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Kristina Nordlander & Patrick Harrison
Sidley Austin

Abuse of Regulatory Procedures in the Pharmaceutical Sector—Developments Since the General Court's Judgment in *AstraZeneca*

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I. INTRODUCTION

In June 2005, the European Commission ("Commission") issued a decision finding that AstraZeneca had breached Article 102 TFEU by engaging in conduct aimed at blocking or delaying market access for generic alternatives to its blockbuster Losec product.[2] The decision was highly controversial at the time, and the Commission acknowledged that it was making "novel" findings of abuse of regulatory procedures, but, in July 2010, the EU's General Court handed down a judgment largely upholding the Commission's decision.[3] Many commentators—including the authors of this article—thought at the time that the terms of the General Court's judgment might embolden the Commission and the EU Member States' National Competition Authorities ("NCAs") in their enforcement of Article 102 TFEU in the pharmaceutical sector.[4]

This article explores key developments in the concept of abuse as applied in the pharmaceutical sector since the General Court's landmark July 2010 judgment in *AstraZeneca*. The article focuses on: (i) the April 2011 decision of the Office of Fair Trading ("OFT") in relation to *Reckitt Benckiser*;[5] (ii) the January 2012 Autorità Garante della Concurrenza e del Mercato ("AGCM") decision in relation to *Pfizer Italy*;[6] and (iii) the May 2012 Opinion of Advocate General ("AG") Mazak in the appeal to the European Court of Justice ("ECJ") of the General Court's *AstraZeneca* judgment itself.

The authors conclude that NCAs do indeed appear to have been emboldened in their enforcement of Article 102 TFEU in the pharmaceutical sector and that in subtle, but important, ways, recent NCA decisions may have expanded the notion of abuse of regulatory procedures which lay at the heart of the Commission's seminal *AstraZeneca* case. Indeed, it even appears from the *Pfizer Italy* decision, that NCAs may be using the observations made by the Commission in its 2008-2009 Pharmaceutical Sector Inquiry as a means of further expanding the

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[1] Kristina Nordlander is a partner in Sidley Austin's Brussels office. Patrick Harrison is an associate in Sidley Austin's London office. The views expressed in this article are exclusively those of the authors and do not necessarily reflect those of Sidley Austin LLP, its partners, or clients. The authors are grateful for the assistance of Angelene Duke of Sidley Austin's London office in the preparation of this article.

[2] Commission decision of June 15, 2005, *available at*: http://ec.europa.eu/competition/antitrust/cases/dec_docs/37507/37507_193_6.pdf.

[3] Case T-321/05 *AstraZeneca v Commission*, judgment of 1 July 2010.

[4] *See*, Nordlander & Harrison, *General Court's AstraZeneca Judgment Set to Embolden Commission*, 9(2) CPI ANTITRUST CHRON., (September 2010), *available at* https://www.competitionpolicyinternational.com/file/view/6362.

[5] Decision in case 53/11 of 13 April 2011.

[6] Decision in case A/431 of 11 January 2012.

concept of abuse as set out in *AstraZeneca*. Before addressing these developments, it may be helpful to summarize the key findings in the *AstraZeneca* case itself.

II. ASTRAZENECA

In its June 2005 decision in the *AstraZeneca* case, the Commission identified two distinct abuses of dominance for purposes of Article 102 TFEU. First, the Commission found that AstraZeneca had made misleading representations before patent authorities in a number of Member States in order to obtain Supplementary Protection Certificates ("SPCs") to which it was not entitled. Second, the Commission found that AstraZeneca had (mis)used the applicable regulatory procedures in some Member States by securing deregistrations of certain of its marketing authorizations with the aim of hindering parallel trade and the introduction of generics.

AstraZeneca appealed to the General Court seeking annulment of the Commission's decision on the basis that the Commission had erred in: (i) defining the relevant product markets; (ii) finding AstraZeneca dominant; and (iii) classifying AstraZeneca's rational commercial behavior as abusive. The General Court's judgment largely upholding the Commission's decision came as something of a blow to many in the innovative pharmaceutical industry who had been hopeful that the Commission's decision would be overturned. The General Court's findings on market definition and the concept of dominance are of great interest but are not the focus of this article. Rather, the focus of this article is on the types of conduct that can be deemed to constitute abuse for purposes of Article 102 TFEU.

The judgment confirmed that the Commission (and the NCAs in the EU's Member States) could penalize the misuse (or even use) of regulatory or patenting procedures where such misuse (or use) impeded the entry of generics. The essence of the General Court's judgment in this regard is perhaps best summed up in the following extract:

> in the absence of grounds connected with the legitimate interests of an undertaking engaged in competition on the merits and in the absence of objective justification, an undertaking in a dominant position **cannot use regulatory procedures solely in such a way as to prevent or make more difficult the entry of competitors on the market**.[7] (Emphasis added.)

The judgment also confirmed that misrepresentations to regulators could constitute abuses for purposes of Article 102 TFEU even absent bad faith on the part of the entity making the (mis)representation. The General Court's language in this regard on disclosure standards was particularly controversial. Paragraph 500 of the judgment was perhaps the most striking: "Consequently, all the applicants' arguments […] are irrelevant, since they can have no bearing on the **abusive nature of the lack of transparency** which AZ displayed when filing the SPC applications." (Emphasis added.) This formulation led to widespread fears that the General Court might have made a finding that a simple "lack of transparency" could constitute an abuse, thus imposing on dominant companies standards of disclosure that were impossibly burdensome.

In these ways, the General Court's judgment appeared to have imposed significant constraints on dominant innovator companies seeking to compete effectively with generic

[7] Case T-321/05 *AstraZeneca v Commission* [2010] 5 C.M.L.R. 28 ¶ 817.

entrants. When considered alongside the concerns expressed by the Commission in the context of its Pharmaceutical Sector Inquiry (regarding matters such as patenting strategies and the use of objection procedures in relation to generic manufacturers' applications for marketing authorizations), it seems those constraints may be even more significant.

Shortly after the General Court's judgment, the authors published an article (in the September 2010 edition of CPI) in which they explained that, whether right or wrong, the General Court appeared to have given the Commission and Member State NCAs license to adopt a more aggressive approach in relation to patent and regulatory procedure-related abuse cases in the pharmaceutical sector.

The subsequent decisions in *Reckitt Benckiser* and *Pfizer Italy* seem to have proved that thesis correct. Section III of this article discusses the OFT's decision in relation to *Reckitt Benckiser* while Section IV discusses the AGCM's decision in *Pfizer Italy*. Both relied heavily on the General Court's *AstraZeneca* judgment as support for their theories of harm but both appear, arguably, to have extended the concept of abuse as set out in *AstraZeneca*. Section V concludes by discussing AG Mazak's Opinion in the appeal of the *AstraZeneca* judgment and the trends that might emerge going forward, depending on the approach taken by the ECJ in the *AstraZeneca* case.

III. *RECKITT BENCKISER*

In April 2011, the OFT announced a decision finding that Reckitt Benckiser had breached Article 102 TFEU and the U.K.'s domestic equivalent, the Chapter II Prohibition, in the market for the supply of certain types of heartburn medicines in the NHS prescription channel in the United Kingdom. The conduct at issue in the *Reckitt Benckiser* case consisted in the withdrawal and de-listing of on older, off-patent product—Gaviscon Original Liquid—from the NHS' computerized prescribing formulary in 2005. At the time of the delisting, although patent protection for Gaviscon Original had long since expired (in 1997), the generic name for its equivalents had yet to be published in the NHS' prescribing software (the generic name was scheduled to be published later that year).

The de-listing of Gaviscon Original meant that when a General Practitioner ("GP") searched for "Gaviscon" within the NHS' formulary of approved products, that GP would only find the entry for Reckitt Benckiser's newer, patent-protected product, Gaviscon Advance Liquid. If the GP then pressed "Crtl + G"—the standard function to check if a generic existed—no generic would appear, meaning that the GP would tend to write a prescription for the patent-protected Gaviscon Advance and the pharmacist in receipt of the prescription would not be able to substitute a generic alternative.

Had Gaviscon Original remains on the formulary, and had the generic name been published alongside Gaviscon Original in the NHS prescribing software later in 2005, it would have been possible for a GP searching for the term "Gaviscon" to identify the generic name of the product from the formulary and then write a prescription allowing a pharmacist to issue a generic alternative to Gaviscon Original.

Given the apparent similarities between AstraZeneca's actions in deregistering Losec in capsule form and Reckitt Benckiser's actions in delisting Gaviscon Original in the NHS prescription channel, it is perhaps unsurprising that the OFT decision—which was issued

following the conclusion of an "Early Resolution Agreement" (i.e. settlement) between Reckitt Benckiser and the OFT—quotes extensively from the General Court's judgment in the *AstraZeneca* case. However, the findings in the OFT's decision could be construed as going further than the General Court's judgment in the *AstraZeneca* case. While the General Court had specifically stated in *AstraZeneca* that there was "no reason to reproach [AstraZeneca] either for launching [a new product] or for withdrawing [the old product] from the market, since those acts were not such as to raise the legal barriers to entry complained of by the Commission[...],"[8] the OFT's decision in *Reckitt Benckiser* gets very close to classifying as an abuse conduct which consisted in the simple withdrawal of an older, less effective version of a product.

It is, of course, the business of innovative companies in the pharmaceutical, technology and other sectors to introduce new products that are better than their older predecessors. It is also highly pro-competitive of such companies to do so. With this in mind, in *AstraZeneca*, the General Court had appeared to set the bar deliberately high for a finding that a removal of an old product could constitute an abuse. First, in general terms, as the General Court observed, there was no reason to reproach an innovative company for launching a new product or withdrawing its older equivalent. Second, the General Court focused its finding of abuse on the deregistration of Losec, *i.e.* not so much the actual withdrawal of the product but rather a particular administrative step taken in the overall context of a withdrawal. Third, the General Court was careful to highlight the geographical selectivity of AstraZeneca's withdrawals and their exclusionary potential as being key to its finding of abuse. Finally, although the General Court accepted that intention could be a relevant factor in identifying what conduct constituted abuse (paragraph 359), it reiterated the findings of the ECJ in the seminal *Hoffmann-La Roche* case, in which it was emphasized that abuse is an objective concept, in relation to which intention is only of secondary importance.

The OFT seems to have approached the task of determining whether a withdrawal could constitute an abuse in a different manner. At Section 6 of its decision, the OFT assesses the Withdrawal (defined at Section 1.2 of the OFT's decision as consisting in the withdrawal and the delisting of Gaviscon Original in the NHS prescription channel). The OFT's analysis opens with an assessment of Reckitt Benckiser's contemporaneous documents in order to determine: (i) whether the internal rationale for the Withdrawal was to hinder generic competition; and (ii) whether the Withdrawal would have been commercially rational were it not for the anticipated hindering of generic competition. Such a central focus on the "intent" of Reckitt Benckiser seems to run counter to the terms of the ECJ's judgment in *Hoffmann La-Roche* (as referenced in the General Court's judgment in *AstraZeneca*) on the objectivity of the concept of abuse and must risk findings of abuse being made largely (if not purely) on the basis of a few unfortunate internal communications.

In addition, by merging in its analysis the actual withdrawal of an older product and the delisting of that product in the NHS formulary, the OFT risks: (i) undermining the helpful comments of the General Court in the *AstraZeneca* judgment on the right of innovators to withdraw products; and (ii) ignoring the fact that it was AstraZeneca's deregistrations—not the actual withdrawals from sale—that constituted the abuse for purposes of Article 102 TFEU.

[8] Judgment, ¶ 811.

IV. *PFIZER ITALY*

In January 2012, the AGCM adopted a decision finding that Pfizer Italy had abused a dominant position in prostaglandin analogs (a type of glaucoma treatment): (i) by engaging in "vexatious" litigation against generic manufacturers looking to enter the relevant market in Italy on which its latanoprost product (Xalatan) was present; and (ii) by applying for a divisional patent in Italy in relation to Xalatan, a supplementary protection certificate ("SPC") in relation to that divisional patent, and a pediatric-specific extension, thereby delaying the expiry of Pfizer's patent coverage for Xalatan from September 2009 to January 2012.[9]

For current purposes, the authors focus on the finding of abuse that is more directly relevant to the *AstraZeneca* judgment, *i.e.* that relating to Pfizer's obtaining of SPCs.[10] The decision appears to extend what constitutes an abuse beyond the terms of the General Court's *AstraZeneca* judgment and places a troubling reliance on concepts considered in the Commission's Sector Inquiry but never tested in a Commission decision—never mind a Court judgment.

The facts of the *Pfizer Italy* case may be summarized as follows. In 1997, Pharmacia (subsequently purchased by Pfizer) filed applications, in most European countries apart from Italy, for SPCs for the main patent of relevance to its Xalatan product. These SPCs extended—entirely legitimately—the protection for Xalatan in those other European countries until July 2011. In Italy, however, where no SPC had been applied for on the main patent, protection was due to expire in September 2009. In 2002, Pharmacia applied for a divisional patent in Italy that related to the main patent of relevance to Xalatan. That divisional patent was granted in January 2009 and had, as is customary, an expiry date equivalent to that of the related main patent in Italy, *i.e.* September 2009.[11] On grant of the divisional patent, Pfizer (which had by now completed its purchase of Pharmacia) set about preparing the formalities for obtaining an SPC on the divisional patent. In June 2009, the Italian patent agency duly granted Pfizer's application for an SPC on the Xalatan divisional patent in question, extending protection until July 2011 when the SPCs on the main patent in other European countries were set to expire. In January 2011, Pfizer then applied for a pediatric-specific six-month extension of the divisional patent, which resulted in protection existing right through to January 2012, the month of the AGCM's decision.

Neither Pfizer nor Pharmacia made any misrepresentations to the relevant authorities in the context of obtaining the patents and SPCs to which they were entitled under the applicable patenting rules. However, that did not prevent the AGCM from concluding that Pfizer's conduct in extending its patent protection for Xalatan constituted an abuse for purposes of Article 102 TFEU.

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[9] The AGCM's decision was contested at the time by Pfizer and is under appeal.

[10] The authors would note, however, that the litigation Pfizer was alleged to have conducted in a "vexatious" manner consisted exclusively in defending actions brought by generic companies challenging its various patents and SPCs. Where an entity only ever responds to litigation filed against it, it is difficult to see how such responses could be viewed as "vexatious."

[11] Divisional patents, which are a legitimate way of splitting an initial patent application, cannot, by definition, exceed the scope of the parent patent. Rather than serving to register new inventions they serve procedural purposes such as ensuring unity of invention or accelerating other patent claims.

There are a number of notable points common to the approaches of the NCAs in the *Pfizer Italy* and *Reckitt Benckiser* decisions. First, the AGCM's *Pfizer Italy* decision quotes extensively from the General Court's judgment in *AstraZeneca*. Second, the AGCM places great reliance on the General Court's dicta regarding conduct constituting abuse under Article 102 TFEU where it is not "competition on the merits." Third, the starting point for the AGCM's assessment of the conduct at issue appears to have been a detailed review of the internal documents evidencing Pfizer's intent, rather than an assessment of whether the conduct—considered objectively—amounts to abuse. Finally, as with the OFT's approach in *Reckitt Benckiser*, the result of the AGCM's approach in *Pfizer Italy* appears to be an unwarranted extension of the concept of abuse under Article 102 TFEU.

In *Reckitt Benckiser*, the unwarranted extension of the *AstraZeneca* judgment lay both in the over-reliance on evidence of intent as evidence of abuse and in the conflation of a legitimate withdrawal of an older product and an arguably exclusionary delisting of that same product. In *Pfizer Italy*, the extension may be even more concerning. The decision appears to hold that not only can misuse of the patent system constitute an abuse (as with AstraZeneca's allegedly misleading representations, which resulted in the grant of SPCs that were not due) but also that the entirely legitimate use of the patent system can constitute abuse.

Clearly, the specific abuses identified in *AstraZeneca* are not the only forms of patent-related (or regulatory procedure-related) abuses that pharmaceutical companies could commit. But surely more must be needed for a finding of abuse than the entirely lawful use of regulatory or patent procedures together with a few internal documents observing that that lawful use might result in better protection of an innovator's commercial interests?

Another troubling aspect of the AGCM's decision is that it appeared to rely on—as precedent—observations made by the Commission in the context of its 2008-2009 Pharmaceutical Sector Inquiry. As noted above, the observations made by the Commission in its Sector Inquiry were precisely that—observations. The Sector Inquiry did not constitute on articulation of the law on abuse of dominance. Indeed, in the annex titled "EC Competition Law" to the Final Report in the Sector Inquiry, the Commission noted, "the purpose of the report [...] is not to carry out a competitive assessment of any of the agreements or company practices described. Such an assessment would require a case by case assessment taking into account all relevant facts."

At the time of issue of the Final Report in the Sector Inquiry, many observers commented that there was a danger that NCAs and national courts might read the Commission's observations as an expression of the law. These observers seem to have been proven right in *Pfizer Italy*. The following two particular instances of the AGCM's reliance on the Sector Inquiry findings seem to be of particular importance to the case and appear particularly concerning in that they demonstrate a willingness to rely on observations in the Sector Inquiry in preference to the precise terms of the General Court's judgment in *AstraZeneca*.

> For the purposes of evaluating the anti-competitive nature of Pfizer's behaviour, it is first and foremost to be pointed out that they fall within the scope of the excluding strategies identified by the European Commission in the recent investigation into competition in the pharmaceuticals sector, engaged in by the originator companies for the purpose of delaying or preventing access to market

> of generic proprietary medicinal products. One of the defensive strategies of the innovative undertakings is the submission of numerous divisional applications for the same patent aimed at blocking the development of a new competing drug through the creation of a dense patent network for the purpose of protecting the same proprietary medicinal product. […] The community court reached the same conclusion in the AstraZeneca case in which it affirmed that the submission of evasive information, even if not directly untruthful, which is such as to lead authorities into error and allow the granting of intellectual property rights to which an undertaking would not be entitled or would only be entitled for a more limited period […] constitutes a case that is particularly restrictive of competition.[12]

In this first excerpt, the AGCM's reference to the Commission's observations on allegedly exclusionary strategies in the Sector Inquiry appears to cause it to ignore the key difference between AstraZeneca's allegedly misleading submissions and the fact that Pfizer's submissions were not misleading.

> Pfizer has pointed out the inapplicability of the AstraZeneca case law to the facts in question since the company did not in any way provide misleading information to the [Patent Office]. Rather, the procedure for evaluating the divisional patent application, which lasted seven years, was completely transparent and fully involved interested third parties. […] Contrary to the defence presented by the party, the Commission Inquiry into the pharmaceutical sector showed, at paragraph 274, the very limited role of third parties in the procedure before the EPO and the scarce transparency of the procedure.

In this second excerpt, the AGCM appears to rebut Pfizer's argument that its submissions to the patent authorities were true and the patent office's procedure perfectly transparent simply by reference to the Commission's observation (in passing) in the Sector Inquiry that patent office procedures were not as transparent or accessible as they might be. Surely perceived imperfections in the patent or regulatory procedures themselves cannot be the basis of a finding of abuse on the part of a company that has to take those procedures as it finds them?

V. AG MAZAK'S OPINION IN *ASTRAZENECA* AND POSSIBLE DEVELOPMENTS GOING FORWARD

Sections of the General Court's judgment in *AstraZeneca*, and the terms of the Commission's Sector Inquiry do indeed appear to have given NCAs the tools with which to pursue abuse of regulatory procedure cases in the pharmaceutical sector. The General Court's upholding of the Commission's controversial 2005 decision, and the General Court's language on conduct that is not "competition on the merits" constituting abuse for purposes of Article 102 TFEU, have given NCAs added confidence in challenging innovative pharmaceutical companies' attempts to defend their commercial interests against ever increasing levels of competition from generic manufacturers. What might in the industry be considered standard life cycle management strategies (such as those adopted by Pfizer in relation to Xalatan) now risk being the source of infringement decisions if an NCA investigates and happens to uncover unhelpful documents.

[12] Decision, ¶¶ 178 and 179.

There must, however, be limits on where the language of the General Court's judgment in *AstraZeneca* can be taken. The OFT's decision in *Reckitt Benckiser* was the result of a settlement agreement, so was not as fiercely contested as perhaps it might have been. The excessive focus on the intent of Reckitt Benckiser and the conflation of the concepts of delisting and withdrawal risk being viewed (albeit erroneously) as precedents for a proposition that all withdrawals of older versions of products are potentially problematic. The AGCM's decision in *Pfizer Italy* is under appeal and sections of the decision may well be deemed to have departed too far from the terms of the *AstraZeneca* judgment. However, Article 102 TFEU cases are seldom won by applicants in the European Courts and there must be a risk that the decision will survive. Indeed, even if the decision is overturned on appeal, it still serves as a reminder of the kind of aggressive approach to innovator conduct that NCAs are looking to take in (purported) reliance on the terms of the *AstraZeneca* judgment.

So what is next in this ever-changing area? AG Mazak's May 15, 2012 Opinion advising the ECJ to reject the arguments put forward by AstraZeneca in its appeal of the General Court's July 2010 judgment certainly appears to be a further blow to the innovative pharmaceutical industry. However, a close analysis of the AG's Opinion does reveal some glimmers of hope for dominant innovator companies concerned with their patent and regulatory-related obligations under Article 102 TFEU.

By way of example, although AG Mazak advises the rejection of AstraZeneca's arguments that the General Court erred in law in suggesting that a simple "lack of transparency" could suffice for a finding of abuse, it is interesting—and not unhelpful—that he appears to be of the view that the relevant standard for a finding of abuse in the context of representations to a regulator is not that there is a simple "lack of transparency" but rather that the conduct in question was "highly misleading" and "characterised by a manifest lack of transparency." This appears to be a much higher bar than the simple "misleading"/"lack of transparency" standard, and, if adopted by the ECJ, may help to address concerns around the standards of disclosure to which dominant companies are held. If adopted by the ECJ, this higher standard may cause NCAs to think twice when considering exactly what types of dealings with patent or regulatory authorities can be classed as abusive.

Even if it does not lead to an overturning of the General Court's judgment, the ECJ's judgment in *AstraZeneca* might lead to a clarification of the relevant legal standards in a way that might be of assistance to the innovative pharmaceutical industry. The ECJ's judgment in the *AstraZeneca* case will certainly constitute the most important word on the application of Article 102 TFEU in the pharmaceutical sector and will doubtless be closely scrutinized. However, unless the ECJ overturns the General Court's judgment, or takes great care in circumscribing the concepts of patent and regulatory-related abuse, it is unlikely to be the last word.