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I. INTRODUCTION

By its decision of July 1, 2010 in *AstraZeneca*[2] the General Court upheld the decision of the European Commission that AstraZeneca had abused a dominant position in breach of Article 82 (now 102).

The abuse consisted of two courses of conduct. First, AstraZeneca was found to have blocked or delayed market access for generic versions of AstraZeneca's Proton Pump Inhibitor, Losec, by making misrepresentations to certain EEA national patent offices in order to obtain supplementary protection certificates for Losec. Second, AstraZeneca was found to have prevented parallel imports of Losec by deregistering market authorizations in a number of countries.

By its decision, the Court reaffirmed two basic principles of EU jurisprudence, put a silver spike through one common argument of the research-based drug industry, and raised some fascinating questions for the future.

II. TWO UNSURPRISING FINDINGS AND PRINCIPLES

1) This was an Article 82 (now 102) case and the Commission won, which is about as shocking as learning that water is wet. The Commission does not lose Article 102 cases.[3] There are many reasons for this, but the practical take away is that a defendant needs either to convince the Commission not to bring the case, or it needs to win the case at the Commission. It will not win the case on appeal.

   But this decision also makes clear that the Commission still needs to prove its case. The good news on the general legal front is that the Commission was not totally affirmed. The fine was reduced because the Commission failed to prove that the deregistration of the marketing authorizations was capable of preventing parallel imports in Denmark and Norway.[4]

2) All of the neat legal questions as to market definition and what constitutes abuse are secondary to the impact of the facts (as found) as to what AstraZeneca did. If a defendant deliberately lies to the Government to get added exclusivity (via Supplementary

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[2] AstraZeneca v Commission, Case T-321/05 (July 1, 2010), *available at* http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=EN&Submit=rechercher&numaff=T-321/05 , *hereinafter* "AstraZeneca."

[3] *See* the materials cited in K. Bernard, *Some Thoughts on Article 82 Jurisprudence*, 8(1) GLOBAL COMPETITION POL'Y 2-3, (August 2009,). The Commission's track record in Court on these cases is somewhat awe-inspiring.

[4] AstraZeneca, at ¶¶ 852-855, 913.

Protection Certificates, "SPCs"), Commissions and Courts will find a way to condemn that company with whatever theory will work. And if a company does those things, it taints whatever else it does—here, withdrawing the approval for the old form of the drug where there was no plausible reason to do so except to block competition. Had there not been the misconduct to get the SPCs, the withdrawal would not have looked quite as bad (although it still would not have looked good).

III. THE SILVER SPIKE

For many years the research-based drug industry has argued that the market for prescription drugs in the EU is not the free market that you find with other goods. Governments, in fact, set reimbursement levels or directly control prices in some cases, so that to apply the "normal" competition rules without modification is incorrect practice.[5] The high point for the recognition of this argument was probably the opinion of Advocate General Jacobs in the *Syfait* case.[6] The argument has the most force on issues of restricting parallel trade. The underlying rules governing such restrictions assume that the manufacturer voluntarily puts its goods on the market in each country at the price there in effect, and hence has no legal basis to impede diversion from one country to another. In fact, however, prices are not freely set by the manufacturers. Countries have health budgets and often determine pricing or reimbursement within their borders.[7]

The problem is not with the argument as such, but rather with the context. To apply the argument that drugs are a different type of product and need different rules, when you are defending a case of conduct that is sufficiently "bad" on its face (and would be bad whether you treated drugs as a separate category or not) not only fails as a defense but also weakens the argument everywhere.

Prescription drugs are not widgets. They are researched, developed, approved, promoted, and sold differently than are most other products. They interact with intellectual property rules differently. All true; all good. But what the Court in *AstraZeneca* makes clear is that while an argument of difference can still be made, it needs to be made on a much more fact-specific basis than what has gone before. What is still open for argument is that, based on the reimbursement decisions and criteria for a given drug in a given country, certain specified distortions to normal competition rules are imposed.

Nothing in the decision forecloses the argument that AstraZeneca lacked market power (and hence a dominant position) in Germany based on the way the reimbursement authorities treated H2 receptor antagonists ("H2 Antagonists") versus Proton Pump Inhibitors ("PPIs"). This argument was rejected on its facts,[8] but it was legitimate conceptually. It is at this level of fact and detail that the next battles need to be fought.

IV. SOME QUESTIONS FOR FUTURE CASES

The combination of a market defined so as to leave AstraZeneca with a dominant position, combined with conduct towards national patent and regulatory authorities that was—at

[5] AstraZeneca, at ¶¶ 113-115, 131-135.
[6] Cited and discussed in AstraZeneca, at ¶ 223.
[7] AstraZeneca, at ¶¶ 169-174.
[8] AstraZeneca, at ¶¶ 205-213.

best—not fully transparent, made this a relatively easy case for the Court. But it also raises two questions for later discussion.

First, the market definition in effect created an asymmetrical market. In most cases, if two things are in the same market, they act as restraining forces on each other. Here, the market defined had PPIs acting to create a price ceiling on H2 Antagonists, but did not have H2 antagonists as restricting the pricing of PPIs.

Second, while AstraZeneca's conduct may not have qualified them for an award for sportsmanship in competition, what would have happened if AstraZeneca had been fully transparent even as it sought the same actions from the national authorities?

A. Are There Asymmetrical Markets?

AstraZeneca argued that the Commission incorrectly defined the relevant market as being only that of PPIs and not the combined market for PPIs and H2 Antagonists. Although it was generally recognized in the scientific community that PPIs were therapeutically superior to H2 Antagonists, the increase in use of PPIs was only gradual as prescribing doctors did not immediately recognize that superiority and continued to prescribe both drugs for the same diagnosis.

This gradual increase shows that H2 Antagonists exerted a competitive constraint on PPIs; otherwise, substitution would have taken place earlier. The Commission said that the therapeutic superiority of PPIs meant that, from 1993, PPIs were part of a different market than H2 Antagonists. In its judgment, the Court found that the Commission was entitled to take that position, and to reject the argument that the gradual nature of the increase in sales of PPIs at the expense of H2 Antagonists meant that H2 Antagonists exercised a significant competitive constraint over PPIs and, therefore, H2 Antagonists had to be included in the relevant product market.[9]

This finding led to the strange result that the market was asymmetrical. While PPIs exercised a competitive constraint over H2 Antagonists, H2 Antagonists did not exercise a competitive restraint over PPIs. The Court's analysis is detailed.[10]

Part of that strangeness goes away upon recognition that the products were perceived to be on a therapeutic continuum, with PPIs being seen as stronger as and more effective than H2 Antagonists and, for certain conditions, PPIs became the accepted form of treatment.[11] If H2 Antagonists were not effective treatments for a condition, clearly they were not in the "market" consisting of treatments for that condition. But at the same time, the presence of PPIs (and especially generic PPIs once launched) acted as a cap on H2 Antagonist pricing, since the PPIs could be used to treat the conditions for which the H2 Antagonists were prescribed.[12]

This idea of migration from one product to another is probably most commonly found in medicine, as treatment options evolve. But as the Court notes, it also applies elsewhere.[13] If one

[9] AstraZeneca, ¶¶ 83–107.

[10] AstraZeneca, ¶¶ 147-217.

[11] AstraZeneca, ¶¶ 68-75.

[12] The mathematics here would be fascinating, since PPIs were considerably more expensive than H2 Antagonists, so one would think that they would leave a lot of room for price increases on the H2 Antagonist side.

[13] AstraZeneca, ¶ 53, citing Case T-340/03 France Telecom v. Commission [2007] ECR II-107, ¶¶ 88-89, regarding low speed and high speed internet access.

were to generalize, it appears that when a new product is in the process of supplanting an older one for all or a large part of the original product's uses, then the market will be at least temporarily asymmetrical with the newer product acting to constrain the older one (but not vice versa). These types of markets deserve deeper exploration, especially in technology cases.

B. Is Lying to National Patent Authorities Permissible?

The Court makes it clear that a company in a dominant position abuses that position by deliberately giving misleading or false data to national patent authorities in order to obtain longer exclusivity for its product.[14] Similarly, there is abuse when a company in a dominant position deliberately withdraws the registration for a product with no credible explanation other than to block generic competition.[15] Withdrawing the registration was not illegal in and of itself. Withdrawing the registration with no affirmative justification in order to prevent competing products from referencing it and coming on to the market, and in fact having that effect, was what was deemed to be abusive.

As far as the SPC filings went, AstraZeneca used the date of pricing approval, rather the date of first marketing authorization, and did not disclose that fact to the national authorities. In addition, it made this choice of date only for this one product—for all other products and applications it used the date of the first marketing authorization.[16] There were some unhelpful documents on the record as regards these choices.

Had the company not been in a dominant position, it is unlikely that this conduct would have triggered an Article 82 (now 102) case or remedy—there are already laws in place to deal with lying to the national patent authorities. One needs to remember that just because something isn't a competition law violation doesn't mean that it isn't a violation of some other law.

On the withdrawal of the registration, questions are only likely to arise where the registration is uniquely facilitating. If there were three registrations upon which generics could rely, withdrawing one would have had little impact. AstraZeneca argued that nothing required it to maintain any registration, and that withdrawing one for a form of a drug that it no longer wished to sell was not irrational. This triggered a response concerning the special responsibility of a dominant party, and the need to show that any action was protecting a legitimate commercial interest of competition on the merits of the products.[17]

AstraZeneca claimed that it withdrew the registration to avoid ongoing pharmacovigilance obligations, something that unfortunately did not appear in any of the internal documents concerning the decision. It also was inconsistent with the fact that the withdrawal was country selective, deregistering in three countries but leaving the registration in place in six others.[18] The only logical explanation was that the registration was pulled in certain countries to block generic competition there.

The conclusion here is that a party with a dominant position that lies, or misleads government authorities into strengthening that dominant position, will be found to violate Article 102. This is hardly a stunning result

[14] AstraZeneca, ¶¶ 591-598.
[15] AstraZeneca, ¶¶ 817.
[16] AstraZeneca, ¶¶ 488.
[17] AstraZeneca, ¶¶ 355, 672.
[18] AstraZeneca, ¶¶ 688-689.

C. How Important is Intent in These Cases?

The idea that good intent can "save" a bad act, or that bad intent can condemn an otherwise good one, has led to much confusion at both the levels of knowledge (how does one know what the other party intended?) and of proof. This case gives us some guidance on the point.

First, a dominant undertaking cannot use the regulatory process in such a way as to make it more difficult for competitors to enter the market "in the absence of grounds relating to the defence of the legitimate interests of an undertaking engaged in competition on the merits or in the absence of objective justification.[19] This may be useful—if a company can set up a pro-competitive rationale before it acts, the action may be more defensible.

Second, while intent to exclude (here, to exclude parallel trade by deregistering the original dosage format in certain countries) may be taken into account in identifying an abuse of a dominant position, "that identification must first and foremost be based on the objective finding of conduct which, in the context in which it is implemented, is such as to restrict competition."[20] As a warning to the Commission that bad intent (or, more likely, a bad document or two) is not enough to establish abuse, this is salutary. For a company to assert this, however, is a plea of Innocence by Incompetence—it wanted to exclude a competitor from the market, it tried to exclude a competitor from the market, but it picked something that didn't work. That's a position not likely to garner a lot of sympathy.

The moral here seems to be that a company needs to get its rationale and its files in order before acting in a way that could be viewed as anticompetitive. If the plan is to do something that will likely be very effective, it needs a strong pre-existing justification before the action takes place. If there are "bad" intent materials, then one needs either to do nothing, or to at least wash out the taint from the intent before taking action.

D. How Far Can Transparency Get You?

It is clear from what has been said before that a company that is lacking a dominant position can take the actions identified here, and not be guilty of an article102 violation. One cannot abuse a dominant position that one does not have. But what if a company is dominant, but transparent in what it files? The starting point is the language in *AstraZeneca*:

> Given that AZ was seeking to defend a particular interpretation of Regulation No. 1768/92 the onus was on it to communicate the various relevant items of information in a transparent manner, in order to enable the public authority to adopt the appropriate decision and not to be misled as a result of an undisclosed ambiguity.[21]

At the same time, the judgment also says that as it held a dominant position, AstraZeneca was obliged to correct any mistaken or inaccurate information it gave to patent offices and courts:

> In so far as an undertaking in a dominant position is granted an unlawful exclusive right as a result of an error by it in a communication with public

[19] AstraZeneca, ¶¶ 672.
[20] AstraZeneca, ¶¶ 849.
[21] AstraZeneca, ¶¶ 565.

> authorities, its special responsibility not to impair, by methods falling outside the scope of competition on the merits, genuine undistorted competition in the common market requires it, at the very least, to inform the public authorities of this so as enable them to rectify those irregularities.[22]

So what would have happened if AstraZeneca was dominant, but also made full disclosure of the position that it was taking as to the time of approval, [23] and the National Patent Authorities granted the SPCs? We see two possible paths here. First, if on the facts disclosed there are no legitimate grounds for the SPC, then it could be argued that the attempt to obtain one has no redeeming social value and should be condemned even if not misleading. The analogy would be to trying to get a patent that you know will be invalid. It is hard to see the social utility in allowing that conduct, even if all the facts are laid out.

But there is a second path, one where there are possible grounds to obtain the SPC on the facts as presented. People bring cases where precedent is against them, hoping to be distinguished on the facts or that the Court will change the law. People legitimately file patent application where there is "prior art" against them which must be, and is, disclosed. There needs to be some flexibility here. Just because an argument is not successful doesn't mean that it was fraudulent, or misleading.

V. WHERE DOES THIS TAKE US?

On its facts, this is a narrow decision. And it seems to follow the classic line of formalistic Article 82/102 decisions, rather than what many hope will be a more effects based approach resulting from the 2008 Guidance on exclusionary abuse. However, taken along with the 2008 Sector Inquiry, the message seems to be that conduct hindering generic drugs will be looked at under a microscope.

The most obvious take away is that conduct that violates another law may still violate Article 102. The fact that fraudulent conduct towards national patent offices may be illegal as such, does not provide a defense to a charge that it is also conduct violating article 102.[24]

The second take away is that conduct which does not violate any other law may, if done by a dominant party with the effect of hindering competition, violate article 102. This is identified as part of the "special responsibility" of dominant parties, and nothing suggests that this approach is going to change any time soon.

Third, market definition in these cases (and hence the determination of whether the company involved has a dominant position) will be increasingly detailed and fact-based. The concept of sequential therapy or treatment, partial overlaps of indications, and the time factor on changing medical practice will all play a role going forward. These are all arguments that will have to be made at the Commission level and made in detail, perhaps even on a country-by-country basis.

Finally, if a pharmaceutical company wants to argue that Government reimbursement policy and practice negates the idea of dominance, it will have to make that argument on the

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[22] AstraZeneca, ¶¶ 358.

[23] Whether AstraZeneca also discloses that this is a new interpretation of the rules is a subtlety with which we need not grapple right now.

[24] Nor would you expect it to be. While you need some limits—shooting the president of the generic company should likely be prosecuted as murder, rather than as an article102 abuse—the argument that you are innocent here because your conduct is illegal for other reasons has a very odd taste to it.

facts as well. Arguing the general principles of the need to fund research, and the fact that markets are not free in the prescription drug realm, will not carry the day.