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I. INTRODUCTION

On July 1, 2010, the General Court issued its long awaited judgment in *AstraZeneca v Commission*,² almost five years after AstraZeneca launched its appeal against the EUR 60 million fine imposed on it by the Commission for abuse of dominance in 2005. The original Commission Decision was ground-breaking. It was the Commission's first abuse of dominance case in the pharmaceutical ("pharma") sector, a rare example of a case addressing the interaction between EU competition law and Intellectual Property ("IP") rights, and the types of abuse involved were novel. The decision launched the Commission on the path that eventually led to its 2009 pharmaceuticals sector inquiry; it also set the tone for a series of cases dealing with abuse of dominance in relation to the acquisition of IP rights, in particular patents, including *Rambus* and *Qualcomm*.³ The importance of the case is underlined by the persistent rumor that the Commission has delayed launching cases based on the results of the sector inquiry pending the outcome of the appeal. Many thought the Commission Decision would be overturned on appeal.

However, the General Court not only upheld the Commission's novel theories of abuse, it also appears to have extended their potential scope of application. And, in dismissing an appeal that challenged all aspects of the Commission Decision, the decision addresses a number of important issues, including the proper approach to market definition in the pharma sector, the scope for abuse in the context of applications for IP rights and litigation, and the circumstances in which *prima facie* legitimate behavior may be abusive—although it arguably leaves much scope for interpretation. This article discusses some of the issues raised in these important areas.

It should, however, be noted that the General Court's decision is itself under appeal to the European Court of Justice, so the law will remain uncertain for some time yet.

II. THE COMMISSION DECISION

The 2005 Commission Decision concerned AstraZeneca's behavior in relation to its blockbuster ulcer drug Losec in the period from 1993 to 2000, during which time AstraZeneca's original patents in relation to Losec were beginning to expire. The Commission found AstraZeneca guilty of two abuses of dominance:

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² Case T-321/05 *AstraZeneca v Commission*, judgment of 1 July 2010. All references in this article are to this judgment unless otherwise specified.

³ *Rambus*, OJ C 30, 2010, p. 17 and *Texas Instruments/Qualcomm*, Press Releases 07/389 of 1 October 2007 and 09/516 of 24 November 2009.

- the submission of misleading information to national patent offices in order to acquire supplementary protection certificates (“SPCs”) which would extend the patent protection for Losec, and the subsequent defense of those SPCs in court (the first abuse); and
- misusing national rules and procedures relating to medicinal products to block generic competition to Losec by launching a tablet form of the drug and withdrawing marketing authorizations for the capsule form in selected markets subject to early patent/SPC expiry (the second abuse).⁴

Losec was the first of a new generation of drugs for stomach ulcers and other acid-related disorders—so-called proton pump inhibitors (“PPIs”)—which had a different mode of action from established treatments, in particular antihistamines (“H2 blockers”). PPIs and H2s fell within the same ATC level 3 classification as they shared a common therapeutic indication. ATC level 3 classifications had been the traditional starting point for the definition of markets by the Commission in the pharma sector.⁵ Despite this, the Commission defined a separate market for PPIs—a market definition based on mode of action and equivalent to an ATC level 4 classification—in which it found AstraZeneca to be dominant.

III. THE GENERAL COURT’S JUDGMENT

A. Market Definition

The Commission’s focus in the sector inquiry on unilateral behavior by pharma companies gives increased weight to the importance of defining the market sector. Such behavior is only unlawful if markets can be defined sufficiently narrowly that these companies are dominant, particularly in relation to their blockbuster drugs. A key issue, therefore, is the extent to which the Commission is moving towards defining markets for single active substances, so-called “molecule” markets. This would be equivalent to market definition at ATC level 5. There were indications that this might be the direction of the sector inquiry results—in particular the figures indicating that across the EU the average price drop for a pharmaceutical product following generic entry is well in excess of the 5 percent to 10 percent threshold,⁶ and in some recent merger decisions such as *Teva/Barr*⁷ and *Sanofi-Aventis/Zentiva*⁸.

While the market definition at issue in *AstraZeneca* was at ATC level 4 rather than the molecule level, a number of factors in the case are in line with a trend towards a narrower market definition in pharma cases. First, the arguments made by the Commission in support of its approach in the case actually appear consistent with a molecule-based approach. Among others, the Commission argued that:

⁴ At the time, generic entry and parallel trade were only possible in certain states where the originators marketing authorization remained in force. Changes in EU legislation mean this is no longer the case.

⁵ See, e.g. Case M.1403 Astra/Zeneca, 26 February 1999.

⁶ Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, §§ 211 to 229.

⁷ Case M.5295 Teva/Barr, 19 December 2008, e.g. at § 17 (“The market investigation has indicated that—in particular for drugs purchased by hospitals—competition takes place between drugs based on the same molecule ... in particular for serious illnesses”).

⁸ Case M.5253 Sanofi-Aventis/Zentiva, 4 February 2009, e.g. at § 18 (“The market investigation in the present case indicates that it is only in a minority of cases that products based on alternative active pharmaceutical ingredients (“APIs”), i.e., alternative molecules, can be considered as perfect substitutes for each other.”)

- in the case of products based on the same active substance, price competition is “intense,” while changes in relative prices have very limited relevance in relation products based on different active substances;
- the price of AstraZeneca’s product Losec was much more sensitive to the market entry of medicines based on similar or identical molecules than it was to inferior drugs such as H2 blockers; and
- the price of Losec and other PPIs dropped significantly after the entry of generic omeprazole.⁹

Second, the General Court found that health care systems in Europe generally have the effect of suppressing competition—in particular price competition—between pharmaceutical products, making narrower market definitions more appropriate:

The fact that, in the present case, the regulatory systems did not influence the prices or the amount of sales of PPIs by reference to the lower prices of H2 blockers leads to the conclusion that the reimbursement levels granted to PPIs to a large extent prevented the lower prices of H2 blockers from exercising a competitive constraint over them. It should be recalled in this respect that the purpose of defining the relevant market is to determine the competitive constraints on the product on the basis of which the market is defined. The fact that the absence or insignificance of those competitive constraints is due to the regulatory framework which determines the conditions under, and the extent to, which competitive interactions between products take place does not affect the relevance, in the context of market definition, of the finding that those competitive constraints are non-existent or insignificant.¹⁰

Third, in assessing market definition, the General Court focused in some detail on actual use and the prescribing practices of doctors. It emphasized that, while PPIs and H2 blockers were administered to treat the same conditions, “PPIs were generally prescribed to treat the severe forms of the conditions while H2 blockers were generally prescribed to treat their mild or less serious forms.”¹¹ This is very much in line with the Commission’s focus in merger cases like *Teva/Barr* and *Sanofi-Avenis/Zentiva* on how medicines are prescribed in practice.

B. Dominance

The General Court’s judgment also supports a narrow approach on dominance. The General Court rejected the argument that the innovation-driven nature of competition in pharma markets made it inappropriate to apply usual standards of dominance:

The fact, relied upon by the EFPIA, that innovation is an essential parameter of competition in the pharmaceutical sector does not call in question the relevance that must be attached to AstraZeneca’s very high market share, as assessed in its context.¹²

Indeed, the General Court turned the position on its head, finding that the impact of health systems is to soften competition and increase the likelihood of dominance:

⁹ ¶¶ 130, 133 and 134.

¹⁰ ¶ 174.

¹¹ ¶ 69.

¹² ¶ 254.

The health systems which characterize markets for pharmaceutical products tend to reinforce the market power of pharmaceutical companies, since costs of medicines are fully or largely covered by social security systems, which to a significant extent makes demand inelastic.¹³

In addition, the General Court found that, in finding AstraZeneca dominant, the Commission was entitled to rely on a range of supporting factors that are likely to be common to originator companies, including (i) ownership and use of IP rights (ii) first mover status, and (iii) superiority in terms of financial strength and human resources.¹⁴

Overall, the General Court's decision seems likely to make it easier for the Commission to find pharma patent holders dominant going forward.

C. Abusive Application for IP Rights

The General Court upheld the Commission's finding that the submission of misleading information to a public authority was capable of constituting an abuse. Such behavior was not in keeping with the special responsibility of an undertaking in a dominant position.¹⁵ However, while the Commission had found AstraZeneca guilty of abuse on the basis that it had acted dishonestly (specifically that it had "knowingly" made misleading SPC applications),¹⁶ the General Court held there was no need to show that AstraZeneca acted intentionally or in bad faith. Rather, consistent with the principle that abuse is an objective concept, the misleading nature of submissions should be assessed on the basis of "objective factors."¹⁷ It was sufficient that AstraZeneca "could not reasonably be unaware" that, absent further explanation, its submissions would be misleading.¹⁸ Somewhat inconsistently, the General Court also held that intention nonetheless constituted a "relevant factor" in the assessment of abuse.¹⁹ And that AstraZeneca had in fact acted intentionally.²⁰

In addition to expanding the basis on which misleading submissions can be found abusive, by rejecting the requirement for intentional deceit the General Court's decision appears to impose two active obligations on dominant companies. AstraZeneca had argued that its representations to the patent offices could not be considered misleading. It had submitted what it believed to be appropriate data as to the date of Losec's first marketing in the EU on the basis of its interpretation of the underlying SPC legislation. Although the interpretation of that legislation was later clarified by the European Court of Justice, it was at the time ambiguous, and AstraZeneca had obtained two independent legal opinions supporting its (ultimately incorrect) interpretation of the legislation. The General Court rejected this argument on the grounds that AstraZeneca had "refrained from disclosing" to the patent offices both (i) the manner in which it was interpreting the SPC legislation and (ii) information as to what the first date of marketing

¹³ See also ¶ 254 ("The fact, relied upon by the EFPIA, that innovation is an essential parameter of competition in the pharmaceutical sector does not call in question the relevance that must be attached to AstraZeneca's very high market share, as assessed in its context. In this respect, it is apparent from the contested decision that AstraZeneca's privileged position stems precisely from an innovative breakthrough by it, which enabled it to develop a new market and to have the advantageous status of first mover on that market as a result of marketing the first PPI.")

¹⁴ ¶¶ 275, 283, and 285, respectively.

¹⁵ ¶ 355.

¹⁶ Commission Decision, ¶ 626.

¹⁷ ¶ 356.

¹⁸ ¶ 493.

¹⁹ ¶ 359.

²⁰ See, e.g. ¶¶ 495, 498, 519, 553 and 599.

would have been (and, as it transpired, was) in the event AstraZeneca's interpretation was not correct.²¹ It seems to follow that, in practice, a dominant company may have a duty to disclose both potentially adverse interpretations of the law and potentially adverse facts in the context of applications for IP rights.

Further, the General Court held that, in order to allow the public authority the opportunity to correct the error, AstraZeneca had a duty to notify the patent authorities once it had become aware that certain of the submissions it had made (regarding the date of the first marketing of Losec in the EU) were inaccurate and, as a result, it had been granted an unlawful extension of its patent rights.²² Both this duty and the obligation of disclosure in the event of ambiguity flow from the special obligation on dominant companies.

Finally, while the Commission had been careful to examine the effect of AstraZeneca's actions in restricting competition, the General Court found this was not necessary. There was no requirement to show even that SPCs had been granted as a result of AstraZeneca's actions. It was sufficient that the misleading applications were "liable" to lead to the wrongful grant or extension of exclusive rights.²³ The applications themselves constituted the abuse.

The General Court's findings in relation to this abuse raise a number of issues. First, in what circumstances is a submission likely to be considered misleading? It is to be hoped that the thresholds are high. Having dismissed the need for intentional dishonesty, the General Court raises the specter of accidental abuse of dominance. In this case the General Court was clear that AstraZeneca acted intentionally. It is hard to believe this did not affect the General Court's conclusions. At a minimum, it is to be hoped that, for a submission to be abusive, it will be necessary that the author "could not reasonably be unaware" that it would be misleading.

Second, and related, when does the duty to clarify the interpretation of ambiguous legal issues—and it would seem provide potentially adverse facts—arise? Again, the threshold should be high. Much, if not all, law is ambiguous to some degree. A situation in which dominant companies must set out all potentially material interpretations and facts would be extremely burdensome if not unworkable. The General Court considered AstraZeneca's behavior to have involved a "manifest lack of transparency" and this should be a minimum requirement.²⁴ But even this is far from a bright line standard.

A third question is the extent to which these principles apply in relation to applications for IP rights other than SPCs. The role of a patent office in the context of an SPC application is very much administrative, something of a rubber-stamping exercise, and the General Court does emphasize that:

the limited discretion of public authorities of the absence of any obligation on their part to verify the accuracy or veracity of the information provided may be relevant factors to be taken into consideration for the purposes of determining whether the practice in question is liable to raise regulatory obstacles to competition.²⁵

²¹ ¶ 496 and 591.

²² ¶ 358.

²³ ¶ 355.

²⁴ ¶ 493.

²⁵ ¶ 357.

So, in principle, it is arguable that, for example, a patent application including inaccurate information as regards inventive step would not be abusive to the extent it was made to an authority charged with carefully examining that issue, such as the U.K. patent office. Against that, as discussed further below, the General Court also found that misleading representations made by AstraZeneca to various EU courts constituted part of the abuse. If a misleading representation to a court in judicial proceedings, whose very purpose is to rigorously test the evidence, is potentially abusive, it is not unlikely that the same will apply in relation to all public authorities (although the degree of misrepresentation may be relevant).

Finally, the foundation for the General Court's various findings of abuse—including in relation to the original misleading application—is the special obligation on dominant undertakings. The duty to avoid misleading representations, as well as the duties to clarify ambiguity and notify errors all stem from that obligation. It would seem to follow that abuse can only occur where the company making the application is already dominant and is seeking an extension of its exclusive rights, *e.g.* via an SPC or a follow-on patent. If so, there should be little or no risk of abuse in relation to applications for fundamental patents over new treatments. This may not however be the case. Two points are worth bearing in mind. One is the duty to seek to correct errors: an undertaking that was not dominant at the time of a misleading patent application but becomes dominant as a result of it may be bound by this duty. If so, it could be guilty of abuse if it were not to seek to have the patent set aside by reason of the errors in the original application. Another is the willingness of the Commission to pursue an infringement action in *Rambus* despite the fact that, in that case, the deceptive act giving rise to the abuse took place prior to the acquisition of dominance.

D. Abusive litigation

In addition to finding AstraZeneca guilty of abuse in relation to the process of obtaining SPCs, the General Court upheld a finding by the Commission that misleading representations made by AstraZeneca in the course of defending SPCs in courts in Germany and Norway formed part of the overall abuse.²⁶ Although not technically a stand-alone finding of abuse, the implication would appear to be that AstraZeneca's conduct in the relevant litigation was itself abusive.

To date, the leading case on abusive litigation is *ITT Promedia*, which suggests that litigation will only be abusive where:

- the litigation is “manifestly unfounded” in that it cannot reasonably be considered an attempt to establish the rights of the undertaking; and
- forms part of a plan to eliminate competition.²⁷

On its face, the General Court's decision would appear to extend the situations in which the conduct of litigation may be abusive. However, AstraZeneca possessed “consistent information” that facts it submitted were not accurate²⁸ and pursued legal arguments on which “it could not reasonably rely.”²⁹ In the circumstances, the position AstraZeneca took may have qualified as manifestly unfounded for the purposes of *ITT Promedia*. And since the litigation

²⁶ ¶ 597.

²⁷ Case T-111/96 *ITT Promedia* c Commission [1998] ECR II-2937.

²⁸ ¶ 582.

²⁹ ¶ 587.

formed part of a wider, intentional abuse, it could arguably be said to form part of a plan to eliminate competition. Even so, the implication that AstraZeneca could be guilty of abuse in the context of litigation that it did not initiate is worthy of note.

E. Misuse of Rights

AstraZeneca had challenged the second finding of abuse on various grounds: (i) in withdrawing marketing authorizations for the capsule form, it was exercising its statutory rights, (ii) it was under no obligation to actively assist generic entry by maintaining the marketing authorizations, and (iii) withdrawal of the marketing authorizations was objectively justified as a means of avoiding pharmacovigilance obligations (ongoing reporting obligations in relation to, *e.g.*, adverse side-effects).

The General Court dismissed all these arguments. Neither the existence of statutory rights nor the absence of a positive duty to assist competitors justified the use of regulatory procedures where the sole purpose was to exclude competition.³⁰ This is especially true, in particular where, as here, there was no basis for AstraZeneca's behavior in "competition on the merits" (*i.e.* competitive action which could benefit consumers).³¹ Withdrawal of the capsule marketing authorizations was not "necessary, or even useful" in relation to the introduction of the tablet formulation.³²

The General Court found that AstraZeneca was barred from raising arguments on objective justification based on pharmacovigilance obligations, as it had not raised them during the Commission proceedings.³³ In any event, such obligations did not represent a sufficient burden to constitute a "serious" objective justification.³⁴

The latter point, the General Court's willingness to dismiss an objective justification for AstraZeneca's behavior, is potentially the most significant part of this aspect of the General Court's judgment. A principle that states that behavior whose sole purpose is to hinder competition is abusive is unlikely to be frequently used in practice if any reasonable justification will be sufficient to avoid an abuse finding. If, however, authorities are free to assess whether a proffered justification is sufficient, it potentially has much broader application. In this case, it may be important that the General Court also found that AstraZeneca's arguments on objective justification lacked credibility, because they were not supported by internal documentation.³⁵

IV. FINAL REMARKS

On its face, the General Court's judgment opens the door to increased enforcement of Article 102 TFEU in relation to both the pharma sector and IP rights generally. If it is upheld on appeal to the European Court of Justice, the Commission will find it easier to find pharma patent holders dominant and to identify abuses in relation to IP/patent applications, litigation, and misuse of rights/procedures.

Whether this is altogether a good thing is open to question. In particular, the General Court's disregard of the effect of AstraZeneca's behavior and its heavy reliance on concepts such

³⁰ ¶¶ 816 and 817.

³¹ ¶ 812.

³² ¶ *Id.*

³³ ¶¶ 686 and 687.

³⁴ ¶ 692.

³⁵ ¶ 688.

as “competition on the merits” and the “special responsibility” of dominant undertakings suggest a continuing rift between the courts and the Commission in relation to the importance of economic assessment in the context of Article 102.