Property and Technology Law Journal*, 2015, No. 6, pp. 3-17; D. GERADIN, D.H. GINSBURG, G. SAFTY, *Reverse Settlements in the European Union and the United States*, in G. PITRUZZELLA, G. MUSCOLO (eds.), *Competition and Patent Law in the Pharmaceutical Sector: An International Perspective*, Alphen aan den Rijn, 2016, pp. 125-146, at pp. 139-143; V. SCHRÖDER, *Pay-for-delay settlements in the EU: did the Commission go too far?*, in *European Competition Law Review*, 2016, pp. 506-512.

product patents on citalopram and process patents to produce the active product ingredient (hereinafter also API) that were granted in most Western European countries between 1977 and 1985, but the drug was only introduced in the EEA markets in the mid-1990s. Therefore, the available time to exploit the product was relatively short, as the patent expiry of the compound in a significant number of European countries was due in 2002. Lundbeck started setting up a strategy to face the approaching generic entry into the citalopram market, which comprised the filing of numerous patent applications for manufacturing processes of the API, including a new crystallisation process, and persuading generic manufacturers to stop their efforts to enter the market. The ultimate goal was to create a «window of opportunity»⁵ for Lundbeck's successor product escitalopram before the entry of generic citalopram, in order to switch the patients to the new drug and to ensure continued high turnover and profitability. The strategy was partly successful, as Lundbeck managed to eliminate the competitive threat of the earliest generic API producers between 1999 and 2000, though other manufacturers kept on planning their entry. Following the expiry of the product patent, the originator thus responded by threatening, or in some instances actually starting, infringement litigation in 9 different EEA contracting States using its remaining process patents. Moreover – and this is the most relevant conduct from a competition law perspective – to the other generic suppliers that appeared undeterred by the legal disputes, Lundbeck offered to reach separate agreements in which the originator transferred lump sums of money to the generic companies in exchange for the delay, for a given period of time, in entering into the citalopram market with their versions of the product. It is worth noting that even though these agreements were concluded against the background of patent litigation, they did not actually resolve the underlying disputes, but «rather postponed generic entry for a certain period of time, leaving open what would happen afterwards»⁶. Therefore, they should not be regarded as patent settlements in the narrower sense, but the case is nonetheless to be included in the pay-for-delay category.

⁵ Commission decision of 19 June 2013, *Lundbeck*, cited above, paras. 135-143.

⁶ *Ibid.*, para. 194.

As to the merits of the case, the Commission adopted a three-pronged approach to carry out its assessment of the agreements between Lundbeck and the four generic manufacturers. Firstly, it had to establish whether the involved undertakings «were at the time of the events at least potential competitors»⁷ taking into account the originator's existing patents. In this regard the EU antitrust enforcer observed that Lundbeck's patent protection on the API had already expired by January 2002 in most EEA contracting States, and that the remaining process patents were not capable of blocking all marketable versions of the citalopram compound. Therefore, potential competition from the generic undertakings was not only theoretically possible, but also very likely, once they had obtained the necessary marketing authorisation. It is also worth mentioning that the Commission disregarded Lundbeck's claim according to which the generic undertakings could not be considered potential competitors because they were manufacturing their products by infringing its patents. Indeed, the EU institution reminded that as long as a court had not ruled on the infringement proceedings, the generic versions of the drug could only be regarded as potentially infringing, and the generic suppliers may nonetheless resort to an amended and non-infringing process to produce the relevant API.

Then the Commission analysed the restriction of competition pursuant to Art. 101(1) TFEU for the case at hand. After holding that a settlement concluded in the context of a patent dispute between originators and generics would normally not infringe said provision if the agreed conditions did not overcome the rights granted by patent law, the EU antitrust authority underlined, however, that «the means used by patent holders to defend their rights matter»⁸. In fact, even though the limitations provided in such a settlement do not go beyond the substantive scope of a patent, they are still likely to run afoul of EU competition law if they result from a transfer of value flowing in favour of the generic companies and inducing them to refrain from entering the market with their competing products. The infringement is all the more likely when said restrictions overcome the exclusionary

⁷ Commission decision of 19 June 2013, *Lundbeck*, cited above, paras. 610-636.

⁸ *Ibid.*, para. 641.

boundaries of patent protection, given that they could have never been obtained even through a court ruling. This second circumstance precisely occurred in the *Lundbeck* case: on the one hand, competition in the citalopram market was in principle open upon expiration of the originator's patent on the API and, on the other hand, the commitment from the generic undertakings to delay their entry for a given period could not be justified on the basis of the process patents still in force, because their scope was «limited to the particular process covered by that [exclusive right] and products directly obtained by the patented process»⁹. Moreover, the Commission noted that it was actually in the interests of both parties to enter into an agreement like those in question. For the originator company it would evidently eliminate the risk of a court ruling establishing the invalidity or the non-infringement of its patent and the consequent loss of a significant amount of profits, but the generic manufacturer would benefit as well, by making the same earnings, or even more, as when entering the market with its competing product, but without any of the risks related thereto.

Thirdly, the Commission examined the amount of value transferred from Lundbeck to the generic companies in each settlement. This assessment confirmed that the payment agreed upon in exchange for the commitment not to enter the market ultimately influenced the parties' anticompetitive behaviour also from an economic point of view.

The legal consequence of said circumstances is therefore the existence of a restriction of competition by object under Art. 101(1) TFEU, because the value transfer from the originator to the generic undertakings had the very purpose of limiting the entry into the market of potential competitors.

Having considered the infringement of Art. 101(1) TFEU as founded, the Commission furthermore examined possible justifications pursuant to Art. 101(3) of the same Treaty (and Art. 53(3) of the EEA Agreement). In this regard, it concluded that none of the involved companies submitted enough evidence to substantiate the four cumulative conditions required to benefit from an individual exemption, particularly the one regarding the efficiency gains claimed by the parties.

⁹ *Ibid.*, para. 642.

Both the originator and the generic manufacturers have lodged an appeal with the EU General Court for the annulment of the decision, questioning, in particular, the Commission's assessment of potential competition and the finding of a restriction of competition by object under Art. 101(1) TFEU. The EU Court delivered its judgments on 8 September 2016, rejecting all pleas in law raised by the applicants and dismissing the actions in their entirety¹⁰. Given that these rulings share a common line of reasoning concerning the main issues at stake, they can be examined together under this perspective. With regard to the argument that Lundbeck and the generics were potential competitors at the time the agreements were concluded, it maintained that the Commission had carried out a thorough assessment, regarding each of the generic undertakings involved, of «the real concrete possibilities they had of entering the market»¹¹. Indeed, such finding was supported by objective evidence¹², having established that each of the generic undertakings already had (or could have obtained within reasonable time) a non-infringing version of the drug about to enter the market when the agreements with

¹⁰ General Court, judgments of 8 September 2016, case T-460/13, *Sun Pharmaceutical Industries Ltd, formerly Ranbaxy Laboratories Ltd and Ranbaxy (UK) Ltd v. European Commission*, EU:T:2016:453; case T-467/13, *Arrow Group ApS and Arrow Generics Ltd v. European Commission*, EU:T:2016:450; case T-469/13, *Generics (UK) Ltd v. European Commission*, EU:T:2016:454; case T-470/13, *Merck KGaA v. European Commission*, EU:T:2016:452; case T-471/13, *Xellia Pharmaceuticals ApS and Alpharma, LLC, formerly Zoetis Products LLC v. European Commission*, EU:T:2016:460; case T-472/13, *H. Lundbeck A/S and Lundbeck Ltd v. European Commission*, EU:T:2016:449. All CJEU judgments cited in the present work are available at <http://curia.europa.eu>. For further comments see B. BATCHELOR, H. SHERATON, F. CARLIN, M. HEALY, *Lundbeck raises more questions than answers on “pay for delay” settlements; creates damaging divergence from US law*, in *European Competition Law Review*, 2017, pp. 3-7; R. SUBIOTTO, J. FIGUS DIAZ, *Lundbeck v Commission: Reverse Payment Patent Settlements as Restriction of Competition by Object*, in *Journal of European Competition Law & Practice*, 2017, pp. 27-29.

¹¹ General Court, judgment of 8 September 2016, *Lundbeck*, cited above, para. 142.

¹² The General Court underlined that the Commission had in fact considered various circumstances in this regard, among which the significant investments undertaken by the generic manufacturers in order to prepare their entry into the market and the fact that some of them had already obtained a MA for their products.

Lundbeck were concluded. According to the Court, this was sufficient to state that the generics exerted effective competitive pressure on the originator, without the Commission being required to show that they would have been able to actually enter the market with a commercially viable and non-infringing process during the term of the agreements.

As to the existence of a restriction by object within the meaning of Art. 101(1), which represents the core argument of the contested decision, the General Court carried out a comprehensive assessment ultimately confirming such strict legal standard. First of all, it acknowledged, however, that the mere presence of a reverse payment in the context of a patent settlement does not by itself raise competition law concerns. What distinguished the agreements at issue was rather the fact that they replaced, by means of reverse payments, the uncertainty deriving from a situation of potential competition with the certainty that the generic undertakings would not have entered the market with their products during the term of the agreements. The payments, in fact, amounted to a «buying-off of competition»¹³, which did not actually reflect the strength of the underlying patents, as it would be in the context of a proper settlement. The General Court further qualified the agreements between Lundbeck and the generics undertakings as «market exclusion agreements»¹⁴, which is as an extreme form of the desire to share a market and limit production resulting from the combination of points (b) and (c) of the non-exhaustive list provided in Art. 101(1) TFEU. Therefore, on the basis of objective evidence, it concluded that the agreements in question restricted competition «in a sufficiently serious manner as to be classified as a restriction ‘by object’». As it will be thoroughly discussed in the last chapter¹⁵, the standard applied by the Commission and confirmed by the General Court was considered to be consistent with previous CJEU case law on the distinction between restrictions of

¹³ General Court, judgment of 8 September 2016, *Lundbeck*, cited above, para. 352.

¹⁴ This notion is recurring in the mentioned decisions of the General Court: see judgments of 8 September 2016, *Sun Pharmaceuticals*, cited above, para. 222; *Arrow Group*, cited above, para. 230; *Merck*, cited above, para. 210; *Xellia Pharmaceuticals*, cited above, para. 267; *Lundbeck*, cited above, para. 435.

¹⁵ See *infra*, Chapter three, Section 3.1.

competition by object and by effect, and therefore an assessment of their anticompetitive effects in light of the legal and economic context was not required. This conclusion, moreover, was not excluded by the circumstance that the Commission had not ruled in the past on whether this type of agreement constitutes a restriction by object or by effect¹⁶.

The General Court has also explicitly rejected the legal standard of the scope-of-the-patent test to assess patent settlement agreements under Art. 101.1 TFEU, referring to the approach already adopted by the US Supreme Court in *Actavis*¹⁷. In this regard, it held that such a test proved to be problematic in a competition law context and, in any case, it is based on a subjective evaluation of the scope of the patent and its validity taken by the involved companies. In any case, the agreements at issue went even beyond the specific subject matter of Lundbeck's IPRs, because they did not include the right to pay potential competitors in exchange for the commitment not to enter the market with their products.

On 18 November 2016, Lundbeck filed an appeal with the Court of Justice, asking to set aside the General Court judgment¹⁸.

The first judgments by a EU court concerning reverse payment settlements thus confirm the narrow approach already taken by the Commission, even though the case law is still developing and appears to have further questions to assess in this matter.

Johnson&Johnson and Novartis case.

The second Commission decision was rendered on 10 December 2013 and concerned the brand drugmakers Johnson&Johnson (J&J) and Novartis, which

¹⁶ Also this argument is a common ground of all the General Court's decisions regarding the *Lundbeck* case: see judgments of 8 September 2016, *Sun Pharmaceuticals*, cited above, para. 272; *Arrow Group*, cited above, para. 281; *Generics (UK)*, cited above, para. 151; *Merck*, cited above, para. 212; *Xellia Pharmaceuticals*, cited above, para. 319; *Lundbeck*, cited above, para. 438.

¹⁷ General Court, judgment of 8 September 2016, *Lundbeck*, cited above, paras. 478-516.

¹⁸ Case C-591/16 P, *H. Lundbeck A/S, Lundbeck Limited v. European Commission*, OJ C 30 of 30 January 2017, p. 25.

were held liable under Art. 101(1) TFEU and fined for entering into a co-promotion agreement through their respective subsidiaries¹⁹.

The facts of the case involve fentanyl, a synthetic opioid that is used to treat chronic pain and was introduced to the market by J&J in the 1960s. Its compound patent expired in 1982 and has been commercialised in the European market in various forms, the most common of which is the transdermal patch. The first type of product developed by the pioneer company was the depot (or reservoir) patch, while the second-generation product was the matrix patch, which replaced the previous version of the medicine after the expiry of the data exclusivity for the purposes of marketing authorisation. In the Netherlands, in particular, even though no granted patent protected either versions of the product, the depot patch lost its exclusivity on 4 March 2004 and the matrix patch was launched in August of the same year. Generic competitors were therefore preparing to enter the market with their own depot patches. Novartis' Dutch subsidiary Hexal B.V./Sandoz B.V. was in an advanced stage of development and was expected to launch its product in the second quarter of 2005. However, this launch never took place because of a subsequent agreement concluded in July 2005 between Hexal/Sandoz and J&J's Dutch subsidiary Janssen-Cilag B.V., which was already marketing the matrix patch in said Member State. Under the terms of the agreement Hexal/Sandoz committed to promote Janssen-Cilag's matrix patch within the Netherlands by providing a series of non-specified services, whereas Janssen-Cilag granted monthly payments to its competitor. The parties also concluded an addendum to further extend the validity of the agreement for another year, until 10 July 2007, but it was eventually terminated beforehand on 15 December 2006. The co-operation however continued in the form of a supply agreement that granted Hexal/Sandoz the non-exclusive right to purchase and sell fentanyl patches under its

¹⁹ Commission decision of 10 December 2013, case AT.39685, *Fentanyl*, published on 5 March 2015, available at <http://ec.europa.eu/competition>; see also the press release IP/13/1233, available at <http://europa.eu/rapid>. For further comments see D. GERADIN, D.H. GINSBURG, G. SAFTY, *Reverse Settlements*, cited above, pp. 139-143; D.W. HULL, M.J. CLANCY, *The Application of EU Competition Law in the Pharmaceutical Sector*, in *Journal of European Competition Law & Practice*, 2016, pp. 150-161, at p. 153 f.

generic brand. In parallel, the same supply agreement was concluded also with a third independent party.

Preliminarily it must be borne in mind that this case needs to be distinguished from the others investigated by the Commission in this context. In fact, the co-promotion agreement between Janssen-Cilag and Hexal/Sandoz did not relate to patent litigation, as no patent protection on the compound was in force in the Netherlands at the time of the agreement, and the data exclusivity had already expired. Nonetheless, the EU institution adopted a legal reasoning similar to the *Lundbeck* case.

Also in this case the concept of potential competition played a major role in the assessment²⁰. Hexal/Sandoz was not only capable of entering the Dutch fentanyl market with its generic version of depot patches, but the evidence showed that it was also very close to doing so by August 2005 at the latest, when the originator's second-generation product was about to be launched. Therefore, J&J perceived the generic company as its most advanced potential competitor.

Then the Commission analysed in detail the content, objectives and implementation of the agreement in question. On the one hand, it considered the co-promotion activities required from Hexal/Sandoz under the terms of the agreement, concluding that they were actually limited in their scope and «of only marginal importance for Janssen-Cilag»²¹. On the other hand, it focused on the «prominent feature»²² of the agreement, namely the termination clause installing a non-entry mechanism. More precisely, the provision of immediate termination of the agreement by Janssen-Cilag in case of generic entry by Hexal/Sandoz, paired up with the value transfer that considerably exceeded the generic's expected profits, rendered the launch of Hexal/Sandoz's competing product «financially completely unattractive»²³. Moreover, the mentioned objective elements were confirmed by the intentions of the parties, who acted in full knowledge of the implications of their agreement.

²⁰ Commission decision of 10 December 2013, *Fentanyl*, cited above, paras. 226-256.

²¹ *Ibid.*, para. 310.

²² *Ibid.*, para. 314.

²³ *Ibid.*

As to the legal assessment of the infringement ensuing from said agreement, the Commission confirmed the approach adopted in *Lundbeck* and concluded with a finding of a restriction of competition by object under Art. 101(1) TFEU. Indeed, the agreement made it possible for Janssen-Cilag to maintain its supra-competitive prices on the fentanyl patch market and to share them with a potential competitor that would have posed a serious threat to its monopoly. The case is thus included in the broader «pay-for-delay» category and follows the Commission's precedent on this matters.

Servier case.

The EU antitrust enforcer issued its third (and so far last) decision in this regard on 9 July 2014²⁴. The *Servier* case provides the most comprehensive assessment of a proper patent settlement under a competition law perspective, because an infringement of both Arts. 101 and 102 TFEU was found, and in addition the restriction on competition pursuant to Art. 101(1) was examined under both by object and by effect legal standards.

The factual context refers to perindopril, a drug used in the area of cardiovascular diseases that was developed by the French company Servier and marketed under the brand names «Coversyl» and «Prestarium». The compound patent was granted in 1981 and during the 1980s the protection was also obtained for a number of key processes required for its preparation. The medicine became a blockbuster over the years and therefore Servier devised a strategy against the entry of generic competition in preparation of the expiry of its patents, which occurred on 29 September 2001 for the compound patent (prolonged until 2003 in some

²⁴ Commission decision of 9 July 2014, case AT.39612, *Perindopril (Servier)*, published on 14 July 2015 in a provisional non-confidential version available at <http://ec.europa.eu/competition>; see also the press release IP/14/799, available at <http://europa.eu/rapid>. For further comments see A. EUFINGER, „pay-for-delay-agreements” als wettbewerbswidrige Patentverlängerungen im Pharmabereich, in *Pharmarecht*, 2015, pp. 385-390; C. DESOGUS, *Manovre di avvicinamento tra l'Europa e gli Stati Uniti: il caso Servier sui patent settlements*, in *Mercato concorrenza regole*, 2016, pp. 249-278; D. GERADIN, D.H. GINSBURG, G. SAFTY, *Reverse Settlements*, cited above, pp. 139-143; V. SCHRÖDER, *Pay-for-delay settlements in the EU*, cited above.

Member States through SPC extensions). The originator's scheme comprised several practices, including the filing of a patent cluster²⁵, the acquisition of alternative technologies to produce the API²⁶, the conclusion of patent settlements agreements and, ultimately, the switch to its own second-generation product that had already obtained both patent protection (until 2023) and marketing authorisation, even though it did not possess an actual added therapeutic value. With particular regard to the patent agreements, they were concluded between 2005 and 2007 to settle the challenges brought against Servier's secondary patents by the most advanced competitors at that time, namely Niche/Unichem, Matrix, Teva, Krka and Lupin. The generic companies committed to end the patent litigation and refrain from launching their competing products in exchange for large cash payments and other inducements from Servier.

The Commission first assessed the alleged infringement under Art. 101(1) TFEU. After recalling previous CJEU case law, in particular the 2008 *Irish Beef* judgment²⁷ on the concept of «agreement having as its object the restriction of competition», the EU institution carried out a three-pronged analysis of the patent settlements in question, similarly to it did in the *Lundbeck* case. On the basis of the legal and economic background in which the agreements were reached, that is a context of patent litigation entailing uncertainty as to the infringement and the

²⁵ Some of them were labelled as «paper patents» by Servier itself, however other process patents had the potential to hinder generic competition in the relevant market. In particular, the '947 patent was strategically important as it covered the crystalline alpha form of the compound, which the vast majority of generic manufacturers implemented as alternative way to synthesise perindopril. It was granted by the EPO in 2004, but later revoked by decision of 6 May 2009. Also, the validity of the '947 patent was challenged in several national jurisdictions, for example before the Court of Appeal of England and Wales.

²⁶ In this regard the Commission drew its attention particularly to the acquisition of the patent applications and know-how of the Swiss company Azad regarding an advanced non-alpha form for manufacturing perindopril API. The agreement with Azad took place in 2004. For a specific comment see O. GURGULA, *Anti-competitive patent acquisitions in the pharmaceutical industry*, in *European Competition Law Review*, 2017, pp. 35-38.

²⁷ Court of Justice, 20 November 2008, case C-207/09, *Competition Authority v. Beef Industry Development Society Ltd and Barry Brothers (Carrigmore) Meats Ltd*, EU:C:2008:643.

validity of the exclusionary rights, it was established that the mere existence of Servier's remaining patents «did not bar all scope for potential or actual competition»²⁸ from the generic companies. Then, the Commission considered the contents of the settlements, in particular the contractual limitations imposed on the generic manufacturers and the transfer of value in a form of a reverse payment from the patent holder to the generics. In this regard it was again stressed that where said agreements are «affected by elements extraneous to the dispute/litigation»²⁹, notably payments and other inducements, they would impose limitations on the independent choices of the competitors in violation of Art. 101(1) TFEU, even if they do not overcome the material scope of the underlying patent. These considerations led the EU authority to conclude that there was a restriction of competition by object, in accordance with its previously examined decisions, given the settlements' capacity to collusively remove potential competitors and to affect the structure of the market.

The Commission's evaluation under Art. 101(1) TFEU went even further, analysing «for the sake of completeness, (...) the likely restrictive effects of the agreements on competition»³⁰. The *Servier* decision thus adds a new perspective to the legal assessment of patent settlement cases, whereby the restriction of competition by effect was ultimately considered founded as well. To this end the Commission largely relied on its Guidelines on Horizontal Agreements³¹, as well as the relevant CJEU case law, and took into account the actual conditions in which each of the patent settlements at issue was concluded. More precisely, the restrictive effects were assessed from a counterfactual perspective aimed at establishing the degree of competition (both actual and potential) that would have occurred in the given market without the settlements. Then, the analysis focused on the structure of the market, in particular on Servier's market power, which al-

²⁸ Commission decision of 9 July 2014, *Perindopril (Servier)*, cited above, para. 1179.

²⁹ *Ibid.*, para. 1137.

³⁰ *Ibid.*, para. 1213.

³¹ Communication from the Commission, *Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements*, OJ C 11 of 14 January 2011, pp. 1-72.

lowed the originator to maintain its position by means of the devised anticompetitive strategy.

Concluding the assessment on the restrictive agreements, the exemption pursuant to Art. 101(3) TFEU was also evaluated. According to the Commission, none of the parties submitted the evidence required to support their arguments of claimed efficiencies that could have met the four cumulative conditions of said provision.

With regard to the alleged anticompetitive conducts under Art. 102 TFEU, it appears appropriate to defer the analysis of the *Servier* case to the following section dedicated to abuses of a dominant position. However it is worth mentioning here that the Commission regarded this infringement as founded, thus holding the involved companies liable under both Art. 101 and Art. 102 TFEU, and fining them accordingly.

On 21 September 2014 Servier filed an appeal with the General Court seeking for the annulment of the decision on the basis of seventeen pleas in law. The case is still pending³².

Cephalon and Teva case.

A fourth case of allegedly restrictive agreements in the pharmaceutical sector is still in progress. On 19 April 2011 the Commission opened an *ex officio* antitrust investigation against the originator company Cephalon and the generic manufacturer Teva with regard to a settlement reached in 2005 in the context of patent litigation in the UK and the US concerning the drug modafinil, used to treat sleep disorders and commercialised under the brand name «Provigil»³³. More precisely, the agreement reportedly refrained Teva from selling its generic version of the

³² Case T-691/14, *Servier SAS, Servier Laboratoires Ltd and Les Laboratoires Servier SAS v. European Commission*, OJ C 462 of 22 December 2014, p. 25. The decision was appealed also by Biogaran, which was held jointly liable with Servier with regard to the agreement with Niche/Unichem: case T-677/14, *Biogaran v. European Commission*, OJ C 395 of 10 November 2014, p. 59 s.

³³ See the press release IP/11/511, available at <http://europa.eu/rapid>.

drug within the EEA markets until October 2012. The EU institution has yet to issue its Statement of Objections.

These decisions thus attest to a strict approach taken by the European Commission towards patent settlements between originators and generic manufacturers, as demonstrated by the finding, in each of the examined cases, of a restriction of competition by object under Art. 101(1) TFEU. The adoption of this legal standard is of particular importance, as is well known, because of its consequences on the burden of proof placed on the enforcement authority, being a *prima facie* case where a demonstration of actual anticompetitive effects is not needed.

2.1.2. IN THE UNITED STATES

Actavis case.

The previous chapter addressed how the specific regime provided by the Hatch-Waxman Act does to a certain extent affect the incentives to settle patent litigation in the US. This explains why cases of reverse payment patent settlements between originator and generic companies have undergone an intense scrutiny by both the Federal Trade Commission (hereinafter also FTC) and the courts since the early 1990s³⁴. Therefore, the US approach to these matters actually dates back to the past decades and has been developing through a significant case law, providing a qualified term of comparison for the more recent EU practice. In particular, different positions have emerged regarding the antitrust assessment of these agreements and the role (if any) played by patent law within such evaluation³⁵.

On the one hand, the FTC since the start of its enforcement actions in this regard has supported the position of per se illegality insofar as the settlement entailed a significant compensation that was not justified by reasons other than accepting to postpone the generic drugs' entry into the market. This reasoning is ultimately grounded on the increased costs imposed on consumers as a consequence of said settlements. Some commentators, however, have criticised this view for being too rigid, not distinguishing between anticompetitive and pro-competitive

³⁴ In this regard, a distinction between «first-wave» and «second-wave» settlements is usually adopted. The former refer to agreements dating back between 1993 and 1999, which were rather basic and envisaged a «direct monetary payment» against a delayed entry until patent expiration, whereas the latter have emerged since 2005 and assumed a «more sophisticated form», e.g. an agreed entry prior to the expiration date, or indirect value transfer from the originator: as underlined by P.L. PARCU, M.A. ROSSI, *Negotiated Foreclosure and IPRs: Recent Developments*, in G. CAGGIANO, G. MUSCOLO, M. TAVASSI (eds.), *Competition Law and Intellectual Property. A European Perspective*, Alphen aan den Rijn, 2012, pp. 155-176, at p. 160.

³⁵ For an overview of the cases and the related courts' opinions see S. DE MARGERIE, 'Pay-for-Delay' Settlements: In Search of the Right Standard, in 36 *World Competition*, 2013, pp. 85-98.

settlements³⁶. Nevertheless, it was also maintained by the Court of Appeals for the Sixth Circuit in 2003, which held that the settlement at stake was a horizontal agreement and hence a per se illegal restraint of trade³⁷. Following the same approach, the Third Circuit in 2012 however adopted a slightly different reasoning and ruled in favour of a quick-look rule of reason analysis³⁸. According to this court, reverse payment settlements were presumed *prima facie* to unreasonably restrain trade, but the case was rebuttable by demonstrating either a different purpose than delayed entry, or pro-competitive benefits of the payment.

On the other hand, the opposite position applied the so-called “scope-of-the-patent test”, according to which a patent settlement shall be considered immune from antitrust scrutiny under certain requirements: first, the exclusionary effect must fall within the scope and the term of the underlying patent; second, the patent holder’s infringement claim must not have been objectively baseless; and third, the patent must not have been procured by fraud on the US Patent and Trademark Office (PTO). This second view represented the prevailing opinion among US courts, having been upheld by, as well as by the Second Circuit (in 2002)³⁹, as well as the Eleventh (in 2003)⁴⁰ and the Federal Circuits (in 2008)⁴¹.

The existing split among the Circuits was ultimately solved by the Supreme Court in its decision rendered on 17 June 2013 in the *Actavis* case⁴², which consti-

³⁶ For example, according to B.M. DICKEY, D. RUBINFELD, *Would the per se illegal treatment of reverse payment settlements inhibit generic drug investment?*, in *Journal of Competition Law and Economics*, 2012, pp. 615-625, at p. 621, the FTC’s approach «appears to be that for every “reverse payment” settlement there exists a settlement without a payment and an earlier entry date that will increase social welfare. Whether such an outcome is indeed feasible is not at all clear».

³⁷ *In Re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003). All US decisions cited in the present work are available at Westlaw database (www.westlaw.com).

³⁸ *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3rd Cir. 2012).

³⁹ *In Re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2nd Cir. 2002).

⁴⁰ *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003).

⁴¹ *In Re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008).

⁴² *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). The Court reached a 5-3 decision, which was delivered by Justice Breyer. Chief Justice Roberts delivered the dissenting opinion. The judgment gave rise to a heated debate in the literature, splitting between those who sustained the Supreme

tutes a turning point in the recent developments regarding the extent of the anti-trust scrutiny into patent law.

The case was brought before the Supreme Court following the appeal by FTC of the *FTC v. Watson* decision of the Court of Appeals for the Eleventh Circuit given in 2012⁴³. The factual background refers to a settlement reached between the brand company Solvay, which held a patent for the drug AndroGel, and three generic manufacturers (Watson Pharmaceuticals, Paddock Laboratories and Par Pharmaceuticals) in the context of a patent litigation stemming from two separate ANDAs with Paragraph-IV Certifications. Under the terms of the settlement the generic drug's entry into the market was basically delayed until 2015 (that was five years after the patent expiry) in exchange for annual cash payments from Solvay amounting to millions of dollars. The FTC thus filed a lawsuit against all the settling parties claiming an antitrust violation. However, the District Court⁴⁴ did not regard it as founded and dismissed the complaint. The decision was ap-

Court's position, and those who deemed it as excessively strict. For the former, see for example A. EDLIN, S. HEMPHILL, H. HOVENKAMP, C. SHAPIRO, *Activating Actavis*, in 28 *Antitrust*, Fall 2013, pp. 16-23; and by the same Authors, *Actavis and Error Costs: A Reply to Critics*, in *The Antitrust Source*, October 2014, available at www.antitrustsource.com; H. HOVENKAMP, *Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision*, in 15 *Minnesota Journal of Law, Science & Technology*, 2014, pp. 3-39. For the latter, see for instance R.J.R. PERITZ, *The Competition Question Unasked in Actavis: What is the Scope of the Patent Right to Exclude?*, in 28 *Antitrust*, Fall 2013, pp. 45-49; A.P. REEVES, *Muddying the Settlement Waters: Open Questions and Unintended Consequences Following FTC v. Actavis*, in 28 *Antitrust*, Fall 2013, pp. 9-14; G.S. LUNNEY, JR., *FTC v. ACTAVIS: The Patent-Antitrust Intersection Revisited*, in 93 *North Carolina Law Review*, 2015, pp. 375-458. The decision had resonance also in the European literature: see, among others, G. GÜRKANYAK, A. GÜNER, J. FILSON, *The Global Reach of FTC v. Actavis – Will Europe Differ from the US Approach to Pay-for-Delay Agreements?*, in *International Review of Intellectual Property and Competition Law*, 2014, pp. 128-160; F. LA ROCCA, *Le problematiche dei "reverse payment settlement agreements" rispetto alla normativa antitrust*, in *Rivista di Diritto Industriale*, 2014, II, pp. 199-206. For an interesting perspective on the impact of *Actavis* even beyond pay-for-delay agreements, see A. DEVLIN, *Antitrust and Patent Law*, Oxford, 2016, pp. 24-38.

⁴³ *F.T.C. v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298 (11th Cir. 2012).

⁴⁴ *In re Androgel Antitrust Litigation (No. II)*, 678 F.Supp.2d 1371 (N.D. Ga. 2010).

pealed before the Court of Appeals for the Eleventh Circuit, which affirmed the District Court and resolved the case applying the above-mentioned scope-of-the-patent test. On the contrary, the Supreme Court ruled in favour of an antitrust-oriented approach, under which «the opportunity to prove [the] antitrust claim»⁴⁵ should be given to the plaintiff in a dispute regarding reverse payment settlements. By rejecting the resort to presumptive rules, it thus held that the appropriate standard is the rule-of-reason doctrine, leaving it to lower courts to further adjust this legal assessment to each individual case. It provided five sets of considerations to support this reasoning.

The first ground regards the potential adverse effects on competition that these settlements entail. The agreement at issue actually amounted to a purchase by the patentee himself of the exclusive right to sell its brand product that allowed him to maintain prices at high level of profit and share them with the competing patent challengers. In sum, by agreeing on dividing the patent-related return «the patentee and the challenger gain; the consumer loses»⁴⁶. This is all the more so where the settlement involves, as in the present case, the first Paragraph-IV ANDA filers within the regulatory framework of the Hatch-Waxman Act, who represent the most advanced competition against the brand company.

Secondly, the Court admitted a reverse payment may serve different purposes, which under given circumstances do not raise antitrust concerns. For example, they may roughly amount to the litigation expenses expected from the parties, or reflect compensation for other services performed by the generic manufacturer. Nevertheless, this possibility should not amount to a presumption of validity, but rather both parties are required to prove their respective claims (in particular, the defendant needs to show the legitimate justifications underlying the agreement).

As third reason the decision considered the power of the brand drugmaker to charge anticompetitive prices and thus bring anticompetitive harm in practice. This position on the market can be inferred by the size of the payment flowing

⁴⁵ *F.T.C. v. Actavis, Inc.*, cited above, at 2234.

⁴⁶ *Ibid.*, at 2235.

from the brand to the generic, which «is itself a strong indicator of [such] power»⁴⁷.

The fourth consideration is probably the most crucial of the whole decision, in that it explains the feasibility of the antitrust claim under the rule of reason standard as opposed to the Eleventh Circuit's opinion. Indeed, according to the Supreme Court, the assessment of the antitrust question can be carried out on the basis of the size of the payment, without litigating the validity and/or infringement of the patent and thus avoiding a complex and cost-consuming proceeding. In the Court's words, «the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself»⁴⁸. A large payment would normally hint at the doubts the patentee has about the strength of its exclusionary right's strength; as the literature has underlined, «the size of the payment may actually be a more reliable indicator to the extent it reflects the settling parties' market-based judgment about the patent's probable prospects in a fully litigated infringement suit»⁴⁹, and further that applying this rationale to large reverse payments creates «an inference that the settlement is anticompetitive»⁵⁰. The Court therefore supports the view of a general harm to competition arising from this kind of settlements.

Fifthly, the Court stressed that the possibility of facing the antitrust scrutiny does not rule out every incentive for the parties to settle their patent disputes, as there may be other ways to reach an agreement that do not include a reverse payment. On the contrary, when the underlying reasons would result in an anticompetitive market sharing, the settlement is likely to be found illegal under antitrust laws.

⁴⁷ *Ibid.*, at 2236.

⁴⁸ *Ibid.*, at 2236-2237.

⁴⁹ H. HOVENKAMP, *Anticompetitive Patent Settlements*, cited above, p. 21.

⁵⁰ A. EDLIN, S. HEMPHILL, H. HOVENKAMP, C. SHAPIRO, *Activating Actavis*, cited above, at p. 16, where they refer to this consideration as «the essence of the Court's opinion».

The Supreme Court thus concluded by leaving to the lower courts «the structuring of the present rule-of-reason antitrust litigation»⁵¹ on the basis of the guidance it provided in its judgment. In this regard it reminded that the courts should direct the scrutiny «so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences»⁵².

After analysing the arguments of the Court’s decision, it is also worth to briefly examining the dissenting opinion in the case at hand. The main criticism to the majority regarded the choice of assessing the settlement between the patentee and the generic according to antitrust policies, rather than patent law policy, as it should be when the case involves a question of validity and/or infringement of a patent. Although the dissent admitted that patent agreements may sometimes be found unlawful under antitrust laws, it underlined that «those some times»⁵³ have already been well established by the Court’s precedents as a matter of scope of the patent to be evaluated under patent law. Moreover, the dissenting opinion pointed out the mistaken consideration of the majority according to which it would not be necessary to litigate the validity of the patent in the context of an antitrust suit. This would imply that the defendant (*i.e.* the patent holder) could not invoke the exclusionary rights legitimately granted by its patent as a defence, thus depriving patent law of its aim. It ultimately concluded by foreseeing a general discouragement for the generic manufacturers from challenging drug patents as a result of the stricter boundaries (*i.e.* without resorting to payments) for settling such claims⁵⁴.

⁵¹ *F.T.C. v. Actavis, Inc.*, cited above, at 2238.

⁵² *Ibid.*

⁵³ *Ibid.*, at 2242.

⁵⁴ The dissenting opinion has been subjected to much debate in the legal literature as well. In particular, among those who supported the majority’s view and affirmed the importance of the antitrust scrutiny in assessing reverse payment settlements, see M.A. CARRIER, *A Response to Chief Justice Roberts: Why Antitrust Must Play a Role in the Analysis of Drug Patent Settlements*, in 15

Post-Actavis cases.

Even after *Actavis*, complex issues related to the antitrust assessment of reverse payment patent settlement remain open in the US. Indeed, District Courts that have addressed them following the Supreme Court decision have not always applied its principles in a consistent manner.

A question immediately perceived as problematic after the Supreme Court judgment deals with the determination of a «large and unjustified payment» flowing from the originator to the generic company. In particular, two aspects of this notion need to be further assessed by lower courts, namely what constitutes a payment under *Actavis* principles and what makes such a payment large.

With regard to the concept of payment, the Supreme Court actually analysed a case of cash transfer and made reference to this throughout its judgment. This provided the ground for two district courts to hold that *Actavis* only applies to reverse payment involving money, so other types of compensation such as a no-AG (authorised generic) agreement⁵⁵ or a co-promotion agreement⁵⁶, should not undergo antitrust scrutiny. However, the majority of the lower courts that have al-

Minnesota Journal of Law, Science & Technology, 2014, pp. 31-40 (his critique was grounded on three main aspects: the role of patent law, the role of antitrust policies and the regulatory regime provided by the Hatch-Waxman Act).

⁵⁵ *In re Lamictal Direct Purchaser Antitrust Litigation*, 18 F.Supp.3d 560 (D.N.J. 2014). The settlement in this case was said not to trigger antitrust scrutiny «since there was no transfer of money» in it. However, the judgment was later vacated and remanded on appeal by direct purchasers: *King Drug Company of Florence, Inc. v. Smithkline Beecham Corporation*, 791 F.3d 388 (3rd Cir. 2015).

⁵⁶ *In re Loestrin 24 FE Antitrust Litigation*, 45 F.Supp.3d 180 (D.R.I. 2014), in which the settlement involved a no-AG agreement as well. In particular, the Court held that «*Actavis* requires cash consideration to trigger rule of reason scrutiny». This judgment was also subsequently vacated and remanded by the Court of Appeals for the First Circuit on appeal by direct purchasers and end payors: *In re Loestrin 24 Antitrust Litigation*, Case no. 15-1250, 2016 WL 698077, 22 February 2016, where it was established that «non-monetary reverse payments fell under the scope of Supreme Court's 2013 *Actavis* decision».

ready examined the same issue after *Actavis* did not accept this opinion and found that the form of the payment is not a decisive element⁵⁷.

There are in fact strong arguments to support the broader reading of the Supreme Court judgment, regardless of the payment's cash or noncash form. The most evident of them is the risk of directing the settling parties to other types of consideration rather than cash, which would not amount to antitrust violations but would give rise to the same, or maybe even more significant, anticompetitive effects. Moreover, the narrower approach is not substantiated by any economic reason, since some noncash payment could nonetheless produce monetary benefits in favour of the generic company. Of course, should the value transfer be in a form other than cash, the courts would be required to perform a further level of analysis. In particular, the facts underlying each actual case would need to be addressed from the perspective of the originator, in order to establish whether the sacrifice undertaken by settling the litigation ultimately resulted in an anticompetitive advantage⁵⁸.

Also related to the concept of payment under *Actavis* is the specific assessment of a no-AG agreement in the context of reverse payment settlements. It is an issue at the forefront of the debate given their increasing use and the range of their consequences. An authorised generic is the generic version of a branded drug that is authorised by the patent holder itself under its FDA approval. The brand company may decide to directly market this version of the product or to reach an agreement with a generic manufacturer to this end. Therefore, there could be room for strategies affecting competition within the given market. In this regard a no-AG clause

⁵⁷ See for example *In re Nexium (Esomeprazole) Antitrust Litigation*, 968 F.Supp.2d 367 (D.Mass. 2013); *In re Lipitor Antitrust Litigation*, 46 F.Supp.3d 523 (D.N.J. 2014); *In re Effxor XR Antitrust Litigation*, Civil Action No. 11-5479, 2014 WL 4988410 (D.N.J. 2014). The literature consistently rejects the narrower opinion as well: among others, J.P. DAVIS, R.J. MCEWAN, *Deactivating Actavis: The Clash between the Supreme Court and (Some) Lower Courts*, in 67 *Rutgers University Law Review*, 2015, pp. 557-584, at 567-573; A. EDLIN, S. HEMPHILL, H. HOVENKAMP, C. SHAPIRO, *The Actavis Inference: Theory and Practice*, in 67 *Rutgers University Law Review*, 2015, pp. 585-635, at 592-595.

⁵⁸ This point is underlined by A. EDLIN, S. HEMPHILL, H. HOVENKAMP, C. SHAPIRO, *The Actavis Inference*, cited above, pp. 593-594.

between an originator and a generic producer, whereby the former commits not to introduce an authorised generic, could be a valuable element for a prospective settlement, especially with the first ANDA filer during its 180-day market exclusivity. Such an agreement can in fact provide for a further type of consideration (albeit in a noncash form) that the generic could not obtain even by succeeding in the patent challenge against the originator, as the latter could still be able to launch its authorised generic in this case. A no-AG provision, moreover, holds an anticompetitive potential far greater than a mere cash payment, in that it confers a considerable bargaining power to the brand company against the generic and it results in a form of market division capable of reducing generic competition beyond their delayed entry into the market⁵⁹. All these reasons thus support the broader interpretation of *Actavis* principles to the extent that they encompass noncash forms of payment as well, and in particular no-AG agreements.

Given the relevance of no-AG agreements, it is worth briefly discussing the first challenge brought by the FTC against this kind of practice. In March 2016 the Commission filed a complaint before the District Court for the Eastern District of Pennsylvania against two settlements between Endo Pharmaceuticals Inc. and the Japan-based patent holder Teikoku Pharma USA, Inc., on the one hand, and the generic manufacturers Watson Laboratories, Inc. (and its owner, Allergan plc) and Impax Laboratories, Inc., on the other hand⁶⁰. The agreements essentially aimed at settling the Hatch-Waxman litigation regarding the brand drugs Opana ER and Lidoderm, both marketed by Endo, whereby the originator committed not to launch its own AGs competing with the generic product of Impax and Watson. In its complaint, the FTC carried out an assessment of the unlawfulness of said

⁵⁹ As to this last ground, in particular, it has been noted that the combination of the generic's commitment to delay its entry and the no-AG agreement ultimately amounts to «an extended period of brand-only sales, followed by 180 days of sales of the brand and only one generic»: M.A. CARRIER, *Eight Reasons Why "No-Authorized-Generic" Promises Constitute Payment*, in 67 *Rutgers University Law Review*, 2015, pp. 697-720, at p. 719. The Author also provides an extensive comment on the other ground mentioned above.

⁶⁰ *F.T.C. v. Endo Pharmaceuticals Inc. et al.*, Case No. 2:16-cv-01440-PD filed on 30 March 2016 (E.D. Pa.).

no-AG commitments according to the *Actavis* benchmarks, in that they constituted large and unjustified payments from the brand firm to the generic manufacturers. Moreover, with specific regard to Opana ER, the FTC also considered that the settlement with Impax was part of a broader strategy to facilitate the introduction of Endo's reformulated second-generation product, which ultimately triggered the originator's obligation to provide the generic company with a further large cash payment. The District Court, however, did not assess the merits of the case as it granted the defendants' severance motion and the FTC voluntarily dismissed its complaint in November 2016.

Later on, in January 2017, the claims against Endo were settled by means of a proposed stipulated order filed before the District Court for the Northern District of California⁶¹, under whose terms Endo is prevented from entering into patent settlement agreements containing reverse payments or no-AG commitments for a period of ten years. In addition, the FTC refiled charges against Watson and Allergan for entering into the unlawful Lidoderm agreement with Endo, and also issued an administrative complaint against Impax as to the similar agreement regarding Opana ER⁶². The dispute is therefore still open, and it will be interesting to see whether the strict approach adopted by the FTC with regard to no-AG agreements is going to be further maintained.

As to the second aspect of the notion adopted by the Supreme Court, namely the requirement for the payment to be large, lower courts have discussed this question following the basic guidance provided in *Actavis*. As already underlined, in the judgment a large payment is deemed to work as a surrogate of the patent's weakness. The question thus shifts to the possible justifications of such payment that need to be proven by the defendant. The Court made several references to the litigation costs avoided by the payer's (patentee) as a possible ground under this aspect: if the settlement covers the expected expenses of the lawsuit and other

⁶¹ *F.T.C. v. Endo Pharmaceuticals Inc. et al.*, Case No. 3:17-cv-00312-JCS filed on 23 January 2017 (N.D. Cal.).

⁶² On these most recent developments of the dispute, see the FTC press release *Endo Pharmaceuticals Inc. Agrees to Abandon Anticompetitive Pay-for-Delay Agreements to Settle FTC Charges; FTC Refiles Suits Against Generic Defendants*, 23 January 2017, available at www.ftc.gov.

costs related thereto, it could prove to be justified and therefore not amount to an antitrust violation. Similarly, a payment could refer to services undertaken by the generic manufacturer, for example a co-branding deal. Other justifications, on the contrary, give rise to concern to the extent that their practical effect amounts to a delay of a generic drug's entry into the market⁶³. Lower courts dealing with reverse payment settlements after *Actavis* have supported this view⁶⁴, even though the analysis of the cases at hand plays a crucial role in this regard and thus there is no general consensus yet.

Another crucial issue regards the actual structuring of the rule-of-reason antitrust litigation that was left to the lower courts to establish according to *Actavis*. Preliminarily, it is worth mentioning that said legal standard must not be confused with the five sets of considerations provided by the Supreme Court to support its position. Rather, the Court's reasoning implies the application of a streamlined rule-of-reason standard under two aspects. First, the large reverse payment (in the broader sense) can satisfy the plaintiff's initial showing of a restraint on trade that has anticompetitive effects, and second, the defendant's burden of proving pro-competitive effects can be based on a limited set of justifications (namely, avoided litigation costs or other services performed by the generic). The final showing of more pro-competitive means to achieve said effects or that the anticompetitive effects outweigh the pro-competitive effects then remain the same and it is again up to the plaintiff⁶⁵.

⁶³ In this regard see H. HOVENKAMP, M.D. JANIS, M.A. LEMLEY, C.R. LESLIE, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law*, 2nd edition, New York, 2013 Supplement, § 15.3a1(E) and, extensively, M.A. CARRIER, *Payment After Actavis*, in 100 *Iowa Law Review*, 2014, pp. 7-49, especially at pp. 19-25.

⁶⁴ See, among others, *In re Lipitor Antitrust Litigation*, cited above, at 547; *In re Solodyn (Minocycline Hydrochloride) Antitrust Litigation*, Civil Action No. 14-md-02503-DJC, 2015 WL 5458570 (D.Mass. 2015), at 7. For a further comment on this issue see also L.J. FALES, P. FEINSTEIN, *Two Years and Counting Since Actavis: Developments in the Law*, in 30 *Antitrust*, Fall 2015, pp. 31-36, at pp. 32-33.

⁶⁵ For a detailed comment, including practical aspects of the litigation, see L.P. TAAVOLA, *Jumping into the Actavis Briar Patch – Insight into How Courts May Structure Reverse Payment*

Courts have nonetheless applied different versions of the described standard, in some cases even giving rise to misinterpretation of the *Actavis* principles⁶⁶. One of the most detailed insights into the structure of the rule-of-reason applied to reverse payment settlements has been however provided by the California Supreme Court *In re Cipro Cases I & II*⁶⁷, which held that *Actavis* also applied to state anti-trust law (in particular, the Cartwright Act⁶⁸, that mirrors the Sherman Antitrust Act⁶⁹ in many respects). When summarising the structure of the rule of reason, it explained that for an agreement to be found *prima facie* as an unlawful restraint of trade, the plaintiff must show both «a limit on the generic's challenger entry into the market and compensation from the patentee to the challenger». Then it is up to the defendant to offer «evidence of litigation costs or valuable collateral products or services that might explain the compensation». Should the defendant do so, the burden shifts again to the plaintiff to demonstrate that «the compensation exceeds the reasonable value»⁷⁰ of said justifications.

A further question, also related to the analysis of the justifications that could be invoked under the rule-of-reason standard, is whether the merits of the settlement,

Antitrust Proceedings and the Questions That Actavis Left Unanswered, in 40 *William Mitchell Law Review*, 2014, pp. 1370-1406, especially at pp. 1395-1405.

⁶⁶ See *In re Lamictal Direct Purchaser Antitrust Litigation*, cited above, at 565-566. To sum up in an effective way the District Court's opinion in the case at hand, see J.P. DAVIS, R.J. MCEWAN, *Deactivating Actavis*, cited above, p. 574: «*Lamictal* is illustrative because the district court quoted the summary in *Actavis* of why the Court imposed the rule of reason and treated it as if it addressed how the legal standard should apply».

⁶⁷ *In re Cipro Cases I & II*, 348 P.3d 845 (Cal. 2015). See extensively J. ELIAS, *Putting Cipro Meat on Actavis Bones: A Case Study in Filling the Legal Gaps*, in 24 *Journal of the Antitrust and Unfair Competition Section of the State Bar of California*, 2015, No. 2, pp. 1-6; C.L. JOHNSON, *CIPRO's \$400 Million Pay for Delay: How California Law and Courts Can Make a Difference in Reverse Payment Challenges*, in 67 *Rutgers University Law Review*, 2015, pp. 721-753.

⁶⁸ Stat. 1907, c. 530, p. 986, §§ 1-12. The Act was later incorporated into the California Business and Professions Code in 1941 by Stat. 1941, c. 526, § 1.

⁶⁹ As it is well known, it is a federal antitrust and antimonopoly statute, which was passed in 1890 as 15 U.S.C. §§ 1-7 and amended by the Clayton Act in 1914 (15 U.S.C. § 12-27). The full text is available at www.law.cornell.edu/uscode.

⁷⁰ *In re Cipro Cases I & II*, cited above, at 871.

and therefore of the patent dispute itself, should be subject to some level of inquiry. In this regard, as already mentioned, *Actavis* held that the size of the unexplained reverse payment serves as a workable surrogate for the patent's weakness. Therefore, a full-blown evaluation should not be required when the patentee's motive to settle was to obtain an anticompetitive advantage avoiding the uncertainty of patent litigation. This guarantee in fact cannot be covered by the legitimate exclusionary effect of its right, since patent protection does not immunise from anti-trust scrutiny under said circumstances.

It should then be safe to say that the so-called "*Actavis* inference" entails a complex factual and juridical assessment for both the parties and the court called upon to decide. However, a thorough account of the principles of the judgment need to be taken, albeit requiring a further and deepened analysis in light of the specific background of each individual case.

2.1.3. IN THE UNITED KINGDOM

It is now worth considering the practice of Member States as regards the issue of anticompetitive agreements in the pharmaceutical sector. In particular, a recent decision of the CMA⁷¹ dealt with a case of reverse payment settlement agreements similar to those investigated by the European Commission.

The facts of the case concerned the brand anti-depressant drug Seroxat, which is based on paroxetine API and was launched by GlaxoSmithKline (hereinafter also GSK) in the UK in 1991, becoming one of the originator's blockbuster products. The compound patent expired in 1999, while certain process patents remained in force even afterwards. In the late 1990s three generic manufacturers, namely IVAX, Generics UK (hereinafter also GUK) and Alparma, took steps to enter into the paroxetine market with their version of the drug. GSK first struck an agreement with IVAX, even though no patent litigation had started between them. Later, it instigated patent infringement proceedings against GUK and Alparma, both of which were settled by GSK. Under the terms of the latter agreements, significant value transfers were made by GSK to the generic companies in return for their commitment not to enter the market independently of the originator during the time the agreements were in place. After the CMA launched its probe into these settlements, it issued the final decision on 12 February 2016, holding GSK liable of infringing the Chapter I prohibition of the Competition Act 1998⁷² and/or Art. 101 TFEU, as well as the Chapter II prohibition of the same Act⁷³. Moreover, it found that both GUK and Alparma infringed the Chapter I prohibition, while the settlement between GSK and IVAX was exempted from said prohibition by

⁷¹ UK Competition and Markets Authority, decision of 12 February 2016, *Paroxetine* – case CE/9531-11, available at www.gov.uk/cma-cases.

⁷² The Competition Act 1998 (1998 c. 41, available at www.legislation.gov.uk) was enacted with the purpose of harmonising the domestic legal system with EU competition law and entered into force on 1 March 2002. In particular, the Chapter I Prohibition mirrors the contents of Art. 101 TFEU and deal with restrictive agreements.

⁷³ The Chapter II Prohibition of the Competition Act 1998 refers to the abuse, by an undertaking or undertakings, of a dominant position in the UK.

virtue of the Vertical Agreement Exclusion Order⁷⁴. The originator and the generic companies were consequently fined, with the total amount imposed approximately £ 50 millions.

As both these findings were based on a common reasoning, the restrictive agreements and the abuse of dominant position will be here assessed together, as opposed to the previous EU *Servier* case. The settlements concluded between GSK and GUK and Alparma, respectively, were deemed to have as their objective aim a restriction of competition in the UK paroxetine market. Indeed, the CMA observed that the value transfers from the originator to the generics⁷⁵ could only be explained on anticompetitive grounds, namely to induce the latter companies' «acceptance of entry restrictions and delay [their] potential independent market entry»⁷⁶. More precisely, the payments could neither be explained by the avoidance of costs and disruption of litigation, nor by the avoidance of potential exposure to damages by GSK under the cross-undertaking⁷⁷. These arguments paralleled the justifications for reverse payments that are held acceptable under the US Supreme Court judgment in *Actavis*, which refer to avoided litigation expenses.

⁷⁴ The Competition Act 1998 (Land and Vertical Agreements Exclusion) Order 2000 (SI 2000/310, available at www.legislation.gov.uk). On 1 May 2005 it was repealed by the Competition Act 1998 (Land Agreements Exclusion and Revocation) Order 2004 (SI 2004/1260, available at the same website). Since then, only the EU provisions on vertical restraints are applicable in the UK (currently, the Commission Regulation (EU) No. 330/2010 of 20 April 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of vertical agreements and concerted practices, *OJ L* 102 of 23 April 2010, pp. 1-7). The lack of an infringement decision as regards IVAX indeed appears to rely on the fact that in this case the agreement was not intended to settle a patent dispute.

⁷⁵ Namely, the value transfers consisted in marketing allowances, the purchase of GUK's stock of paroxetine and profit margins obtained by GUK by supplying a limited volume of GSK's product, amounting to a total of at least £ 21.3 millions over the three-year term of the agreement.

⁷⁶ UK Competition and Markets Authority, decision of 12 February 2016, *Paroxetine*, cited above, para. 6.113, as regards GUK. The same finding was held in relation to Alparma at para. 6.177 of the decision.

⁷⁷ *Ibid.*, paras. 6.115-6.133 and paras. 6.179-6.196.

In addition to the finding of a restriction of competition by object, the CMA carried out an effects assessment of both agreements. In accordance with the Commission’s guidance and well-established EU case law, the effects were evaluated from a counterfactual perspective, *i.e.* «in comparison to the actual legal and economic context in which competition would occur in the absence of the agreement»⁷⁸. In this regard, the CMA found that if the patent litigation between GSK and the generics had continued, the validity of the originator’s patent would have been tested, or anyway the subsequent settlement would have reflected the real uncertainty as to the strength of the patent claims, without involving transfers of value by the incumbent to the challengers. As a result, the likely restrictive effects of the settlements with both GUK and Alpharma were established as well.

As to the abuse of a dominant position by GSK, the CMA considered the agreement with IVAX in addition to those already scrutinised under the Chapter I prohibition. To this end it held that the value transfers made to the generic manufacturers in order to induce them to delay their independent entry into the market did not amount to a conduct falling within competition on the merits. Since it had the likely effect of restricting competition, and the originator had not demonstrated the existence of any objective justifications, the UK Authority concluded that GSK had infringed the Chapter II prohibition of the Competition Act 1998⁷⁹.

These findings thus confirm, also at the national level, the narrow approach of classifying reverse payment settlements as restrictions of competition by object, as the European Commission already held in its decisions, as did the General Court in its *Lundbeck* judgment. In addition, similar to in the *Servier* case, the CMA found that the originator also abused its dominant position in the market, focusing its argument on the circumstance that the inducements could not be regarded as “normal competition”, *i.e.* on the merits.

⁷⁸ *Ibid.*, para. 7.7.

⁷⁹ *Ibid.*, paras. 8.1-8.45.

The pharmaceutical companies have appealed the CMA decision before the Competition Appeal Tribunal and the case is currently pending⁸⁰. It is interesting to note that the Tribunal ordered each appellant to file specific pleadings as regards the relevance (if any) of the General Court's *Lundbeck* judgment⁸¹, thus confirming the close correlation between these reverse payment cases.

⁸⁰ Competition Appeal Tribunal, case No. 1255/1/12/16, registered on 12 April 2016, *Merck KGaA v. Competition and Markets Authority*. The status of the case is available at www.catribunal.org.uk.

⁸¹ Competition Appeal Tribunal, case No. 1255/1/12/16, *Merck KGaA v. Competition and Markets Authority*, order of the President (case management directions) of 13 May 2016, available at www.catribunal.org.uk.

2.1.4. IN ITALY

In this section the focus remains on Member States' practice, dealing with the investigation carried out by the Italian Competition Authority against five brand drug manufacturers, namely F. Hoffman-La Roche Ltd., Genentech Inc., Roche S.p.A., Novartis AG and Novartis S.p.A., regarding an allegedly anticompetitive agreement related to the sales of the products Avastin and Lucentis in Italy, which concluded with a decision issued on 27 February 2014⁸². As opposed to the cases examined so far, the perspective thus shifts to competition between originators.

The factual background of the case had its start in the US and then developed in the EU, insofar as is here relevant in Italy. Therefore, it is useful to go over it in full. The APIs at issue are bevacizumab and ranibizumab, which the US-based pi-

⁸² Autorità Garante della Concorrenza e del Mercato, proceeding I760, *Roche-Novartis/Farmaci Avastin e Lucentis*, decision No. 24823 of 27 February 2014, in *Bollettino AGCM* No. 11 of 17 March 2014, available at www.agcm.it, pp. 78-154. In the literature see L. ARNAUDO, *The strange case of Dr Lucentis and Mr Avastin: The Italian Competition Authority fines Roche and Novartis for collusion*, in *European Competition Law Review*, 2014, pp. 347-351, and by the same Author, *The Avastin-Lucentis Case: an illicit agreement between Roche and Novartis condemned by the Italian Competition Authority*, in *Italian Antitrust Review*, 2014, No. 2, pp. 126-129; A. MASTRORILLI, *Farmaci di lusso e medicinali a buon mercato*, in *Mercato concorrenza regole*, 2014, pp. 489-501; R. PARDOLESI, in *Foro italiano*, 2014, III, cc. 278-280; J. KILLICK, P. BERGHE, *Pharmaceutical Sector: Can Non-Authorised Products be Included in the Relevant Market for the Assessment of an Alleged Anticompetitive Conduct? A Short Analysis of the Recent Italian Avastin-Lucentis Decision*, in *Journal of European Competition Law & Practice*, 2015, pp. 102-109; A. ROCCHIETTI, *I recenti interventi dell'Autorità nel settore farmaceutico*, in E.A. RAFFAELLI (ed.), *Antitrust fra diritto nazionale e diritto dell'Unione europea. XI Convegno*, Bruxelles, 2015, pp. 371-387; M. COLANGELO, *Il caso Avastin-Lucentis: violazione antitrust o regulatory failure?*, in *Rivista di Diritto Industriale*, 2016, II, pp. 218-230. The case also had a vast resonance in the public opinion as the media extensively covered the various steps of the litigation: see for example the interviews with Mr. F. Massimino (Legal governance and compliance Roche), *Sovrapponibile non vuol dire sostituibile*, 16 May 2014, available at www.lapresse.it; and with Prof. V. Salvatore, *Pericoloso orientamento su off label per risparmiare sui costi*, 6 June 2014, available at www.quotidianosanita.it; the article by Prof. P. Sirena, *Prescrizione off-label: quali rischi sul vantaggio competitivo*, 23 April 2015, available at www.sanita24.ilsole24ore.com.

ioneer Genentech (subsidiary of Roche Group) developed during the 1990s as a treatment to neutralise the molecule known as VEGF (Vascular Endothelial Growth Factor) that drives the physiological process of angiogenesis. More precisely, bevacizumab was synthesised first and entered the US market in 2004 under the brand name «Avastin» as a remedy for metastatic tumors. Ranibizumab was synthesised as a derivative of bevacizumab, and has been commercialised in the US market since 2006 under the brand name «Lucentis» for the treatment of the eye disease called wet AMD (Age-related Macular Degeneration).

Then Genentech continued operating in the US market only and concluded separate licensing agreements with the originator companies Roche and Novartis, which were awarded worldwide commercial rights on Avastin and Lucentis, respectively. Both drugs were granted MAs by the EMA for the same registered uses as in the US: Avastin in 2005 for cancer treatments and Lucentis in 2007 for ophthalmic therapies. In-between the respective approvals, an off-label (*i.e.* unregistered) use of Avastin (bevacizumab) was developed by ophthalmologists, which consisted of treating AMD by an intravitreal injection of a small amount of said drug. The equivalence of the two uses – registered and unregistered – was also later supported by independent comparative studies carried out in the US⁸³ and the UK⁸⁴. Moreover, there is a considerable difference when comparing the costs of the two eye therapies: in Italy, where the antitrust investigation was carried out, Lucentis was launched at a price of approximately 1800 euros per injection (after decreased to 900 euros), while Avastin cost around 80 euros per injection. Consequently, during the time Lucentis was not available in Italy (it was commercialised by the end of 2008), the off-label use of Avastin for AMD was acknowledged by the Italian Medicines Agency (Agenzia Italiana del Farmaco – AIFA) pursuant

⁸³ The CATT Research Group, *Ranibizumab and Bevacizumab for Neovascular Age-Related Macular Degeneration*, in 364 *The New England Journal of Medicine*, 2011, pp. 1897-1908.

⁸⁴ IVAN Study Investigators, *Ranibizumab versus bevacizumab to treat neovascular age-related macular degeneration: one-year findings from the IVAN randomized trial*, in 119 *Ophthalmology*, 2012, pp. 1399-1411.

to the provisions of Law No. 648/1996⁸⁵, and its costs were covered by the Italian National Healthcare System (NHS). More precisely, this legal instrument allows the unregistered uses of a drug insofar as there is no equivalent medicine already registered for the same treatments, which are listed on the so-called “Lista 648” (list 648). After Lucentis’ registration procedures were carried out, the off-label uses of Avastin were de-listed accordingly⁸⁶ and Roche never pursued the formal registration of its drug for those purposes. Rather, in June 2011, the Italian branch of Roche sought to obtain a modification of the Summary of Product Characteristics (SmPC) of Avastin so as to include a reference to the risks deriving from the ophthalmic use of its product, which was granted (with some changes) by the EMA. In addition, it requested the Agency to adopt a formal communication towards healthcare professionals (a DHPC) in order to inform them of said modification, which was however denied. As a result of this regulatory change, the SmPC of Lucentis was also modified by referring to undesirable effects that were common to all anti-VEGF medicines.

In this complex situation the ICA began its antitrust investigation on 6 February 2013 for an alleged infringement of Art. 101 TFEU related to the “Italian side” of the Avastin/Lucentis controversy. Assessing the conducts of the Italian branches of both Roche and Novartis, it affirmed the existence of a collusive agreement aimed at an «artificial product differentiation»⁸⁷ of the two drugs concerning their ophthalmic uses. With regard to the relevant market, the Authority thus considered the medicines used for AMD treatments and other eye-related diseases, which comprised both the registered use of Lucentis and the unregistered use of Avastin according to a factual interpretation of product substitutability. The anticompetitive behaviour consisted in the dissemination of misgiving infor-

⁸⁵ Law of 23 December 1996, No. 648, *OJ* 300 of 23 December 1996. The overview of the relevant Italian regulatory framework is thoroughly assessed in G.F. FERRARI, F. MASSIMINO, *Diritto del farmaco. Medicinali, Diritto alla salute, politiche sanitarie*, Bari, 2015.

⁸⁶ More precisely, on 18 October 2012 Avastin was completely taken out of “Lista 648” by decision of the AIFA.

⁸⁷ Autorità Garante della Concorrenza e del Mercato, *Roche-Novartis/Farmaci Avastin e Lucentis*, cited above, para. 189.

mation about the safety of Avastin's off-label uses among the medical community, in order to have an impact on doctors' prescriptions. Moreover, the Authority contested a concerted position taken by the originators towards the media, industry stakeholders and policymakers. The pieces of evidence taken into account included e-mail exchanges between the management of the two companies and the modification of Avastin's SmPC based on the extra wording that emphasized the risks in its ophthalmic use. The ultimate purpose of the devised strategy was to boost sales of Lucentis, which both Roche and Novartis benefited from – the former gaining indirect returns through the royalties paid by Novartis to the licensor Genentech, and the latter earning direct profits from its licensed drug.

The legal consequence deriving from the outlined conducts was a horizontal agreement having an anticompetitive object pursuant to Art. 101(1)(c) TFEU (market sharing agreement). As the European Commission did in the *Servier* case, the ICA further evaluated its illicit effects, in particular it estimating the larger expenditure incurred by the NHS due to the increased demand of Lucentis as a result of the coordination between the two originators⁸⁸. The Italian branches of Roche and Novartis were thus held liable of said infringement and fined accordingly.

Both the parent companies, Hoffman-La Roche Ltd. and Novartis AG, as well as their Italian branches, later appealed the ICA decision before TAR Lazio, the administrative Court of First Instance having jurisdiction, which rendered its judgment on 2 December 2014⁸⁹. In sum, the originators questioned the Authority's evaluation in establishing a situation of competition in the relevant market between both the Italian companies and the registered and unregistered uses of the drugs in question. In their view, the ICA made an error when it did not consider the licencing agreements through which the originators were able to enter into the market, and moreover it erroneously considered off-label Avastin as a treatment

⁸⁸ In this regard the Authority estimated increased costs amounting to 54 million euros for 2012. Should Avastin's off-label uses have been completely replaced by Lucentis, the estimate would raise to 600 million euros in 2013 and 678.6 million euros in 2014. See Autorità Garante della Concorrenza e del Mercato, *Roche-Novartis/Farmaci Avastin e Lucentis*, paras. 228-229.

⁸⁹ TAR Lazio, judgment of 2 December 2014, No. 12168, available at www.giustizia-amministrativa.it.

for eye diseases, which they said should not have been included in that category given the wrongfulness of such use. Consequently, there were no grounds for maintaining the finding of an infringement under Art. 101(1) TFEU.

The administrative Court upheld the ICA decision and its reasoning. First, it confirmed the substitutability between off-label Avastin and Lucentis for ophthalmic uses, and therefore the rationality of the market definition adopted by the Authority⁹⁰. In addition, it considered the issues of the licensing agreements and the performance of the duties in accordance with the respective pharmacovigilance responsibilities, unrelated to the subject matter of the dispute. Then, re-examining the evidence at its disposal, particularly the mail and the documents exchanged between the Italian companies, the court affirmed the existence of an anticompetitive agreement between Roche and Novartis aimed at defining a common strategy to restrain the establishment of the off-label uses if Avastin, and consequently at expanding Lucentis' sales to their own benefit⁹¹. This justified the legal assessment pursuant to Art. 101(1) TFEU and the fines that were consequently imposed.

This judgment was appealed before Consiglio di Stato, the administrative Supreme Court. Again, the parent companies Hoffman-La Roche Ltd. and Novartis AG and their Italian branches contested the rationale of the lower court's assessment and sought to overturn its decision. They also submitted a request for a preliminary ruling to the Court of Justice, which the Supreme Court accepted, albeit partially rephrasing the questions⁹². More precisely, the issues now pending before the EU court refer to: the possibility to consider the parties of a licensing agreement as competitors insofar as the licensee has entered the relevant market only by means of that agreement; the relevant market that the ICA defined, regardless of the content of the marketing authorisations granted by the EMA and

⁹⁰ TAR Lazio, judgment of 2 December 2014, No. 12168, cited above, para. 4.

⁹¹ *Ibid.*, paras. 5-6.

⁹² Consiglio di Stato, order of 11 March 2016, No. 966, available at www.giustizia-amministrativa.it. The preliminary ruling procedure is now pending: see case C-179/16, *F. Hoffmann-La Roche AG, La Roche SpA, Novartis AG and Novartis Farma SpA v. Autorità Garante della Concorrenza e del Mercato*, OJ C 222 of 20 June 2016, p. 4 f.

AIFA; the inclusion in the same relevant market of off-label and authorised drugs, which were regarded as substitutable; the importance of whether the drugs entered into the relevant market in accordance with the pharmaceutical regulatory framework and lastly, whether a conduct aimed at spreading misgiving information about the safety and effectiveness of a drug may be held restrictive of competition by object where there is an actual uncertainty as to the product's effects among the scientific community. Essentially, it appears that the Supreme Court argues about the market definition purported by both the ICA and the first instance court as the safety of Avastin's off-label uses were objectively unclear, and more importantly, had not been formally acknowledged by the competent regulatory authorities. It will thus be interesting to see which guidance the Court of Justice will provide in this regard.

SECTION TWO

CASE LAW ON ABUSES OF DOMINANCE

Again taking into account the findings of the 2009 Pharmaceutical Sector Inquiry, this section will deal with follow-up cases in which pharmaceutical companies have been questioned for an alleged abuse of their dominant position in the relevant market pursuant to Art. 102 TFEU.

In this regard, the Court of Justice rendered a landmark judgment in 2012 in the *AstraZeneca* case, following the decisions of the Commission and the General Court. It provides a comprehensive example of conducts that can be caught under the prohibition at issue, namely an abuse of regulatory procedures and a switch from the brand drug to its follow-on version to prevent generic entry (so-called “product hopping”). Moreover, at the EU level the previously examined *Servier* case will be discussed again insofar as the Commission also found an infringement of Art. 102 TFEU.

Moving to the US practice, on the one hand the *Buspirone* case is examined as it concerns an abuse of the regulatory framework provided by the Hatch-Waxman Act; on the other hand the *TriCor*, *Nexium* and the most recent *Namenda* cases are particularly instructive to analyse product-hopping strategies.

Finally, Italian case law is again relevant in this context, as the *Pfizer* case gave rise to much debate regarding how to define the notion of abuse compared to the exercise of IP laws in the pharmaceutical sector.

2.2.1. IN THE EUROPEAN UNION

AstraZeneca case.

The *AstraZeneca* dispute is particularly relevant since it is the first fully litigated case about the patent/antitrust interface in the pharmaceutical industry, and therefore provides a reliable indication for future cases as to the EU courts' approach to this matter⁹³.

The underlying facts refer to the brand drug Losec, commercialised by the Swedish-based originator company AstraZeneca (hereinafter also AZ) and based on the API omeprazole. The medicine obtained patent protection from both the EPO and national patent offices that was set to expire during 1999. Its therapeutic use is to treat acid-related gastro-intestinal diseases, for which several classes of drugs exist. There are, among others, histamine receptor antagonists (so called "H2 blockers") and proton pump inhibitors (so called "PPIs"), whose respective action is similar, but while the former act indirectly on the proton pump (an enzyme of the stomach), the latter do so directly. The category of PPI, to which Losec belongs, thus possesses advanced characteristics and is more effective than

⁹³ The case has been extensively commented upon in the literature. For example see M.P. NEGRINOTTI, *Abuse of Regulatory Procedures in the Intellectual Property Context: the AstraZeneca Case*, in *European Common Market Law Review*, 2008, pp. 446-459; M. MAGGIOLINO, M.L. MONTAGNANI, *AstraZeneca's Abuse of IPR-Related Procedures: A Hypothesis of Antitrust Offence, Abuse of Rights and IPR Misuse*, in *World Competition*, 2011, pp. 245-260; I. OTTAVIANO, *Industrial Property and Abuse of Dominant Position in the Pharmaceutical Market: Some Thoughts on the AstraZeneca Judgment of the EU General Court*, in G. CAGGIANO, G. MUSCOLO, M. TAVASSI (eds.), *Competition Law and Intellectual Property*, cited above, pp. 191-202; M. COLE, *Pharmaceutical and competition: first strike to the Commission?*, in *European Competition Law Review*, 2013, pp. 227-232; J. DREXL, *AstraZeneca and the EU sector inquiry: when do patent filings violate competition law?*, in J. DREXL, N. LEE (eds.), *Pharmaceutical Innovation, Competition and Patent Law. A Trilateral Perspective*, Cheltenham-Northampton, 2013, pp. 290-322; R. PODSZUN, *Can competition law repair patent law and administrative procedures? AstraZeneca*, in *Common Market Law Review*, 2014, pp. 281-294; A. SPILLMANN, *Transparency obligations for holders of EU IP assets in the pharmaceutical industry*, in *Journal of Intellectual Property Law & Practice*, 2014, pp. 125-132.

the others. In fact, sales of PPIs proved to be successful, although they were pricier than H2 blockers, and steadily increased at the expense of the latter during the 1990s. Losec, in particular, became a blockbuster drug that accounted for almost 40% of AZ's total sales at the end of that decade.

Preparing to the approaching patent expiry on omeprazole, AZ filed applications with national patent offices within the EEA (Belgium, Denmark, Germany, the Netherlands, the UK and Norway) in 1993 and 1994 to obtain SPCs pursuant to Regulation (EEC) No. 1768/92⁹⁴, seeking to extend its exclusionary rights (called "SPC strategy"). According to Art. 8(a)(iv) of the mentioned Regulation, the applicant for an SPC had to provide the number and date of the first authorisation to place the product on the market in order to calculate the length of the supplementary protection. Moreover, such a date was relevant to whether the SPC could be granted in the first place, given that AZ's applications were filed during a transitional period of implementation of the Regulation. When instructing its patent agents, the originator company chose a certain view, which was more favourable for its applications with regard to the relevant date of the first authorisation⁹⁵, without duly informing the involved patent offices. Subsequently, the strategy concerning SPCs had a further development in that AZ's conduct before the patent offices resulted in litigation in certain Member States brought by generic manufacturers. AZ also filed applications for SPCs in other 3 EEA contracting States.

From the late 1990s, AZ pursued a second scheme to hinder generic entry into the omeprazole market (called "post patent strategy"). In Denmark, Sweden and Norway it requested the deregistration of the Losec's capsule formulation combined with its replacement with a newly developed tablet version of the drug, Losec MUPS (Multiple Unit Pellet System). This conduct was aimed at prevent-

⁹⁴ For the overall legal framework on SPCs see *supra*, Chapter one, Section 2.2.1.

⁹⁵ Namely, it preferred the effective marketing authorisation date (*i.e.* the first date of the publication of the price of the drug, which was on 21 March 1988 in Luxembourg) to the technical marketing authorisation date (the earliest was granted on 15 April 1987 in France) in those States where the former was able to confer extra months of protection. However, the latter date has been conventionally referred to as the relevant one in this context.

ing generic companies from resorting to the simplified procedure for market authorisation under Art. 4, para. 3, point 8(a)(iii) of Directive 65/65/EEC⁹⁶, which required an established use of the brand product. Moreover, it affected parallel imports of Losec capsules as a result of the import licences being revoked.

In 2003 the European Commission initiated its antitrust proceedings under Art. 82 TEC (now Art. 102 TFEU) and Art. 54 of the EEA Agreement (both having the same scope of application) concerning the facts at issue, and rendered its decision on 15 June 2005⁹⁷. It held AZ liable of infringing the mentioned provisions and therefore fined the company 60 million euros for misusing the patent system and marketing procedures to prevent generic entry to its blockbuster drug Losec.

The EU enforcer's assessment will be discussed here, starting from its evaluation of the relevant market⁹⁸. In this regard, it took a rather factual and detailed approach considering the above-mentioned categories of H2 blockers and PPIs during the time of the alleged abuse, which spanned from 1993 until 2000. Indeed, it built its analysis according to ATC levels – as is convention in the pharmaceutical sector – but referring to a narrower level than the one generally used in competition cases, namely the fourth level based on chemical subgroups instead of the third level based on therapeutic indications. The Commission stressed the revolutionary and innovative character of PPIs, and therefore their therapeutic superiority when compared to H2 blockers, maintaining that the two categories «have a mode of action which is fundamentally distinct»⁹⁹ from one another. This led the EU authority to support the view of the relevant product market comprising only PPIs. Furthermore it considered the aspect of substitutability between H2

⁹⁶ Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products, *OJ* 22 of 9 February 1965, pp. 369-373, repealed by already mentioned Directive 2001/83/EC (for an overview of the relevant EU legislation see *supra*, Chapter one, Section 2.2.1).

⁹⁷ Commission decision of 15 June 2005, case COMP/A.37.507/F3, *AstraZeneca*, published on 19 July 2006, available at <http://ec.europa.eu/competition>; see also the press release IP/05/737, available at <http://europa.eu/rapid>.

⁹⁸ Commission decision of 15 June 2005, *AstraZeneca*, cited above, paras. 329-504.

⁹⁹ *Ibid.*, para. 376.

blockers and PPIs in terms of prescriptions and demand trends: it observed that the decreasing demand of the former and the increasing demand of the latter during the given period were not inconsistent with the narrower view of the relevant market, but rather reflected the situation of gradual establishment of PPIs over H2 blockers due to other factors such as a lack of information in doctors' practice.

Then the Commission established AZ's dominance during the time of the alleged abuse both in the product market as above defined and in the national markets involved, considering in particular its market shares, its IPRs and other regulatory rights deriving from pharmaceutical law, and its ability to maintain higher prices¹⁰⁰.

In light of this preliminary evaluation, the EU institution assessed the two alleged abuses separately. It is worth underlining that the actual anticompetitive effects of both conducts were examined, even if such evidence is not strictly required to ground an infringement of Art. 102 TFEU¹⁰¹. First, it addressed the misleading representations made by AZ in order to obtain an extended patent protection through SPCs. To this end it identified two stages of the abusive conduct: firstly, AZ gave instructions to its patent agents when filing applications for SPCs in several EEA contracting States; and secondly, AZ supplied misleading information before other national patent offices and national courts during judicial proceedings. Nonetheless, it described the abuse as «of a single and continuous nature», showing AZ had «a high degree of centralisation and coordination»¹⁰². On this basis it concluded that the company has abused its dominant position under

¹⁰⁰ *Ibid.*, paras. 505-601.

¹⁰¹ This principle has been consistently affirmed by the Court of First Instance/General Court (among others, see judgment of 30 September 2003, case T-203/01, *Manufacture française des pneumatiques Michelin v. Commission of the European Communities*, EU:T:2003:250, paras. 239 and 241; judgment of 30 January 2007, case T-340/03, *France Télécom SA v. Commission of the European Communities*, EU:T:2007:22, para. 195), although the Court of Justice has in some instances stressed the relevance of such finding (see for example judgment of 14 October 2010, case C-280/08 P, *Deutsche Telekom AG v. European Commission*, EU:C:2010:603, paras. 250-261).

¹⁰² *Ibid.*, paras. 774-775.

the meaning of Art. 82 TEC (now Art. 102 TFEU) and Art. 54 of the EEA Agreement.

Secondly, the EU institution analysed AZ's practice of selective deregistration of Losec capsules combined with the switch to the new formulation of the product, Losec MUPS. This second abuse directly tackled the extent of the antitrust interference into the exercise of patent rights. In fact, even though such conduct was not in itself abusive under the relevant legislative framework, it nonetheless constituted a violation of Art. 102 TFEU given the absence of any objective justifications and its departure from the standard competitive behaviour to protect legitimate commercial interests. Moreover, it successfully prevented parallel imports of Losec capsules because the related licenses were revoked.

AZ lodged an appeal with the EU General Court against the Commission's decision. The Court of first instance, however, substantially upheld the EU competition authority, holding that both the above-mentioned abuses committed by AZ amounted to an infringement of Art. 82 TEC (now Art. 102 TFEU)¹⁰³. The decision was reversed only in relation to the claimed restriction of parallel imports, which in the General Court's view had not been sufficiently supported by evidence. Without repeating the already examined Commission's reasoning, it is useful to focus specifically on the key arguments in law that the Court supported in its judgment.

With regard to the first abuse concerning the misleading representations provided to the authorities, the General Court resorted to a parameter often referred to, but of rather vague meaning, which is the notion of «competition on the merits»¹⁰⁴. By falling outside the scope of such a concept, the practice of leading in

¹⁰³ General Court, judgment of 1 July 2010, case T-321/05, *AstraZeneca AB, AstraZeneca plc v. European Commission*, EU:T:2010:266. During the proceedings the European Federation of Pharmaceutical Industries and Associations (EFPIA) served as intervener and supported AZ's appeal.

¹⁰⁴ *Ibid.*, para. 355. Among the CJEU precedents, see Court of Justice, judgment of 9 November 1983, case 322/81, *NV Nederlandsche Banden Industrie Michelin v. Commission of the European Communities*, EU:C:1983:313; General Court, judgment of 30 September 2003, *Michelin*, cited above.

error the national patent offices and the courts was indeed inconsistent with the special responsibility imposed on the undertaking in a dominant position, thus resulting in a restriction of competition. Furthermore, in order to establish the misleading nature of AZ's representations, the Commission correctly carried out a factual assessment on the basis of objective factors, being the proof of the intention relevant to the limited extent of supporting such findings. To this end, the Court also confirmed the Commission's ground that the conduct at stake must not bear direct effects on competition in order to amount to an abuse of a dominant position. Rather, from the considerations on competition of the merits it followed that it was sufficient to establish the capability of AZ's behaviour to restrict competition in light of the regulatory context in which it took place¹⁰⁵.

As to the second abuse, the General Court maintained the Commission's legal assessment that «the illegality of abusive conduct under Article 82 EC [now Art. 102 TFEU] is unrelated to its compliance or non-compliance with other legal rules»¹⁰⁶, and, indeed, that abuses of dominance are often lawful practices under branches of law other than competition law. This consideration outweighed the fact that AZ was entitled to request the deregistration of Losec capsules marketing authorisation under the mentioned Directive 65/65/EEC. Moreover, such conduct could not be consistent with the standard of competition on the merits, since it did not pursue the legitimate protection of an investment.

Both reasons given by the General Court therefore rely heavily on the notion of competition on the merits, and they both show a renewed intensity of the antitrust scrutiny into the realms of patent law.

AZ took the case further to the Court of Justice, seeking an annulment of the General Court's decision. The final judgment, delivered on 6 December 2012¹⁰⁷ did not uphold any of the grounds of appeal raised by AZ, thus confirming the reasoning of the lower court in its entirety. Again, it is worth focusing in particu-

¹⁰⁵ General Court, judgment of 1 July 2010, *AstraZeneca*, cited above, paras. 376-377.

¹⁰⁶ *Ibid.*, para. 677.

¹⁰⁷ Court of Justice, judgment of 6 December 2012, case C-457/10 P, *AstraZeneca AB, AstraZeneca plc v. European Commission*, EU:C:2012:770.

lar on the main arguments in law, as they are the most relevant feature of the decision.

In its assessment of the first abuse, the Court of Justice stressed that an undertaking in a dominant position cannot resort to any possible means to lay claim on a right, including deliberate recourse to highly misleading representations in order to lead the authorities into an error. Indeed, by adopting the same parameter the General Court referred to, it confirmed that this conduct «would be manifestly not consistent with competition on the merits»¹⁰⁸. In this regard the Court of Justice also specified how each case must be proved *in concreto* according to the factual circumstances, without inferring from the above-mentioned argument that even an unintentional and immediately rectified misrepresentation made to a public authority would constitute an abuse under Art. 102 TFEU. When considering the effects of AZ's abusive behaviour, the Court also upheld the General Court, and maintained it was sufficient to demonstrate a potential anticompetitive effect. In fact it was established that AZ's misleading representations «were very likely to result in the issue of unlawful SPCs»¹⁰⁹.

In addition, when evaluating the grounds of appeal regarding the second abuse, the Court of Justice supported the line of reasoning of the lower instance. In particular, in two significant paragraphs of its decision it confirmed a rather strict approach regarding the extent of competition law enforcement. Both arguments followed from the broad notion of competition on the merits: on the one hand, the Court reasserted the autonomy of a finding of illegality under Art. 102 TFEU from the compliance or non-compliance with other legal rules (in the case at issue, the Directive 65/65/EEC)¹¹⁰; and, on the other hand, it held that an undertaking in a dominant position, given its special responsibility, has to submit to «a straightforward restriction of the options available under European Union law»¹¹¹ (in the case at issue, the deregistration of the market authorisation for Losec capsules

¹⁰⁸ *Ibid.*, para. 98.

¹⁰⁹ *Ibid.*, para. 111.

¹¹⁰ *Ibid.*, para. 132.

¹¹¹ *Ibid.*, para. 149.

provided for in Directive 65/65/EEC), unless it demonstrates the existence of legitimate interests or objective justifications for its conduct.

This ruling of the Court of Justice thus represents a turning point in the EU case law, and consequently for the Member States. As will be discussed in the following chapter, its implications seem particularly far-reaching and entail a renewed balance in the interplay between competition policy and patent law.

Servier case.

Keeping in mind these considerations, it is now worth focusing on the most recent case law concerning Art. 102 TFEU in a context of pharmaceutical patent litigation, namely the Commission decision in the *Servier* case, which has already examined here, in the section on restrictive agreements¹¹². As will be recalled, in this case the EU antitrust authority has assessed the application of the provision at issue for the first time with regard to a proper patent settlement agreement. To this end it took into account Servier's conducts as an acquirer of API technology to produce perindopril, and as a party of the agreements concluded with competing generic manufacturers.

Regarding the technology acquisition, the Commission carried out its assessment in light of the relevant legal framework on technology transfers, as well as CJEU case law on acquisitions of IP rights that constitute an abuse of dominant position under Art. 102 TFEU (in particular, the *Tetra Pak I* and *AstraZeneca* judgments¹¹³). Also in this decision the concept of competition on the merits represented the legal standard under which the Commission evaluated the circumstances of the case. Three elements were especially highlighted in this context, namely the competitive threat posed by the acquired technology to Servier's existing patents, the removal of a potentially enabling source of competition through the technology acquisition and the capability to restrict competition by rendering

¹¹² Commission decision of 9 July 2014, *Perindopril (Servier)*, cited above.

¹¹³ Court of First Instance, judgment of 6 October 1994, case T-83/91, *Tetra Pak International SA v. Commission of the European Communities*, EU:T:1994:246; General Court, judgment of 1 July 2010, *AstraZeneca*, cited above; Court of Justice, judgment of 6 December 2012, *AstraZeneca*, cited above.

it more difficult for generic suppliers to enter the market. Consequently, the EU institution held that Servier deviated from competition on the merits, as its conduct was able to produce foreclosure effects on the given market.

Regarding the patent settlements concluded with the five generic manufacturers, the Commission stressed the difference in its assessment under Art. 101 and Art. 102 TFEU. In the latter perspective the crucial issue became the «distinct unilateral aspect»¹¹⁴ possessed by said agreements, which was based on Servier using its market power to induce the most advanced generic competitors to refrain from entering the market. In particular, such an additional element was inferred from the central role held by the originator in all settlements and the cumulative self-reinforcing effect of the pattern of agreements.

The two conducts were thus respectively held as abusive within the meaning of Art. 102 TFEU. Furthermore, according to the Commission, said behaviours constituted «a single and continuous exclusionary strategy infringing Article 102»¹¹⁵, on the basis of their complementarity, as well as their combined effects and overlapping timeline. Together they consistently pursued the common goal of delaying or blocking generic entry into the perindopril market, thus deviating from Servier's special responsibility as the dominant company, and implementing measures that do not qualify as competition on the merits.

This second case is thus significant in that it builds upon the main reasoning of the CJEU judgments in *AstraZeneca*, and also shifts the perspective to a different factual background, which is a patent settlement case. A more critical assessment of its impact on future cases will be carried out in the next chapter.

¹¹⁴ Commission decision of 9 July 2014, *Perindopril (Servier)*, cited above, para. 2931.

¹¹⁵ *Ibid.*, para. 2961.

2.2.2. IN THE UNITED STATES

The case law analysis regarding the US takes into account two different types of conduct that can be caught under the provision of Section 2 of the Sherman Act and examined together with the abuses of dominance established by the CJEU in the *AstraZeneca* case. However, the legislative divergence existing between the EU and the US legal systems in this regard must be borne in mind. Art. 102 TFEU and Section 2 of the Sherman Act, in general terms, are not perfectly comparable, in that the latter actually prevents monopolization or attempted monopolization, which requires at least a larger market share and is broadly described in the mentioned provision, without references to any specific conduct¹¹⁶. Still, the comparison allows drawing further considerations on EU case law that has recently developed.

Buspirone case.

The first case that provides a useful term of reference to this end is the *Buspirone* antitrust dispute dating back to 2002¹¹⁷. The facts of the case concern a multidistrict litigation that involved the drug buspirone, used to treat anxiety and sold by Bristol-Myers Squibb (BMS) under the brand name «BuSpar». The antitrust dispute was brought before the Southern District of New York by generic manufacturers who sought to enter the buspirone market, as well as direct purchasers of the drug, end payers and consumer organisations, collectively claiming that BMS had violated, insofar as is here relevant, Section 2 of the Sherman Act having extended an unlawful monopoly over the drug market by abusing certain provision of the Hatch-Waxman Act. More precisely, BMS obtained the original patent covering buspirone in 1980 and had been selling the drug since 1986. The patent

¹¹⁶ Extensively E.M. FOX, *Monopolization and Dominance in the United States and the European Community: Efficiency, Opportunity and Fairness*, in 61 *Notre Dame Law Review*, 1986, pp. 981-1020, and by the same Author, *Monopolization and abuse of dominance: Why Europe is different*, in 59 *The Antitrust Bulletin*, 2014, No. 1, pp. 129-152.

¹¹⁷ *In re Buspirone patent litigation/In re Buspirone antitrust litigation*, 185 F.Supp.2d 363 (S.D.N.Y. 2002).

was set to expire on 21 November 2002, and only 12 hours before the expiry BMS was granted a new patent on the drug, which was immediately submitted to the FDA for listing in the Orange Book (the publication for Approved Drug Products with Therapeutic Equivalence Evaluations)¹¹⁸. This move actually prevented the FDA from approving any pending ANDAs regarding generic buspirone products that competitor manufacturers had submitted when the original patent expiry was approaching. The antitrust plaintiffs argued the new patent did not claim the use of buspirone and thus BMS had fraudulently represented to the FDA that the new patent covered approved uses of the drug. Moreover, they claimed BMS took further advantage from the false statements to the FDA by pursuing patent infringement suits against generic suppliers of the drug and therefore obtaining the automatic 30-month stay of the approval applications.

The reasoning adopted by the District Court is particularly interesting in that it examined the application of the *Noerr-Pennington* doctrine¹¹⁹, as claimed by the defendant BMS, in the context of Orange Book listings and then of the exception to this immunity set forth in the *Walker Process* case¹²⁰. *Noerr-Pennington* in fact provides immunity from federal antitrust liability insofar as a concerted effort of two or more individuals is directed to petition the government, with this conduct

¹¹⁸ For a broader framework of the US regulatory system with regard to the approval of generic drugs see *supra*, Chapter one, Section 2.2.2.

¹¹⁹ The US Supreme Court first articulated this doctrine as an interpretation of the Sherman Act in *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) and *United Mine Workers v. Pennington*, 281 U.S. 657 (1965). As an in-depth discussion of the doctrine cannot be carried out in this limited context, for a comprehensive framework and the application in the pharmaceutical sector see, *inter alia*, E.H. STEINHAEUER, *Is Noerr-Pennington Immunity Still a Viable Defense Against Antitrust Claims Arising from Hatch-Waxman Litigation?*, in 61 *Food and Drug Law Journal*, 2006, pp. 680-700; M. AVERY, M. NEWSOM, B. HAHN, *The antitrust implications of filing “sham” citizen petitions with the FDA*, in 65 *Hastings Law Journal*, 2013, pp. 113-152.

¹²⁰ The US Supreme Court established this ground of exception in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965). As will be explained, *Walker Process* is intended to overcome *Noerr-Pennington* immunity beyond the mere sham-litigation standard.

falling within the scope of the fundamental right to communicate with government entities granted by the First Amendment to the US Constitution. In this regard, the Court held that BMS' conduct of requesting the FDA to list its new patent in the Orange Book did not qualify as petitioning activity for *Noerr-Pennington* purposes, since in this case the public authority's actions «were non-discretionary and [did] not reflect any decision as to the validity of the representations [made by BMS] in an Orange Book listing»¹²¹. Nonetheless, the Court also went on to consider whether the exception provided under *Walker Process* if the *Noerr* doctrine were to apply to BMS' conduct. According to this exception, a patent holder may be subject to antitrust liability when it attempts to maintain its monopoly over a product by bringing patent infringement suits against competitors based on a patent procured through fraudulent representations to the PTO. After establishing a similarity between the submissions made to the PTO when applying for a patent and those made to the FDA in an Orange Book listing application, the District Court considered that BMS had knowingly made false statements about the scope of its new patent to the FDA, and held as founded the plaintiff's allegations that no reasonable patent infringement claim could have been asserted against generic competitors on the basis of said patent. Therefore, it concluded that *Walker Process* could be applied in the case at hand¹²².

The *Buspirone* litigation thus confirms that misleading (or rather, false) statements to public authorities in the context of Orange Book filings can be caught under the prohibition of Section 2 of the Sherman Act, similar to AstraZeneca's first abuse concerning the misleading representations submitted to national patent offices in order to obtain the SPCs.

Two other cases can offer a comparison with EU case law with regard to the different conduct known as “product hopping”, which consists of making use of the regulatory framework by switching between different formulations of a drug in order to prevent competition from generic manufacturers. The analysis focuses

¹²¹ *In re Buspirone patent litigation/In re Buspirone antitrust litigation*, cited above, at 371.

¹²² *Ibid.*, at 373-375.

on three cases, *TriCor*, *Nexium*, and *Namenda*, which are worth examining together as the courts have moved towards a narrower approach to these matters.

***TriCor* case.**

The factual background of *TriCor* refers to fenofibrate API, which is used to treat high levels of triglycerides, as well as high cholesterol, and is marketed by the brand company Abbott on the basis of a licensing agreement from another manufacturer, Fournier. The first NDA for *TriCor* was approved by the FDA in 1998 for its capsule formulation and then listed in the Orange Book with the underlying patent. Two generic producers (Novopharm – later acquired by Teva – and Impax) filed ANDAs with Paragraph-IV Certifications between 1999 and 2000 for this fenofibrate formulation, to which Abbott and Fournier responded by suing them for patent infringement, thus triggering the thirty-month stay of the approval of generic products provided by the Hatch-Waxman Act. Pending this dispute, Abbott submitted another NDA, this time for a tablet formulation of the drug, which was approved in 2001. Subsequently, the company engaged in a conduct known as “market cannibalization”, which consisted of stopping the sale of the prior capsule formulation and buying back the existing supplies of the capsules from pharmacies, so that generic substitution would no longer be possible. Moreover, it changed the capsule formulation’s code in the National Drug Data File to «obsolete» in order to prevent pharmacies from filling *TriCor* prescriptions with the generic substitute¹²³. The generics then developed equivalent versions of the new tablet formulation, filing their respective ANDAs with Paragraph-IV Certifications, and again between 2002 and 2003 Abbott and Fournier filed patent infringement lawsuits against them, triggering another regulatory thirty-month stay. In addition, as they did before, the originators submitted a NDA for a new tablet formulation based on a different dosage and a label change (the “no food effect

¹²³ The National Drug Data File (NDDF) is a private database that provides information about FDA-approved drugs. The change of code pursued by Abbott eliminated the reference to the brand drug that pharmacies would have needed to effectively substitute it with its generic equivalent.

label”), paired up with a cannibalization strategy to block generic competition on the previous tablet formulation.

Teva and Impax, together with direct and indirect purchasers, brought the resulting antitrust litigation against Abbott and Fournier before Delaware District Court¹²⁴, claiming that the defendants had engaged in a conspiracy that amounted both to a restraint of trade in violation of Section 1 of the Sherman Act and a monopolization of the fenofibrate market in violation of Section 2 of the same Act. The originator companies, on their part, moved to dismiss the case, maintaining that each new formulation they introduced reflected improvements over the prior ones, and therefore must be deemed lawful under antitrust rules, and that they had no obligation to help their competitors by allowing them to free-ride on the brand product.

The Court eventually ruled in favour of the plaintiffs, explaining that the appropriate standard to assess such claims had to be the rule of reason approach given the peculiarities of the pharmaceutical drug market. Hence, in such a product-hopping case, the plaintiff was initially required to «show anticompetitive harm from the formulation changes, [and] that harm [was going to] be weighed against any benefits presented by the [d]efendant»¹²⁵. In this regard it found that Abbott and Fournier’s conducts actually prevented an unfettered consumer choice between brand and generic versions of the drug, thus resulting in potentially anti-competitive «consumer coercion»¹²⁶. This assessment did not have to establish to-

¹²⁴ *In re TriCor Direct Purchaser Antitrust Litigation*, 432 F.Supp.2d 408 (D. Del. 2006). For a comprehensive comment see S.D. SHADOWEN, K.B. LEFFLER, J.T. LUKENS, *Anticompetitive product changes in the pharmaceutical industry*, in 41 *Rutgers Law Journal*, 2009, pp. 1-81; for a comparative perspective with the EU system, see J. WESTIN, *Product switching in the pharmaceutical sector – an abuse or legitimate commercial consideration?*, in *European Competition Law Review*, 2011, pp. 595-601.

¹²⁵ *In re TriCor Direct Purchaser Antitrust Litigation*, cited above, at 422.

¹²⁶ *Ibid.*, at 424. This consideration allowed the Court to distinguish this case from the Second Circuit’s precedent in *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2nd Cir. 1979), in which the introduction of new products on the market (namely, a Kodak camera and related film cartridges) was not accompanied by the withdrawal of any prior versions, and their acceptance on the market was based purely on consumer free choice.

tal foreclosure effects, but rather that generics were «barred from the cost-efficient means of competing»¹²⁷ in the given market.

It is also worth mentioning what the Court ruled regarding to the defendants' argument that they were not required to aid their competitors. Indeed, they had no duty to do so, but nonetheless it acknowledged the particular situation existing in a monopoly, where a monopolist is not free to adopt certain conducts that a company in a competitive market may pursue because of the lack of market constraints. This consideration mirrors in many respects the concept of special responsibility applied by the CJEU to dominant companies, thus confirming a common background for comparing the respective case law.

Nexium case.

Two years after *TriCor*, another court was called upon to rule on a product hopping case, namely in the already mentioned *Walgreen Co. v. AstraZeneca Pharmaceutical* case (also known as *Nexium*)¹²⁸.

The facts at issue concern Nexium, a prescription drug for heartburn treatments containing the API esomeprazole whose patent is held by the brand company AstraZeneca. Nexium was actually a follow-on product for Prilosec, a blockbuster prescription drug that the originator started marketing in 1989 and whose patent expired in October 2001. AstraZeneca obtained FDA approval for Nexium in February 2001, and also for a new over-the-counter formulation of Prilosec capsules in June 2003. Upon the introduction of Nexium on the market, the originator engaged in an aggressive activity of promoting and detailing the second-generation product to doctors, while it ceased its marketing efforts for Prilosec. However, no withdrawal of the latter drug from the market ever took place, and it remained available in both prescription and over-the-counter formulations.

¹²⁷ *In re TriCor Direct Purchaser Antitrust Litigation*, cited above, at 423.

¹²⁸ *Walgreen Co. v. AstraZeneca Pharmaceuticals L.P.*, 534 F.Supp.2d 146 (D.D.C. 2008). Also in this regard see, for example, S.D. SHADOWEN, K.B. LEFFLER, J.T. LUKENS, *Anticompetitive product changes*, cited above, and J. WESTIN, *Product switching in the pharmaceutical sector*, cited above.

Generic competitors for Prilosec therefore filed an antitrust suit against AstraZeneca before the District Court for the District of Columbia. They claimed the originator pursued an exclusionary strategy in violation of Section 2 of the Sherman Act by switching the market from Prilosec, which faced generic competition, to Nexium, which did not, and, in addition, had no therapeutic superiority over its predecessor. The District Court, however, granted the defendants' motion to dismiss and distinguished this case from *TriCor*, again on the basis of consumer choice. Here it found that «there [was] no allegation that AstraZeneca eliminated any consumer choices[, r]ather [it] added choices»¹²⁹ by introducing its follow-on drug. Moreover, with regard to the claim of Nexium's lack of superiority, the Court held that the determination of which product among several is superior should be «left to the marketplace», not to judiciary bodies.

The combined analysis of these two cases is particularly instructive in that they also highlight another critical aspect of the pharmaceutical market. Indeed, while the court in the *Nexium* case appears to have reasonably relied on the absence of any gaming of the regulatory system by AstraZeneca (as opposed to Abbott and Fournier in *TriCor*), it did not duly consider the price disconnect that results because doctors who prescribe the drug do not pay for it, and patients (or insurers) who pay do not choose the drug. The trade-off between prices and quality is not up to the final consumer, as it is in most markets, and therefore the argument regarding the main role of the marketplace in determining the therapeutic superiority of a product seems to be inconsistent with the actual conditions of the market in question.

***Namenda* case.**

Among the most recent cases on product reformulations, *Namenda* occupies a central role in that it is the first and only appellate decision to date.

The factual background refers to a memantine-based drug designed to treat Alzheimer's disease, which has been marketed since 2004 by Forest Laboratories (a wholly-owned subsidiary of Actavis) in a twice-daily formulation under the

¹²⁹ *Walgreen Co. v. AstraZeneca Pharmaceuticals L.P.*, cited above, at 151.

brand name «Namenda IR». The drug soon became one of the originator's best selling products and Forest began developing a once-daily extended-release formulation, «Namenda XR», in order to align its production with all other dementia treatments that are administered once a day. This follow-on drug was approved by the FDA in June 2010 and entered into the market in June 2013, approximately two years ahead of IR's patent expiry date. Initially, Forest adopted a "soft-switch" strategy to transition patients from IR to XR, which envisaged a heavy promotion of the latter formulation, as well as its sale at a discounted rate. As the patent cliff was quickly approaching, however, the originator employed a more direct approach trying to set up a "hard switch". More precisely, it publicly announced it would soon discontinue Namenda IR and notified the FDA of its intent, but due to an interruption in XR production, it was forced to sell the first-generation product until the autumn of 2014.

Before IR withdrawal could ultimately take place, New York State filed a complaint in the District Court for the Southern District of New York against Forest and Actavis, claiming that the planned hard switch violated Sections 1¹³⁰ and 2 of the Sherman Act. Indeed, the plaintiff alleged that the originators' plan was actually to impair generic entry into the memantine market by means of the launch of Namenda XR, forcing patients to switch to the reformulated drug and preventing substitution with generic IR as provided by most states' laws. The District Court granted the plaintiff's request for preliminary injunction and ordered Forest and Actavis to continue production of Namenda IR and to inform the medical community of its continued availability until thirty days after the date when generic memantine would first have been available (*i.e.* after 11 July 2015)¹³¹.

Forest and Actavis appealed the grant of the preliminary injunction before the Court of Appeals for the Second Circuit, which rendered its judgment on 22 May

¹³⁰ The claim based on Section 1 of the Sherman Act referred to an agreement that Forest and Actavis entered into with Foundation Care, a mail-order-only pharmacy, in order to limit access to Namenda IR. However, for the purposes of this analysis it will not be touched upon, as the Court of Appeals for the Second Circuit ultimately did not address this claim.

¹³¹ *The People of the State of New York v. Actavis, PLC, et al.*, Civ. No. 14-7473 (S.D.N.Y. 2014).

2015 upholding the lower court's injunction¹³². When stating its antitrust reasoning, the appellate court considered the two benchmarks of consumer coercion and anticompetitive exclusionary effects, as the Delaware District Court already did in *TriCor*. As to the former, the anticompetitive threshold of the originators' "hard switch" was found on the removal of Namenda IR from the market *prior* to generic entry, which deprived consumers of the choice as to «whether the benefits of switching to once-daily Namenda XR would outweigh the benefits of adhering to twice-daily therapy using less expensive generic IR»¹³³. As regards the anticompetitive effects of said conduct, it relied on the «dangerous probability» that the originator companies would maintain their monopoly power in the relevant market after generic entry. Indeed, even though patients in theory would not be prevented from switching back to IR generic treatment, «in practice, such a reverse commute would be a highly unlikely occurrence»¹³⁴ due to the successful "hard switch".

Then, the Second Circuit assessed the defendants' argument that their patent rights on the two formulations of the drug would shield them from antitrust liability. To this end, it recalled the landmark finding in *Actavis* under which patent and antitrust policies are both relevant to determine the scope of a patent and concluded that in the case at issue the attempted use of patent rights to extend the exclusivity period on the relevant market (namely, the «*combination* of (...) withdrawal of IR and introduction of XR»¹³⁵) pushed the conduct beyond the scope of those rights, and thus subject to antitrust liability.

The significant reach of this judgment thus resides not only in the fact that it confirmed the special attention paid by US courts to the unique phenomenon of product hopping, but also in that it is the only case where the court handed down a

¹³² *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2nd Cir. 2015). For a comment see, among others, E. LACY, "Hard Switch" a Violation of the Sherman Act in "Product Hopping" Case - *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015), in 12 *Journal of Health and Biomedical Law*, 2016, pp. 91-109.

¹³³ *Ibid.*, at 655.

¹³⁴ *Ibid.*, at 656.

¹³⁵ *Ibid.*, at 660.

remedy, namely a preliminary injunction. The Second Circuit, moreover, properly stressed the anticompetitive effects deriving from the combination of product withdrawal with other conducts in order to ground its finding. Nonetheless, it appears to have relied too heavily on the distinction between “soft” and “hard switch” that does not ultimately constitute the deciding element on which the anti-trust scrutiny should focus¹³⁶, as will be argued in more detail in the following chapter¹³⁷.

¹³⁶ Taking this view, M.A. CARRIER, S.D. SHADOWEN, *Product Hopping: A New Framework*, in 92 *Notre Dame Law Review*, 2016, pp. 167-230. Among those who strongly criticised the judgment, see J. SHEPERD, *Deterring Innovation: New York v. Actavis and the Duty to Subsidize Competitors’ Market Entry*, in 17 *Minnesota Journal of Law, Science & Technology*, 2016, pp. 663-707, stressing in particular the reduced incentives for innovation arising out from the duty to continue marketing superseded drugs as a consequence of the Second Circuit’s findings.

¹³⁷ *Infra*, Chapter three, Section 3.2.

2.2.3. IN ITALY

Pfizer case.

Concerning the present topic of abuses of dominance, Italian practice provides a fully litigated case that is particularly relevant when compared with the CJEU landmark judgment in *AstraZeneca*. Indeed, the *Pfizer* case builds up on the EU precedent and seems to push the antitrust scrutiny over the exercise of IPRs even further, as will be described below.

The facts underlying the case refer to the European patent held by the Swedish-based company Pharmacia covering the API latanoprost, which is used to treat glaucoma and other eye-related diseases and commercialised under the brand name «Xalatan». The patent protection was due to expire in September 2009, but was later extended until July 2011 thanks to the grant of SPCs in those Member States where it had been validated, except in Italy and Spain. After being acquired by Pfizer in 2003, the originator devised a strategy to align the patent protection throughout all European countries, namely by filing an application for a divisional patent also claiming the compound latanoprost¹³⁸, which was indeed granted in 2009, and for the SPC related thereto. The protection was thus matched until July 2011. Moreover, Pfizer applied for a paediatric extension of the SPC, as allowed by the regulatory system¹³⁹, which granted an additional six-month protection until January 2012. In Italy, meanwhile, generic manufacturers (including Ratiopharm) relied upon the expiry date of the “parent” patent, *i.e.* September 2009, and planned their entry into the latanoprost market accordingly. Pfizer, however, engaged in various conducts (even in litigation) aimed at warning potential competitors of its extended exclusionary rights, ultimately causing generic suppliers to

¹³⁸ More precisely, it was filed as a divisional application of a further divisional patent (see EPO Technical Board of Appeal, decision of 10 May 2012, case T-2402/10, available at www.epo.org/law-practice/case-law-appeals).

¹³⁹ The relevant provisions are set forth in Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No. 726/2004, *OJ L 378* of 27 December 2006, pp. 1-19.

delay production of competing drugs. On this basis, Ratiopharm filed a complaint with the ICA, which started its investigation against Pfizer in October 2010 for an alleged violation of Art. 102 TFEU.

The ICA issued its decision on 11 January 2012 and affirmed the existence of an abuse of dominant position within the meaning of Art. 102 TFEU¹⁴⁰, thus imposing fines on Pfizer. The infringement was pursued through a complex exclusionary strategy comprising the artificial extension of Xalatan's patent protection in Italy beyond the expiry of the parent patent in September 2009, the judicial litigation brought against generic competitors, and the paediatric extension of the compound patent obtained until January 2012. As to the first conduct concerning the divisional patent and the SPC, the Authority listed the following grounds on which its decision relied: the timing of the application for such patent, which was much more delayed than the one on the original compound and yet concurrent with generic entry into the given market; the validation of the divisional patent only in Italy, where the expiry of the parent patent was due earlier than in other Member States, and the following application for the SPC in the same country; and the lack of the launch of any new product on the market, contrary to what would have been expected after the grant of a divisional patent¹⁴¹. With regard to

¹⁴⁰ Autorità Garante della Concorrenza e del Mercato, proceeding A431, *Ratiopharm/Pfizer*, decision No. 23194 of 11 January 2012, in *Bollettino AGCM* No. 2 of 30 January 2012, available at www.agcm.it, pp. 5-56. The whole *Pfizer* case was extensively commented upon in the literature: see, *inter alia*, M. COLANGELO, *Dominanza e regulatory gaming: il caso Pfizer*, in *Mercato concorrenza regole*, 2012, pp. 325-336; E. AREZZO, *Strategic patenting e diritto della concorrenza: riflessioni a margine della vicenda Ratiopharm - Pfizer*, in *Giurisprudenza commerciale*, 2014, I, pp. 404-426; D. GERADIN, *The Uncertainties Created by Relying on the Vague 'Competition on the Merits' Standard in the Pharmaceutical Sector: The Italian Pfizer/Pharmacia Case*, in *Journal of Competition Law & Practice*, 2014, pp. 344-352; C. STOTHERS, M. VAN KERCKHOVE, *Is winter coming? The competition chill continues in Italian Antitrust Authority v Pfizer (Xalatan)*, in *European Intellectual Property Review*, 2014, pp. 729-732; G. GHIDINI, G. CAVANI, P. PISERÀ, *Il caso Pfizer*, in *Rivista di diritto civile*, 2015, pp. 1565-1594; A. ROCCHIETTI, *I recenti interventi dell'Autorità nel settore farmaceutico*, in E.A. RAFFAELLI (ed.), *Antitrust fra diritto nazionale e diritto dell'Unione europea. XI Convegno*, cited above.

¹⁴¹ Autorità Garante della Concorrenza e del Mercato, *Ratiopharm/Pfizer*, cited above, paras. 182-203.

the legal proceedings initiated by Pfizer, the ICA highlighted the situation of uncertainty resulting from those actions that effectively contributed to postpone the entry of bioequivalents of latanoprost¹⁴². The litigation, in fact, appeared merely vexatious and did not lay claim to Pfizer's rights. Finally, when examining the paediatric extension of the patent, the Authority concluded that on the basis of the drug's characteristics, this application was purely instrumental and did not appear to pursue any actual interests.

The legal assessment also referred to the role of intent in abuse of dominance cases, confirming the CJEU approach that said evaluation is not required in this context, but may nevertheless constitute the connecting element of the whole anti-competitive strategy. In the case at issue, the collected evidence supported the finding of such an exclusionary intent.

Pfizer brought an appeal before the administrative court of first instance (TAR Lazio), which delivered its judgment on 3 September 2012¹⁴³, overturning the Authority's decision. Assuming that Pfizer did nothing more than exercising its rights before patent offices and courts, the court's reasoning established whether the conducts in question had been characterised for a clear exclusionary intent given by something more (*quid pluris*) than the mere combination of lawful behaviours. To this end, it held that the main argument on which the ICA relied was actually the EPO annulment of the divisional patent¹⁴⁴. This circumstance, however, fell short insofar as the EPO Board of Appeal ultimately ruled on the validity of said patent and the decision was thus vitiated under this aspect. Indeed, the administrative court also maintained that the Authority should have considered

¹⁴² *Ibid.*, paras. 182-203.

¹⁴³ TAR Lazio, judgment of 3 September 2012, No. 7467, available at www.giustizia-amministrativa.it. In the literature see G. SENA, *Esclusiva brevettuale e strategia escludente*, in *Rivista di Diritto Industriale*, 2012, II, pp. 626-630; E. AREZZO, *Strategic patenting*, cited above.

¹⁴⁴ More precisely, the administrative court drew this conclusion notwithstanding the contrary statements made by the ICA in its decision (see Autorità Garante della Concorrenza e del Mercato, *Ratiopharm/Pfizer*, cited above, para. 185). This further element thus confirmed the inconsistency of the position taken by the Authority with regard to the annulment of the divisional patent (TAR Lazio, judgment of 3 September 2012, No. 7467, cited above, para. 4.1).

staying the proceedings until the Board of Appeal had rendered the final decision on the annulment. Since it did not, its decision was rather based on provisional determinations and was found to be lacking the evidence and reasoning necessary to conclude that there was an abuse of dominant position.

The ICA, for its part, appealed the first instance judgment before the administrative supreme court (Consiglio di Stato). The final decision on the case was thus issued on 12 February 2014¹⁴⁵. It found the lower court's arguments unpersuasive in that they evaluated Pfizer's behaviours against the background of patent law (in particular, the EPO annulment of the divisional patent). This aspect was, however, irrelevant to the main issue of establishing the anticompetitive nature of a number of conducts that were *per se* lawful under patent law. Indeed, the supreme court in this regard offered a particular qualification of the abuse of dominance as a «specification of the broader category of abuse of rights»¹⁴⁶, since Pfizer's instrumental exercise of rights granted by the legal system resulted in the exclusion of competitors from the latanoprost market. Therefore, according to the supreme court, the ICA correctly argued that the originator pursued a different and further aim than mere patent protection, and that its conducts were distinguished by a clear exclusionary intent in order to hinder the entry of generic drugs. One of the decisive factors in this reasoning was that Pfizer did not market a new drug after having obtained the divisional patent. In light of the above, the administrative supreme court reversed the lower court's judgment and confirmed the findings of the Authority.

¹⁴⁵ Consiglio di Stato, judgment of 12 February 2014, No. 693, available at www.giustizia-amministrativa.it. For further comments see C. D'AMORE, *The Administrative Supreme Court confirms the ICA's decision to condemn Pfizer for abuse of dominant position aimed at delaying the market entry of generic pharmaceutical companies*, in *Italian Antitrust Review*, 2014, No. 1, pp. 77-81, and by the same Author, *Il caso Ratiopharm/Pfizer e l'abuso del diritto*, available at www.competition-law.eu; G. GHIDINI, G. CAVANI, P. PISERÀ, *Il caso Pfizer*, cited above. Among those who expressed criticism towards the supreme court's approach, see C. OSTI, *The Italian way to antitrust judicial review: a few oddities of the Pfizer case*, in *Italian Antitrust Review*, 2014, No. 3, pp. 115-132.

¹⁴⁶ Consiglio di Stato, judgment of 12 February 2014, No. 693, para. V), C).

The Italian *Pfizer* case followed the approach of the CJEU in *AstraZeneca*, but also took the antitrust scrutiny over the exercise of IPRs to an extreme intensity in the sense that here the originator's conducts were lawful according to the patent law framework, as opposed to the misleading position taken by *AstraZeneca* towards patent offices and courts. This explains their qualification in terms of abuse of rights, as claimed by the court, which requires the existence of a right and its exercise in a way that is not consistent with the aim provided by the relevant legal system. As will be further discussed in the next chapter, the need to establish a *quid pluris* that shows the objectively anticompetitive nature of otherwise lawful conducts appears a reasonable application of both *AstraZeneca* and *Pfizer* precedents. In particular, for industries that rely heavily on R&D such as pharmaceutical companies, a reasonable distinction between legitimate protection of IPRs and anticompetitive strategies could be again based on innovation, *i.e.* on the launch of new products on the given market. In this regard, the conclusion of the administrative supreme court in *Pfizer* seems to have been correctly drawn.

Aspen case.

This recent case investigated by the ICA has concluded with the decision to impose a fine of over 5 million euros on *Aspen Pharma* for having infringed Art. 102 TFEU, by increasing prices of its life-saving anti-cancer medicines by up to 1500%¹⁴⁷. The case does not actually involve patent law issues, but rather a strategy of aggressive price negotiation undertaken by the dominant company towards the competent regulatory body, *i.e.* AIFA. For this reason, an in-depth analysis of the decision will not be carried out in the context of this thesis. Nonetheless, it is worth mentioning, as the ICA continues to pay particular attention to various issues pertaining to the regulatory framework in the pharmaceutical sector – in this instance, pricing procedures – that may amount to anticompetitive conducts.

¹⁴⁷ Autorità Garante della Concorrenza e del Mercato, proceeding A480, *Incremento prezzi farmaci Aspen*, decision No. 26185 of 29 September 2016, in *Bollettino AGCM* No. 36 of 17 October 2016, pp. 5-99, available at www.agcm.it.

CHAPTER THREE

CRITICAL ASSESSMENT

This third chapter aims at providing a more critical insight into some of the unresolved issues within the debated interplay between antitrust and patent law in the pharmaceutical industry. Indeed, as can be inferred from the analysed case law, under many respects the complex accommodation of the two bodies of law seems far from settled.

Firstly, the main questions concerning the practice of restrictive agreements will be addressed. In this regard, the competition law standard to ground a finding of infringement under Art. 101 TFEU, *i.e.* a restriction by object or by effect, constitutes one of the key aspects of the discourse and will be thoroughly examined against the background of the relevant CJEU case law, as well as the landmark US *Actavis* case. Then, further remarks concerning the particular nature of co-promotion and co-marketing agreements will be proposed. Lastly, this section will discuss the reach of the recent request for preliminary ruling submitted in the context of the Italian *Roche-Novartis* case.

The second section will deal with the most significant developments of case law on abuses of dominance/monopolisation. Here the perspective shifts to the rather elusive standard of competition on the merits as applied to conducts that are on the one hand exclusionary practices, and on the other may be found lawful under other branches of law. By recalling the relevant case law, it will be argued that the application of more sector-specific benchmarks appears more appropriate to ground a finding of abuse under Art. 102 TFEU in a highly regulated context such as the pharmaceutical industry. Furthermore, some considerations will be also put forth as to a relatively unexplored question, namely the concept of competition in innovation between originator companies in non-existing markets, where a proper dominant position has not yet emerged. Finally, the separate aspect of vexatious litigation as an anticompetitive practice within the meaning of Art. 102 TFEU will be touched upon.

The last section of the chapter will discuss an issue that has not yet found a proper assessment in EU and US case law, which is the combined anticompetitive

effect of a reverse payment settlement agreement and a switch from the first- to second-generation brand drug. Indeed, these conducts taken together may cause the most serious harm to final consumers (*i.e.* patients), and seem to warrant further specific scrutiny by enforcement authorities and courts.

3.1. THE INTERFACE BETWEEN COMPETITION AND PATENT LAW AS APPLIED TO RESTRICTIVE AGREEMENTS: PROBLEMATIC ISSUES

After having analysed the most relevant EU case law regarding cases of restrictive agreements, an issue that appears to merit further discussion is of course the application of the strictest legal standard of restriction of competition by object pursuant to Art. 101(1) TFEU, which has been not only a common assessment in all the above-mentioned Commission decisions (*Lundbeck*, *J&J and Novartis*, *Servier*), and is the ground of the complaint in the on-going *Cephalon and Teva* case, but has also been confirmed at the national level in the UK *Paroxetine* case. In particular, this aspect needs to be examined within the broader framework of the two notions of restrictions encompassed by the said provision, namely «by object» and «by effect»¹. The topic is one of the most typical in EU competition law, in that it constitutes one of the legal bases for its enforcement, yet it has been often discussed, even in recent times, both in CJEU case law and the literature.

In this regard, a turning point can be found in the Commission's initiative of modernisation of competition law that was gradually introduced from the early 2000s and involved a process of reform on many levels². It was essentially grounded on a shift from a form-based to an effects-based approach in the enforcement in this field and required, among other aspects, a clearer distinction between the two types of restriction in Art. 101 TFEU in order to convey legal certainty. The practical consequence is of great importance for the purposes of establishing an infringement, given that a restriction by object amounts to a presump-

¹ For an overview of the two notions see, for example, A. JONES, B. SUFRIN, *EU Competition Law*, 5th ed., Oxford, 2014, pp. 203-249; H. SCHRÖTER, T. JAKOB, R. KLOTZ, W. MEDERER (Hrgs.), *Europäisches Wettbewerbsrecht*, 2. Auflage, Baden-Baden, 2014, Rn. 120-127; L. VOGEL, *European Competition Law*, Paris, 2015, pp. 84-89.

² Among the extensive literature, see, for example, D. SCHMIDTCHEN, M. ALBERT, S. VOIGT (eds.), *The More Economic Approach to European Competition Law*, Tübingen, 2006; J. DREXL, W. KERBER, R. PODSZUN (eds.), *Competition Policy and the Economic Approach. Foundations and Limitations*, Cheltenham-Northampton, 2011.

tion of illegality of the agreement, which can be rebutted by the other party by demonstrating pro-competitive effects pursuant to Art. 101(3)³. By contrast, in the assessment of a restriction by effect the enforcement authority bears the burden of proof of showing the actual impact on competition of the alleged anticompetitive conduct. However, as the literature has stressed, the modernised approach has actually had a limited impact on the interpretation and application of the two categories⁴. On the one hand, the identification of by object restrictions is broadly drawn and, on the other, a common understanding in determining the existence of by effect restrictions is still lacking. At times, the positions emerging from the Commission's practice and the CJEU case law have not been sufficiently consistent with the objectives of the reform towards an effective enforcement.

More specifically, the notion of a by object restriction has been assessed many times by the CJEU since its very early judgments. The essential feature of said infringement lies in its own restrictive nature, to be inferred from the purpose of the agreement itself, which must reveal a «sufficiently deleterious»⁵ effect on competition. Along the same path, other formulations of the by object substantive standard refer to conducts that are «by their very nature injurious»⁶ to the proper func-

³ In practice, however, this kind of «severe restrictions of competition are unlikely to fulfil the conditions of [Art. 101(3)]», as they are usually “black-listed” in block exemptions regulations or regarded as hard-core restrictions according to the Commission's guidance: see Communication from the Commission, *Guidance on the application of Article 81(3) of the Treaty*, OJ C 101 of 27 April 2004, pp. 97-118, para. 46.

⁴ See the opinions expressed by A. JONES, *Left Behind by Modernisation? Restrictions by Object Under Article 101(1)*, in *European Competition Journal*, 2010, pp. 649-676, at pp. 650-665; C. LEMAIRE, *Object vs. Effect After the Modernisation of EU Law: What Has (or Should Have) Changed?*, in *New Frontiers of Antitrust 2012*, Brussels, 2013, pp. 163-182; D. WAELBROECK, D. SLATER, *The Scope of Object vs Effect Under Article 101 TFEU*, in J. BOURGEOIS, D. WAELBROECK (eds.), *Ten years of effects-based approach in EU competition law. State of play and perspectives*, Brussels, 2013, pp. 131-157.

⁵ The reference is taken from the well-known judgment of the Court of Justice of 30 June 1966, case 56/65, *Société Technique Minière v. Maschinenbau Ulm GmbH*, EU:C:1966:38, p. 249.

⁶ See, among others, Court of Justice, judgment of 20 November 2008, case C-209/07, *Competition Authority v. Beef Industry Development Society Ltd and Barry Brothers (Carrigmore) Meats*

tioning of free and undistorted competition, or that reveal «a sufficient degree of harm to competition»⁷, or further that are «obvious restrictions of competition»⁸. Should this not be the case, the «consequences of the agreement» would then be taken into account and, for a restriction by effect to be found, the court would have to establish that «competition has in fact been prevented or restricted or distorted to an appreciable extent»⁹.

The distinction, however, has been blurred by more recent case law that culminated in the *Allianz Hungária* judgment of 2013¹⁰. The Court of Justice here held that in carrying out the evaluation of an agreement allegedly restricting competition by object, «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 appropriate 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»¹¹. Moreover, in order to affirm the existence of said restriction, it specified that «it is sufficient that it has the potential to have a negative impact on competition, that is to say, that it be capable in

Ltd., EU:C:2008:643, para. 17; judgment of 13 December 2012, case C-226/11, *Expedia Inc. v. Autorité de la concurrence and others*, EU:C:2012:795, para. 36.

⁷ See, for example, Court of Justice, judgment of 6 October 2009, joined cases C-501 P, C-513 P, C-515 P and C-519/06 P, *GlaxoSmithKline Services Unlimited and others v. Commission of the European Communities*, EU:C:2009:610, para. 55.

⁸ This standard has been more rarely recalled: see Court of First Instance, judgment of 15 September 1998, joined cases T-374, T-375, T-384 and T-388/94, *European Night Services Ltd (ENS) and others v Commission of the European Communities*, EU:T:1998:198, para. 136.

⁹ Court of Justice, judgment of 30 June 1966, *Société Technique Minière*, cited above, p. 249.

¹⁰ Court of Justice, judgment of 13 March 2013, case C-32/11, *Allianz Hungária Biztosító Zrt and others v. Gazdasági Versenyhivatal*, EU:C:2013:160. Previous cases that similarly contributed to a wider interpretation of the notion of restriction by object are: judgment of 4 June 2009, case C-8/08, *T-Mobile and others v. Raad van bestuur van de Nederlandse Mededingingsautoriteit*, EU:C:2009:343, regarding information exchange; judgment of 13 October 2011, case C-439/09, *Pierre Fabre Dermo-Cosmétique SAS v. Président de l'Autorité de la concurrence, Ministre de l'Économie, de l'Industrie et de l'Emploi*, EU:C:2011:649, dealing with a selective distribution agreement.

¹¹ Judgment of 13 March 2013, case C-32/11, *Allianz Hungária*, cited above, para. 36.

an individual case of resulting in the prevention, restriction or distortion of competition within the internal market»¹². The consequences of such an extensive approach are rather problematic: not only would the assessment of a restriction by object become too general, even encompassing conducts that do not meet the «sufficiently deleterious» requirement mentioned above, but it would also entail the risk of overlapping the analysis of the object and the effects of the agreement, resulting in a finding of an infringement on both levels.

In a subsequent ruling – *Groupement des cartes bancaires* of 2014¹³ – the Court of Justice nonetheless appears to retract from this precedent and to endorse a narrower interpretation of the concept of restriction by object. It reaffirmed, in fact, that «the essential legal criterion for ascertaining whether coordination between undertakings involves such a restriction of competition ‘by object’ is the finding that such coordination reveals in itself a sufficient degree of harm to competition»¹⁴.

As to the actual distinction between by object and by effects restrictions, the Court recalled the substantive standard already explored in its case law prior to *Allianz Hungária*, but it also added a further qualification that appears to be rele-

¹² *Ibid.*, para. 38.

¹³ Court of Justice, judgment of 11 September 2014, case C-67/13 P, *Groupement des cartes bancaires (CB) v. European Commission*, EU:C:2014:2204. For further comments, taking into account also the precedent of *Allianz Hungária*, see J. KILLICK, J. JOURDAN, *Cartes Bancaires: A Revolution or a Remainder of Old Principles We Should Never Have Forgotten?*, 2014, available at www.competitionpolicyinternational.com; G. BRUZZONE, S. CAPOZZI, *Restrictions by Object in the Case Law of the Court of Justice: in search of a Systematic Approach*, in G.A. BENACCHIO, M. CARPAGNANO (a cura di), *L'applicazione delle regole di concorrenza in Italia e nell'Unione europea. Atti del V Convegno biennale Antitrust, Trento, 16-18 aprile 2015*, Napoli, 2015, pp. 217-236; P. FATTORI, *The Impact of Groupement des Cartes Bancaires on Competition Law Enforcement*, in *Italian Antitrust Review*, 2015, No. 2, pp. 22-28; J.R. RUIZ CALZADO, A. SCORDAMAGLIA-TOUSIS, *Groupement des Cartes Bancaires v Commission: Shedding Light on What is not a ‘by object’ Restriction of Competition*, in *Journal of European Competition Law & Practice*, 2015, pp. 495-498; S.-P. BRANKIN, *The substantive standard behind the object-effect distinction post-Cartes Bancaires*, in *European Competition Law Review*, 2016, pp. 376-383.

¹⁴ Court of Justice, judgment of 11 September 2014, *Groupement des cartes bancaires (CB)*, cited above, para. 57.

vant in this context. Indeed, it held that the by object category «can be applied only to certain types of coordination between undertakings which reveal a sufficient degree of harm to competition *that it may be found that there is no need to examine their effects*, otherwise the Commission would be exempted from the obligation to prove the actual effects on the market of agreements which are in no way established to be, by their very nature, harmful to the proper functioning of normal competition»¹⁵. Moreover, the Court acknowledged that its settled case law leads to consider certain collusive behaviours between undertakings «*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 [Art. 101(1) TFEU], *to prove that they have actual effects on the market*»¹⁶. In this regard, the judgment also confirms the relevance of the experience as an element that must be accorded full consideration when assessing an alleged restriction by object. It follows that an anticompetitive conduct possessing distinctive characteristics would hardly fall within the scope of said notion: in such a case it would be advisable to carry out a full-blown evaluation of its restrictive effects in order to support a finding of infringement under Art. 101(1) TFEU.

Cartes Bancaires thus seems to provide additional guidance in order to properly establish a by object restriction, to the extent that the level of harm to competition revealed by the investigated conduct «must *justify* the avoidance of a full effects analysis»¹⁷. The unresolved question regards, however, the circumstances in which such avoidance becomes justified. To this end, the opinion given by Advocate General Wahl in the case at issue could prove helpful, by explaining that a by object classification should be limited to cases of «(i) conduct[s] entailing an inherent risk of a particularly serious harmful effect or (ii) conduct[s] in respect of which it can be concluded that the unfavourable effects on competition outweigh the pro-competitive effects»¹⁸. The latter instance, in particular, could represent an

¹⁵ *Ibid.*, para. 58 (emphasis added).

¹⁶ *Ibid.*, para. 51 (emphasis added).

¹⁷ As underlined by S.-P. BRANKIN, *The substantive standard*, cited above, p. 380.

¹⁸ Opinion of Advocate General Wahl delivered on 27 March 2014, case C-67/13 P, *Groupe-ment des cartes bancaires (CB) v. European Commission*, EU:C:2014:1958, para. 55.

objective benchmark to ground the distinction between by object and by effect restrictions. Indeed, whenever it is clear that the «net effects»¹⁹ of the individual restriction in the context the overall agreement will be negative, a by object qualification would appear justified.

More recently, the *Toshiba* case²⁰ has followed the mentioned guidance of *Cartes Bancaires*, while also suggesting a further level of assessment of by object restrictions. As the case concerned a market-sharing agreement between undertakings possessing an «object restrictive of competition» and «fall[ing] within a category of agreements expressly prohibited»²¹ by Art. 101(1) TFEU, the Court of Justice held that the analysis of the economic and legal context of which such practice forms part may be «limited to what it is strictly necessary»²² in order to establish a restriction by object. Within the by object category itself, the Court thus seems to point to a further distinction between hard-core restraints (such as market-sharing agreements, as well as the other conducts listed in Art. 101(1) TFEU) and the other infringements. The former would in fact allow a truncated evaluation to be carried out, while the latter would require a «more thorough»²³ analysis of the economic and legal context, which remains, beside the contents and the object of the agreement, one of the elements to be taken into account when assessing the degree of harm produced by an alleged restrictive conduct²⁴. Even though the wording is different, this distinction could actually come close to the two instances mentioned by Advocate General Wahl in *Cartes Bancaires* when establishing the narrow boundaries of by object restrictions.

¹⁹ The evocative terms are by S.-P. BRANKIN, *The substantive standard*, cited above, p. 381 f.

²⁰ Court of Justice, judgment of 20 January 2016, case C-373/14 P, *Toshiba Corporation v. European Commission*, EU:C:2016:26.

²¹ *Ibid.*, para. 28.

²² *Ibid.*, para. 29.

²³ Opinion of Advocate General Wathelet delivered on 25 June 2015, case C-373/14 P, *Toshiba Corporation v. European Commission*, EU:C:2015:427, para. 90, which was upheld by the subsequent judgment of the Court of Justice.

²⁴ For an extensive comment on restrictions by object in light of the mentioned CJEU judgments see G.L. ZAMPA, A. DI GIÒ, *The Conundrum of Restrictions “by Object”: Rationale, Scope, Impact and a Proposal*, in *Italian Antitrust Review*, 2015, No. 3, pp. 13-44.

Moving to the application of these principles to the specific case of reverse payment settlement agreements, the crucial issue then becomes whether they produce the particularly serious degree of anticompetitive harm to be regarded as hard-core restrictions, therefore requiring a limited analysis of their contents, object and legal and economic context to ground a by object qualification. However, in light of the narrower approach supported by the recent CJEU case law, one could also argue that, given the said agreements atypical and complex features, it would be rather necessary to carry out a more thorough evaluation of their negative net effects in order to establish a by object infringement, or even to perform a full effects analysis showing that competition has in fact been prevented, restricted or distorted to an appreciable extent. As will be recalled about the three Commission decisions analysed in the previous chapter, only *Servier* added the further evaluation of the likely restrictive effects on competition produced by the patent settlements at issue.

The General Court in *Lundbeck* – the first and so far only judgment on reverse payment cases²⁵ – has resolved this ambiguity, at least for the time being, by taking the view that the Commission had properly applied the above-mentioned CJEU case law when holding that the agreements in question «had as their object the restriction of competition, within the meaning of [Art.] 101(1) TFEU»²⁶. Several grounds were recalled to uphold the Commission reasoning. Essentially, the General Court confirmed that the reverse payments from Lundbeck to the five ge-

²⁵ As already done in the previous chapter, also for the purposes of the critical assessment only the *Lundbeck* judgment will be specifically referred to, but the considerations here proposed also extend to the decisions rendered by the General Court on appeal by the other generic undertakings involved in the reverse payment agreements (case T-460/13, *Sun Pharmaceutical Industries Ltd, formerly Ranbaxy Laboratories Ltd and Ranbaxy (UK) Ltd v. European Commission*, EU:T:2016:453; case T-467/13, *Arrow Group ApS and Arrow Generics Ltd v. European Commission*, EU:T:2016:450; case T-469/13, *Generics (UK) Ltd v. European Commission*, EU:T:2016:454; case T-470/13, *Merck KGaA v. European Commission*, EU:T:2016:452; case T-471/13, *Xellia Pharmaceuticals ApS and Alpharma, LLC, formerly Zoetis Products LLC v. European Commission*, EU:T:2016:460).

²⁶ General Court, judgment of 8 September 2016, case T-472/13, *H. Lundbeck A/S and Lundbeck Ltd v. European Commission*, EU:T:2016:449, para. 354.

nerics entailed a limitation of the incentives to seek market entry, with the consequence that the overall agreements did not reflect the parties' perception of the strength or weakness of the patent, nor were they aimed at finding a compromise solution to the patent disputes, but they basically «replaced the uncertainty as to the possibility of generic entry without being subject to injunctions or infringement actions, or of successfully challenging the validity of the applicants' patents, with the certainty that the generic undertakings would not enter the market during the term of the agreements»²⁷. Indeed, as the US Supreme Court had already held in *Actavis*, it was precisely the disproportionate size of the reverse payments, in addition to other significant factors²⁸, that justified the application of the strictest legal standard²⁹.

As regard the classification of the agreements at issue within the notion of restriction of competition by object, the General Court further specified that they were comparable to «market exclusion agreements», resulting in the «exclusion of competitors from the market [as] an extreme form of market sharing and of limitation of production»³⁰. Accordingly, the Commission had correctly considered them as producing the sufficiently serious degree of harm to competition required to ground such a finding, without having to carry out a full effects analysis (and

²⁷ *Ibid.*, para. 369.

²⁸ In this regard, the General Court stressed that, according to the agreement provisions, the amount of the payments corresponded to the approximate profits of the generic undertakings if they had entered the market with their versions of the citalopram drug, the generics were not allowed to launch their products upon the expiry of the agreements without having to fear infringement actions by Lundbeck, and the restrictions thereby imposed fell beyond the scope of the originator's patents.

²⁹ Particularly instructive to this end is also a passage from the Commission decision in *Servier*: «even if the limitations in the agreement on the generic undertaking's commercial autonomy do not go beyond the material scope of the patent, they constitute a breach of Article 101 of the Treaty when those limitations cannot be justified and do not result from the parties' assessment of the merits of the exclusive right itself but in particular from a transfer of value overshadowing this assessment and inducing the generic undertaking not to pursue its independent efforts to enter the market» (Commission decision of 9 July 2014, case AT.39612, *Perindopril (Servier)*, para. 1137).

³⁰ General Court, judgment of 8 September 2016, *Lundbeck*, cited above, para. 453.

the related counterfactual evaluation). Furthermore, this finding was justified even though the Commission had not ruled in the past on whether this type of agreement constitutes a restriction by object. In relation to the above-mentioned role of experience as referred to in *Cartes bancaires*³¹, the General Court in fact clarified that this argument «does not concern the specific category of an agreement in a particular sector, but rather refers to the fact that it is established that certain forms of collusion are, in general and in view of the experience gained, so likely to have negative effects on competition that it is not necessary to demonstrate that they had such effects in the particular case at hand»³². It thus appears justified to classify reverse payment settlements under the by object category, provided that «an individual and detailed examination having regard to their content, purpose and context»³³ had been performed, in accordance with *Cartes Bancaires* and *Toshiba* precedents.

The finding of a restriction by object, as argued by the Commission and then specified by the General Court, seems to depart from the rule-of-reason standard chosen by the US Supreme Court in *Actavis*, under which both parties need to bear their respective burden of proof. This approach, theoretically, would be more consistent with a full effects analysis pursuant to Art. 101(1) TFEU³⁴, as opposed to a *per se* illegality standard. Upon closer examination, a convergent trend between the two viewpoints may however result³⁵. As underlined in the second chapter³⁶, the Supreme Court's reasoning actually implies the application of a

³¹ Court of Justice, judgment of 11 September 2014, *Groupement des cartes bancaires (CB)*, cited above, para. 51.

³² General Court, judgment of 8 September 2016, *Lundbeck*, cited above, para. 438 (emphasis added).

³³ *Ibid.*

³⁴ For a comprehensive insight on this perspective see M.-A. VOLKS, *The Applicability of a US-Type Rule of Reason under Article 101(1) TFEU. A Comparison of EU with US Law*, Hamburg, 2015.

³⁵ Also taking this view, with regard to the *Servier* case, is C. DESOGUS, *Manovre di avvicinamento tra l'Europa e gli Stati Uniti: il caso Servier sui patent settlements*, in *Mercato concorrenza regole*, 2016, pp. 249-278, especially at pp. 272-275.

³⁶ See *supra*, Chapter two, Section 2.1.2.

streamlined rule-of-reason standard. On the one hand, the large size of the payment serves as a proxy to show the anticompetitive effects of the settlement, and, on the other hand, the originator may have recourse to a limited set of justifications to support its defence and prove the outweighing pro-competitive effects. Especially the first aspect amounts to a (rebuttable) presumption³⁷, which finds a very similar wording in the General Court's *Lundbeck* judgment when it stated: «[t]he size of a reverse payment may constitute an indicator of the strength or weakness of a patent, as perceived by the parties to the agreements at the time they were concluded, and of the fact that [the] originator undertaking was not initially convinced of its chances of succeeding in the event of litigation»³⁸.

As a result, the critical reading of the EU approach, as proposed by some commentators³⁹, does not seem entirely convincing. It is true that the regulatory framework in the EU and the US does affect the level of competition between originators and generic to a different extent⁴⁰. In the latter legal system, an effective market foreclosure can be produced by a single settlement reached by an originator company and the first generic entrant that filed an ANDA with a Paragraph-IV Certification, by means of the 180-day exclusivity period and the potential 30-month stay in case of patent litigation. Conversely, in the EU context, in which the MA procedures are based only on quality, safety and efficacy concerns (absent a patent linkage rule), there is no such limit as to MA applications for generic drugs in relation to the same reference product prior to patent expiry, with the

³⁷ As mentioned, it is the so-called «Actavis inference»: see extensively A. EDLIN, S. HEMPHILL, H. HOVENKAMP, C. SHAPIRO, *The Actavis Inference*, cited above.

³⁸ General Court, judgment of 8 September 2016, *Lundbeck*, cited above, para. 353.

³⁹ Among others, S. GALLASCH, *Activating Actavis in Europe – the Proposal of a “Structured Effects Based” Analysis for Pay for Delay Settlements*, in *CCP Working Papers*, 2015, No. 3, available at <http://competitionpolicy.ac.uk>; G. BRUZZONE, S. CAPOZZI, *The Procompetitive and Anticompetitive Impact of Patent Settlements*, in G. PITRUZZELLA, G. MUSCOLO (eds.), *Competition and Patent Law in the Pharmaceutical Sector: An International Perspective*, Alphen aan den Rijn, 2016, pp. 15-30, especially at pp. 27-29; I.S. FORRESTER, *The Dangers of Settling Patent Litigation*, *ibid.*, pp. 67-76.

⁴⁰ See *supra*, Chapter one, Sections 2.2.1 and 2.2.2.

consequence that an originator would have to pay off *all* generic competition to ensure the same level of market foreclosure as in the US system.

Nevertheless, should an agreement be concluded between an originator and that generic company (or companies) that has been developing its own product, or has even applied for a MA, thus resulting in an advanced potential competitor, the negative impact on competition in the given market would be substantially comparable to that occurring in case of a settlement between originator and first AN-DA filer within the Hatch-Waxman regulatory framework. Consequently, in these instances the finding of a restriction by object would appear justified, since the level of market foreclosure is considerably serious⁴¹. These particular circumstances have indeed occurred in the above-mentioned *Lundbeck* and *Servier* cases, where the reverse payment agreements involved the brand companies and those advanced generic competitors that had been preparing to launch their product into the market⁴². The anticompetitive harm resulting from their delayed entry was thus significant, as the agreements basically eliminated the competitive pressure brought by the generic manufactures.

Conversely, a full-scale effects analysis would seem more proper whenever a certain degree of competition between originators and generics still exists even after a reverse payment agreement was concluded. In this case a finding of infringement of Art. 101(1) TFEU would in fact require the establishment of actual anticompetitive effects by carrying out a counterfactual analysis. As the General Court and the Commission have stated, and as also confirmed by the recent trends resulting from the annual monitoring activity, the sole existence of a reverse payment in the context of a patent settlement is not always problematic from an anti-trust perspective, but it does raise concerns when it is intended to delay generic market entry.

⁴¹ As confirmed by other commentators, for example C. DESOGUS, *Manovre di avvicinamento tra l'Europa e gli Stati Uniti*, cited above, pp. 262-268.

⁴² More precisely, the agreements between Lundbeck and the five most advanced competitors were concluded around the same time, while in *Servier* the elimination of competition developed progressively, as the originator entered into settlements with those generic companies that each time appeared to exert the most effective competitive pressure.

In this regard, a partially different set of considerations is appropriate in relation to the *J&J and Novartis* case. As will be recalled, the agreement at issue was not a patent settlement, but rather a co-promotion agreement by means of which the subsidiary of the most advanced competitor committed to perform a number of promotion services in exchange for monthly payments granted by the originator's subsidiary. The anticompetitive feature of such an agreement, on which the Commission focused its scrutiny, was however the termination clause actually amounting to a non-entry mechanism for the generic undertaking. This was precisely the element that led the EU enforcer to conclude with a finding of a restriction by object within the meaning of Art. 101(1) TFEU. However, one should not jump to conclusions regarding the strictest legal standard adopted in this case in relation to co-promotion (or co-marketing) agreements in general. Indeed, as previous Commission decisions have already pointed out⁴³, in many cases this kind of agreement between companies participating in the same market may actually produce efficiency gains⁴⁴ to be passed on to consumers that can be deemed as worthy of an individual exception under Art. 101(3) TFEU⁴⁵. Again, it was because of the specific circumstances in *J&J and Novartis*, namely the inhibition of generic market entry and the lack of evidence of actual promotion activities, that the Commission did not exempt the agreement at issue under the mentioned provision.

⁴³ See Commission decision 94/770/EC of 6 October 1994 relating to a proceeding pursuant to Article 85 of the EC Treaty and Article 53 of the EEA Agreement (IV/34.776 - *Pasteur Mérieux-Merck*), OJ L 309 of 2 December 1994, pp. 1-23; case COMP/36.932/EISAI/Pfizer, 10 February 1999, available at <http://ec.europa.eu/competition>.

⁴⁴ For example, by means of these agreements the originator can rely on other companies that possess the know-how and the network required to implement a successful promotion or marketing strategy, without incurring in significant investments to carry out such activities on its own and thus being able to focus on its core business.

⁴⁵ On this issue see further J. WESTIN, M. HEALY, B. BATCHELOR, *Pharmaceutical co-promotion, co-marketing and antitrust*, in *European Competition Law Review*, 2014, pp. 402-412; E.A. RAFFAELLI, E. TETI, *Co-marketing and Co-promotion Agreements*, in G. PITRUZZELLA, G. MUSCOLO (eds.), *Competition and Patent Law in the Pharmaceutical Sector*, cited above, pp. 147-160.

Lastly, a separate comment seems appropriate about the only case analysed concerning competition between originators, namely the Italian *Roche-Novartis* case. The most debatable aspect here regards not so much the legal standard adopted by the ICA and confirmed by the administrative Court of First Instance, *i.e.* a restriction by object pursuant to Art. 101(1)(c) TFEU, but rather the preliminary assessment of the relevant market in which the originators operated. As is well known, its definition constitutes an essential element for the enforcement of competition rules, in that it specifies their scope of application on a case-by-case basis.

Just to briefly recall the general framework, at the EU level the Commission has provided guidance on how to determine the concept of relevant market⁴⁶ by combining two distinct dimensions, namely the product market and the geographical market. The former «comprises all those products and/or services which are regarded as interchangeable or substitutable by the consumer by reason of the products' characteristics, their prices and their intended use»⁴⁷, while the latter takes into account «the area in which the firms concerned are involved in the supply of products or services and in which the conditions of competition are sufficiently homogeneous»⁴⁸. Then, after these two aspects have been defined, the enforcement authority is asked to carry out a further analysis on the basis of the concept of substitutability. In this regard, both the demand-side and the supply-side substitution are addressed in order to specify the relevant market with a greater degree of certainty⁴⁹.

In the case of pharmaceutical products, however, the concept of substitutability is peculiar to the extent that certain drugs may possess the same formulation but different therapeutic indications, or conversely may be therapeutically equivalent

⁴⁶ Commission notice on the definition of relevant market for the purposes of Community competition law, *OJ C 372* of 9 December 1997, pp. 5-13.

⁴⁷ *Ibid.*, para. 7.

⁴⁸ *Ibid.*, para. 8.

⁴⁹ For an overview and further references on the notion of relevant market see, for example, V. ROSE, D. BAILEY, *Market Definition. Introduction and Overview*, in V. ROSE, D. BAILEY (eds.), *Bellamy and Child: European Union Law of Competition*, 7th ed., Oxford, 2013, pp. 320-358.

while having different formulations. Indeed, at both EU and national level the relevant market in this sector is commonly defined by referring to therapeutic classes according to the internationally accepted Anatomical Therapeutic Chemical (ATC) classification system⁵⁰. The product market is usually established on the basis of the third ATC level, *i.e.* the pharmacological subgroup⁵¹. This allows a comparison of medicinal products that have similar pharmacological properties, and thus can be prescribed for the same disease. Nonetheless, at times the comparison requires grouping of various therapeutic classes together, or further considering the fourth ATC level based on the active ingredient.

In view of these general principles, it is apparent that the ICA decision in *Roche-Novartis* has added a further aspect in the definition of relevant market, namely by considering an off-label use (Avastin) and an authorised drug (Lucentis) as substitutable treatments for AMD and other eye-related diseases. The off-label use of a certain medicine is a rather sensitive issue not only for the physician who opts for this therapeutic choice⁵², but also from a regulatory perspective. As far as Italy is concerned, this practice has been subject to subsequent legislative

⁵⁰ The ATC system provides for a classification of active substances «according to the organ or system on which they act and according to their chemical, pharmacological and therapeutic properties» (World Health Organization, *Introduction to Drug Utilisation Research*, 2003, pp. 33-37, at p. 33-34, available at <http://apps.who.int/medicinedocs>). The ATC index is periodically updated and is available at www.whooc.no/atc_ddd_index.

⁵¹ In this regard see the Pharmaceutical Sector Inquiry of the ICA, which clarifies the definition of relevant market for the purposes of competition law probes (Autorità Garante della Concorrenza e del Mercato, *Indagine conoscitiva nel settore farmaceutico*, 1997, pp. 9-11, available at www.agcm.it).

⁵² The consequences in terms of civil and criminal liability of the physician fall beyond the scope of this more limited inquiry. For a comprehensive illustration in the Italian legal system see, among others, F. MASSIMINO, *La prescrizione dei farmaci «off label»: adempimenti, obblighi e responsabilità del medico*, in *Danno e responsabilità*, 2003, pp. 925-937; G. IADECOLA, *Prescrizione di farmaci off label e responsabilità penale del medico*, in *Diritto penale e processo*, 2006, pp. 1135-1140; A. QUERCI, *Farmaci off label e nuove frontiere della responsabilità civile*, in *Rassegna di diritto farmaceutico*, 2009, pp. 1-18; F. MASSIMINO, *Recenti interventi normative e giurisprudenziali in materia di prescrizione dei farmaci off label*, in *Danno e responsabilità*, 2010, pp. 1104-1118.

reforms, also at the regional level. In particular, the last amendment has actually been introduced in light of the *Roche-Novartis* case, and establishes that an off-label use can be included in the so-called “Lista 648” (allowing its related expenses to be reimbursed by the NHS) even if another therapeutic alternative exists among the authorised medicines, upon condition that such unregistered use is well-known and consistent with scientific studies carried out by the national and international medical communities, and also according to criteria of economic efficiency and pertinence⁵³. This last reference, in particular, raises more than one doubt as to the ultimate aim of this legislative change, which could be intended to become a tool for overcoming the choice freely made by an undertaking to not ask for a MA for certain uses of a drug, provided that a public interest for allowing those uses exists⁵⁴.

For the purposes of the antitrust assessment, the inclusion of both off- and on-label uses of different drugs to define the relevant market appears to warrant further scrutiny. It is true that account should be taken of factual circumstances, but the choice of relying exclusively on the demand side, namely on consumers and prescribing doctors, does not seem entirely convincing in order to ground the evaluation of substitutability. Beside the demand, it is indeed the regulatory agency (in Italy, AIFA) authorising the placing on the market on grounds of drug safety and efficacy that ultimately determines the definition of relevant market. Only this benchmark ensures that the concept of substitutability is established according to objective criteria, and thus, that the considered drugs are actual “competitors” for the treatment of certain diseases, which consequently can be included in

⁵³ See Art. 3 of the Decree-Law of No. 36 of 20 March 2014, converted into Law No. 79 of 16 May 2014, *Italian OJ* No. 115 of 20 May 2014. For a comment, see G. COMANDÈ, L. NOCCO, «Hard cases make bad law». *O No? L’Antitrust, il caso Avastin-Lucentis ed i farmaci off-label*, in *Rivista Italiana di Medicina Legale*, 2014, pp. 779-791.

⁵⁴ *Ibid.*, p. 789, where the procedure is defined as an instrument of commercial control («da strumento di controllo scientifico dell’appropriatezza clinica [a] (anche forse in maniera preponderante) strumento di controllo commerciale»).

the same relevant market⁵⁵. For these reasons, the request for preliminary ruling submitted to the Court of Justice by the Italian administrative Supreme Court appears a safe move in order to shed light not only on the merits of the case at issue, but more generally to provide guidance for future antitrust cases in the pharmaceutical sector.

Moreover, the ICA *Roche-Novartis* decision offers a further interesting ground to take into account for future cases on restrictive agreements in the pharmaceutical sector. Even though the Authority structured its reasoning on a by object benchmark, it nonetheless performed the evaluation of the actual effects of the agreement as an element to be employed for setting appropriate fines. As some commentators have pointed out, this may also ensure effectiveness for the subsequent judicial review of the merits of the case, to the extent that it does not need to «focus on the details of the economic quantification of the effects of the conduct, which might be subject to a significant degree of dispute but ultimately are not a constituent element of the finding of the abuse»⁵⁶.

⁵⁵ This aspect is particularly stressed by G. GUERRA, *La commercializzazione dei farmaci a confronto con gli usi off-label: il difficile bilanciamento tra tutela della salute e concorrenza*, in *Politiche sanitarie*, 2014, pp. 99-108; J. KILLICK, P. BERGHE, *Pharmaceutical Sector: Can Non-Authorised Products be Included in the Relevant Market for the Assessment of an Alleged Anti-competitive Conduct? A Short Analysis of the Recent Italian Avastin-Lucentis Decision*, in *Journal of European Competition Law & Practice*, 2015, pp. 102-109; M. COLANGELO, *Il caso Avastin-Lucentis: violazione antitrust o regulatory failure?*, in *Rivista di Diritto Industriale*, 2016, II, pp. 227-230. On the definition of relevant market in the pharmaceutical sector see, more in general, M. GRANIERI, *Alcune considerazioni su inibitoria cautelare, danno e mercato rilevante nell'antitrust farmaceutico*, in *Danno e responsabilità*, 2007, pp. 858-865, especially at pp. 862-865; among US commentators, G. FARAH, L. ALEXANDER, *Prominent market definition issues in pharmaceutical antitrust cases*, in *30 Antitrust*, Fall 2015, pp. 46-49.

⁵⁶ As underlined by F. ARENA, R. CHIEPPA, *Italy – The Intersection between Competition Law and Intellectual Property Law: The Public Enforcement Approach Followed by the ICA*, in G. PITRUZZELLA, G. MUSCOLO (eds.), *Competition and Patent Law in the Pharmaceutical Sector*, cited above, pp. 239-252, at p. 251.

3.2. THE INTERFACE BETWEEN COMPETITION AND PATENT LAW AS APPLIED TO ABUSE OF DOMINANCE CASES: PROBLEMATIC ISSUES

The case law examined in the second chapter raises several questions with regard to abusive conducts falling within the meaning of Art. 102 TFEU and Section 2 of the Sherman Act. Here an attempt will be made to evaluate these from a more critical perspective.

Preliminarily, it is worth underlining that the anticompetitive conducts previously analysed in this regard seem to share atypical and sector-specific features as opposed to other practices that have traditionally been deemed to constitute abuses of dominance (just to name a few: excessive or unfair prices, predation, margin squeeze, tying, etc.). Indeed, in some cases they are exclusionary practices that may be found lawful under other branches of law – especially, insofar as is here relevant, IP laws⁵⁷ – and such circumstance adds a further level of complexity (and also uncertainty) to the antitrust scrutiny. The question, which in the early debates on the problematic intersection between IP and antitrust did not even appear conceivable, thus becomes to establish to what extent competition law enforcement applies in order to counter potential failures or shortcomings of the patent systems and to pursue the fundamental goals of maintaining a competitive market and ensuring consumer welfare.

In such a context, the traditional distinction between existence and exercise of patent rights⁵⁸ no longer seems relevant, in that the unilateral conducts in question directly involve the right to patent protection, especially as concerns the so-called follow-on or second-generation drugs. This is a crucial issue within the broader framework of the pharmaceutical industry, which lies at the very centre of the patent/antitrust interface. The competitive dynamics between blockbuster drugs and

⁵⁷ For an overview, see M. DE LA MANO, R. NAZZINI, H. ZENGER, *Specific abusive practices in Relation to IP Rights*, in J. FAULL, A. NIKPAY (eds.), *Faull & Nikpay: The EU Law of Competition*, cited above, pp. 490-512.

⁵⁸ See *supra*, Chapter one, Section 1.2.

their generic competitors following the patent cliff, whereby the former experience a considerable price drop⁵⁹, make it all the more evident that the development of said follow-on products becomes a key factor in the strategies of “evergreening” pharmaceutical patents. Although the activity of patent filing for such products may well be encompassed within the statutory scope of the protection conferred by IP laws, the above-mentioned *AstraZeneca*, *Servier*, *TriCor*, *Namenda* and *Pfizer* cases have blazed a trail in subjecting this conduct to scrutiny under the competition law standard of abuse of dominance/monopolisation⁶⁰.

Just to briefly recall the respective factual backgrounds, in the first European case the anticompetitive practice consisted in the selective deregistration of the first-generation product⁶¹ combined with the switch to a new drug formulation, while in the second one the relevant conduct was the IPRs’ acquisition from another API producer that removed a potentially enabling source of competition; the

⁵⁹ According to the Commission’s Inquiry, in case of generic entry an average price drop of 20% is observed after the first year following loss of exclusivity of the brand product, and about 25% after two years: see *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, para. 212, available at <http://ec.europa.eu/competition>.

⁶⁰ Essentially, as the Court of Justice effectively expressed in *AstraZeneca*: «the illegality of abusive conduct under Article 82 EC is unrelated to its compliance or non-compliance with other legal rules and, in the majority of cases, abuses of dominant positions consist of behaviour which is otherwise lawful under branches of law other than competition law» (Court of Justice, judgment of 6 December 2012, case C-457/10 P, *AstraZeneca AB, AstraZeneca plc v. European Commission*, EU:C:2012:770, para. 132).

⁶¹ It is however to be considered that the factual circumstances of the *AstraZeneca* case will not likely occur again in practice, as the Directive 65/65/EEC has been repealed by the Directive 2001/83/EC and, even before the legislative amendment, the CJEU in 2003 held that it was not required, for generic undertakings to obtain MA by means of the abridged procedure, that the reference medicinal product still be sold on the market (Court of Justice, judgment of 16 October 2003, case C-223/01, *AstraZeneca A/S v Lægemiddelstyrelsen*, EU:C:2003:546, especially para. 27). Consequently, a strategy of deregistration as implemented by *AstraZeneca* would not have impeded an abridged application for MA. See further J. DREXL, *AstraZeneca and the EU sector inquiry: when do patent filings violate competition law?*, in J. DREXL, N. LEE (eds.), *Pharmaceutical Innovation, Competition and Patent Law. A Trilateral Perspective*, Cheltenham-Northampton, 2013, pp. 290-322, at p. 291 f.

two US cases dealt with practices falling under the meaning of product hopping; and the Italian case addressed the filing of a divisional patent and the related SPCs that served to align patent protection throughout European countries, as well as the application for a paediatric extension that granted an additional period of exclusivity.

The common line of reasoning in these decisions has led to ascertaining a *quid pluris* that serves as a distinguishing factor between a lawful entitlement to a patent right and its abuse: in sum, it was the finding that the above-mentioned conducts were not pursuing a legitimate aim of protecting an investment, *i.e.* they could not be regarded as «competition on the merits»⁶². Or even, as the Italian administrative supreme court stated in *Pfizer*, these conducts fell within the meaning of the general notion of «abuse of rights», of which the abuse of dominant position constitutes a specification⁶³. Some further points are however to be noted with regard to EU and US case law.

AstraZeneca and *Pfizer* shared an approach that ultimately brought enforcement authorities and courts to establish a “deviation” from the exercise of rights granted by the respective regulatory frameworks, which could not be explained

⁶² The literature has indeed extensively commented on the significant reach of this body of case law: among others, see M. SIRAGUSA, *The EU Pharmaceutical Sector Inquiry. New Forms of Abuse and Article 102 TFEU*, in G. CAGGIANO, G. MUSCOLO, M. TAVASSI (eds.), *Competition Law and Intellectual Property. The European Perspective*, Alphen aan den Rijn, 2012, pp. 177-190; A. MUSELLI, *La difficile riconciliazione del diritto della proprietà intellettuale e del diritto della concorrenza: note a margine dei casi AstraZeneca e Pfizer*, in *Concorrenza e mercato*, 2013, pp. 759-778; J. DREXL, *AstraZeneca and the EU sector inquiry*, cited above; H. ULLRICH, *Strategic patenting by the pharmaceutical industry: towards a concept of abusive practices of protection*, in J. DREXL, N. LEE (eds.), *Pharmaceutical Innovation, Competition and Patent Law*, cited above, pp. 241-272; M. COLANGELO, *Concorrenza sui meriti, regolazione di settore e condotte abusive nel mercato farmaceutico*, in *Foro italiano*, 2014, III, cc. 514-518; G. PITRUZZELLA, *Life-Cycle Management Strategies in the Pharmaceutical Patent Sector*, in G. PITRUZZELLA, G. MUSCOLO (eds.), *Competition and Patent Law in the Pharmaceutical Sector*, cited above, pp. 74-84.

⁶³ Consiglio di Stato, judgment of 12 February 2014, No. 693, para. V), C). Due to the limited purposes of this inquiry, for a thorough assessment of the concept of abuse of rights in its various application see, in the Italian literature, G. VISINTINI (ed.), *L'abuso del diritto*, Napoli, 2016; F. PIRAINO, *Il divieto di abuso del diritto*, in *Europa e diritto privato*, 2013, pp. 75-173.

but for the purpose of extending the exclusionary rights to the detriment of generic competitors. More precisely, in the European case, the deregistration of the first-generation drug (the originator's second abuse) neither sufficiently referred to the grounds of pharmacovigilance⁶⁴, nor was justified by other valid economic reasons. In the Italian case, the element that appeared most at odds with the usual trends of patent filings in the pharmaceutical sector was the timing of the request of the divisional patent, which was actually filed at a much later stage in relation to the R&D activity⁶⁵ carried out on the dosage of the API claimed in such an application. Indeed, this invention had been marketed in the form of Pfizer's brand drug Xalatan since long before the divisional patent was even granted, with the consequence that the request for the divisional patent could only be explained as a means to obtain additional SPC protection to which it would not otherwise be entitled⁶⁶.

Servier instead dealt with a different conduct, *i.e.* the acquisition of patents and patent applications from a competitor that had been pursuing the activity of inventing around the originator's patent and appeared to have developed a non-infringing API. The anticompetitive character of such technology acquisition was found in the absence of any further development of those IPRs by the originator, thus resulting in a mere defensive mechanism rather than an improvement of its production processes.

On the other hand, the US courts in *TriCor* and *Namenda* concluded that, in the context of product reformulations, neither product withdrawal nor product im-

⁶⁴ As to the suspension or revocation of MA, the Directive 65/65/EEC explicitly referred to cases «where that product proves to be harmful in the normal conditions of use, or where its therapeutic efficacy is lacking, or where its qualitative and quantitative composition is not as declared» (Art. 11).

⁶⁵ This is in fact the relevant benchmark to assess the lawfulness of the conduct under Art. 102 TFEU: cp. H. ULLRICH, *Strategic patenting by the pharmaceutical industry*, cited above, p. 265.

⁶⁶ In this regard the literature criticising the finding of abuse pursuant to Art. 102 TFEU has argued that even if the originator had applied for the SPC in Italy at the same time than in the other Member States, the exclusionary effect towards generic competitors would have been the same (C. OSTI, *The Italian way to antitrust judicial review: a few oddities of the Pfizer case*, in *Italian Antitrust Review*, 2014, No. 3, pp. 129-130).

provement were alone capable of raising competition law concerns, but it was the combination – undertaken by monopolist firms – of introducing a follow-on drug *and* withdrawing the first-generation drug from the market (a so-called “hard switch”) that produced the overall effect of consumer coercion and market foreclosure.

These elements, which share the common background of a departure from the standard of competition on the merits, do not seem however to constitute solid arguments to maintain a finding of abuse with a sufficient degree of certainty. As has been pointed out, the conducts at issue also depend, at least in part, upon the intention of the dominant originators to exclude their competitors from the market⁶⁷. This subjective element appears too unpredictable, and may also require an excessive burden of proof that could in some cases prove difficult to bear for enforcement authorities and courts⁶⁸. Similarly, the evidence required to establish that a certain patent strategy pursued by an undertaking did not make actual economic sense but for its capability to impair competition would entail a complex assessment in practice, and in some instances could also run the risk of underdeterrence⁶⁹. In other words, even though the standard adopted in these cases led to reasonably affirm the antitrust liability of the dominant originators, they nevertheless seem to possess a certain “artificial” character that does not ensure their relevance also under different factual circumstances.

By contrast, the application of standards that, although related to the broad concept of competition on the merits, also possess an additional sector-specific character, seems better attuned to support the antitrust scrutiny in relation to prac-

⁶⁷ See M. SIRAGUSA, *The EU Pharmaceutical Sector Inquiry. New Forms of Abuse*, cited above, p. 185.

⁶⁸ On this aspect see C. OSTI, *What Is in a Name: The Concept of Abuse in Sui Generis Abuse*, in G. PITRUZZELLA, G. MUSCOLO (eds.), *Competition and Patent Law in the Pharmaceutical Sector*, cited above, pp. 93-106, at pp. 100-101.

⁶⁹ More generally, on the difficulties to structure the assessment under Art. 102 TFEU see for example R. O'DONOGHUE, *Verbalising a General Test for Exclusionary Conduct under Article 82 EC*, paper delivered at the 12th Annual Competition Law and Policy Workshop, 8-9 June 2007, EUI, Florence, available at www.eui.eu.

tices that may be found lawful under other branches of law. These benchmarks would properly consider the conditions of a regulated market that is not fully competitive, as is the case with the pharmaceutical industry. For example, by taking into account whether a certain strategic patenting pursued the aim of channeling the capability to innovate solely towards the dominant undertaking to the detriment of competition by substitution, a more intense antitrust inquiry into the field of patent law would appear justified to ensure market conditions that are sufficiently open to new sources of competition⁷⁰. As has been underlined, it is the «regulatory interoperability»⁷¹ created by the originator that has undermined the possibility for generic manufacturers of market entry, thus precluding patients from benefitting from a competing drug.

By the same token, in a product hopping case the substantial anticompetitive nature of such conduct would not depend on whether the originator performed a “soft” or a “hard switch” between first- and second-generation drugs (*i.e.* with or without the withdrawal of the first product from the market), but rather on whether the move of the prescription base from one drug to the other is successful before the generic entry into the market. This is in fact the clinching factor that properly considers the regulatory framework of the pharmaceutical market, where there is a disconnection between the choice, the payment and the intake of a given prescription drug⁷². When such an effect is achieved, the product hop has ultimately impaired competition by substitution, in that the absence of prescriptions for which the generic can automatically be substituted deprives consumers of the possibility to make the relevant choice.

⁷⁰ Among those who support this view, see C. DESOGUS, *Nuove frontiere tra regolazione, proprietà intellettuale e tutela della concorrenza nel settore farmaceutico: le pratiche di brevettazione strategica*, in *Rivista della Regolazione dei mercati*, 2015, No. 1, pp. 59-96.

⁷¹ The effective wording is by C. DESOGUS, *Nuove frontiere tra regolazione, proprietà intellettuale e tutela della concorrenza nel settore farmaceutico*, cited above, p. 93.

⁷² In this regard see M.A. CARRIER, S.D. SHADOWEN, *Product Hopping: A New Framework*, cited above. For a European perspective also B. DOMEIJ, *Anticompetitive marketing in the context of pharmaceutical switching in Europe*, in J. DREXL, N. LEE (eds.), *Pharmaceutical Innovation, Competition and Patent Law*, cited above, pp. 273-289.

Moreover, these sector-specific standards would explain why the counterargument that the technological progress on the relevant market could in any case be ensured by the originator company does not appear convincing. Indeed, it is precisely the plurality of sources of innovation coming from the coexistence of both originators *and* generics competing on the market that is able to overcome the “market failures” characterising the pharmaceutical industry⁷³, where the competition in innovation (*i.e.* by investing in R&D) does not develop at the same rate and capacity as other non-regulated sectors. Consequently, when the right to patent protection itself, as well as its exercise, are used as a means to hold up (or to remove) potential sources of innovation, so as to restrict dynamic competition, a heightened antitrust scrutiny not only becomes justified, but necessary to compensate for the patent systems’ own shortcomings.

These considerations may furthermore provide a valuable background against which to assess a different, and still relatively unexplored, aspect of defensive patent strategies, namely that involving competition in innovation between originator companies. The Commission’s Sector Inquiry has only touched upon the issue⁷⁴, so how competition law may face a restrictive conduct that aims at excluding potential entrants into a non-existing market, that occurs «when the relevant technology or product markets are still to emerge», remains relatively unex-

⁷³ More precisely, MA and drug pricing procedures that affect the rate of entry of new products into the market, high costs for pharmaceutical R&D, inelasticity of the demand due to the price disconnect (see *supra*, Chapter one, Sections 2.1 and 2.2).

⁷⁴ *Pharmaceutical Sector Inquiry Final Report*, cited above, paras. 1090-1144. The main findings are summarised in the *Executive summary of the Pharmaceutical Sector Inquiry Report*, COM(2009) 351 final of 8 July 2009, para. 4.1, p. 19, available at <http://ec.europa.eu/competition>, where the Commission adopts a general commitment for future investigations: «[w]ith regard to competition between originator companies in particular, defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts and/or the refusal to grant a license on unused patents will remain under scrutiny in particular in situations where innovation was effectively blocked».

plored⁷⁵. In such an instance, it becomes clear that the usual toolbox of competition law enforcement may fall short, especially as regards Art. 102 TFEU in that it requires, in principle, an undertaking with a market-dominant position. Although any guidance from case law and practice is still lacking⁷⁶, the issue is actually not merely theoretical given the significant downtrend in the entry of innovative drugs as opposed to a steady increase in R&D and patenting activities.

By taking into account the above-mentioned standard of dynamic competition, it is indeed possible to argue that even a patent-related unilateral conduct occurring outside the market, which is able to reduce other originators' incentive for innovation, amounts to a position of economic strength that falls within the meaning of the well-known CJEU definition of dominant position as «the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of the consumers»⁷⁷. Again, it is the harm brought to other sources of innovation, even where a defined relevant market has not yet emerged, that leads to the conclusion of an anticompetitive infringement in terms of abuse of a (*sui generis*) dominant position⁷⁸, with the result that not every R&D-based rivalry be-

⁷⁵ J. DREXL, *Anticompetitive stumbling stones on the way to a cleaner world: protecting competition in innovation without a market*, in *Journal of Competition Law & Economics*, 2012, pp. 507-543, at p. 529.

⁷⁶ To date, the only EU investigation on alleged anticompetitive conducts between originators has been the Boehringer Ingelheim case (case COMP/39246 – *Boehringer*, initiated by the Commission decision of 22 February 2007), in which said pharmaceutical company was deemed to have filed for unmeritous patents regarding lung cancer drugs that would have potentially blocked the market entry of Almirall's competing brand product. The parties later concluded a settlement agreement that addressed the antitrust concerns and the Commission closed the case in 2011 (see press release IP/11/842, available at <http://europa.eu/rapid>). The facts, however, referred in any case to a situation where the originators were competing in an already existing market, namely that of treatments of chronic obstructive pulmonary disease (COPD).

⁷⁷ Court of Justice, judgment of 13 February 1979, case 85/76, *Hoffmann-La Roche & Co. AG v. Commission of the European Communities*, EU:C:1979:36, para. 38.

⁷⁸ In this regard, see the insightful comments by A. PEZZOLI, *Originators versus Originators: Competition before the Market and Market Power beyond Dominance*, in G. PITRUZZELLA, G. MUSCOLO (eds.), *Competition and Patent Law in the Pharmaceutical Sector*, cited above, pp. 31-42, especially at pp. 36-38.

tween originators would raise competition law concerns, but only insofar as the patent strategy is pursued without any innovative efforts.

A different set of considerations are here proposed with regard to the other abusive practices that have been analysed in the previous chapter, namely the misleading (or even false) representations made by originator companies in the context of administrative patent-filing procedures before the competent authorities. In this regard, as will be recalled, the first abuse in *AstraZeneca* and the US *Buspirone* case are particularly instructive⁷⁹.

This issue touches upon the broader framework of vexatious litigation, and its US equivalent of sham litigation⁸⁰. These two doctrines share the common background of condemning abusive litigation before administrative or judicial authorities that has no reasonable grounds of success, but it is pursued as an anticompetitive practice. As opposed to the above-mentioned atypical conducts falling within the meaning of Art. 102 TFEU (and Section 2 of the Sherman Act), it is a conduct that finds its basis on an abuse of procedure and, from a general viewpoint, it has been rarely referred to and applied in the context of antitrust litigation. Indeed, as far as EU case law is concerned, this kind of abuse has occurred only in one case, *ITT Promedia*⁸¹. Here the Court of First Instance adopted a particularly narrow approach in order to establish a finding of abuse under Art. 102 TFEU, by holding that «only wholly exceptional circumstances»⁸² are required thereto. More pre-

⁷⁹ Also in the Italian *Pfizer* case, one of the alleged anticompetitive conducts concerned a number of baseless disputes brought by the originator against the generic competitors. However, insofar as such aspect did not play an essential role in the finding of the infringement under Art. 102 TFEU, the case will not be referred to in this further context.

⁸⁰ For a comprehensive overview of the issue see V. GUIMARÃES DE LIMA E SILVA, *Sham Litigation in the Pharmaceutical Sector*, in *European Competition Journal*, 2011, pp. 455-503; S. VEZZOSO, *Towards an EU Doctrine of Anticompetitive IP-Related Litigation*, in *Journal of European Competition Law & Practice*, 2012, pp. 521-535; G. MUSCOLO, *Abuse of Litigation, Abuse of Patent and Abuse of Dominance: Where Do We Stand?*, in G. PITRUZZELLA, G. MUSCOLO (eds.), *Competition and Patent Law in the Pharmaceutical Sector*, cited above, pp. 107-124.

⁸¹ Court of First Instance, judgment of 17 July 1998, case T-111/96, *ITT Promedia NV v Commission of the European Communities*, EU:T:1998:183.

⁸² *Ibid.*, para. 60.

cisely, it upheld the Commission decision and ruled that an abuse may only be found «where an undertaking in a dominant position brings an action (i) which cannot reasonably be considered as an attempt to establish its rights and can therefore only serve to harass the opposite party, and (ii) which is conceived in the framework of a plan whose goal is to eliminate competition'»⁸³.

The narrow view taken by the EU court parallels the ground of antitrust immunity laid down in the US *Noerr-Pennington* doctrine, which covers the right to petition the government granted by the First Amendment of the US Constitution⁸⁴. However, there is also an essential difference between the two legal systems, in that in the EU the fundamental right to access to court does not amount to granting competition law immunity. Rather, the abusive resort to litigation is directly subject to antitrust scrutiny under Art. 102 TFEU, without the need to previously overcome any ground of immunity.

Both doctrines are furthermore characterised by a determining role of intent, namely the aim to impair competition, which ultimately does not fit properly into competition law standards. As explained above with regard to other kinds of abusive conducts, it appears in fact more appropriate to refer to objective criteria, and even more to sector-specific benchmarks, in order to ground a finding of abuse of dominant position. This has indeed been the solution preferred by the General Court in *AstraZeneca* when assessing the first abuse. Indeed, following the reasoning of the Commission in its decision, it distinguished the conduct at issue from a case of vexatious litigation, confirming not only the narrow interpretation already established in *ITT Promedia*, but also focusing on the objective nature of the concept of abuse of dominant position⁸⁵.

⁸³ *Ibid.*, para. 30.

⁸⁴ For further references on *Noerr-Pennington*, as well the related *Walker-Process* exception, see *supra*, Chapter two, Section 2.2.2. For a comprehensive comparison between the EU and the US approaches see S. GALLASCH, *AstraZeneca v the Walker Process—A real EU-US divergence or just an attempt to compare apples to oranges?*, in *European Competition Journal*, 2011, pp. 505-526.

⁸⁵ General Court, judgment of 1 July 2010, case T-321/05, *AstraZeneca AB, AstraZeneca plc v. European Commission*, EU:T:2010:266, paras. 356-363.

3.3. THE COMBINED IMPACT OF PATENT SETTLEMENTS AND PRODUCT REFORMULATIONS: A NEW ENFORCEMENT PERSPECTIVE

This section of the critical assessment tries to shed light on a new dimension of antitrust scrutiny into the pharmaceutical industry, which, as far as EU case law is concerned, has been evaluated (albeit partially) only in the context of the *Servier* case. Namely, it is the use of reverse payment settlements as a means of pursuing an anticompetitive switch to a follow-on brand drug, with the result that the combined conduct in question infringes both Art. 101 and Art. 102 TFEU. Even though the mentioned case is still ongoing, as the Commission decision is under appeal before the EU General Court, it is still possible to set out some considerations also taking into account the points already made in the previous sections.

For the sake of clarity, a brief review of the relevant facts in *Servier* seems appropriate⁸⁶. The originator had set up a broad defensive strategy of its patented API, perindopril, that encompassed several conducts: filing a patent cluster, raising technical entry barriers, acquiring alternative, non-infringing technologies and accompanying IPRs, settling patent disputes with the most advanced generic competitors and selectively switching to its patented second-generation product. For the purposes of the present inquiry, the most relevant of them are the technology acquisition and the patent settlement agreements, in that they block the two viable options to launch a generic product into market when the brand drug is still patent-protected. Their anticompetitive character lay in the fact that, on the one hand, Servier never made use of the acquired technology in its R&D activities, and, on the other hand, it concluded the agreements to settle patent disputes with each of the most advanced competitors who posed an actual threat to its market power. Indeed, as will be recalled, these two conducts, taken together, constituted

⁸⁶ For more details see *supra*, Chapter two, Section 2.2.1.

«a single and continuous exclusionary strategy»⁸⁷ infringing Art. 102 TFEU in addition to the separate liability under Art. 101 and Art. 102.

The aspect that the Commission decision nevertheless appears to have failed to appreciate⁸⁸ is the further complementarity between the mentioned conducts and the ultimate goal of the exclusionary strategy, which is the development of the brand follow-on drug towards which the product demand was channelled in order to impair generic substitution. In this regard, the patent settlement agreements in fact have the potential to play a key role for the reasons proposed below⁸⁹.

As already explained, the launch of a second-generation product by an originator company does not amount to an abuse itself, as long as it does not prevent other sources of innovation from entering and competing in the relevant market. In such an instance, where the follow-on drug coexists with generic entry into the market, the consumer (even taking into account the sector-specific price disconnect) may still make its own choice on the basis of the innovative features of the product and its price. Consequently, even the switch of the prescription base is not likely to be substantially successful as it would be in the absence of generic competition.

In this context, however, should the originator enter into a reverse payment settlement with the most advanced sources of competition in order to plan the switch of the prescription base to its second-generation product while resting assured that generic undertakings would not pose any competitive threat, it is all the more evident that this conduct may raise the most serious antitrust concerns. Indeed, by means of the agreement the brand company is able to perform a switch from its

⁸⁷ Commission decision of 9 July 2014, case AT.39612, *Perindopril (Servier)*, paras. 2961-2998.

⁸⁸ As the literature has indeed pointed out: see C. DESOGUS, *Manovre di avvicinamento tra l'Europa e gli Stati Uniti*, cited above, pp. 277-278.

⁸⁹ The issue has been relatively addressed by commentators so far: see M.A. CARRIER, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, in 62 *Florida Law Review*, 2010, pp. 1009-1036; S. GALLASCH, *Adding a New Dimension to EU Pharmaceutical Antitrust – Pay for Delay Settlement as Part of a Unilateral Strategy such as Product Hopping*, in *CCP Working Papers*, 2015, No. 2, available at <http://competitionpolicy.ac.uk>.

original drug to its follow-on that has a near-certain probability of success and furthermore that takes place «at a later stage than under the normal competitive process, even after the expiry of the marketing exclusivity period»⁹⁰. Even in case of generic entry after the agreement has expired, the product demand would be ultimately directed towards the brand follow-on drug and the generic product would not exert any effective competitive pressure on the first-generation product (should it still be marketed).

One could object that such an agreement may well amount to a legitimate legal tool to protect IPRs and R&D investments from generic competition prior to patent expiry⁹¹. Nevertheless, as already mentioned with regard to the separate assessment of patent settlement, it is the substantial transfer of value flowing from the brand company to the generic manufacturer that distinguishes the agreement and triggers the “inference” of its anticompetitive nature.

In sum, the framework resulting from a combination of reverse payment settlement and product hopping would be as follows: the originator would benefit from the commitment of the generic manufacturer not to challenge its patent for a certain period of time, and additionally, even after generic entry, the originator would benefit from a lack of any viable competition given the successful switch of the prescription base to its brand follow-on drug. Moreover, the combined assessment allows the antitrust scrutiny to also be directed towards conducts that would otherwise be exempted. Even settlements that provide for the possibility for generics to enter into the market before patent expiry, which are usually not subjected to inquiry, would not produce any actual pro-competitive effect if the brand firm has previously performed a successful product hop⁹². By this time, the

⁹⁰ *Ibid.*, p. 18.

⁹¹ In a similar fashion, also the deregistration of MA for the reference product in AstraZeneca had amounted to a lawful practice under the relevant regulatory framework, but was nevertheless found to be anticompetitive to the extent that it fell outside the scope of competition on the merits insofar as it allowed the subsequent switch to the brand follow-on product. On this aspect see S. GALLASCH, *Adding a New Dimension to EU Pharmaceutical Antitrust*, cited above, p. 19.

⁹² This point is particularly stressed by M.A. CARRIER, *A Real-World Analysis of Pharmaceutical Settlements*, cited above, p. 1036.

entry of generic versions of the brand-generation product would not offer an effective competition and would not take advantage of substitution laws, thus resulting in a relevant harm to consumers.

Therefore, this appears an issue worth of further attention by enforcement authorities and courts when called upon to rule on cases involving both reverse payment settlements and practices of switching from a brand's first- to second-generation products. The capability of producing foreclosure effects on the relevant market is indeed particularly intense and it seems that only by taking into account the combined perspective of the two conducts would the antitrust scrutiny be able to evaluate the resulting anticompetitive harm to an effective extent. By contrast, in *Servier* the Commission did not seem to properly consider this causal link between the technology acquisition and the patent settlements, on the one hand, and the switch to the brand follow-on drug, on the other hand.

Moving to US case law, where in any case the phenomenon of product hopping has been tackled in several antitrust probes, the analysed decisions have not yet assessed the actual cumulative effects of pay-for-delay agreements and drug switching, which remains a key defensive strategy for brand companies. Actually, the issue appears to have been touched upon only briefly in the FTC complaint filed against Endo and other pharmaceutical companies in the *Opana ER-Lidoderm* case⁹³. As will be recalled, the action specifically tackled no-AG commitments undertaken by the originator in the context of patent settlements in exchange for the delay of generic entry into the market. With specific regard to the agreement between Endo and Impax concerning Opana ER, the originator's strategy was furthermore aimed at introducing a reformulated brand drug that would not have been subject to automatic substitution from generic versions of the first-generation product. Indeed, FTC argued that Endo already knew that «it would be unable to obtain FDA approval for its Reformulated Opana ER and convert the market *before* Impax could enter with its generic version of Original Opana ER»,

⁹³ *F.T.C. v. Endo Pharmaceuticals Inc. et al.*, Case No. 2:16-cv-01440-PD filed on 30 March 2016 (E.D. Pa.).

and thus it was its precise purpose to «purchase *the time it needed*»⁹⁴ by entering into the reverse payment agreement and paying off the generic competitor to stay out of the market. When assessing the harm to consumers caused by the settlement at issue, the FTC moreover stated that such agreement facilitated Endo's strategy to transition from its first- to second-generation drug to the extent that the prescription base was successfully switched before Impax could enter into the market in 2013. As a result, its generic product did not fall within the scope of application of state substitution laws and was able to capture only a residual share of the relevant market⁹⁵.

As already mentioned, the charges brought against Endo were recently settled, with the originator committing to refrain from concluding similar reverse payment agreements for ten years. Thus no court specifically addressed the claim regarding the link between the Opana ER settlement and the product hop. This case nonetheless shows a continuous effort by the US enforcement agency towards an effective antitrust scrutiny into anticompetitive patent strategies.

⁹⁴ *Ibid.*, at 59 (emphasis added).

⁹⁵ *Ibid.*, at 163-164.

FINAL REMARKS

THE PHARMACEUTICAL INDUSTRY BETWEEN COMPETITION, PATENT LAW AND REGULATION

After having assessed the state of play and the current developments in the case law regarding the interface between competition and patent law in the pharmaceutical sector, here an attempt will be made to propose some broader considerations regarding the overall balancing of interests underlying the industry in question.

As mentioned above, the pharmaceutical market belongs to those industrial sectors where regulation plays an essential role in defining their features. In this regard, patent law constitutes an integral part of its regulatory framework, aiming at driving innovation and competitiveness through granting exclusionary rights to compensate the high investments in R&D incurred by pharmaceutical companies.

Beside regulation, however, the interference of competition law as a further “presence” within the said industry has progressively amplified, reaching significant lengths in recent times. As both EU and US case law have shown, the traditional opinion supporting a reciprocal autonomy between competition and patent law has ultimately been superseded by a growing complementarity of the two sets of law. Indeed, it can be argued that antitrust now defines, together with patent law, the boundaries of the scope of a patent by preventing the exclusionary rights granted by the latter to be procured and exercised in a way that leads to foreclosure effects on the relevant market. In this regard, *AstraZeneca*¹ and *Actavis*² well

¹ As will be recalled, especially relevant is the already mentioned passage of the decision: « the fact that, in the light of its special responsibility, an undertaking in a dominant position cannot make use of [the] possibility [of deregistering a MA] in such a way as to prevent or render more difficult the entry of competitors on the market, unless it can, as an undertaking engaged in competition on the merits, rely on grounds relating to the defence of its legitimate interests or on objective justifications, does not constitute either an ‘effective expropriation’ of such a right or an obligation to grant a licence, but a straightforward restriction of the options available under European Union law» (Court of Justice, judgment of 6 December 2012, case C-457/10 P, *AstraZeneca AB, AstraZeneca plc v. European Commission*, EU:C:2012:770, para. 149).

summarise the current stance of competition law towards the pharmaceutical patent system: a not-so-veiled preference towards the enhancement of antitrust scrutiny into the realms of patent law as a means to counterbalance the failure of the latter to pursue its pro-competitive purposes. Some further thoughts on the possible grounds of this change of mind-set therefore seem appropriate.

It has been argued that the strengthened role of competition may find its background in the developing trend considering the promotion of consumer welfare as the primary goal of this field of law³. In particular, such an aspect would be able to overcome the other objective of protecting the process (or structure) of competition itself by employing an approach that is more outcome/effect-oriented⁴, namely that is based on the actual economic effects of the considered practices, rather than their form. The European Commission's modernisation initiative has

² In this regard, see the following passage of the Supreme Court judgment: «patent and antitrust policies are both relevant in determining the “scope of the patent monopoly”—and consequently antitrust law immunity—that is conferred by a patent» (*F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), at 2231).

³ In this regard R. CAFARI PANICO, *Concorrenza, benessere del consumatore e programmi di compliance. Nuove tendenze*, in AA.VV., *Scritti in onore di Giuseppe Tesauro*, vol. II, Napoli, 2014, pp. 1473-1503. More generally, among others, also K.J. CSERES, *The Controversies of the Consumer Welfare Standard*, in *The Competition Law Review*, 2007, No. 2, pp. 121-173; G. AMATO, F. DENOZZA, H. SCHWEITZER, A. NICITA, D. STALLIBRAS, *Tutela della concorrenza e tutela dei consumatori. Due fini confliggenti?*, in *Mercato concorrenza regole*, 2009, pp. 381-400; V. DASKALOVA, *Consumer Welfare in EU Competition Law: What Is It (Not) About?*, in *The Competition Law Review*, 2015, No. 1, pp. 131-160.

⁴ The debate regarding the different objectives of competition law has indeed been a traditional topic among scholars, and cannot be here reviewed in its complexity. In a nutshell, two economic theories have been proposed, originally in the US, but soon followed also in the EU: the Harvard School (e.g. D.F. Turner, P. Areeda), which presumed the illegality of any conduct aimed at obtaining, enhancing or exercising market power, and the Chicago School (e.g. R. Bork, R. Posner), which instead required an extensive factual inquiry into the effects of a given conduct on consumers to ground a finding of illegality. For further comments see H. HOVENKAMP, *The Harvard and Chicago Schools and the Dominant Firm*, in *University of Iowa Legal Studies Research Papers*, 2010, No. 19, available at <http://papers.ssrn.com>; with regard to the EU legal order, P. MANZINI, *The Goals of EU Competition Law*, in B. CORTESE (ed.), *EU Competition Law. Between Public and Private Enforcement*, Alphen aan den Rijn, 2014, pp. 21-33.

indeed supported said view, by increasingly introducing the reference to consumer welfare in its guidance papers and notices⁵, but over time it has also preferred to formulate such a concept in the broader terms of positive effects as regards price, quality and choice⁶. EU case law has followed a similar path, albeit generally expressing in more cautious terms. The *Post Danmark I* judgment offers a relevant example, as the Court of Justice, with regard to Art. 102 TFEU, held that it «applies, in particular, to the conduct of a dominant undertaking that, through recourse to methods different from those governing normal competition on the basis of the performance of commercial operators, has the effect, *to the detriment of consumers*, of hindering the maintenance of the degree of competition existing in the market or the growth of that competition»⁷. Moving to a case pertaining specifically to the pharmaceutical industry, the ICA's decision in *Roche-Novartis* best illustrates such an approach. The Authority evaluated the strategy undertaken by the two originator companies in relation to the higher costs incurred by the

⁵ See Communication from the Commission, *Guidelines on the application of Article 81(3) of the Treaty*, OJ C 101 of 27 April 2004, pp. 97-118, para. 13, where the objective of (now) Article 101 TFEU is presented as the protection of competition «as a means of enhancing consumer welfare and ensuring an efficient allocation of the resources»; similarly, Communication from the Commission, *Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings*, OJ C 45 of 24 February 2009, pp. 7-20, para. 19.

⁶ Particularly instructive is the Commission Regulation (EU) No. 1217/2010 of 14 December 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of research and development agreements, OJ L 335 of 18 December 2010, pp. 36-42, para. 10, where it is stated that the benefits towards consumers result in «the introduction of new or improved products or services, a quicker launch of those products or services, or the reduction of prices brought about by new or improved technologies or processes».

⁷ Court of Justice, judgment of 27 March 2012, case C-209/10, *Post Danmark A/S v. Konkurrencerådet*, EU:C:2012:172, para. 24 (emphasis added). For an in-depth analysis of the decision, see for example S. BARAZZA, *Post Danmark; The CJEU Calls for an Effect-Based Assessment of Pricing Policies*, in *Journal of European Competition Law & Practice*, 2013, pp. 466-468; F. BIEN, M. KRAH, *The Ruling of the CJEU in Post Danmark: Putting an End to Selective Price Cuts as an Abuse Under TFEU Article 102 and Turning Towards a More Economic Approach*, in *European Competition Law Review*, 2012, pp. 482-487.

Italian NHS (and, consequently, by the patients as final users) as a result of the alleged product differentiation carried out between the registered use of the higher-priced drug (Lucentis) and the off-label use of the lower-priced drug (Avastin)⁸.

A specific inquiry into the reasons underlying this change of policy perspective would fall outside the more limited scope of these concluding remarks. Nonetheless, insofar as here relevant, it seems that setting the focus on the anticompetitive effects from the viewpoint of consumer welfare may be capable of drawing competition law closer to regulation, to the extent that the former pursues the further regulatory purpose of defining economic policy objectives in light of what is most beneficial to consumers⁹. As a result, the well-known distinction between regulation, considered as the *ex ante* activity laying down the rules governing the markets, and competition, understood as the *ex post* enforcement of those rules, may progressively lose its meaning¹⁰.

The question thus becomes whether antitrust enforcers are indeed properly equipped to carry out such tasks, especially in regulated sectors – such as the pharmaceutical industry – where governments have established public agencies with the precise aim of providing an autonomous control of the market. Again, the ICA's *Roche-Novartis* decision may serve as a good example to this end. In that case, as has been stressed by some commentators¹¹, the antitrust authority ap-

⁸ See *supra*, Chapter two, Section 2.1.3.

⁹ R. CAFARI PANICO, *Concorrenza, benessere del consumatore e programmi di compliance*, cited above, p. 1477-1478.

¹⁰ The literature has extensively commented upon this relationship. Among recent works, see J.C. LAGUNA DE PAZ, *Regulation and competition law*, in *European Competition Law Review*, 2012, pp. 77-83; R. PARDOLESI, A. PALMIERI, *Sull'interfaccia (problematica) fra regolazione economica e disciplina della concorrenza*, in *Foro italiano*, 2012, III, pp. 493-496; N. DUNNE, *Between competition law and regulation: hybridized approaches to market control*, in *Journal of Antitrust Enforcement*, 2014, pp. 225-269; G. PITRUZZELLA, *Concorrenza e regolazione*, in *federalismi.it*, 2014, No. 22, available at www.federalismi.it; J. DREXL, F. DI PORTO (eds.), *Competition Law as Regulation*, Cheltenham-Northampton, 2015.

¹¹ See S. SILEONI, *Caso Avastin/Lucentis. La regolazione del commercio dei farmaci, tra tutela della salute e vincoli di spesa pubblica*, in *IBL Briefing Papers*, 2014, No. 141, pp. 9-15, available at www.brunoleonimedia.it; J. KILLICK, P. BERGHE, *Pharmaceutical Sector: Can Non-Authorised*

peared to have overcome its statutory limits by reviewing the choices of the regulatory agencies (namely, EMA and AIFA) as regards the therapeutic safety of the unregistered use of Avastin. The substitutability between registered Lucentis and off-label Avastin, which the competent authorities had not endorsed, was in fact the ground on which the ICA built its notion of relevant market, and consequently its finding of restriction of competition pursuant to Art. 101 TFEU.

Moreover, this overlap between competition law and regulation calls into question whether the former should be more broadly underpinned by socioeconomic aims such as ensuring general accessibility to certain goods and services, among which pharmaceutical products may well stand in the forefront.

Such a trend, however, may also be read from another perspective. Indeed, one could consider that strong active ingredient patents are gradually losing importance among the key drivers of the pharmaceutical market¹². The widespread practice of ancillary patents (also known as “weak” patents) granted for chemical variants, alternative formulations, and different dosages, which make up a web of overlapping claims around the compound patents, is thus leading to frequent challenges and infringement disputes between brand firms and generic manufacturers and, in the long term, to a steady slowdown of innovation and technological progress. This slowdown also results from the difficulties encountered by patent offices, as they are required to evaluate hundreds of thousands of applications per year in a resource-constrained situation¹³. A similar scenario would thus call for a more intense activity by antitrust enforcement authorities, in a sort of inversely

Products be Included in the Relevant Market for the Assessment of an Alleged Anticompetitive Conduct? A Short Analysis of the Recent Italian Avastin-Lucentis Decision, in *Journal of European Competition Law & Practice*, 2015, pp. 102-109, at pp. 106-108.

¹² For a more general inquiry see N. TUOMINEN, *An IP perspective on defensive patent strategies of the EU pharmaceutical industry*, in *European Intellectual Property Review*, 2012, pp. 541-551; as regards the US system see A.F. ABBOTT, *The evolving IP-antitrust interface in the USA—the recent gradual weakening of patent rights*, in *Journal of Antitrust Enforcement*, 2014, pp. 363-388, who particularly criticises the effects of an enhanced antitrust scrutiny.

¹³ See C.S. HEMPHILL, B.N. SAMPAT, *Weak Patents are a Weak Deterrent: Patent Portfolios, Orange Book Listing Standard, and Generic Entry in Pharmaceutical*, 2011, p. 22, available at www.nber.org.

proportional ratio between the two bodies of law. This heightened scrutiny, in particular, would be directed at assessing the right of patent holders to exercise the market power deriving from such weak patents, thus attempting to provide a counterbalance to the patent systems' own deficiencies. Hence, competition law would be able to prevent unlawfully obtained exclusionary rights being used to the detriment of other competitors, and ultimately of consumers.

Both these hypotheticals – the growing importance of consumer welfare among competition law goals and the shortcomings of the patent systems – should furthermore be viewed in the broader context underlying the pharmaceutical industry, namely referring to human rights considerations such as the access to affordable treatments and to safe and effective medicines¹⁴. As already mentioned, the sector in question has a unique nature in the sense that it touches upon further sensitive interests pertaining to all individuals, which requires enforcement authorities and courts, when called upon to strike a proper balance between competition and patent laws, to take these considerations into account.

Irrespective of which of the proposed grounds may be found more convincing, legitimate doubts arises as to whether this “interventionist” approach endorsed by competition law enforcers could be more effectively undertaken by EU and national legislators, in particular through specific acts regulating the competitive process of bringing generic drugs onto the market while preserving the incentives for originator companies to continue innovating. In this regard, the US system may provide for a qualified guidance with the already analysed Hatch-Waxman Act, which was enacted with the very purpose of favouring generic entry to the advantage of patients and insurers. At the same time, however, case law has shown the potential anticompetitive abuse of such regulatory framework arising especially (but not only) in relation to restrictive agreements concluded between originators and generic manufacturers¹⁵.

¹⁴ See *supra*, Chapter one, Section 1.3.

¹⁵ In the literature see, among others, K.E. BEHRENDT, *The Hatch-Waxman Act: Balancing Competing Interests or Survival of the Fittest?*, in 57 *Food & Drug Law Journal*, 2002, pp.247-271; J. ROSENTHAL, *Hatch-Waxman Use or Abuse – Collusive Settlements between Brand-Name and Generic Drug Manufacturers*, in 17 *Berkeley Technology Law Journal*, 2002, pp. 317-335;

It is indeed a hard task to balance the conflicting interests at stake in an objective piece of legislation, and whether the legislator will actually embark on such an ambitious project of accommodating competition into patent laws remains to be seen. In addition, the mentioned difficulties would be even more evident in a supranational context such as the EU, where the institutions should attempt to lay down regulatory procedures that apply to 28 (or, following Brexit, 27) Member States.

In light of the foregoing, it could be therefore concluded that the more intense antitrust scrutiny exercised with regard to pharmaceutical patent strategies appears to some extent justified, at least for the time being, on the grounds of maintaining a competitive market structure in a sector characterised by a relatively low level of competition in innovation (or by substitution).

By the same token, a more active approach of antitrust law towards pharmaceutical patents would serve the further purpose of contributing to patients' welfare by allowing for a timely entry of generic products, thus triggering substitution laws and the related lower costs for NHSs. This consideration, nonetheless, should not be taken to extreme consequences illustrated in the ICA's *Roche-Novartis* decision by drifting towards a form of "regulation in disguise", which does not pertain to the *ex post* enforcement of rules defined by the legislator on economic policy grounds.

L.P. NUSSBAUM, J.D. RADICE, *Where Do We Go Now? The Hatch-Waxman Act Twenty-Five Years Later: Successes, Failures, and Prescriptions for the Future*, in 41 *Rutgers Law Journal*, 2009, pp. 229-253.

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