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The AstraZeneca Case

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Matteo Pierangelo Negrinotti¹

On June 2005, after a five year investigation, the Commission imposed a 60 millions euros fine on AstraZeneca (hereinafter AZ) for having abused its dominant position in several Member States in the market for proton-pump inhibitors (PPI)². It was alleged that AZ misused the patent system and procedures for marketing pharmaceuticals to block or delay the entry of generic competitors and parallel traders to its ulcer drug Losec³.

This decision is a seminal one. The political and legal importance of the CFI judgment that will review the case (and the ECJ appeal that is likely to follow) cannot be understated. On the one hand the incentive to innovate and to undertake R&D is at stake, on the other, the uncertain boundaries between competition and intellectual property law should once again be explored.

In contrast to the US, where many cases concerning the abuse of regulatory and governmental procedures have already been dealt with competition authorities and courts, it is the first time in Europe that such conduct is subject to scrutiny through an anti-trust lens. Moreover, following the appeal brought by AZ against the Commission decision, the CFI will be confronted for the first time with an abuse of a dominant position in the pharmaceutical sector, which explains why this judgment is eagerly anticipated⁴.

1. Regulatory background

It is well known that the pharmaceutical sector is highly regulated both at national and at Community level. Consequently, before moving to an examination of the Commission decision,⁵ a brief overview of the relevant regulatory provisions in force at the time the alleged abuses took place is necessary.

In order to market a pharmaceutical product within the EU, a market authorization shall be issued beforehand. The market authorization can be obtained through two different procedures, namely: a centralized procedure and a decentralized one. The former necessitates that an application to be lodged with the European Medicines Agency (hereinafter the EMA) for an authorization that covers all the member states⁶. The latter requires that an application be lodged an application with at the relevant national authority that covers only one Member State. Once this national authority has authorized the product's marketing, through the Mutual Recognition Procedure (the "MRP" hereinafter) it is possible to

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² Proton-pump inhibitors are a group of [drugs](#) whose main action is pronounced and long-lasting reduction of [gastric acid](#) production. They are the most potent inhibitors of acid secretion available today.

³ See Commission Press Releases IP/03/1136 of July 31, 2003 and IP/05/797 of June 15, 2005 as well as the Commission Decision (finally published on June 2006) Case COMP/A. 37.507/F3 – AstraZeneca of June 15, 2005, O.J. [2006] L 332/24 (hereinafter referred as "Commission Decision"). The Commission investigation was opened in February 2000 and its object was the conduct of AZ between 1993 and 2000. In July 2003 the Commission addressed a statement of objection to AZ. An oral hearing took place on February 2004 and the decision was adopted on June 2005 and finally published on November 2006.

⁴ The Court in fact declined to rule on the very first case involving art. 82 in the pharmaceutical sector, rejecting on procedural grounds, the preliminary ruling addressed by the Greek national competition authority in the Case C-53/03 *Syfait and others v. Glaxosmithkline AEEV*, ECR [2005], p. I-4609. The same questions have been now referred by the Court of Appeal of Athens to the ECJ see the eleven preliminary rulings from C-468/06 to C-478/06 asked by the Court of Appeal and published O.J. [2007] C 20/3.

⁵ It is important to stress already now that following the modifications (repealing or amendments) occurred to the legislation in force at the time of the Commission investigation, the alleged abuses are unlikely to occur in the future. Some considerations on this point will be pointed out *infra* at paragraph 3.

⁶ This procedure was firstly introduced by the Council Regulation n. 2309 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medical products for human and veterinary use and establishing a European Agency for the Evaluation of Medical Products, O.J. [2003] L 214/1 which has been recently repealed by Regulation No. 726 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and the supervision of medical products for human and veterinary use and establishing a European Medicines Agency O.J. [2004] L 136/1.

obtain the authorization from all other Member States⁷. The aim of both procedures is to check that only safe drugs are marketed in the EC.⁸

Under the centralized procedure, a drug manufacturer must submit a dossier to the EMA containing all the relevant information concerning tests and trials carried out in order to assess side and/or adverse effect of the medication, as specified in Art. 3 of Regulation 762/04 (and previously in Art. 3 of Regulation 2309/93). Once the Committee for Medical Products for Human Use have examined the application, the EMA will issue a market authorization valid for the entire Community⁹.

Under the decentralized procedure, the application for a market authorisation of a medication is made in one Member State, known as the Reference Member State (RMS). Once a marketing authorisation has been issued by the RMS, then via the mutual recognition procedure laid down in the regulation it is possible to obtain market authorisations for the remaining 26 Member States¹⁰.

Both procedures provide for abridged (or simplified) procedures for the granting of a marketing authorization of generic drugs referring to drugs already authorized under the Regulation or the directive. The aim of such abridged procedures is to speed the access of generic drugs up, once the patent protection expired¹¹. In particular, the abridged procedure allows the generics' manufacturers to place their drugs on the market without carrying out new clinical trials insofar as the generic is therapeutically equivalent to the branded (i.e. the originally patented) drug¹².

As far as the present case is concerned the relevant rules are those laid down in art. 4 third paragraph point 8 (a) (iii) of Directive 65/65 (now repealed by Directive 2001/83, in particular art. 10). According to these provisions in order to obtain a market authorization or an import licence a generic producer or a parallel importer should fulfill the following cumulative conditions: that the generic was *essentially similar* to the reference product, that the so-called *data exclusivity*¹³ has expired, that the original reference medicinal product was authorized and *marketed* in the Member States in which the application is filed.

Considering the time elapsing between the patent registration and the obtainment of the market authorization under one of the two procedures above-mentioned, in 1992 by mean of a Regulation the Community introduced the so-called Supplementary Certificate Protection ("SPC" hereinafter)¹⁴. The aim of SPC consists in granting extra-time protection to pharmaceutical products in order to spur innovation allowing pharmaceutical industries to recoup the huge costs invested in R&D. In fact, without the SPC, the twenty years protection

⁷ This procedure was introduced in 1965 after the well-known "thalidomide disaster", occurred in the early 1960s by the Council Directive 65/65/EEC of 26 January 1965, O.J. [1965] L 22/369, which was repealed by Directive 2001/83 of the European Parliament and of the Council of 6 November 2001 OJ [2001] L 311/67.

⁸ Both the Regulation and the Directive provide for a system pharmacovigilance, i.e. a control in the therapeutic usage of the drug after it has been placed on the market, in order to monitor whether adverse effects or side effects, not discovered during the trials, appear. In case, a withdraw procedure is in place to avoid the risk or harmful effects to human health (see art.21 and following of Reg. 726/04 and art. 101 and following of Directive 2001/83). For the same provisions in the previous legislative framework see Art. 19-26 of Regulation 2309/93 and Art. 11-12 of Directive 65/65.

⁹ According to the Annex I of the Regulation for certain categories of drugs (such as treatments for AIDS, cancer or neuro-degenerative diseases) the centralized procedure is mandatory. For the others, it is optional to use centralized procedure.

¹⁰ In case of objections concerning the safety of the product by a national health authority in the framework of the mutual recognition procedure, specific sub-procedures are in place in order to facilitate coordination and the review the assessment made by the first national authority, see Artt..27-39 of Directive 2001/83.

¹¹ It is important to stress that the abridge procedures do not trigger the patent protection. In fact, if the generic producer places on the market the generics before the expiration of the patent, it could be sued for patent infringement.

¹² The principles at the basis of the introduction of the abridged procedure can be found at recital 14 of the Directive 2004/27 as well as at recital 1 and 3 of Directive 87/21.

¹³ Data exclusivity accords further market protection to the originator of pharmaceutical data, by preventing health authorities from accepting applications for generic drugs during the period of the exclusivity. It was firstly introduced by Directive 65/65 and now is regulated under Art. 10 of Directive 2001/83, as amended in 2004 by Directive 2004/27, which, finally, harmonized the data exclusivity period at EU level.

¹⁴ Council Regulation no. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medical products, O.J. [1992] L 198/1.

granted by a patent would be eroded because of the time necessary to develop and submit to trials the chemical patented substance, being the object of the patent protection itself. The extra-protection granted via a SPC cannot exceed the five years after the expiration of the patent. According to the provisions into force at the time when the alleged abuses took place a SPC could be obtained if the following cumulative conditions were met: “a) the product is protected by a basic patent in force; b) a valid authorization to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65 or Directive 81/851, as appropriate; c) the product has not already been the subject of a certificate; d) the authorization referred to in (b) is the first authorization to place the product on the market as a medicinal product” (art. 3 Reg. 1768/92).

The regulation set up a transitional provision in order to also allow drugs whose first market authorization was granted before the coming into force of the regulation, but after 1st January 1985, to be eligible for a SPC. However, the cut-off date of January 1985 was not uniform throughout the Community Derogations were introduced in order to take the specificities of single Member States into consideration.¹⁵ Such heterogeneity as well as the unclear provisions of the regulation; as it will be examined further, gave AZ the incentive to “play around” with the dates and the notion of “first market authorization”.

2. The Commission decision

The analysis of the Commission decision will focus on the three pleas in law raised by AZ in its appeal to the CFI¹⁶ against the Commission Decision, namely: the error in the definition of the relevant market, the error in considering that AZ intentionally provided national patent offices with misleading information in order to gain SPC protection for its expiring patented drug Losec, the error in finding the deregistration of the market authorisation for the Losec capsule formulation and its replacement with the tablet formulation on certain relevant markets as abusive.

Losec (whose active principle is omeprazole) is one of the best selling drugs on record (in 2000 the worldwide turnover for this drug reached 6.3 billions of dollars) and its therapeutic employment mainly relates to acid-related gastro-intestinal diseases¹⁷.

2.1 The market definition and the assessment of dominance

The Commission Decision is extremely interesting not only because it added two new forms of abuse to the open-ended list laid down in Art. 82 EC, but also because for the first time the Commission was called to define the relevant market under Art. 82 in the pharmaceutical sector. In undertaking such a task the Commission relied on the experience gained and on the practice developed in the field of mergers amongst pharmaceutical companies¹⁸.

As for the product market dimension, the Commission rightly highlights that the specific characteristics of the pharmaceutical market that makes price competition less relevant than non price-competition. Firstly the price of patented drugs is normally regulated by national health authorities which act as a monopoly on the buyer side (monopsony); secondly, in the pharmaceutical market the final consumer (the patient) does not choose the product, but the doctor makes the decision for him. Moreover, the final consumer bears only partially bears the

¹⁵ According to Art. 19 (2) and (3) of Reg. 1768/92, the cut-off date for Denmark and Germany was 1 January 1988, while for Belgium and Italy was 1 January 1982.

¹⁶ Cf. Notice for the O.J., Action brought on August 25 August 2005 S *AstraZeneca/Commission*, Case T-321/05, O.J. [2005] C 271/27.

¹⁷ In particular: peptic ulcer diseases, gastro-intestinal oesophageal reflux and dyspepsia, see Commission Decision recital 24-28. Omeprazole was patented in 1979, so its patent expired in 1999.

¹⁸ From the beginning of the 1990s the European pharmaceutical industry has gone through a wide restructuring process which has been mainly achieved via merger and acquisitions see *Innovation in the pharmaceutical sector a study undertaken for the European Commission by Charles River Associates* (8th November 2004). Amongst others, the following merger decisions are particularly relevant for the way in which the Commission has shaped its way of defining the market for in the pharmaceutical sector: Commission Decision M. 3544, *Bayer Healthcare/Roche*, November 19, 2004; M:3354 *Sanofi-Sybelabo/Aventis*, April 26, 2004; and *Pfizer/Pharmacia*, February 27, 2003.

For an introduction to the problems arising in defining markets in the pharmaceutical sector and for a proposal for the modification of the current approach see A. COSCELLI AND A. OVERD, *Market definition in the pharmaceutical sector*, in *E.C.L.R.* 2007, p. 294.

costs of the drugs which are generally fully or partially covered by public or private insurance schemes¹⁹.

The Commission therefore relied on the product characteristics, in particular on the therapeutic use as evidence of competitive constraints as well as on price pattern substitutability in the relevant period of time.

For the assessment of competition constraints concerning the therapeutic use, the Commission based its analysis, as it did in merger cases, on the Anatomical Therapeutic Chemical (ATC) classification system as laid down by the European Pharmaceutical Market Research Association (EPHMA). In the context of the ATC, medicines are classified into groups at five different levels, according to the diseases they are suitable to treat and the organs on which they operate, moving from a general classification (level 1) to a more detailed one (level 5)²⁰. Level 3 encompasses medicines in terms of their therapeutic use, i.e. their intended use. This is in general the level from which the Commission begins its product market definition in competition cases, being aware that it is just a starting point and that the classification can be narrowed or broadened, according to the evidence and the information at disposal.

In the present case the Commission started from third ATC class “*drugs for the treatment of peptic ulcer*”²¹, including besides omeprazole, histamine antagonists (also known as H2 blockers) which were widely used for the treatment of ulcers before the launch of omeprazole. In particular, the Commission narrowed the market to the mere omeprazole (PPI), by dint of the different modes of action between H2 blocker and omeprazole. The former in fact has only indirect effects on the treatment of acid related diseases, while omeprazole has a direct effect on proton pump in the stomach’s cells²².

As for the price substitution, the Commission noticed that in the relevant period of time the H2 antagonist did not exert any competitive pressure on Losec, whose market share kept growing steadily and fast, though Losec was priced three times higher than H2 drugs.

This way of defining the relevant market has been recently endorsed by the CFI in its *GlaxoSmith* judgment of September 2006, concerning a Commission decision in the pharmaceutical sector where Art. 81 was at issue²³.

With regard to the geographic dimension of the market, the Commission considered the relevant market national in scope, considered the fact that national regulations and in particular different administrative and purchasing policies by national health authorities tend to delineate geographic markets along national borders²⁴.

Moving to the assessment of AZ’s dominance, the Commission looked not only to the market shares, but also to other factors. Especially, the first mover advantage enjoyed by AZ in the PPI market, which enabled AZ to maintain higher prices even after the entrance of competitors in the PPI market²⁵, as well as the strong protection of its omeprazole patent which conferred AZ a great bargaining power with respect to national buying authorities (monopsony buyers)²⁶.

¹⁹ See the Commission Decision, para. 362-370. These conclusions of the Commission are in line with the peculiarities of the (European) pharmaceutical market individuated by AG Jacobs in his Opinion in *Syfait* see AG Jacobs’ opinion C-53/03 *Syfait et al. v. Glaxosmithkline AVEE, O.J.*, para 75-99, in particular 75-88.

²⁰ For a more detailed explication of the functioning of the ATC Classification and its application to competition cases see, EFPIA, *Art: 82 EC: Can it be applied to control sales by pharmaceutical manufactures to wholesalers?*, EFPIA Study, November 2004, p. 23.

²¹ Commission decision, para. 372.

²² Commission decision, para. 374-379.

²³ Case T-168/01, *GlaxoSmithKline Services v. Commission* of 27 September 2006, *not yet reported*, para. 155.

²⁴ In particular, looking at the merger decisions, on the geographic definition of the relevant market, the following elements were taken into account to define it nationally: direct or indirect state control of the prices, different level of reimbursement by the social security system, differences in terms of brand and pack size strategies as well as of distribution systems, see *ex multis* Commission Decision *Pfizer/Pharmacia*, *supra*, para. 62-64.

The relevant geographic markets identified by the Commission are: Belgium, the Netherlands, Denmark, the United Kingdom, Norway, Sweden and Germany

²⁵ Commission Decision para. 541.

²⁶ Commission Decision, at para. 517 where it is pointed out that, through its strong patent protection, AZ was able to put pressure on its competitors via patent infringement actions, and para. 553, where it is observed that the bargaining power of monopsony buyers is reduced with respect to companies offering innovative products such as Losec and, moreover, national health systems have no power of controlling the market entry.

2.2 The misleading information infringement (or SPC abuse)

The first alleged abuse consists of the provision of misleading information to national authorities in various Member States in order to obtain undue SPC protection, thereby unlawfully extending the patent protection beyond its natural expiration. The infringement took place in the framework of AZ applications for SPCs in June 1993 (for Germany and Denmark) and December 1994 (for Austria, Finland and Norway). According to AZ the infringement, if any, took place because of the lack of clarity in the wording of the regulation as far as the meaning of “*first authorisation to place [...] on the market*” contained in art. 19(1) of Regulation 1768/92 is concerned.

In particular, it is argued by AZ that unlike the other provision contained in the Regulation 1768/92, Art 19(1) of the above mentioned regulation does not refer to « art. 3 lett b) » of the Regulation, referring to the technical market authorization under directive 65/65 (as for instance art. 8 and art. 10(5) do), but simply refer to the first market authorization. Therefore this expression could be interpreted in several ways, in particular: as the first market authorisation as granted under directive 65/65 or the date of the official price publication by the national authority, or in many other ways²⁷.

Furthermore, AZ contends that this obscurity was implicitly recognized by the ECJ which ruled on the issue, affirming that “[...] *the concept of first authorisation to place [...] on the market [...] in the Community in Article 19(1) of Regulation No 1768/92 refers solely to the first authorisation required under provisions on medicinal products, within the meaning of Council Directive 65/65[...]*”²⁸. In any case, AZ refuses to be held responsible for an infringement that was occurred because of several and different possible interpretation of the legal provisions.

On the contrary, the Commission found AZ guilty, not of having deliberately misinterpreted the meaning of Art. 19 provisions, but of having setting up a “*pattern of misleading representation to patent agents, patent offices and national courts as part of its overall SPC strategy*”²⁹.

In particular, AZ would have concealed information in order to obtain SPC protection in Denmark and in Germany, both countries in the 1988 cut-off date list. More specifically, AstraZeneca did not disclose the fact that it was granted a market authorisation under art. 4 of directive 65/65 in France on March 1987, therefore before the 1st January 1988 cut-off date for Germany and Denmark, disqualifying AZ from SPCs in these countries. Additionally, when filling in its application for those countries, AZ indicated March 1988 as first date of authorization, the date in which the price of Losec was published by the Luxembourg authority in its official publication.

It is worthwhile to remark how AZ, according to its “effective marketing theory”, made use of three different types of dates in the framework of the two rounds of SPC application between 1993 and 1994, according to the specific situation of each country and in particular to the cut-off date cluster in which the country was listed³⁰. The Commission could therefore reasonably infer, as it did, that “*the purpose underlying AZ’s strategy for omeprazole was to strengthen its position on the market by delaying the entry of generic versions of omeprazole and to create extra hurdle for generic firms.*”³¹.

2.3 The selective “deregistration” of market authorization for Losec capsules

The second alleged infringement concerns the application made by AZ to certain national agencies (in Sweden, Denmark and Norway) to authorise the marketing of a tablet formulation of Losec, combined with the request of de-registering the market authorization for the Losec formulation in capsule. This strategy, according to the Commission, was aimed at preventing or delaying the entry of generic producers and parallel traders, via a misuse of the rules concerning the abridged procedure as laid down in Art. 4 directive 65/65.

In particular, as seen above para. 1, the relevant legislation at the time required, in order to take advantage of the abridged procedure for obtaining a market authorization or an import

²⁷ See Commission Decision, at para. 168.

²⁸ Cf. Case C-127/00 *Hassle AB v. Ratiopharm GmbH*, ECR.[2003], p. I-14781, para.79. Considered the clarification made by this judgment, it is very unlikely for this infringement to occur in the future.

²⁹ Commission Decision, at para. 666.

³⁰ Commission Decision, para. 246 and 646.

³¹ Commission Decision, para. 677.

licence, that the reference product was authorized in the Community and that the reference product was marketed in the Member States in which the application was referred³².

According to the Commission AZ used the loopholes present in the legislation in order to enable it to extend the protection granted by the patent beyond the period that the legislator found appropriate to grant to the innovative effort. More specifically, by withdrawing its market authorization for capsule, AZ prevented competitors from accessing to the abridged procedure, thereby raising their costs to enter the market.

AZ contends that it is fully legitimate to switch from one formulation to another according to its right to decide on its business strategy.

The Commission correctly acknowledged the right for a pharmaceutical company to take business decision in line with its commercial policy. However, it is stressed that such business decision should not undermine the competitive process, generating foreclosure effects in the market. In particular, the Commission, relying on the documents found at AZ's premises, argued that there was no acceptable justification for the selective deregistration of Losec capsule other than the intent to delay the entry of generic manufacturers and of parallel traders until the improved version of omeprazole's successor, esomeprazole, was ready to be marketed³³. This conclusion is reinforced by the fact that this strategy was put in place only on those markets (Denmark, Sweden and Norway) where it was likely (as it was) to be successful, bearing in mind the way in which national authorities interpreted the legal provisions. On the contrary in other countries such a strategy was not used with respect to the capsule formulation that, even after the launch of the tablet version, continued to be marketed³⁴.

Therefore, according to the Commission, it was neither the superior quality of the tablet version nor its enhanced effectiveness with respect to the capsule formulation (both legitimate reasons to switch from one to another formulation), but the anticompetitive goal of foreclosing the market to the detriment of competitors (and ultimately of final consumers) that determined AZ's strategy.

3. Comment

Some commentators have recently argued that the Commission should have abstained from imposing fines on AZ for the alleged abuse or at least that it should have imposed a lower fine, considering the novelty of the abuse and the fact that at the time the legislation was not crystal clear³⁵. According to these commentators, AZ just pursued its own commercial strategy using the instruments at its disposal, which should not be deemed contrary to Art. 82³⁶.

In both abuses, loopholes and provisions which were far from clear-cut contained in Directive 65/65 and Regulation 1768/92 were used by AZ in order to prevent competitors and parallel importers from accessing the market of proton-pump inhibitors. This had the knock-on effect of

³² This abuse, as it has been correctly argued, is unlikely to be replicated due to the amendment of Directive 2001/83 (whose art. 10, before the amendments, was basically identical to art. 4 of Directive 65/65) by directive 2004/27 (O.J.2004 L 136/34). According to the new formulation of Art. 10, it is in fact sufficient in order to benefit from the abridged procedure that the generic manufacturer demonstrates that "the medical product is a generic of a reference medical product which is or has been authorised under art. 6 for not less than eight years in a Member State or in the Community". Therefore it is no longer necessary that a market reference authorization is effective in the Member State where the generic manufacturer wish to penetrate. Pending the present Commission investigation, two cases were ruled by the ECJ under art. 234 procedure, concerning whether generic marketing authorizations and parallel import licence could be granted once the market authorization has been withdrawn, see Case C-223/01 *AstraZeneca A/S v. Laegemiddelstyrelsen* [2003] ECR I-11809 and Case C-113/01 *Paranova Oy* [2003] ECR I-4243. In particular, an affirmative answer was given by the Court in the latter judgment the principles expressed were transposed in the amendments to directive 2001/83.

³³ Commission Decision, para. 807.

³⁴ Commission Decision, para. 805.

³⁵ M.I. MANELY AND A. WRAY, *New pitfall for the pharmaceutical industry*, in *Journal of Intellectual Property Law and Practice*, 2006, 2, p. 269 and 271 and S. LAWRENCE AND P. TRACY, "The Commission's AstraZeneca decision. Delaying generic entry is an abuse of dominant position", in *Journal of Intellectual Property Law and Practice*, 2005, 1, p. 7.

As far as the level of the fine imposed to AZ is concerned, it is important to remark that it is true that novel abuses, as in the present case, are in general fined more generously. However, as it is apparent from the Commission's decision, a series of factors were taken in consideration, such as: the nature of the infringements and their impact on the market; their duration; the extension of the geographic market concerned in order to establish such a high fine.

³⁶ M.I. MANELY AND A. WRAY, *ibidem*, p. 268-269.

depriving the final consumers (and the national health system) of their “*entitlement to cheaper equivalent generic drugs or upgraded versions of patented drugs if the companies which try to bring these drugs to the market do so without infringing the existing patents*”³⁷. It is worthwhile to analyze separately the issues related to the two alleged infringements.

With regard to the SPC abuse, it is evident how AZ “has played around” the relevant date in order to obtain a protection it was not entitled to. If the aim of SPC protection, as well as of patents, is to reward the innovative effort, in this specific case carried out by pharmaceutical companies, it is evident that in this case the legislator put a limit to this benefit, striking a balance between competition and innovation protection. AZ by its conduct tried to undermine the legislator’s objectives, by conducting itself in a manner that contrasted with the aim of SPC, i.e. rewarding genuine innovation. It is therefore self-evident how AZ tried to misuse the provisions of the Regulation in order to gain a right it was not entitled to³⁸³⁹. As a consequence of the illicit supplementary protection acquired AZ was able to extract monopoly profit for longer than it should have been and to limit the potential innovation of its competitors.

Trying to unlawfully obtain an intellectual property right, by providing misleading information to national administrative authorities, does neither belong to the specific subject matter of the intellectual property right (the SPC in the case), nor it steers innovation (on the contrary if such a practice is not sanctioned there is the serious risk that not genuine innovation is protected to detriment of further innovation and finally of consumers). The prohibition of a practice such the one carried out by AZ should therefore be straightforward under EC competition law.

It is apparent the difference existing between the present case and the many others ruled by the European Courts, where the intellectual property rights were lawfully acquired/obtained and the holder was alleged of using them in an anticompetitive manner (in the refusal to licence cases, for instance)⁴⁰.

As a consequence we maintain that in the present case the question of the delicate balance between innovation and competition is not at stake⁴¹. It is in fact evident that AZ was seeking for a protection it was not entitled to, since the legislator had established that only if the first market authorization had been obtained after the cut-off dates indicated in the directive, the SPC protection could be granted. This means that according to the legislation AZ’s patent was not eligible for SPC protection in certain Member States.

Therefore no striking exercise is needed in the present case since AZ “effort” did not deserve protection under IPR regime and we have to move immediately to assess whether its behaviour can be deemed anticompetitive under Art. 82 EC.

Consciously concealing information, as it results from AZ internal memoranda⁴², cannot be held legitimate under EC competition law. This strategy can severely harm the competition in the market, keeping artificially competitors (generic drugs’ manufacturers) at the gate and thereby reinforcing and extending AZ’s dominant position.

³⁷ Cf. M. MONTI, “*EC Antitrust Policy in the Pharmaceutical Sector*”, speech at the Alliance Unichem Conference, Brussels, March 26, 2001, p. 14. See as well Commissioner NEELIE KROES’ reply to the Oral Question put by the honourable Member of the European Parliament Mr Von Boguslaw Sonik on 13th June 2006 (H-0459/06) reported by N. DE SOUZA, “*Competition in Pharmaceuticals: the challenges ahead post AstraZeneca*” in *Competition Policy Newsletter*, 2007, 1, p. 39 at 41.

³⁸ See N. FAGERLUND AND S.B. RASMUSSEN, *AstraZeneca: the first abuse case in pharmaceutical sector*, in *Competition Policy Newsletter*, 2005, 3, p. 55. *Contra* M.I. MANELY AND A. WRAY, *supra*, p. and S. LAWRENCE AND P. TRACY, *supra*, p. 270.

³⁹ It is important to stress at this point the difference between the present case and the Italian Merck case (on which see Ibanez Colomo’s contribution). In the Italian Merck case the issue concerned the use of a valid intellectual property right and the refusal to licence the patent for the production of the relevant active ingredients for the use in other countries. In AstraZeneca the issue is raised with respect to the distortion of the procedures in order to be granted an IPR.

⁴⁰ See for instance Joined Cases C- 241 and 242/91, *Radio Telefis Eirann v. Commission* (Magill), [1995] ECR I-743 or Case 238/87, *Volvo (UK) Ltd. v. Veng AB*, [1988] ECR p. 6211 or Case C-418/01, *IMS Health GmbH &Co. OHG v. NDC Health GmbH &Co. KGm*, [2004] ECR I-5039.

⁴¹ This conclusion seems to be suggested as well by I.S. FORRESTER, *Regulating Intellectual Property Via Competition? Or Regulating Competition Via Intellectual Property? Competition and Intellectual Property: Ten Years On the Debate Still Flourishes*, in C.D. EHLERMANN AND I. ATANASIU, *The Interaction between Competition Law and Intellectual Property Law*, Hart Publishing, London, 2007, p. 59, at 70.

⁴² Commission Decision, para. 163 and followings as well as para. 648 and followings.

Furthermore it has been argued that the existence of specific remedies under IPR law, namely the nullity of the SPC, could by themselves cope with situation like these making competition law protection redundant⁴³. It has been correctly observed that the fact that other remedies exist, does not exclude the possibility to apply competition law provisions, if the conditions for antitrust infringements are fulfilled. This is foremost true, considering that it is possible that IPR remedies could be unsatisfactory or unavailable in particular circumstances⁴⁴.

Such a conclusion is reinforced if one endorses the perspective according to which IPR and competition rules have as their ultimate scope the fostering of innovation and the increase of consumer welfare⁴⁵. It is therefore arguable and desirable that the remedies offered by the two sub-systems of law are used as complement rather than as alternative tools.

Furthermore it is worthwhile to remark that a concurrence of remedies in the pursuit of antitrust goals is enshrined in the Treaty provisions itself. In fact, under Art. 81(2) an agreement violating Art 81(1) is declared null and void. Nullity is a sanction typical of the contract law legal order and its application together with antitrust fines is an example on how different branches of the legal system can interact in order to achieve common goals/objectives. In the case of Art. 81(1) infringements nullity and antitrust fine are not mutually exclusive on the contrary they apply cumulative to the same illicit behaviour.

Moreover, in its seminal judgments *Crehan vs. Courage*, the Court of Justice ruled that liability for damages constitutes an essential instrument in order to assure the effectiveness and the of Art. 81⁴⁶.

Once again, it resorts that different sub-system of law can be called into application in order to assure the maximum compliance of competition rules and the achievement of its aims.

As it is clear from the consideration developed above the fact that a remedy exists under IP law does not rule out the possibility of applying antitrust remedies (and vice-versa) and I think that this was implicit in the early judgments of the Court where it firstly applied competition law provisions to IPRs⁴⁷.

Of course, antitrust sanctions will be imposed insofar as/to the extent that an antitrust infringement can be established on the basis of the undertaking's conduct. The fact that the IPR and competition remedies are complementary does not imply that from the application of one follows the application of the other, it simply means that they could be granted cumulative, according to the conditions under which each remedy is granted.

Turning to the issue of the selective withdraw of the Losec capsule formulation and its substitution with the tablet one (Losec MUPS), it is important to stress from the outset that the alleged abuse was achieved/carried out without (mis)using IPR protection, but by strategically misusing regulatory procedures and rules concerning the market authorization of generic drugs.⁴⁸.

⁴³ M.I. MANELY AND A. WRAY, *supra*, p. 268.

⁴⁴ N. FAGERLUND AND S.B. RASMUSSEN, *supra*, p. 55 who correctly point out how in many cases "there would be no sanction apart from the annulment of the SPCs" and in others, such as failed attempts to obtain SPCs through misleading information, no sanction would be imposed under the IPR regime.

⁴⁵ See *ex multis*, P. LOWE AND L. PEEPERKORN, *Intellectual Property: How Special is its Competition Case?*, in C.D. EHLERMANN AND I. ATANASIU, *The Interaction between Competition Law and Intellectual Property Law*, Hart Publishing, London, 2007, p. 91.

⁴⁶ In particular the Court stated that "[...] the full effectiveness of Article 81 of the treaty and, in particular, the practical effect of the prohibition laid down in Article 81(1) would be put at risk if it were not open to any individual to claim damages for loss caused to him by a contract or by a conduct liable to restrict or distort competition [...] the existence of such a right strengthens the working of the Community competition rules and discourages agreements or practices, which are frequently covert, which are liable to restrict or distort competition. From that point of view, actions for damages before the national courts can make a significant contribution to the maintenance of effective competition in the Community [...]" Case C-453/99, *Courage Ltd v. Bernard Crehan*, [2001] ECR I-6297, para. 26 and 27.

⁴⁷ See Joined Cases 56 and 58/64 *Costen and Grundig v. Commission*, [1966] ECR p. 299; Case 24/67 *Parke Davis v. Probel and others*, [1968] ECR p. 55; Case 78/70, *Deutsche Grammophon v. Metro*, [1971] ECR p. 487.

⁴⁸ In fact, as explained above, at the time the alleged abuse occurred for taking advantage of the abridged procedure for the authorization of generic drugs provided by art. 4 paragraph 3 point 3(a) (iii) of directive 65/65 it was considered necessary that the authorization for the reference medical product was still in place when the assessment of the generic drug took place.

In such a way, making use of a regulatory gap, AZ was able to raise its rival's costs to access the market⁴⁹, reserving for its extra-monopoly profit to which it was not entitled to. More specifically, AZ's behaviour was aimed at preventing generic competitors from entering the market using a strategy that have no other objective than extending *de facto* its monopoly over certain markets for a period longer than the expiration of its patent rights.

In its decision the Commission correctly points out/acknowledges that "[...] *single acts involving the launch, the withdrawal or requests for deregistration of a pharmaceutical product would not normally be regarded as an abuse*",⁵⁰ so reaffirming the principle of commercial freedom, implying that all undertakings must in principle be able to pursue the commercial strategy that better suits their business.

However, this principle is not absolute and it cannot be used for threatening the competitive process.

In particular, it results that this strategy was planned by AZ in order to delay the entry and the parallel trade of omeprazole generic until the launch of a new patented product, the esomeprazole: an improved version of omeprazole⁵¹. Moreover, the replacement of Losec capsule with Losec tablets took exclusively place in those countries where AZ believed there were chances to keep generics out of the market⁵².

Furthermore it seems that there is no room for an objective justification's defence by AZ. First of all, its strategy did not represent a standard practice applied by the undertakings, considered that it took place only in certain markets, suggesting that a market for capsule could coexist with the one for tablet⁵³. Secondly, the withdrawal was not justified by the superior characteristics of the tablet version, seen that in other countries the capsule continued to be marketed.

In order to tackle this kind of abuse, we agree with the perspective suggested by certain authors⁵⁴ according to whom cases involving abuse of regulatory or government procedures should be assessed in the light of the principles elaborated for vexatious litigation⁵⁵. In fact as in the case of vexatious litigation, in the case of abuse of regulatory procedure we are dealing with the exercise of faculties granted by the law. It is however indispensable to draw the line between the exercise of the such rights and their abuse. Therefore we maintain that, as in vexatious litigation cases only under exceptional circumstances the exercise of a faculty (like withdrawing a market authorization) may be caught by Art. 82⁵⁶. As to the standard of scrutiny it should take into account on one hand whether the behaviour is baseless and on the other whether it is conceived in the framework of a strategy aiming at eliminating competition⁵⁷.

It is apparent from the discussion above that both criteria were fulfilled in the present case and that the anticompetitive effects of keeping competitors out of the market was achieved thanks to the employ of larger strategy, coupling the withdraw abuse in itself with the SPC abuse.

It is finally worthwhile to remember that according to the case law, the notion of abuse encompasses not only the undertaking's behaviour in the market, but also the its behaviour outside the market⁵⁸.

⁴⁹ Indeed, in the absence of data to which refer, the generic manufacturer would have needed to carry out its clinical tests, which discourages the incentive to penetrate the market.

⁵⁰ Commission Decision, at para. 792. At para. 793 the Commission states/affirms: "[...]it is not the Commission's case that the launch of a new formulation of Losec (Losec MUPS) and/or the withdrawal of Losec capsules could as such constitute an abuse"

⁵¹ Commission Decision, para. 807 and followings.

⁵² Commission Decision, para. 800 and followings.

⁵³ Commission Decision para. 821.

⁵⁴ R. O' DONOUGHE AND J. PADILLA, *The law and economics of Art. 82 EC*, Hart Publishing, London, 2006, p. 530.

⁵⁵ The leading case is the Case T-111/96, *ITT Promedia NV vs. Commission*, [1998] ECR- II 2937, but see as well Case 222/84, *Johnston v. Chief Constable of the Royal Ulster Constabulary* [1986] ECR 1651.

⁵⁶ See Case T-111/96, *ITT Promedia NV vs. Commission*, para. 60.

⁵⁷ Case T-111/96, *ITT Promedia NV vs. Commission*, 55-57. See as well . O' DONOUGHE AND J. PADILLA, *The law and economics of Art. 82 EC*, p. 526 and 530.

⁵⁸ Joined Cases C-395/96 P and C-396/96 P, *Compagnie Maritime belge and others v. Commission*, [2000] ECR I-1365, para. 82-88 and T- 24/93 para. 108.

Eventually, the special responsibility born by a dominant undertaking obliges it to interpret and construct the meaning of Community secondary sources (such as Regulation 1762/92 on SPCs or Directive 65/65 on market authorization) in line with primary competition law provisions laid down in Art. 81 and 82.

Loopholes in a regulation or in a directive cannot be used to frustrate the aims of the Treaty (the establishment of an internal market where competition system of undistorted competition). Nor can unclear provisions contained in secondary legislation be interpreted or applied in a way contrary to the Treaty's superior provisions⁵⁹. Foremost, in the case of the withdraw abuse it is evident how the way in which was even in contrast with the aim of the directive, whose objectives via the introduction of an abridged procedure were to foster the entry of generic, eliminating the burden of carrying out further clinical trials.

It could be argued after the recent opinion delivered by AG Jacobs in *Syfait* and the recent judgment by the ECJ in *Bayer (Adalat)*⁶⁰ and *GlaxoSmithKline*⁶¹ that the Court is moving towards a more lenient application of competition rules in the pharmaceutical sector. In particular, as far as infringements of art. 82 are concerned (as in the present case) this statement seems not to be true. Taking a closer look at the very persuasive opinion of the AG in *Syfait*, it is evident that his doctrine is strictly applicable and far from opening the floodgates for the non-application of competition rules in the pharmaceutical sector.

In particular the AG emphasised the specificities of the pharmaceutical industry, namely: the highly regulated environment, the economics of pharmaceutical industry and the consequences of parallel trade for consumers and purchasers. He then went on arguing that because of these specificities the restriction of parallel trade via the refusal to supply customers beyond their actual needs could be justified if reasonable and proportionate. In particular, due to the fact that the market is already partitioned because of the state-imposed price disparities and of the public service obligation imposed on pharmaceutical manufacturers, the restriction stemming from the refusal to supply is marginal and moreover *"to require the undertaking to supply all export orders placed with it would in many cases impose a disproportionate burden given the moral and legal obligations on it to maintain supplies in all Member States"*⁶².

However, it is important to note what was stated in the second last recital of the opinion: *"Lastly, I would note that the above analysis does not preclude the possibility that a restriction of supply by a dominant pharmaceutical undertaking might fall foul of the Court's established case-law on refusal to supply if it had negative consequences for competition arising other than as a consequence of its restriction of parallel trade"*⁶³.

It is apparent how this last sentence narrows down the conditions under which the proposed doctrine can be applied. In particular, in *AstraZeneca* the abuses were not only aimed at restricting parallel trade, but they mainly prevented generic manufacturers from entering the market. It would be quite surprising if the CFI found AZ's behaviour justified in the light of AG Jacobs' opinion in *Syfait*.

The *"Syfait doctrine"* as laid down by AG Jacobs, in fact, justifies only *"reasonable and proportionate measures in defence of [...] undertaking[s] commercial interests"*⁶⁴. In AZ not only the abuses had effects going beyond the mere restriction of trade for the protection of business's interests, but further, the very protection of the undertaking's interests was neither reasonable nor proportional. It has been demonstrated how in AZ the restrictions are far from being justified considering that they are aiming at obtaining an extra-protection AZ was not entitled to via IPR misuse or regulatory procedure distortion. Contrary to *Syfait*, in the present case the interests behind the conduct are not legitimate, consequently any step taken to defend such interests cannot be deemed reasonable and proportionate.

⁵⁹ See as well for the withdrawal abuse Commission Decision, para. 833.

⁶⁰ Case C-2/01 P and 3/01 P, *BAI and Commission v. Bayer*, [2004] ECR I-23.

⁶¹ Case T-168/01, *GlaxoSmithKline Services vs. Commission*, not yet reported.

⁶² AG Jacobs' Opinion in *Syfait*, *supra*, para 100.

⁶³ AG Jacobs' Opinion in *Syfait*, *supra*, para. 104. Furthermore, paragraph 103 reads as follow: *"also consider that conduct by a dominant pharmaceutical undertaking which more clearly and directly partitioned the common market would not be open to a similar line of defence. The proportionality of the restriction of supply derives in part from the very limited contribution which it makes, in the pharmaceutical sector, to market partitioning."*

⁶⁴ AG Jacobs' Opinion in *Syfait*, *supra*, para 100.

In conclusion, even if these abuses, are unlikely to occur again as the relevant legislation has either been amended or repealed⁶⁵, I think that this decision, if upheld by the European courts, is landmark one for European competition policy.

Firstly, it reaffirms that there are no safe-harbours from the application of Art. 82 and, in particular, that abuse of regulatory or government procedures is caught by the Treaty rules on the abuse of dominant position. In fact, this case illustrates that in the context of highly regulated sectors, such as the pharmaceutical one, undertakings are keen on indulging in subtle attempts to distort procedures to gain protection from competition. Nonetheless, it is unquestionable that if the undertaking is able to provide a legitimate business justification for its behaviour, such as health/security reason or product quality, Art. 82 should be set aside.

Secondly, the present decision is a step further toward a convergent (uniform) application of competition rules on both sides of the Atlantic. In the US in fact the so-called “Orange book abuses”, that are similar to the SPC abuse in AstraZeneca, are caught by paragraph 2 of the Sherman Act, according to a constant position of the American antitrust authorities and jurisprudence of the American courts⁶⁶.

Thirdly, the decision is a signal to private parties aimed at enhancing the private enforcement of competition law provisions. By this decision in fact the Commission is drawing to the attention of generic manufactures, parallel traders and small and medium size innovative firms that they can rely not only on the traditional IPR protection, alleging the invalidity of an IPR, but also that competition law can offer them a remedy against illicit conduct by dominant undertakings. The importance of affirming this principle is self-evident, considered that after the coming into force of Reg. 1/2003 national courts are fully involved in the application of European competition law provisions. Competitors affected in their innovative process by the misuse of regulatory procedures will be able to go to national courts and to attempt to put an end to the infringement as well as to ask for the damages stemming from it.



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⁶⁵ See *supra* note 32.

⁶⁶ For a summary of the American way of approaching the misuse of regulatory and governmental procedures in the pharmaceutical sector, see J GUNTHER AND C. BREUVAR, “*Misuse of Patent and Drug Regulatory Approval System in the Pharmaceutical Industry: an Analysis of US and EU Converging Approaches*”, in *ECLR* 2005, p. 669.

A useful source of information concerning the FTC and DOJ practice in these cases can be found at the following link: http://www.usdoj.gov/atr/public/hearings/single_firm/sfcdec.htm.

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