Competition and Patent Law in the Pharmaceutical Sector
An International Perspective

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Co-marketing and Co-promotion Agreements

Enrico Adriano Raffaelli & Elisa Teti

1 INTRODUCTION

The pharmaceutical industry is of fundamental importance to human health; specifically, access to innovative, safe and affordable medicines should be available to all. In particular, the pharmaceutical sector differs from other markets in light of the characteristics of its products, the relations between the involved market agents (pharmaceutical companies, National Health System, doctors and pharmacists, patients) and the presence of a particularly rigid and complex regulatory and operating mechanism. The element that most distinguishes the pharmaceutical sector is the necessary balance that must be made between, on the one hand, the strong presence of public intervention, affecting both the supply side and the demand side, and on the other, continuous innovation, which is essential for the development of the sector.

Innovation in the pharmaceutical sector has notably allowed patients to benefit from new treatments barely conceivable in the past. To this day and age, the lack of

sufficiently adequate and effective drugs necessitates continuous investments in research and development (R&D), both by pharmaceutical companies manufacturing and marketing innovative drugs (the so-called originators), as well as by other entities such as universities and R&D centres. The pharmaceutical sector, in fact, is at the forefront in R&D in Europe, investing significantly to this effect, and relies very much on intellectual property rights to protect innovation (exclusive rights granted, for instance, by patents and certificates’ supplementary protection), which represent important incentives for the originator to continue with its investment efforts in R&D.

At the same time, attention should be paid to State intervention relative to costs imposed on the national budget, including those intended to cover health care expenditure. Competition, particularly in the generic drugs market, is considered an essential instrument to keep the State budget under control and ensure broad access to drugs in the interest of patients. Specifically, from the supply side, there may be two

2. According to the European Commission Industrial R&D Investment Scoreboard, at worldwide level, the pharmaceutical industry is the leading player as regards investments in research and development. In Italy, according to the data collected by Farmindustria, in 2014 more than 90% of the pharmaceutical R&D was financed by pharmaceutical companies, totalling to EUR 2.3 billion investment and 62,500 employees (5,950 in the R&D sector). See Press Releases Farmindustria (July 2014) and Farmindustria Brochure (data from Efpia, Eurostat, Fondazione Edison), available at: http://www.farmindustria.it/index.php?option=com_jdownloads&Itemid=0&view=finish&cid=80086&catid=36.


4. Final Conclusions and Recommendations of the High Level Pharmaceutical Forum, 2 Oct. 2008 (http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/pharmaforum_final_conclusions_en.pdf) wherein it was stated that:

The High Level Pharmaceutical Forum: welcomes the development of a shared understanding that pricing and reimbursement policies need to balance (1) timely and equitable access to pharmaceuticals for patients all in the EU, (2) control of pharmaceutical expenditure for Member States, and (3) reward for valuable innovation within a competitive and dynamic market that also encourages Research & Development.

types of pharmaceutical companies operating on a relevant market: (i) the originators, companies which are active in research, development, management of the regulatory process for new products, including the clinical tests necessary for trading permits, production, trading and supply of innovative medicines, generally protected by patents (which, on the one hand, compensates for R&D costs and, on the other hand, publishes information on the inventions at stake); and (ii) companies producing generic drugs, which may enter the market with drugs that are equivalent to the original drug, following patent expiry. The prices of generic drugs are normally lower, ensuring savings on public expenditure, leading to consumer benefit. The entry of generic companies in the market has always been perceived by antitrust authorities as an opportunity to obtain similar treatments at lower costs, decreasing public funds, which may be used for the purpose, inter alia, of financing the development of new innovative medicines.7

The pharmaceutical sector is also characterized by peculiar characteristics on the demand side: the consumer or patient is not always the one who decides whether to purchase a drug rather than another. These decisions are generally taken by doctors who prescribe drugs (in certain states, pharmacists also play an important role). This reflects the existence of an information asymmetry between the patient (i.e., the consumer), the doctor (who chooses the drug) and the National Health System (which, generally, bears the cost). The pharmaceutical market is neither transparent nor does it permit free negotiations between the parties; moreover, in many cases, neither the patient nor the doctor or pharmacist directly sustain most of the costs, which are charged to the national health systems.

Another peculiar element is represented by the articulated and stringent regulation which rules the pharmaceutical sector. All stages of production and marketing of a drug are, indeed, subject to strict regulations, which limit freedom of the market players, to the extent of nullifying their discretion in deciding their business strategies.8

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6. European Commission, Pharmaceutical Sector Inquiry – Final Report, cit., p. 48: ‘The protection is limited in time, encouraging the company to bring the innovation to market as quickly as possible and ensuring that the company continues to innovate and bring forward future innovative products.’


Many Member States recognize that generic medicines play an important role in helping to limit their healthcare expenditure in their reimbursement and prescribing practices. Competition with off-patent products enables sustainable treatment of more patients with less financial resources. The generated savings create financial headroom for innovative medicines. All actors should therefore ensure that generics can enter the market after expiry of patent and data exclusivity protections and compete effectively.

8. Specifically, in order to obtain a marketing authorization for certain products (all medicines derived from biotechnology and other high-tech processes, as well as for human medicines for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other
Moreover, particularly relevant is price regulation, which is often the result of a regulated decision process, that also includes negotiations between the interested parties, and that strongly influences and characterizes the pharmaceutical sector.\textsuperscript{9}

It is worth mentioning that, also due to the innovation processes above considered, the pharmaceutical sector is continuously being developed and transformed. In this regard, in light of the investigation into the pharmaceutical sector by the European Commission (EC) that ended in 2008,\textsuperscript{10} it emerged that in recent years, patents of some ‘blockbuster’ drugs\textsuperscript{11} expired or are about to expire. In addition, it has to be noted that, despite the constant growing of investments in R&D,\textsuperscript{12} it seems more difficult for the

immune dysfunctions and viral diseases, and for veterinary medicines for use for growth or yield enhancers) it is compulsory to follow the centralized procedure provided by Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 Mar. 2004 \textit{laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency}, Official Journal of the European Union L 136/1 (Consolidated version available at http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1431624162275&uri=CELEX:02004R0726-20130605). According to such procedure, the European Medicines Agency (EMA), through its Committee for Human Medicinal Products (CHMP), carries out an evaluation on the application for a marketing authorization submitted by a company and if the quality, safety and efficacy of the drug is sufficiently proven, adopts a positive opinion which is sent to the European Commission to be converted into a marketing authorization binding in all Member States (Art. 10, Regulation (EC) No. 726/2004). Alternatively, each Member State could grant a national marketing authorization which could be, therefore, recognized by the other EU States pursuant to the principle of mutual recognition.

Specifically, at national level, the marketing authorization is granted by the appointed competent authority (in Italy, the competent authority is the \textit{Agenzia Italiana Del Farmaco – AIFA}) upon request by the pharmaceutical company interested in obtaining the authorization. On each request, the competent Authority evaluates the safety and efficacy of the drug and the results of clinical researches carried out by the applicant.

It is worth mentioning that, the binding nature of the centralized procedure is limited to the registration of drugs and does not concern the reimbursement of the related costs, which is generally assigned to the national authorities.


\textsuperscript{9} See European Commission, \textit{Pharmaceutical Sector Inquiry – Final Report}, cit., p. 48: ‘Where this is not the case, i.e. in countries with so-called free pricing, prices are dependent on the regulated reimbursement decisions’. Such peculiarity could not be found in the US market, where the pharmaceutical companies could decide on drug prices autonomously.

\textsuperscript{10} European Commission, \textit{Pharmaceutical Sector Inquiry – Final Report}, cit. In the Inquiry, the European Commission focused its attention specifically on the relations between the originator and the generic companies and on the protection of intellectual property rights.

\textsuperscript{11} A blockbuster drug is a drug whose annual global turnover exceeds USD 1 billion. Such drugs represent a substantial part of the sales and profits of big originator companies.

\textsuperscript{12} European Commission, \textit{Pharmaceutical Sector Inquiry – Final Report}, cit., p. 48:

From 2000 – 2007 originator companies spent on average 17% of their turnover from prescription medicines on R&D worldwide (approximately 1.5% of turnover was spent on basic research to identify potential new medicines and 15.5% of turnover was spent on developing the identified potential medicines through trials into products sufficiently safe and efficacious to be marketed). Expenditure on marketing and promotional activities accounted for 23% of their turnover during the period. In the year 2007 manufacturing costs accounted for 21% of originator companies’ total turnover. Originator companies rely, to a significant degree, on the acquisition of compounds from third parties. In 2007 about 35% of originator companies’ molecules where

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originator companies to launch new products on distribution channels, and so the number of new medicines reaching the market has decreased. In light of the above, it seems that originators are increasingly dependent on profit related to successful existing products. The decrease of new drugs will also negatively affect the generic industry, which will have a smaller number of generic products to introduce to the market upon the expiry of patents.\footnote{Communication from the Commission, Executive Summary of the Pharmaceutical Sector Inquiry Report, cit., p. 3: An intensified consolidation in the sector has been observed in recent years. Originator companies have undertaken various acquisitions of both originator companies and generic companies. Smaller originator companies, often biotech based, can deliver potential novel medicines to fill the gap in the pipeline of originator companies. In parallel, many larger originator companies are investing in the growing generics market by taking over generic players. This helps them to diversify their risk structure and can create opportunities to enter into new geographic markets. Finally, various mergers have taken place between generic companies, which may be driven by considerations on economies of scale and opportunities in new geographic markets. The aim of merger control in the EU is to allow these types of consolidation as long as they do not result in a significant impediment to effective competition.}

These needs are shared by the antitrust authorities, which have intervened repeatedly to protect and enhance the efficiency of the pharmaceutical market. As part of its inquiry, the Commission itself highlighted the main critical issues on which it decided to intervene analysing the existing competition relationships and how to reinforce competition. At national level, the Italian Antitrust Authority (IAA) launched an inquiry into the pharmaceutical sector in 1994, ending in 1998, in order to concretely analyse and verify the competitive structure of the pharmaceutical sector.\footnote{IAA, Inquiry on the Pharmaceutical Sector (IC14), no. 2293.}

Although it is clear that the perfect model of competition – based on some fundamental assumptions such as products’ homogeneity, freedom of entry and exit from the market, perfect information and free negotiation – is not feasible, it is still an ideal point of arrival to which markets should tend in order to be really competitive. The pharmaceutical sector seems, however, to have some peculiarities which do not permit it to apply the said principles of competition: none of the above assumptions, which should characterize a perfectly competitive market, appears achievable in this market.\footnote{C. Tesauro, La concorrenza nel settore farmaceutico, cit., p. 374.}

Among the anti-competitive practices carried out by pharmaceutical companies – and subject to control by the competition authorities is the leading role played by the so-called delaying strategies: tactics adopted by originator companies holding patents. These strategies are meant to delay market entry of competitors, manufacturers of marketing authorisation was pending had been acquired or in-licensed. Some of these third parties are small and medium sized enterprises, e.g., in the biotechnology sector. The largest cost block of generic companies in 2007 was manufacturing (51%), followed by marketing (13%) and R&D activities (7%), showing their different cost structure.
this is also achieved by means of artificially extending the duration of a patent. As known, patents grant an exclusive right only for a limited period, aiming to achieve a balance between, on the one hand, the necessity to encourage innovation, and, on the other, the need to avoid the creation of excessively long-lasting monopolies to the detriment of competition. So, if for a given period, the investments made by companies in research are remunerated, and third parties are prevented from exploiting these investments, at the expiry of that period it is necessary to allow competitors to have a chance to enter the market, on the one hand, to ensure competition, and on the other, to incentivize originators to invest in the development of new drugs.\(^16\)

Said delaying tactics may consist in the abuse of dominant position\(^17\) or in anti-competitive agreements, typically the so-called reverse-payment agreements (also pay-for-delay).\(^17\) These agreements, signed close to patent expiry held by the originator,
Co-marketing and Co-promotion Agreements

consist in the payment by this latter of sums in favour of generics, in order to delay the marketing of generic drugs. Such types of agreement, as evident, allow companies involved to retain the totality of the advantages deriving from the marketing at lower cost of the generic drugs, to the detriment of consumers (as well as the national health service or health insurance, in case of drugs supplied or refunded) who are forced to pay a price which is ‘artificially’ high.

In addition to patent settlement agreements, there are other conducts through which pharmaceutical companies enact pay-for-delay mechanisms. For example, it is possible that the originators conclude agreements with the generic companies, such as co-promotion agreements, which, although formally have a different object, are intended to ensure the generic companies an income, in exchange of delaying the entry of generic drugs into the market.

It is in this context, that the debate on co-promotion agreements in the pharmaceutical sector, arises, and it has recently revived, after the publication, in March 2015, of the EC’s decision regarding the marketing of a pain medication (fentanyl) in Netherlands, in the form of transdermal patches. In particular, the EC through its decision of 10 December 2013 (which will be examined in detail in Chapter 4) ascertained a breach of Article. 101, paragraph 1, Treaty on the Functioning of the European Union (TFEU) by the pharmaceutical companies Johnson & Johnson, Janssen-Cilag, Novartis and Sandoz, and imposed sanctions against the latter for a total of over EUR 16 million.²⁰

It is not the first time that competition authorities deal with possible concerns that may arise in the use of co-marketing or co-promotion contracts by pharmaceutical companies.

2 CO-PROMOTION AND CO-MARKETING AGREEMENTS

The ‘co-promotion’ is a joint promotion of the same medicinal product with the same trade name and trademark, carried out by the originator, the owner of the marketing authorization of the drug and one or more companies designated by the same (called ‘co-promoter’).²¹ The co-promoter could be either another pharmaceutical company,


²¹ This contract involves the acquisition of promotional services, which are then made available to the licensee of the product in exchange for a fee. The product is therefore unique and it is sold and marketed with a single trademark and a single marketing authorization. In Italy, this type of agreements was considered out of bounds until 2006. See C. Tesauro, La Concorrenza nel settore farmaceutico, cit., p. 383, footnote 20. G.F. Ferrari, F. Massimino, Diritto del farmaco, Bari, 2015, 251 et seq.
different from the originator, or a company that offers services of medical and scientific information on behalf of a number of different pharmaceutical companies.\textsuperscript{22}

In such agreements,\textsuperscript{23} the originator outsources exclusively the promotional activity and retains control over all the other aspects concerning product marketing.\textsuperscript{24} Therefore, parties launch the product to the market with a single trademark and a single marketing authorization with a common marketing strategy.

Therefore, co-promotion activity can be performed exclusively or jointly with the promotion activities of the drug conducted by the originator; through this agreement – which can also be the evolution of the R&D agreements entered into by companies already in the early stages of pre-clinical or clinical development of the drug\textsuperscript{25} – the co-promoter is committed to promoting others’ drug sales through its network of medical-scientific informers and using the same marketing strategy; the profit is usually defined by the activity carried out by the medical-scientific informers or by the amount of prescriptions of the drug resulting from such activities.\textsuperscript{26}

In this way, the co-promotion relationship allows the originator to exploit the specific know-how and network of informers of a different company in order to optimize the promotion of the drug and to enter the market in a fast and widespread manner; moreover, if the promotion is exclusively in charge of the co-promoter, the originator may also avoid incurring heavy costs for developing a special information network dedicated to the drug covered by the agreement.\textsuperscript{27}

Article 93, paragraph 3, of Directive 2001/83/EC,\textsuperscript{28} recognizing the importance for pharmaceutical companies of such types of agreements, has expressly stated that ‘Member States shall not prohibit the co-promotion of a medicinal product by the holder
Co-marketing and Co-promotion Agreements

of the marketing authorization and one or more companies nominated by him; until the aforementioned recommendation by the Community legislature, co-promotion agreements, even if very common worldwide, were in fact still banned in Italy in 2006, because an undertaking was not allowed to promote a medicine if it also marketed it.

Their recognition at Italian level was granted only with the integration of Article 119 of Legislative Decree No. 219/2006, paragraph V, which provides that advertising among health care professionals could be made, ‘including a collaboration with the originator, on the basis of a specific agreement with, by another undertaking’.

In addition to co-promotion agreements, there are other forms of cooperation between pharmaceutical companies which can be used by the same to increase the penetration of its own products in the market in order to decrease costs and risks arising from promotion of the drug and to allow the originator to recover quickly the large investments made in the development of the medicine. Among these agreements, for the purpose of this chapter, significant are co-marketing agreements, which, in Italy, has been characterizing the dynamics between companies in the pharmaceutical sector also because of the aforementioned ban on co-promotion relationship in force until 2006.

Particularly, a ‘co-marketing agreement’ is a complex relationship through which a pharmaceutical patent holder of an active principle, in exchange for the payment of a fee (royalties on sales; a sum una tantum), licenses marketing and distribution rights of the active ingredient, or finished or semi-finished specialty, that it has supplied to one or more undertakings. These companies, having obtained the access to the registration dossier, will have to get their trademarks on the AIC of the marketed drug.

Through such a ‘production-distribution system’ the promotion and sale of medicinal products based on the same active ingredients is carried out simultaneously by two or more pharmaceutical companies, with different trade names and trademarks, which independently engage in promotional activities for the brand in order to differentiate their products on the market.

31. Article 119 of Law Decree 24 Apr. 2006 no. 219:

‘Implementation of Directive 2001/83/EC (and subsequent amending Directives) concerning the Community code relating to medicinal products for human use and Directive 2003/94/EC’ The article provides that ‘in such cases the originator still remain, however, responsible for both the obligations and the responsibilities of marketing carried out by the other undertaking and the obligation laid down by Article 122, paragraph 3’.
33. F. Gianfrate, Marketing farmaceutico. Peculiarità strategiche e operative, cit.
34. The reasoning behind co-marketing, as defined in theory, is a marketing strategy whose purpose is to use the forces of two or more companies competing on the market for an active
In this way, it is possible to obtain an effective promotion of the active ingredient, thus being able to exploit the experience, the effectiveness, marketing and promotion strategies of the product to several sales networks, and the originator is not obliged to carry out significant investments required to establish a good network. Furthermore, undertakings participating in the co-promotional relationship will adopt policies aimed to promote a greater competition with different active ingredients having the same therapeutic effect, produced by other pharmaceutical companies and included in the same market.

Through co-marketing agreements, originator companies may: (i) promote the active ingredient with regard to a greater number of doctors (ii) achieve specific targets of doctors thanks to the peculiarities of the product range, the specialization in promotional messages and sponsorship deriving from congresses or conferences of each distributor; (iii) reiterate the same message in case informers of different companies visit the same doctor with a consequent increase in the probability of prescription of the molecule, independently of the trademark that the doctor may memorize.  

Thus ‘co-marketing’ is characterized by: (a) a supply relationship between the patent holder of the active ingredient and/or producer of the same, who holds the know-how and the scientific-industrial knowledge for the production of the medicinal product containing the active ingredient, and marketing companies; (b) the existence of several companies (among which the licensor that manufactures and markets the drug based on the same active ingredient), each of which markets and promotes the active ingredient with different trademarks and with their proper marketing authorization.

3 CO-PROMOTION AND CO-MARKETING AGREEMENTS EXAMINED BY ANTITRUST AUTHORITIES

The EC at EU level, as well as national competition authorities in the different Member States, have generally favourably viewed co-promotion and co-marketing, considering the said agreements put in place by competing undertakings as non-restrictive of competition or apt to generate efficiencies outweighing any restrictive effects.

Indeed, generally, co-promotion and co-marketing agreements are entered into by companies participating in the same market and consequently possibly giving rise to antitrust concerns; in fact, it is the competitor active in the same market provided with ingredient. It was developed in the ’80s, after the recognition of the patentability of drugs, and it represents the ways in which foreign multinational companies could get more easily and promptly, by Italian partners, the marketing authorizations for their products. IAA, case No. 7337 (I331) ‘Servier Italia-Istituto Farmaco Biologico Stroder’.


the required expertise, which is able to mitigate deficiencies of the originator in promotion and marketing activities of the product.

Therefore, the EC, in analysing such types of agreements in accordance with European antitrust law on restrictive practices, has primarily assessed the level of competition existing between companies involved in the agreement (actual competition and/or potential competition) and the possible restriction of competition resulting from the cooperation; second, it has checked the possible application to the case examined under Article 101.3 TFEU.

In fact, most of co-promotion and co-marketing agreements may produce efficiency gains by combining complementary skills, thus speeding up the development and marketing of new or improved products and technologies, which lead to greater dissemination of knowledge, generating further innovation and reducing costs. These

37. Being agreements among undertakings, co-promotion and co-marketing agreements between undertakings, must be assessed under antitrust rules governing anti-competitive agreements regulated by Art. 101 TFEU which provides that:

1. The following shall be prohibited as incompatible with the internal market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market, and in particular those which: (a) directly or indirectly fix purchase or selling prices or any other trading conditions; (b) limit or control production, markets, technical development, or investment; (c) share markets or sources of supply; (d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; (e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts. 2. Any agreements or decisions prohibited pursuant to this Article shall be automatically void. 3. The provisions of paragraph 1 may, however, be declared inapplicable in the case of: – any agreement or category of agreements between undertakings, – any decision or category of decisions by associations of undertakings – any concerted practice or category of concerted practices, which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not: (a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives; (b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

38. Guidelines on the applicability of Article 101 TFEU to horizontal cooperation agreements. For the purposes of the horizontal guidelines, the term ‘competitors’ means both actual and potential competitors: while two companies are treated as actual competitors if they are active on the same relevant market, the partner may well be ‘potential competitor’ if it could enter the market within a short period of time in response to a non transitory price increase.

39. According to Art. 101 TFEU on anti-competitive agreements, agreements between undertakings are prohibited (Art. 101(1) TFEU) and void (Art. 101(2) TFEU) when they have, as their object or effect, a restriction of competition which is appreciable, unless the agreement fulfils the four cumulative conditions set forth by Art. 101(3) TFEU and may therefore benefit from the so-called applicable exception system. Particularly, Art. 101(3) TFEU provides that an agreement could be considered legitimate from the antitrust point of view if it meets the following cumulative conditions: (a) to contribute to improving the production or distribution of goods or to promoting technical progress; (b) allowing consumers a fair share of the resulting benefit; (c) avoid to require undertakings restrictions which are not indispensable to the attainment of these objectives; (d) by not giving such undertakings the possibility of eliminating all competition for a substantial part of the market.
efficiency gains which are obtained by indispensable restrictions, to be recognized as worthy of exemption need to be passed on consumers (as, for example, reduction of prices or increase of products quality or variety) in order to outweigh the restrictive effects on competition caused by the anti-competitive agreement.

The EC, which has intervened on several occasions in the past on this subject, considered co-promotion and co-marketing agreements compliant with antitrust rules as pro-competitive.

By way of example, in 1994 the EC recognized as worthy of exemption, and therefore not punishable under Article 101 TFEU (then Article 81 of the EC Treaty), the creation of the joint venture between Pasteur Mérieux and Merck, established to promote research and to provide the development, the registration, the organization of production and the marketing and sale in EC countries (now EU) and The European Free Trade Association (EFTA), of vaccines, immunoglobulin, in vivo diagnostics, sera and other additional products chosen from time to time by the parties. The European antitrust authority, despite recognizing an anti-competitive violation, decided nevertheless to exempt the said agreement due to the improvements that would result in the production and marketing, promotion in terms of technical and economic progress and improvements that in turn would trigger off benefits to public health and the consumer, such as targeted vaccines, stable and easy administration.

Likewise, in the Pfizer/Eisai and Pfizer/Aventis cases, the EC, recognizing the importance of R&D in the pharmaceutical sector, considered in compliance with antitrust law and not punishable under Article 101 TFEU the joint ventures set up by pharmaceutical companies with the purpose of developing, manufacturing and selling new drugs; in both cases the cooperation extended to the marketing in the form of joint promotion of the same brand or sales under different brand names.

40. Case IV/34.776 Pasteur Mérieux/Merk (1994). Pasteur Mérieux and Merck had transferred to the joint venture their existing rights record concerning the products and had licensed exclusively to the joint venture the existing patents and the know-how of which it is the owner or licensee (except for the rights that it reserves to continue to produce products intended solely for sale to the JV in the territory/sale for use outside the territory, and the rights of third parties acquired before the creation of the joint venture). The sale would take place through exclusive distribution agreements of existing vaccines (Pierre Fabre in France and Behring in Germany) and the co-promotion of some new vaccines produced by the JV (Behring in Germany). The evaluation carried out by the European Commission recognized that the creation of the joint venture between Merck and Pasteur Mérieux had restrictive effects on competition in the affected markets; in particular, in consideration of the effects on third parties, the JV and related agreements would have limited considerably the access of competitors to existing and imminent vaccines and vaccine technology (in particular associations of vaccines for pediatric use). However, according to the European Commission, the transaction was worthy of exemption granted until 31 Dec. 2006, due to the fact that the joint venture improved the production and distribution, while also promoting economic and technical progress, improvements in turn trigger advantages for the consumer (targeted vaccines, stable and easy administration in favour of the public health and, therefore, that of the consumer); furthermore, the Commission highlighted the indispensability of the establishment of joint ventures to achieve the proposed aims and the fact that the joint venture would not lead to restrictions of competition in vaccine markets of South Eastern Europe (the restrictive scope of these agreements is therefore limited to the French and German markets).

41. See COMP/36.932 Pfizer/Eisai, Competition Policy Report 2000, p. 239-240. The USA company Pfizer had decided to collaborate with the Japanese Eisai to bring an anti-Alzheimer product...
Particularly, in the first case, Pfizer gave up the marketing of its product for the treatment of Alzheimer’s in favour of that of Eisai; while the latter engaged in most of the R&D and production, Pfizer would use its worldwide distribution network to handle most of the marketing activities. Although the EC considered the fact that Pfizer had given up its R&D as a reduction of competition under Article 101, paragraph 1, TFEU, the obvious advantages from the transaction in question for consumers constituted sufficient grounds for an exemption. In Pfizer / Aventis case, the EC, following the commitment submitted by the parties to reduce the non-compete clause provided by the co-marketing agreements (they reduced the initial period of thirty years plus five years post-termination to organize the practicalities of winding up the cooperation to a period of twenty years plus three years post-termination), did not consider the agreement punishable under antitrust law.42

Finally, it is worth recalling the green light granted by the EC to the joint venture in the pharmaceutical sector between the French company Sanofi and the US Company Bristol – Myers Squibb created with the purpose of developing, manufacturing and selling two new molecules in the cardiovascular area.43

42. See COMP/37.590 Pfizer/Aventis, Competition Policy Report 2000, p. 241-243. Pfizer (USA) was involved in cooperation with one other major player (Aventis) and a smaller USA-based research company called Inhale. The aim was to develop, manufacture and sell an inhalable insulin product in a market which so far comprises only injectable insulin. Pfizer was not present at all in the (injectable) insulin market and Aventis was only the number three player, lagging behind the two leading manufacturers (Novo Nordisk and Eli Lilly) in most Member States. The Commission considered the joint venture (in reality a series of separate joint ventures) not to raise a competition issue under Art. 101(1); however, a non-compete obligation (thirty years plus five years post-termination to organize the practicalities of winding up the cooperation) was considered too long to qualify as an ancillary restraint. The parties gave a commitment to reduce this period to twenty years (plus three years post-termination). The Commission departments accepted the non-compete clause in view of the relatively weak market position of the parties involved and the lack of any appreciable foreclosure effect stemming from the exclusive dealing arrangements between these parties. Under the circumstances, the Commission departments saw no need to determine with absolute precision the exact length of the period which the parties would need to recoup their large investments. It should be noted that the two cases involved cooperation at the marketing level in the form of co-promotion or co-marketing.

The possible problems arising from co-marketing agreements have been examined also at the Italian level. In particular, in 1999 the IAA concluded three investigation proceedings related to restrictive agreements, concerning conducts of undertakings aimed at coordinating pricing policies of third companies by means of co-marketing agreements.\textsuperscript{44}

According to the IAA,\textsuperscript{45} the proliferation of co-marketing agreements may have positive effects in terms of promotion of active ingredients on the market; by using means and information resources of two or more companies, each with its own sales network, an effective interpenetration among physicians is achieved, without forcing the proprietor of the patent covering an active ingredient to make huge investments to establish an adequate network. Since this is the purpose of co-marketing, it proves particularly effective in the event of market launch of a new drug, in such a way that the latter is known as soon as possible. At the same time, as the co-marketers need to promote their product by differentiating it in commercial terms also from the product or products containing the same molecule, they strongly emphasize promotion as a competitive variable. However, this is done, in some cases, at the expense of price competition. As regards drugs not covered by the National Health Service, which therefore must be totally paid by the patient under a free pricing regime, the IAA verified the existence, in relation to co-marketing agreements, of agreements restricting competition which had led to significant price increases to the detriment of consumers.\textsuperscript{46}

The Authority specified that a co-marketing system, though creating a certain linkage between the companies concerned, does not entail any need of coordination in terms of pricing.

In case \textit{Servier Italia-Istituto Farmaco Biologico Stroder},\textsuperscript{47} the companies involved had implemented a co-marketing agreement, which, according to the IAA, could lead to a substantial market-sharing. The investigation revealed that price changes concerning both products resulted from an agreement restricting competition to the detriment of consumers, as well as from the high market share held by the companies concerned. The IAA also verified that the two companies had concluded an agreement to set tender

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\textsuperscript{45} See IAA, Annual Report 1999, cit.

\textsuperscript{46} Ibid..

\textsuperscript{47} IAA, Decision No. 7337 (I331) \textit{Servier Italia-Istituto Farmaco Biologico Stroder}, cit.
prices in tenders for the supply of products to hospitals and public health structures. Eventually, a coordination of the respective activities came to light, aimed at avoiding direct comparison between their drugs for the benefit of physicians, which rendered it more difficult and more expensive to access to the relevant market on the part of potential competitors, especially generics manufacturers.

Similarly, in cases Byk Gulden Italia – Istituto Gentili and Istituto Gentili-Merck Sharp & Dohme -Neopharmed-Sigma-Tau Industrie Farmaceutiche Riunite-Mediolanum Farmaceutici the companies had implemented a co-marketing agreement which was deemed to be aimed at a significant pricing coordination, with restrictive effects to the detriment of the consumer.

More recently, in Arca / Novartis-Italfarmaco the IAA accepted the commitments submitted by the two companies, aimed at modifying the clauses of the existing contract which were considered by the IAA as producing anti-competitive effects. Originally, the IAA had launched the investigation in order to verify the correct performance of some public tenders organized by the purchasing groups of the Lombardia, Veneto and Emilia Romagna regions, for the supply of drugs containing the active ingredient octreotide. In the course of the inspections carried out at the premises of the two companies, the IAA then became aware of a license and supply agreement between the parties for the marketing of the above-mentioned active ingredient. The IAA therefore decided to extend objectively the proceedings, since several clauses of the agreement seemed capable of restricting competition between the parties. It seems peculiar that the focus of the above-mentioned proceeding was shifted from what had initially been highlighted in the decision to initiate the investigation. The discovery of the co-marketing agreement seems to have given rise to a transformation of the IAA’s charge, from an alleged hard-core collusion (in relation to which, if confirmed, it would not have been possible to accept commitments) to an alleged cooperation with potential restrictive effects (by reference to which the aforementioned commitments have been submitted).

4 CO-PROMOTION AGREEMENTS USED TO DELAY MARKET ENTRY OF GENERIC MANUFACTURERS: THE JOHNSON & JOHNSON / NOVARTIS CASE

The EC’s investigation concerned a co-promotion agreement concluded in 2005 between, on the one hand, Janssen-Cilag B.V., a Dutch subsidiary of Johnson &
Johnson, and, on the other hand, Hexal B.V. e Sandoz B.V. (together hereinafter referred to as ‘Sandoz’, since Hexal B.V. was incorporated in Sandoz at the end of 2007), Dutch subsidiaries of Novartis.

In order to understand the Commission’s analysis, it is worthwhile to summarize the main circumstances of law and of fact in the context of which the conduct at issue have been put in place.

The patent covering the active ingredient fentanyl, obtained in the sixties by Johnson & Johnson (originator company), had expired in 1982; the fentanyl transdermal patches were not covered by any patent, in the Netherlands, during the existence of the co-promotion agreement concluded by Janssen-Cilag and Sandoz. However, Directive 2001/83/EC,52 in force at the time of the facts at issue, provided that a marketing authorization for a medicinal product – issued by the competent authorities in each Member State of the (then) European Community – confers on the originator a period of ‘data exclusivity’. 53 Accordingly, the companies which intended to produce and sell generic medicinal products similar to that covered by the period of data exclusivity had to wait until the period indicated by the Directive had expired, in order to be able to apply for a marketing authorization for their generic drugs. In particular, the Directive foresaw a period of six years, or ten years in Member States, including the Netherlands,54 which took a general decision to that effect, for reasons relating to public health.

In view of the fact that between 2004 and 2005, the ten-year period of data exclusivity for fentanyl transdermal patches marketed by Janssen-Cilag (which until then was the only pharmaceutical company marketing such medicinal products in the Netherlands) would expire, with reference to the Netherlands, Sandoz took action to launch the corresponding generic drugs in the Dutch market, aiming to exploit the ‘loss of exclusivity’ which would soon affect Johnson & Johnson’s subsidiary. In this context, a negotiation was started between Janssen-Cilag and Sandoz, which led to the conclusion of the co-promotion agreement at issue, entered into force on 11 July 2005.

53. See Commission Decision of 10 Dec. 2013, Fentanyl, cit., para. 29 et seq. See Art. 10(1)(a)(iii) of Directive 2001/83/EC, pursuant to which the applicant for a marketing authorization shall not be required to provide the results of toxicological and pharmacological tests or the results of clinical trials if he can demonstrate:

that the medicinal product is essentially similar to a medicinal product which has been authorized within the Community, in accordance with Community provisions in force, for not less than six years and is marketed in the Member State for which the application is made. This period shall be extended to 10 years in the case of high-technology medicinal products having been authorised according to the procedure laid down in Article 2(5) of Council Directive 87/22/EEC. Furthermore, a Member State may also extend this period to 10 years by a single Decision covering all the medicinal products marketed on its territory where it considers this necessary in the interest of public health. Member States are at liberty not to apply the six-year period beyond the date of expiry of a patent protecting the original medicinal product.

54. The same choice was made by Belgium, Germany, France, Italy, Sweden, United Kingdom and Luxembourg. See Commission Decision of 10 Dec. 2013, Fentanyl, cit., para. 31, footnote 32.
In summary, the agreement provided that Janssen-Cilag paid to Sandoz a sum of EUR 308,333 per month for one year, with the possibility of a consensual extension, in exchange for a series of promotion activities carried out by Sandoz/Novartis, through its sales network, among the Dutch pharmacists. The agreement was entered into and in August 2006, extended (with retroactive effects, starting from the previous month) until the exercise of the right of withdrawal, in accordance with the terms laid down in the contract, by Janssen-Cilag, in December 2006.

On the outcome of the investigation carried out, with particular reference to the negotiation between the parties, as well as to the subject and performance of the agreement at issue, the Commission concluded that Janssen-Cilag and Sandoz put in place an agreement restricting competition, in violation of Article 101 TFEU.

As determined by the Commission, first, Sandoz, at the time of the conclusion of the co-promotion agreement, was considered by Janssen-Cilag as its main potential competitor, being in the position of placing on the market fentanyl transdermal patches already in August 2005. Second, as results inter alia from internal communications of the two companies, the main objective of the agreement concluded between Janssen-Cilag and Sandoz was to inhibit market entry on the part of the latter, as long as the agreement remained in force. This is demonstrated, according to the Commission, by the fact that Sandoz renounced launching its generic product in exchange for a sum of money exceeding the expected profit the company estimated in the event of marketing its drug. Janssen-Cilag, at the same time, was able, thanks to the co-promotion agreement, to maintain its monopolistic and supracompetitive prices, sharing with Sandoz the income thereof. The agreement contained, accordingly, a genuine non-entry mechanism, achieved through a clause providing that Janssen-Cilag’s payments would cease as soon as Sandoz, or another operator, entered the market; indeed, between July 2005 and December 2006 Sandoz abstained from launching generic fentanyl transdermal patches corresponding to the ones marketed by Janssen-Cilag. Moreover, the decision of December 2006 to exercise the right of withdrawal provided for in the contract would have been taken by Janssen-Cilag following the news that a third company (Ratiopharm Nederland B.V.) was on the point of obtaining an authorization for marketing generic fentanyl transdermal patches. Third, the concrete co-promotion activities carried out by Sandoz have been defined as ‘limited’ and ‘of limited usefulness to Janssen-Cilag’ with reference to the first year of the contract period, while regarding the period following the extension there is no evidence of any promotion activity.

In the light of the elements (briefly) indicated above, the Commission concluded that the co-promotion agreement between Janssen-Cilag and Sandoz constitutes an agreement restricting competition ‘by object’, capable of affecting trade between Member States, and therefore falling within the scope of the prohibition laid down in

55. See, for instance, Commission Decision of 10 Dec. 2013, Fentanyl, cit., para. 114, where the Commission refers to an e-mail sent by an employee of Janssen-Cilag to some colleagues, inviting them to prepare ‘a scenario with a construction whereby [Sandoz] does not launch and gets a part of our cake’. See also para. 118, where another internal Janssen-Cilag e-mail is mentioned, which prefigured a cooperation scenario with Sandoz ‘to keep the high current price level’.
Article 101(1) TFEU. The Commission also excluded the possibility that the co-promotion agreement at issue could be eligible for an exemption under Article 101(3) TFEU, as no sufficient evidence was provided demonstrating possible pro-competitive effects of the said agreement. In view of the above, the Commission imposed fines of: about EUR 10.8 million on Janssen-Cilag and Johnson & Johnson; and about EUR 5.5 million on Sandoz and Novartis.\(^56\)

The Commission Decision has not been contested before the EU Tribunal by the addressees. In a press issued the day after the adoption of the Decision, Janssen-Cilag declared: ‘We accept accountability for our actions […] We regret that […] health insurers did not benefit from lower generic prices during this period’.\(^57\)

The Decision has been read in relation to two other Commission Decisions addressed to operators of the pharmaceutical sector:\(^58\) the first was adopted in June 2013 in case Lundbeck,\(^59\) the second was adopted in July 2014 in case Perindopril (Servier).\(^60\) The common element is the existence of a ‘pay-for-delay’ agreement; the Johnson & Johnson / Novartis case, however, can be distinguished from the others because, unlike these, it did not concern patent settlement agreements, as the patent covering the medicinal products at issue, as mentioned above, had expired many years before.

5 CONCLUSIONS

It seems possible to say that the above-mentioned Commission Decision Johnson & Johnson / Novartis cannot lead to assume that the general approach of antitrust
Indeed, the co-promotion agreement between Janssen-Cilag and Sandoz in the case at issue was essentially aimed at disguising the real purpose of the parties – as is corroborated, inter alia, by the fact that the concrete co-promotion activities carried out by Sandoz were not significant – namely, as mentioned above, delaying the entry to the (Dutch) market of generic fentanyl transdermal patches corresponding to the ones marketed by Janssen-Cilag. The Commission’s analysis therefore focuses mainly on issues related to pay-for-delay, without addressing in the same detail the issue of compatibility of co-promotion agreements, specifically in relation to the pharmaceutical sector, with EU antitrust law.

The particular and continuous attention to the pharmaceutical market, on the part of antitrust authorities, in order to contain prices and to reduce pharmaceutical expenditure, is confirmed: in the Johnson & Johnson / Novartis case, this is done through protection of competition following patent expiry, focusing on prices, in order to stimulate market entry of generic drugs, which could entail a significant price reduction, and therefore major savings for health system and for consumers. In other cases, the authorities censored behaviours which were deemed lawful by sectorial rules.61

On 15 Jan. 2014, the Consiglio di Stato (the Italian Supreme Administrative Court) overruled the decision issued by the Tribunale Amministrativo del Lazio (TAR Lazio, the Regional Administrative Court of Latium) in September 2012, in the case of Pfizer’s abuse of dominant position. In particular, the Consiglio di Stato has confirmed the original judgment issued by IAA in January 2012 that fined Pfizer with a penalty totalling to over EUR 10 million. Indeed the Authority had stated that the company had abused of its dominant position by adopting a complex exclusionary strategy by extending patent protection for its latanoprost based drug, Xalatan, in order to delay the market entry for generic medicines used to treat glaucoma. The judgment issued by the Consiglio di Stato is a peculiar case, in which even if Pfizer had been compliant with the legitimate procedures settled by the Regulator in order to extend the patent protection, nevertheless its behaviour was considered to be in breach of Art. 102 TFEU since this was seen as a strategy aimed to exclude new competitors from the relevant market.

On 27 Feb. 2014, the IAA closed an investigation launched in February 2013 into the Italian market for ophthalmic drugs used to treat certain serious vascular eyesight conditions, following the complaints filed by the Italian Ophthalmologic Association and by an association of private hospitals. The IAA found that the pharmaceutical companies F.Hoffmann-La Roche Ltd., Novartis AG, Novartis Farma S.p.A. and Roche S.p.A. had established a cartel aimed at preventing the off-label promotion of Avastin – a drug manufactured and distributed by Roche – within the Italian market, in order to foster the promotion of Lucentis, a more expensive drug produced by Novartis and licensed by Genentech, a Roche Group company. In particular, the IAA found that the companies had set up since 2011 a complex collusive strategy in the eye treatments market with the intention of causing an artificial product differentiation between Avastin and Lucentis, by asserting that the off-label use of Avastin (the approved use of which is limited to the treatment of some forms of cancer) to treat common eyesight conditions was dangerous. Given the seriousness of the infringement and the estimated amount of damage that the Italian National Health Service had suffered and would suffer in the future because of the illicit collusion, the IAA imposed on Roche and Novartis respectively fines for a total amount EUR 90,500,000 and EUR 92,000,000. Also this case, now subject to the judgment of the Italian Supreme Administrative Court, is peculiar, given that the Authority condemned the conduct of Roche and Novartis that are in compliance with the Italian regulatory law (in terms of pharmacovigilance obligation, prohibition to promote a drug without the marketing authoriza-

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This trend, clearly spurred *inter alia* by the recent European public finance crisis, should nevertheless take into account the fair and equitable balance between the necessities of containing expenditure, which are considered increasingly important, and right to health, which is and must remain a primary value to be protected\textsuperscript{62}.

In Europe, pharmaceutical regulation is more and more intrusive with respect to economic initiative in the industrial sector, which has resulted in a significant saving for health system, but which has also dampened the possibility for undertakings to be able to exploit the competitive variable typical of non-regulated markets, where the competitive dynamics are more developed and, at the same time, there is a considerable impetus towards innovation (as it is, for instance, the case of the US pharmaceutical market, based on the free market, where the prices of medicinal products are set by operators and the purchasers are mainly private).

The particular features of the pharmaceutical sector, as well as the strict regulation provided for in Europe, cannot be ignored by antitrust authorities, as while it is correct to benefit from containing public expenditure, it also has to be considered that an excessively strict application of antitrust law could further undermine the competitiveness of the European pharmaceutical industry and hinder innovation, R&D.

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\textsuperscript{62} European Court of Justice, 29 Mar. 2012, case C-185/10, *Commission v. Poland*, where the Court held that, pursuant to Art. 6 of Directive 2001/83/EC, the marketing of medicinal products on the EU market is conditional upon the achievement of the marketing authorization, thus inextricably relating the safety assessment with the relevant market. In interpreting the notion of *‘special needs’* which, pursuant to Art. 5 of Directive 2001/83/EC, allow derogation from the above-mentioned general principle, the Court stated that this notion shall be read as referred exclusively to individual cases justified by medical considerations, and therefore it assumes that the medical product is essential to satisfy the patients’ need for health care. Similarly, the condition, laid down in the same Art. 5, that medical products have to be supplied in response to a *‘bona fide unsolicited order’* shall be interpreted as meaning that the medical product must have been prescribed by a physician on the outcome of an effective screening of his patients, on the basis of exclusively therapeutic evaluations. The Court consequently held that the derogation provided for in the Directive can be applied only when the physician considers that his patients’ state of health requires the administration of a medical product which does not have on the national market an equivalent product already authorized, or which is not available at national level.