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Kristina Nordlander & Patrick Harrison
Sidley Austin LLP

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I. INTRODUCTION

Five years and two weeks is a long time to wait for a judgment on appeal. For many, it is too long. However, such is the nature of the General Court's July 1, 2010 judgment in *AstraZeneca v Commission*² that innovative pharmaceutical manufacturers and other companies who are at risk of being found dominant may well wish the Court had never issued its judgment at all. Although the precise implications of the *AstraZeneca* judgment for the European Commission's ("Commission") enforcement policy under Article 102 of the Treaty on the Functioning of the European Union ("TFEU")³ will only gradually become known, it seems clear that the Commission will be emboldened in its pursuit of alleged abuses of dominance.

This article seeks to explore key parts of the judgment and their potential impact on Article 102 TFEU enforcement in the EU. Section II of the article sets out the background to the Court's judgment. Section III examines some of the more important points arising out of the judgment, including:

- a) the findings on market definition, where the Court's upholding of the Commission's decision may lead to further Commission enforcement in cases based on narrow and controversial market definitions;
- b) the broad-ranging "transparency" standards for dominant companies when dealing with regulatory authorities;
- c) the findings that representations to authorities can constitute abuses under Article 102 TFEU even absent implementation, fraud, or bad faith and the resultant inconsistency with U.S. jurisprudence;
- d) the Court's observations in relation to the introduction of new products and the withdrawal of their older equivalents;
- e) the Court's pharmaceutical sector-specific observations; and
- f) why the Court's €7.5 million reduction in AstraZeneca's fine is of little significance going forward.

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 comments received from John Treece, partner in Sidley Austin's Chicago office.

² Case T-321/05 *AstraZeneca v Commission*, judgment of 1 July 2010 ('Judgment').

³ Formerly Article 82 EC.

Section IV concludes by commenting on the impact the judgment may have on the Commission's enforcement policy in the pharmaceutical sector and on companies who are at risk of being found dominant on EU markets.

II. BACKGROUND

The *AstraZeneca* judgment relates to a Commission decision dated June 15, 2005⁴ pursuant to which AstraZeneca was fined EUR 60 million for alleged infringements of Article 102 TFEU in relation to its blockbuster antacid product, Losec. The decision found AstraZeneca dominant in a number of national markets for Proton Pump Inhibitors ("PPIs")⁵ and found that it had abused that dominance in two distinct ways.

First, the Commission considered that AstraZeneca had made misleading representations to patent agents, national patent offices, and national courts as part of a strategy aimed at obtaining Supplemental Protection Certificates ("SPCs")⁶ to which it was not entitled. (The "First Abuse.") The Commission concluded that the grant of the SPCs to which AstraZeneca was not entitled had the effect of extending the duration of key Losec patents and preventing generic manufacturers from entering the market. Second, the Commission considered that AstraZeneca had deregistered marketing authorizations for Losec in capsule form in Denmark, Norway, and Sweden in order: (i) to delay and make more difficult the marketing of generic alternatives;⁷ and (ii) to prevent or reduce parallel imports of Losec from EU Members States in which lower prices prevailed. (The "Second Abuse").

AstraZeneca appealed the Commission's two findings of abuse and the finding that Losec formed part of a product market that included only PPIs to the exclusion of other products used to treat acid-related conditions.

III. THE GENERAL COURT'S JUDGMENT

The Court upheld AstraZeneca's claim that the Commission had failed to prove to the requisite standard that the deregistrations of Losec in capsule form in Denmark and Norway were capable of reducing parallel imports. For this reason, the Court reduced AstraZeneca's fine from EUR 60 million to EUR 52.5 million. However, the Court upheld the remainder of the Commission's decision. This Section examines the Court's findings and its observations in a number of areas that will be of interest not only to pharmaceutical companies but also to companies at risk of being found dominant in other sectors.

A. Market Definition

AstraZeneca argued during the administrative proceedings and before the Court that the Commission was wrong to exclude other antacids, specifically products known as H2 blockers, from its assessment of the relevant market. Inclusion of H2 blocker sales would have impacted

⁴ Commission decision of June 15, 2005, *available at*: http://ec.europa.eu/competition/antitrust/cases/dec_docs/37507/37507_193_6.pdf

⁵ PPIs are a type of antacid pharmaceutical product.

⁶ SPCs extend the period for which a patented product is protected in order to compensate the patent holder in respect of a period prior to marketing authorization being granted during which it was not possible to exploit the product.

⁷ Under the regulatory regime applicable at the time of the conduct in question, generics could only avail of an abridged authorizations procedure where the related innovative product was still the subject of a valid marketing authorization.

the Commission's findings as to AstraZeneca's dominance, which would, in turn, have undermined the decision's reliance on the Article 102 TFEU prohibition.

AstraZeneca argued that H2 blockers and PPIs should be deemed to form part of the same market (*inter alia*) for the following reasons: (i) the two products were prescribed to treat the same conditions (i.e. acid-related conditions); (ii) PPIs only gradually replaced the less effective H2 blockers (implying that the latter constituted a significant competitive constraint on the former during the replacement period); and (iii) the large price differentials between PPIs and H2 blockers could not be used as evidence that they belonged to separate markets since prices in the EU's pharmaceutical sector were the product not of ordinary competition but of complex negotiations with individual Member State governments.

The Court rejected AstraZeneca's arguments on market definition and found that the Commission had not committed a "manifest error" of assessment. The Court dealt with the three AstraZeneca arguments outlined above as follows. First, it found that, although PPIs and H2 blockers were both used to treat acid-related conditions, PPIs were used in a different manner to H2 blockers (*i.e.* PPIs were used to treat "severe" forms of the relevant conditions whereas H2 blockers tended to be used to treat the "less severe, or mild, forms of those conditions").⁸ Second, although PPIs had gradually replaced H2 blockers, the Court observed that "the gradual nature of the increase in sales of a new product substituting for an existing product cannot, in itself, suffice to conclude that the existing product exercises a significant competitive constraint over the new one."⁹ Finally, the Court held that, since the prices for new pharmaceutical products agreed as between manufacturers and EU Member State governments depended to a large extent on the products' therapeutic value, price differentials could indeed be used as an indicator that different products belonged to different economic markets.

The Court's findings in relation to the third of the three arguments outlined above will be of particular concern to the innovative pharmaceutical industry, which has repeatedly sought to rely on the government-regulated nature of competition in the pharmaceutical sector as a means of defending conduct that might otherwise be deemed anticompetitive.¹⁰ Indeed, it would appear to be the case that where an innovative pharmaceutical company is successful in negotiating a significantly higher price for its new product (PPIs) than prevailed for its rivals' inferior versions (H2 blockers), that innovative company would automatically be increasing the chances of being found dominant in a separate market encompassing only that new product.

The Court's rejection of AstraZeneca's other arguments (regarding (i) the similar end-uses for H2 blockers and PPIs and (ii) the gradual replacement by a new product of its older equivalent) will be troubling not only for innovative pharmaceutical companies but also for companies operating in other sectors and fearing being found dominant on markets defined narrowly by reference only to newer products.

⁸ Judgment, ¶ 72.

⁹ Judgment, ¶ 90.

¹⁰ Also of concern in the context of the introduction of new pharmaceutical products will be the Court's finding that it was irrelevant for PPI (i.e. new product) market definition that PPIs could be defined as forming part of the H2 blocker (i.e. current product) market.

¹¹ *See, for example*, Cases C-468/06 to C-478/06, *Sot Lélouk kai Sia EE and Others v. GlaxoSmithKline AEEVE Farmakeftikon Proionton*, judgment of the Court of Justice of September 16, 2008 and Case T-168/01, *GlaxoSmithKline Services Unlimited v. Commission*, judgment of the Court of First Instance on September 27, 2006.

B. The Broad-Ranging “Transparency” Standards for Dominant Company Behavior

In assessing AstraZeneca’s arguments in relation to the First Abuse (regarding the granting of SPCs), the Court set out a potentially problematic—and very broad—test that will be of concern to all companies dealing with dominance issues in the EU. The Court relies heavily (indeed, almost exclusively) on the oft-cited—but very general—language in the ECJ’s 1983 judgment in *Michelin v Commission*¹² regarding the “special responsibility [on a dominant company] not to allow its conduct to impair genuine undistorted competition on the market.”¹³ Building on this general language, the Court appears to identify a new category of abuse consisting in a “lack of transparency” when dealing with a regulator. As this is the first judgment from the European Courts to deal with an abuse arising out of dealings with a regulatory authority, the Court’s treatment of the issues at hand may be of significant precedential value going forward.

The Court rejects AstraZeneca’s invitations to focus on whether there was any enforcement of the SPCs at issue or any bad faith or fraud on the part of AstraZeneca in its representations to the relevant patenting authorities when obtaining the SPCs. (See further, section II.c), below.) Rather, the Court holds that Article 102 TFEU “prohibits a dominant undertaking from eliminating a competitor [...] by using methods other than those which come within the scope of competition on the merits,”¹⁴ and that AstraZeneca’s conduct in making the representations was not: “in keeping with the special responsibility of an undertaking in a dominant position not to impair, by conduct falling outside the scope of competition on the merits, genuine undistorted competition.”¹⁵

Having rejected AstraZeneca’s submissions in relation to the requirement for bad faith or fraud in order to ground a finding of abusive misrepresentation, the Court goes on to declare that a mere lack of transparency on the part of a dominant company may be sufficient to give rise to a finding of abuse, stating that: “[AstraZeneca’s] conduct, characterised by a manifest lack of transparency, is contrary to the special responsibility [...]”.¹⁶ Later in the judgment, the Court seems to go even further, referring explicitly to: “the abusive nature of the lack of transparency which AZ displayed when filing the SPC applications.”¹⁷

There also appear to be parallels between, on the one hand, the Court’s dicta in *AstraZeneca* appearing to put in place a transparency obligation on dominant companies when dealing with patent authorities and, on the other hand, both (i) the Commission’s findings in relation to *Rambus*’ alleged withholding of patent information from fellow participants in a standardization group¹⁸ and (ii) the standardization section of the Commission’s draft guidelines on horizontal co-operation agreements.¹⁹ In the draft horizontal guidelines, the Commission addresses the issues arising in the *Rambus* case and states that entities holding patents and

¹² Case 322/81 *Nederlandsche Banden-Industrie-Michelin v Commission* [1983] ECR 3461, ¶ 57.

¹³ *Id.*

¹⁴ Judgment, ¶ 354.

¹⁵ Judgment, ¶ 355.

¹⁶ Judgment, ¶ 493.

¹⁷ Judgment, ¶ 500.

¹⁸ A so-called “patent ambush” whereby an entity holding patents essential to the standard seeks to extract excessive royalties by “holding up” other standard users after adoption of the standard. See further, Commission decision of December 9, 2009 at:

http://ec.europa.eu/competition/antitrust/cases/dec_docs/38636/38636_1203_1.pdf.

¹⁹ Available at: http://ec.europa.eu/competition/consultations/2010_horizontals/guidelines_en.pdf.

participating in standard-setting groups must participate in such groups in an “unrestricted and transparent” manner. Given the Commission’s insistence on transparency in the *Rambus* case and in the draft horizontal guidelines, one consequence of the Court’s *AstraZeneca* comments on “lack of transparency” constituting an abuse in and of itself may be that the Commission is emboldened in its pursuit of the kinds of issues arising in relation to standard-setting organizations.

Certainly, companies at risk of being found dominant in the pharmaceutical or other sectors will find the tests set out by the General Court in its consideration of the First Abuse worryingly broad in scope. The concept of “*competition on the merits*” is clearly of central importance to the question of whether there is abuse under the standard set out by the Court. Yet no definition—or clear guidance—is provided. Further, if a mere lack of transparency can constitute an abuse, the Court appears to be putting all dominant companies to standards of disclosure that are higher than those applicable to other market participants. In a number of instances (including situations having no impact on competition), these higher standards of disclosure could be a significant burden on companies in their dealings with EU and EU Member State authorities. Finally, there must be a risk that the very breadth of the Court’s dicta in this regard will encourage the Commission to make further *de novo* findings of abuse in future, unrelated, dominance cases.

C. Representations Abusive Even Absent Enforcement, Fraud, or Bad Faith

AstraZeneca argued that there could be no abuse under Article 102 TFEU where there was no enforcement of the SPCs it had obtained by means of the misleading representations. For the General Court, however, the question of whether *AstraZeneca* had ever enforced the SPCs to which it was not entitled was irrelevant; it sufficed for the finding of abuse that the SPCs had been obtained as their mere existence would deter generic competitors from entering. *AstraZeneca* had also argued that there could be no abuse under Article 102 TFEU unless the misleading representations had been made in bad faith or were fraudulent in nature. Again, the Court rejected the applicant’s arguments, appearing to conclude that a mere lack of transparency on the part of a dominant company was sufficient to ground a finding of abuse.

In putting its arguments in this regard, *AstraZeneca* referred explicitly to the position in the United States.²⁰ Specifically, *AstraZeneca* pointed out that U.S. jurisprudence (including the Supreme Court judgment in *Walker Process*) required, in order to ground a finding of infringement of Section 2 of the Sherman Act,²¹ that misrepresentations be intentional, and that the “monopolist” takes actions aimed at enforcing the fraudulently obtained patents.

But the Court appeared unconcerned by the potential for U.S.-EU divergence in this area, noting:

with respect to [*AstraZeneca*’s] arguments based on United States law, suffice it to note that the position adopted by the latter cannot take precedence over that adopted by European Union law.²²

Rather, the Court concluded that there was no need for the Commission:

²⁰Judgment, ¶¶ 316 and 317.

²¹The U.S. equivalent of Article 102 TFEU.

²²Judgment, ¶ 368.

to demonstrate [AstraZeneca's] bad faith or positively fraudulent intent [...], it being sufficient to note that [AstraZeneca's] conduct, characterised by a manifest lack of transparency, is contrary to the special responsibility of an undertaking in a dominant position not to impair by its conduct genuine undistorted competition.²³

From a practical perspective, it appears that multinational companies at risk of being found dominant and dealing with patenting and other regulatory authorities on both sides of the Atlantic must now take into account not only the differing obligations imposed on them by the various patenting and regulatory regimes to which they are subject, but also the fact that antitrust rules may impose additional and differing disclosure burdens.

D. The Introduction of New Products and the Withdrawal of Their Older Equivalents

In the context of assessing the Second Abuse (the deregistrations of marketing authorizations for Losec in capsule form in Denmark, Norway, and Sweden), the Court had to consider whether the withdrawal of an old product (the capsule form) and its replacement with a new product (the tablet form) could be sanctioned under Article 102 TFEU. The Court acknowledges that:

the preparation by an undertaking, even in a dominant position, of a strategy whose object it is to minimise erosion of its sales and to enable it to deal with competition from generic products is legitimate and is part of the normal competitive process, provided that the conduct envisaged does not depart from practices coming within the scope of competition on the merits, which is such as to benefit consumers.²⁴

Indeed, the Court specifically states that:

there is no reason to reproach [AstraZeneca] either for launching [the new product] or for withdrawing Losec capsules from the market, since those acts were not such as to raise the legal barriers to entry complained of by the Commission [...].

These observations provide useful guidance to counsel at innovative pharmaceutical (and other) companies who deal on a regular basis with introductions of new, improved products and withdrawals of their older, less effective equivalents.

The Court went on to consider what it thought to be the only aspect of AstraZeneca's conduct in this regard that was open to challenge—*i.e.*, its deregistration of the marketing authorizations for Losec in capsule form. The Court agreed with the Commission's assessment that the deregistrations had the sole aim of dampening competition (whether from generics or parallel importers). AstraZeneca argued before the Court that there were significant costs associated with maintaining in force the marketing authorizations in question and that the Court should take this into account when assessing whether AstraZeneca could, in effect, be forced to maintain the relevant authorizations. However, the Court concluded that, since these arguments were not raised as an objective justification for AstraZeneca's conduct during the administrative proceedings before the Commission, they could not be taken into account by the Court when pronouncing on AstraZeneca's appeal of the Commission decision.

²³Judgment, ¶ 493.

²⁴Judgment, ¶ 804.

E. The Pharmaceutical Sector-Specific Observations

In addition to its helpful clarifications in relation to the introductions of new products and the removals of their older equivalents, the Court also makes a number of sector-specific observations that may be viewed as being of assistance to the innovative pharmaceutical industry. By way of example, the Court acknowledges the veracity of one of the arguments innovators have long made in relation to the specificity of competition in the pharmaceutical sector, commenting that: “In the pharmaceutical sector, competitive relationships respond to mechanisms which differ from those determining competitive interactions normally present in markets which are not so heavily regulated.” The Court’s observations in this regard may be of assistance to innovative pharmaceutical companies attempting to minimize losses associated with the “parallel trade” of products from low price EU Member States into Member States in which higher prices prevail as a result of differing government pricing regimes.

However, the Court’s helpful comments in this regard are balanced by its rejection of AstraZeneca’s submissions that the price differentials as between H2 blockers and PPIs should have been disregarded when considering market definitional issues in light of the unique manner in which prices are negotiated with EU Member State governments. Clearly, any arguments that the specificities of competition in the pharmaceutical sector necessitate a different competition law analysis will have to be well articulated and grounded in compelling, empirical evidence.

F. Why the EUR 7.5 Million Reduction is of Little Significance

Notwithstanding its general support for the Commission’s findings on the Second Abuse, the Court’s review did result in AstraZeneca being granted a EUR 7.5 million reduction of its original fine. The EUR 7.5 million reduction—from EUR 60 million to EUR 52.5 million—was the focus of a good deal of attention in the immediate aftermath of the judgment. However, the reasoning behind the reduction dictates that it is unlikely to be of any great importance going forward.

In short, the Court considered the reduction was necessary because the Commission had failed to prove to the requisite standard that AstraZeneca’s deregistrations of Losec capsules in Norway and Denmark were capable of reducing competition from parallel imports. The fine for the Second Abuse appeared to the Court to be based not only on the possibility for delays to generic entry brought about by the deregistrations (with which the Court concurred) but also on the possibility of a reduction in competition from parallel imports. Although the Court considered that there was no need for the Commission to prove that the abusive deregistrations had actually had the *effect* of reducing competition from parallel imports, the Commission was nonetheless obliged to prove that the deregistrations were *capable* of reducing such competition, something which it had failed to set out in its decision.

It seems, however, that this aspect of the judgment will have little impact going forward. Had the Commission either adduced evidence on its assertion that parallel imports could have been reduced or relied solely on the impact of AstraZeneca’s conduct on generic entry (as opposed to also discussing its impact on parallel trade), it seems unlikely that this aspect of the Commission’s decision would have been quashed.

IV. THE POSSIBLE IMPACT OF THE JUDGMENT

The *AstraZeneca* judgment is clearly a critical interpretation of the scope and effect of Article 102 TFEU. The Court's approval of the Commission's approach to market definition seems set to embolden the Commission in its enforcement of Article 102 TFEU vis-à-vis companies that could be deemed dominant on narrowly-defined product markets. The judgment will also give the Commission greater confidence in tackling further cases in the pharmaceutical sector since so many of the arguments regarding market definition (including product use, gradual replacement, and differential pricing) have been determined in its favor.

In addition, the simple fact that the Court upheld the Commission's novel and controversial findings of abuses of regulatory procedures seems certain to give the Commission an important boost when considering not only other cases in the pharmaceutical sector but also novel cases in other sectors. Indeed, in a statement released on the day of the judgment, the Commission commented that the judgment: "lays down that the misuse of regulatory procedures, including the patent system, may constitute an infringement of EU competition rules." That same Commission statement also noted that the findings on misuse of regulatory procedures are: "significant not least for the follow up to the Commission's [2009] final report on its competition inquiry into the pharmaceutical sector."

The Commission already has a number of ongoing pharmaceutical sector cases,²⁵ some of which appear to have arisen out of information gathered in the context of the sector inquiry.²⁶ The *AstraZeneca* judgment may lead to the acceleration of those ongoing cases and even to the initiation of additional regulatory procedure-related cases in the pharmaceutical sector. By way of example, the Commission may seek to reflect the Court's appraisal of AstraZeneca's conduct in its assessment of practices identified in its sector inquiry (and which it appeared to consider capable of having anticompetitive effects), such as "defensive patenting," "divisional patenting," and litigation strategies around patent applications and opposition procedures.

Finally, the Court's observations in relation to the "abusive nature of the lack of transparency which AZ displayed" in its dealings with the relevant authorities will give cause for concern to almost all companies dealing with dominance issues in the EU. In short, in furtherance of the "special responsibility" to the market as a whole, the Court's findings appear to impose an additional obligation on dominant companies when making required disclosures to relevant regulatory authorities. With many dominant companies being active in regulated sectors, precisely what has been—and what ought to be—disclosed to the relevant authorities risks becoming a day-to-day consideration for a large number of competition-focused in-house counsels.

²⁵ See, for example: Case COMP/39612 - Servier (perindopril); Case COMP/B2/39246 – Boehringer; and Case COMP/39226 – Lundbeck.

²⁶ Pharmaceutical Sector Inquiry Final Report, Adoption Date: July 8, 2009, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf