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Dominant Firms' Duties To Deal With Pharmaceutical Parallel Traders Following *Glaxo Greece*

*Robert O'Donoghue & Louise Macnab**

EU competition policy on dominant firms and pharmaceutical parallel trade—wholesalers taking advantage of arbitrage possibilities to export drugs from a low-priced Member State to a higher-priced one—reminds one of a debate between two famous economists. Each of them had taken opposing sides in a case and, after several discussions, they each remained wholly unpersuaded of the other's view. In a fit of exasperation, one economist said to the other "I agree with you, but you are completely wrong!"

GRAPPLING WITH SUCH OPPOSING POLICY PERSPECTIVES WAS NEVER GOING TO BE EASY FOR THE EU COURTS AND INSTITUTIONS. THIS APPLIES NOT LEAST GIVEN THEIR HISTORICAL FIXATION WITH THE INTEGRATION OF THE SINGLE EU MARKET AND THE NOTION THAT COMPETITION LAW IS (IN PART) A FEDERATING TOOL IN THIS REGARD.

So it is with parallel trade. The virtuous wholesalers say that they bring much-needed price competition to the (higher-priced) market. The no-less-virtuous pharmaceutical companies say that this is true, if at all, only in the short term, and that it comes at the expense of appropriation of manufacturer profits that fund expensive research & development ("R&D")—so there is, they say, less competition in the medium- to long-term. Both may be correct, for different reasons and from different perspectives.

Grappling with such opposing policy perspectives was never going to be easy for the EU Courts and institutions. This applies not least given their historical fixation with the integration of the single EU Market and the notion that competition law is (in part) a federating tool in this regard.

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The EU Courts had something of a false start in *Syfait* where a preliminary reference from the Greek courts squarely raising the issue of when, if ever, it is abusive for a dominant firm to refuse to meet orders from parallel traders was declared inadmissible by the Court of Justice ("ECJ"), following an Opinion by Advocate General Jacobs.[1] Round two has now come in the shape of the ECJ's recent judgment in *Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE*[2] (hereinafter "*Glaxo Greece*"), which, very unusually in competition cases, was a judgment of the full court (as opposed to a smaller chamber).

The judgment is, in many respects, a work of art because it largely avoids taking a firm view, either way, on the underlying policy considerations that affect the assessment of parallel trade as abusive unilateral conduct. Instead, the ECJ adopted an essentially pragmatic approach that a dominant pharmaceutical company may refuse to meet an order that is "out of the ordinary in terms of quantity" even if the refusal is openly designed to restrict parallel trade. This avoids saying whether parallel trade is inherently "good" or "bad" as a competition policy matter in favor of imposing essentially an upper limit on the manufacturer's duty to supply—broadly limited to the quantities ordinarily supplied on the domestic (exporting) market in question. It should be immediately obvious therefore that the upshot of the case is relatively favorable to manufacturers, at least where unilateral refusals to deal with parallel traders are concerned. But, as developed in more detail in this piece, such pragmatism comes at the expense of legal reasoning that is dubious in certain respects.

> THIS CONCLUSION IS A FAIRLY RADICAL SHIFT IN THE ECJ'S HISTORIC APPROACH TO PARALLEL TRADE, WHICH WAS TO REGARD IT AS MORE OR LESS SACRED BECAUSE IT HELPED "INTEGRATE" THE EU MARKETS—I.E., A POLITICAL IDEAL.

The judgment seems to us all the poorer for not grappling with the underlying policy issues in any serious, forensic way. Two well-resourced competing sets of interest were before the ECJ, and plenty of information and evidence were undoubtedly presented to the court. The ECJ also had the power to ask for more if needed. Indeed, the case was unusual in that there were two ECJ references in the same case, as well as various decisions of the national competition agency and courts dealing with the issue. The ECJ thus had a pretty much unblemished 8-year record of what happened in the export and import markets. A text book assessment could therefore have been made without too much difficulty. Important issues like a dominant firm's unilateral freedom to deal with parallel traders should not be decided by the Grand Chamber of the highest EU court essentially in a vacuum, on the basis that a pragmatic outcome can be devised to avoid dealing with the real underlying issues. The contrast between Advocate General Jacobs in *Syfait* and the Advocate General and ECJ in *Glaxo Greece* is striking in this regard.

That said, the ECJ's pragmatic conclusion does mean that, in general, the dominant firm is not obliged to supply much more than ordinary domestic con-

sumption. This conclusion is a fairly radical shift in the ECJ's historic approach to parallel trade, which was to regard it as more or less sacred because it helped "integrate" the EU markets—i.e., a political ideal. But some of the remnants of the old approach remain. Whether this grown-up approach will be maintained by the ECJ in the context of agreements restricting parallel trade under Article 81 will be fascinating to watch in the imminent *Glaxo Spain* appeal.[3]

This short paper tries to do two things. First, it conveys to the reader the essential points in the *Glaxo Greece* judgment. Second, it looks in more detail at the competition law issues raised by the judgment, including by reference to the wider policy issues at stake.

I. What the ECJ Found

The essential facts are as follows: A Greek subsidiary of GlaxoSmithKline ("GSK"), GSK AEVE, imports, warehouses, and distributes pharmaceutical products of the GSK group in Greece. A big issue in Greece is parallel trade because prices there are among the lowest in the EU.

GSK AEVE initially suspended supplies to the Greek wholesalers, citing a shortage of the products at issue for which it denied responsibility. GSK AEVE then began to distribute medicines directly to Greek hospitals and pharmacies. Three months later, GSK partially resumed the supplies, but only in quantities sufficient to meet the demand of the local market. The Greek wholesalers, as well as some Greek associations of pharmacists, started proceedings before the Greek Competition Commission arguing that the actions of GSK constituted an abuse of a dominant position under Article 82 EC. The Greek court made a reference to the ECJ for a preliminary ruling, in *Syfait*, as to the application of Article 82 to the refusal by an allegedly dominant pharmaceuticals supplier to meet wholesalers' orders for the purpose of limiting exports to other Member States. That case was declared inadmissible, since only "courts or tribunals" can make a reference under the Article 234 EC preliminary reference procedure.

Proceedings in the Athens Court of First Instance nonetheless continued in parallel and, after an appeal was brought before the Athens Court of Appeal, led to a reference of essentially the same questions as raised before in *Syfait*.

It is fair to say that the two sets of proceedings—*Syfait* and *Glaxo Greece*—are materially different in their approach on key issues on essentially the same facts (see table in Annex). But the latter will now be the governing law, since, unlike *Syfait*, it did result in an ECJ judgment on the substantive issues.

In 2004 Advocate General Jacobs found that the refusal to deal with the Greek parallel traders was capable of justification, and hence not abusive, as a reasonable and proportionate measure in defense of the undertaking's commercial interests. This is the case, he said, where the price differential giving rise to

the parallel trade is a result of State intervention in the country of export to fix the price at a level lower than that which prevails elsewhere in the EU, combined with the specific economic and regulatory characteristics of the pharmaceutical industry. He did, however, consider it "plausible" that an intention on the part of the dominant undertaking to limit parallel trade "should be one of the circumstances which will ordinarily render abusive a refusal to supply" because such conduct is normally aimed at removing a source of competition for the dominant undertaking in the country of import.[4] Nevertheless, he found that, in parallel trade cases, the partitioning of the market was not usually the primary intent, but, given the characteristics of the market, an inevitable consequence of the attempt by the manufacturer to protect what it saw as its legitimate commercial interests and the distortions of trade that stemmed from unharmonized national price control systems for medicines.

In simple terms therefore, Advocate General Jacobs was pretty sympathetic to the notion that there are unusual features of the pharmaceutical industry and its regulation that may justify a termination or reduced supplies to parallel traders. His conclusion is significant, since he is one of the most respected Advocates General and, moreover, was the author of many of the key opinions on parallel trade issues under the EU's free movement of goods rules.

Four years later in 2008, however, Advocate General Ruiz-Jarabo Colomer effectively went against Advocate General Jacobs' opinion and advised the Court to qualify the limitation of supplies as abusive where there was a refusal to meet "ordinary" orders in order to prevent parallel trade. Whether the orders placed by the Greek wholesalers were reasonable was an issue that had to be referred back to the Greek courts for a final ruling. He also took different views to Advocate General Jacobs on the main policy issues raised by parallel trade and concluded that, while perhaps relevant, they do not provide objective justification for a refusal to deal with parallel traders.

As a matter of (high level) principle, the ECJ accepted that a dominant firm is not obliged to meet orders "way out of the ordinary" and that it can take steps to protect its own "commercial interests" if attacked.

The ECJ's conclusions were similar, in upshot, to Advocate General Colomer's, although its conclusions on the policy issues are interestingly different. The ECJ began by essentially inverting the legal test and saying that where a refusal would lead to the elimination of "effective competition" from parallel importers there is an abuse unless "objective considerations" justify the refusal.[5]

As a matter of (high level) principle, the ECJ accepted that a dominant firm is not obliged to meet orders "way out of the ordinary" and that it can take steps to protect its own "commercial interests" if attacked.[6]

The ECJ then turned to a series of objective justifications advanced by GSK as legitimizing its refusal to deal:

A. THE CONSEQUENCES OF PARALLEL TRADE FOR THE ULTIMATE CONSUMERS

The first argument was that parallel trade does not have much benefit for final consumers: Parallel traders are simply engaged in arbitrage from low price to high price countries and will therefore rationally sell as close as possible to the prevailing price in the import country (which is often regulated anyway).

On this point the ECJ concluded that a manufacturer cannot "base its arguments on the premise that the parallel exports which it seeks to limit are of only minimal benefit to the final consumers."[7] This was on the basis that the benefits to the final consumer result from: (1) the general price pressure that parallel imports exert in the destination market; and (2) the additional choice that parallel imports represent for entities that purchase through public procurement procedures.[8]

B. THE IMPACT OF STATE PRICE AND SUPPLY REGULATION IN THE PHARMACEUTICALS SECTOR

The ECJ then analyzed the possible effect of State regulation of medicine prices on the assessment whether the refusal to supply is an abuse. In the EU, there is no harmonization of national price controls in medicines, with each Member State having autonomy in this regard—leading to a diversity of methods of regulation. Different mechanisms are used to set and control prices, including direct price controls, profit caps, negotiated prices, agreed reimbursement rates, and reference pricing (i.e., when prices are set by reference to prices in other Member States), and internal reference pricing where the price would be based on groupings of supposedly similar products in that Member State. Indeed, parallel trade only exists because of the arbitrage possibilities between Member States that result from different national regulations. So the manufacturers argue that competition is *already* distorted because of national regulation, which is permitted under EU law, and that they are objectively justified in refusing, in effect, to allow one Member State to export aspects of its chosen regulation to another, thereby avoiding a "race to the bottom."

The ECJ found that the control exercised by Member States over the selling prices or the reimbursement of medicines was varied and did not entirely remove the prices of those products from the law of supply and demand.[9] It added that the producers of the medicines take part in the negotiations, where their price proposals act as a starting point and end with the setting of the prices and the amounts of reimbursement to be applied.[10] Thus, the degree of regulation did not remove the scope for competition to an extent that the competition rules did not apply at all.

However, the ECJ added that "it cannot be ignored that such State intervention is one of the factors liable to create opportunities for parallel trade" and that undertakings should not be placed in the invidious position that, "in order to defend its own commercial interests, the only choice left for a pharmaceuticals company in a dominant position is not to place its medicines on the market at all in a Member State where the prices of those products are set at a relatively low level."[11]

Accordingly, the ECJ accepts that the dominant firm can take steps "that are reasonable and in proportion to the need to protect its own commercial interests,"[12] meaning it has no obligation to meet orders "out of the ordinary" relative to the domestic consumption in the export Member State.[13] This was elaborated to mean ordinary "in the light of both the size of those orders in relation to the requirements of the market in the first Member State and the previous business relations between that undertaking and the wholesalers concerned." [14]

C. IMPACT ON R&D

One of the more fundamental objections made to parallel trade by manufacturers is that it involves parallel exporters expropriating profits that would otherwise be invested in R&D—a major feature and cost in pharmaceutical manufacturing—by manufacturers.[15] Thus, they say, the gain to consumers, if any, is short-lived and there will be a reduction in R&D in the medium- to long-term as average prices are forced closer and closer to marginal cost, which will result in less competition not more. The ECJ declined to rule on this issue.[16]

II. What to Make of All This?

From the perspective of pharmaceutical manufacturers the *Glaxo Greece* judgment will largely come as a welcome relief. As embarrassing as it may sound, the notion that it would be *per se* abusive for a dominant firm to unilaterally refuse to meet wholesaler orders if intended to limit parallel trade has been an idea with some serious traction in the EU. The Commission actually advanced an argument in *Syfait* that ran fairly close to a *per se* rule, citing the EU's market integration objectives as support.[17]

FROM THE PERSPECTIVE OF PHARMACEUTICAL MANUFACTURERS THE *GLAXO GREECE* JUDGMENT WILL LARGELY COME AS A WELCOME RELIEF.

The ECJ did not specifically endorse any such argument in *Glaxo Greece*, but remnants of it remain in the judgment. The Advocate General went out of his way to say that there should be no *per se* rules under Article 82 EC, which is a generally helpful conclusion, but he too seemed to think that the political objective of market integration affects competition law analysis. We'll return to this issue later.

In pragmatic terms, pharmaceutical manufacturers' lot has also been improved by the important limiting principle that the dominant firm does not need to supply all quantities that the wholesalers asks for, but can refuse to supply more than the "ordinary" quantities. Equally, the dominant firm needs to guess what the wholesalers might do with the quantities actually supplied (i.e., for export or domestic consumption). Any such rule would have been precarious in the extreme and might actively encourage wholesalers to lie. Instead, the ECJ seems to favor a broadly objective principle, based on anything that would fall outside "ordinary" orders for the domestic market.

Unhelpfully, the ECJ refused to elaborate on what "ordinary" means. It certainly could have said more, since it had the basic facts in the case before it and the question must in part at least have a legal meaning.[18] Indeed, the ECJ made matters worse by adopting different formulations at different places, later saying that the test is whether the orders are "out of all proportion to those previously sold by the same wholesalers to meet the needs of the market in that Member State"[19]—a more permissive test for wholesalers—as compared to the formulation used elsewhere ("out of the ordinary in terms of quantity").

THE UPSHOT IS THAT THE MANUFACTURER DOES NOT NEED TO SUPPLY MUCH MORE THAN DOMESTIC CONSUMPTION. IN THESE CIRCUMSTANCES, EVEN IF THE WHOLESALER COULD, SUBJECT TO ANY PUBLIC SUPPLY OBLIGATION, DECIDE TO EXPORT ALL OF ITS SUPPLY FOR PARALLEL TRADE, THERE IS AN UPPER LIMIT ON THE MANUFACTURER'S DUTY TO SUPPLY (AND THEREFORE EXPOSURE).

But the qualification that "ordinary" is to be interpreted "in the light of both the size of those orders in relation to the requirements of the market in the first Member State and the previous business relations between that undertaking and the wholesalers concerned" is reasonably helpful. This seems to suggest a two-stage inquiry: First, that the dominant firm can refuse if the *individual* orders placed by the wholesaler materially exceed what it ordered before; and Second, that the dominant firm might still be able to refuse to meet an individual order if the total *aggregate* amount supplied in the Member State already materially exceeded domestic consumption (assuming, perhaps, that there is some evidence of the requesting wholesaler also having engaged in parallel trade).

Thus, one might argue that, subject to questions of how the ECJ's test will apply in practice, the overall thrust of the ECJ's conclusion is much more manufacturer- than parallel exporter-friendly. The upshot is that the manufacturer does not need to supply much more than domestic consumption. In these circumstances, even if the wholesaler could, subject to any public supply obligation, decide to export all of its supply for parallel trade, there is an upper limit on the manufacturer's duty to supply (and therefore exposure).

But the route by which the ECJ got to its conclusions is pretty confused and difficult to fathom in many respects. A few brief points should be highlighted.

A. WHY DOES THE DOMINANT FIRM EVEN NEED A DEFENSE OF OBJECTIVE JUSTIFICATION?

The ECJ's analysis posits that a refusal to supply that would result in the elimination of supplies from a parallel trader is *prima facie* abusive unless objectively justified by, e.g., the manufacturer's need to take reasonable steps to protect its commercial interests.

This inverted analysis assumes away rather a lot. Most obviously, it assumes that a dominant firm in general has no unilateral right to refuse to deal in circumstances where the object of the refusal is a parallel traded good. Thus, the fact that the goods in question are intended to cross the border of another Member State apparently makes all the difference: That act takes away any basic right that the dominant firm might otherwise have had to refuse to deal with a third party.

But why does the dominant firm need a defense as a general matter in parallel trade cases? Why does the burden shift to it to show objective justification straight away? Surely it has the basic right, in general, to refuse to deal? The idea that a refusal to deal with a parallel trader is unlawful unless there is an objective justification for the refusal is curious. There are only a handful of very unusual cases in which EU competition law has compelled firms to deal with third parties. Those cases are subject to very strict conditions—in particular the circumstances that the product in question is "indispensable" for rivals; the refusal would eliminate all effective competition in the market; and the decision lacks objective justification.

Not a shred of this forms part of the ECJ's analysis in parallel trade cases. Why not? Indeed, if anything, where, as in parallel trade, the only competition in question concerns resale/distribution, there is arguably even less reason to intervene since it is purely intra-brand competition based on the exact same products—in contrast to refusal-to-deal case law where the issue was access to an input that rivals needed to make their own value-added or innovative finished products.

The ECJ did cite some Article 82 parallel trade cases in support of its view that limiting parallel trade by unilateral refusals to deal is *prima facie* abusive (absent objective justification). But none of them, properly analyzed, really supports its view. *United Brands* did concern a decision by a dominant firm to terminate supplies to its distributor, Oelsen, on the grounds that the distributor had participated in an advertising campaign for a competitor of the supplier. But the rationale was that this was a reprisal abuse, aimed at reducing the distributor pool available to a rival of the dominant firm.[20] The case also involved the dominant firm imposing a clause prohibiting the sale of green bananas (yellow bananas would deteriorate too quickly to allow transportation to other Member States). But this

was an outright agreement excluding all parallel trade, for no good reason, which would probably be *per se* illegal under Article 81 EC anyway. So the case does not say that unilateral conduct limiting parallel trade is an abuse.

Likewise, the cited automotive cases, *British Leyland*[21] and *General Motors*[22] were more concerned with the circumstance that the dominant firm has a 600 percent price difference for performing the same service (issuing certificates for left- and right-hand drive cars). This was an example of unlawful excessive pricing whether or not it happened to involve a comparison between imported cars and domestic cars.

The other legal principle cited by the ECJ—that a refusal to deal with a parallel trader is *prima facie* abusive where it is "liable to eliminate a trading party as a competitor"[23]—also makes an elementary error. The mere fact, if it is a fact, that a particular wholesaler would exit the market has no necessary connection with any adverse effects on competition. There may for example be plenty of other wholesalers (intra-brand competition) or, more importantly, competition from other brands (inter-brand). To suggest otherwise is to say that competitors must be protected under EU competition law, which the Commission has recently emphasized is not the case under Article 82.[24]

TREATING A REFUSAL TO DEAL AS *PRIMA FACIE* ABUSIVE DEPENDING ON WHETHER IT INVOLVES PARALLEL TRADE OR NOT IS ALSO ECONOMICALLY INCOHERENT.

Treating a refusal to deal as *prima facie* abusive depending on whether it involves parallel trade or not is also economically incoherent. A simple example shows why. Suppose a manufacturer, Big Bad Pharmaco, is dominant in a particular class of drug in Greece. It sells Wonderdrug to a Greek wholesaler, called Virtuous, at 10 EURO and the (regulated) retail price in Greece is 12 EURO. Big Bad Pharmaco also sells Wonderdrug to wholesalers in France at 15 EURO. The (regulated) retail price in France of Wonderdrug is 20 EURO. So Virtuous buys in Greece at 10 EURO and exports for sale in France where, quite rationally, it has incentives to price at 20 EURO. Big Bad Pharmaco then refuses to sell to Virtuous (because it is exporting to France) and also simultaneously refuses to sell to the French wholesalers (because it wishes to reduce over-supply in France).

On the ECJ's logic, the former refusal would be *prima facie* illegal (i.e., absent objective justification) whereas the latter would be legal (since there is no cross-border element). But the two situations are, in terms of economic effects, identical. Of course you might say that Virtuous has more margin to play with and so could offer lower prices in France. But this assumes that parallel trade always benefits consumers, a point to which we return later in the paper.[25]

Does it matter that the ECJ effectively reverses the burden of proof and requires the dominant firm to show that its intention to limit parallel trading is objectively justified? Potentially, yes. The (partial) reversal of the burden of

proof could have important consequences, for example, in litigation. Most jurisdictions, for example, allow striking out unmeritorious claims at an early stage to avoid pointless, expensive trials.[26] But if, following *Glaxo Greece*, it is abusive—absent objective justification—to refuse to supply parallel traders, then it may be much more difficult for a manufacturer to have claims struck out, since a parallel trader would be able to establish a *prima facie* abuse for which the manufacturer then needs to advance an objective justification. In the English courts at least, there is some evidence that judges faced with difficult choices in competition law cases will often simply decide that the party bearing the burden of proof has not discharged it.[27] This could be important in practice, since, if a claim survives a strike out, it is more likely to thereafter settle on terms favorable to the parallel trader.[28] By contrast, had the ECJ given more weight, as it should have, to the dominant firm's basic legal right to refuse to deal with anyone, issues like this would be avoided, or at least minimized.

B. UNILATERAL ACTS ARE DIFFERENT

Another flaw in the ECJ's reasoning is that it gives no recognition to unilateral acts being fundamentally different, in competition law terms, to agreements between two or more undertakings. The mere fact that a unilateral act would resemble or have similar effects to an agreement does not mean that they are equivalent in competition law terms. To take an obvious example, an agreement between two competing undertakings not to sell in a particular territory or to limit their output is a hardcore cartel, but a unilateral decision by a firm not to sell in a particular country or to reduce the volumes in that country it sells must, without additional abusive conduct, be legal, even if a firm is dominant. Any firm, dominant or not, has the general right to decide, unilaterally, to whom or where it sells and how much.

ANOTHER FLAW IN THE ECJ'S REASONING IS THAT IT GIVES NO RECOGNITION TO UNILATERAL ACTS BEING FUNDAMENTALLY DIFFERENT, IN COMPETITION LAW TERMS, TO AGREEMENTS BETWEEN TWO OR MORE UNDERTAKINGS.

Remnants of this flawed logic (and conflation of two different things in competition law terms) remain in *Glaxo Greece*. For example, the ECJ noted the strict policy on agreements that limit trade under Article 81[29] and seemed to use that as a basis for justifying the treatment of unilateral acts under Article 82 in a similar fashion.[30] This is wrong: the two cannot be conflated in this way.

Similarly, Advocate General Colomer seemed to attach importance to the fact that Glaxo Greece had moved from a situation of vertical integration to one in which it had contracts with independent distributors, thus suggesting, implicitly but clearly, that the latter arrangements could be analogized with Article 81-type issues,[31] and therefore more deserving of sanction than a situation of vertical integration. But this too is a bogus distinction: Whether a dominant firm is limiting parallel trade through unilateral vertical integration or by unilaterally reducing

supplies to independent distributors is economically indistinguishable. It makes no sense to suggest that the latter is worthy of sanction but the former is not.

The reasons for conflating the analysis of agreements and unilateral acts with facially similar effects is of course bound up in the EU institution's long-held view that, sometimes anyway, EU competition law must be interpreted in a manner that advances the political objective of market integration between Member States. Indeed, the Commission has stated that "it is inconceivable that competition policy could be applied without reference to the priorities fixed by the Community,"[32] which include an internal market without frontiers. The Commission has also spoken of the "federating" role of EU competition law,[33] which explains why the integration of national markets has featured prominently in EU competition case law.

THE IDEA THAT EU COMPETITION LAW MAY MEAN DIFFERENT THINGS DEPENDING ON WHETHER A BORDER IS CROSSED OR NOT IS ODD AND LARGELY UNHELPFUL.

The idea that EU competition law may mean different things depending on whether a border is crossed or not is odd and largely unhelpful. One obvious problem already noted is that the law cannot be different depending on the happenstance of whether a product or service is provided cross-border. Another concern is that the meaning of Article 82—which the Commission at least has gone to great lengths to attempt to clarify in its recent Article 82 Guidance Paper[34]—is likely to be much less clear if it also includes the broad, and generally poorly-defined, political objective of furthering market integration. It is also not clear why parallel traders have typically been regarded as so virtuous by the EU institutions and manufacturer conduct to limit parallel trade so heinous. One could argue that an innovator has a higher moral claim than a reseller because it creates something.[35]

There are signs though of a shift in approach (quite apart from the overall gist of *Glaxo Greece*, which, as noted, seems in pragmatic terms ultimately quite favorable to manufacturers). It is notable that the recent Article 82 Guidance Paper does not mention the single market objectives of the EC Treaty as potentially broadening the interpretation of Article 82. Also, the Court of First Instance in *Glaxo Spain* recently noted that:

> "the mere fact that an agreement is intended to restrict parallel trade is not sufficient to support the conclusion that there is an infringement of Article 81(1) EC. In effect, the objective assigned to that provision is to prevent undertakings, by restricting competition between themselves or with third parties, from reducing the welfare of the final consumer of the products in question."[36]

The imminent ECJ appeal in the case will therefore be watched with great interest.

C. POLICY-LITE

The ECJ's treatment of the underlying policy questions affecting the pharmaceutical industry is also superficial. While, ultimately, the ECJ's adopting a pragmatic test based on whether the orders are "ordinary" or not avoided the need to review these policy questions in any serious way, its apparently unwillingness or inability to do so is regrettable. It is, after all, the EU's highest court and this was the second preliminary reference in the same case. One suspects that the ECJ was unwilling to decide a legal case, either way, against the backdrop of complex, diverse, and constantly evolving national pharmaceutical regulation policies in 27 Member States.

THE ECJ'S TREATMENT OF THE UNDERLYING POLICY QUESTIONS AFFECTING THE PHARMACEUTICAL INDUSTRY IS ALSO SUPERFICIAL.

But a number of the issues raised did involve eminently testable assumptions. For example, the ECJ dismissed the argument that parallel trade does not benefit the ultimate consumers on the basis that it might have some (indirect) positive price effects. This is a pretty fundamental point, since, absent consumer price benefits, a competition law policy that supported parallel trade would, very clearly, be based on the notion that forcing wealth transfers from manufacturers to distributors is a legitimate competition law objective—i.e., protecting competitors. And it is also a point that can be assessed in a fairly reliable quantitative way.

There was no serious analysis at all of this issue in the judgment—only throwaway remarks that had no apparent empirical or objective basis. This issue merited proper attention. There is plenty of evidence, including from the Commission itself, that parallel trade produces minimal/no final consumer benefits.[37] The ECJ had two well-resourced competing interest groups before it, so it is not clear why the evidence was not assessed in a serious and forensic way. While it may ultimately have been difficult for the ECJ to be categorical, either way, on this issue, the conclusions to be drawn from the preponderance of evidence ought to have had very important implications for the analysis. For example, if indeed it is the case that there are limited consumer benefits, one wonders whether treating refusals to deal with parallel traders as even *prima facie* capable of being abusive is a good idea at all.

The same sort of poor reasoning applies to the other key policy questions that the ECJ was confronted with. For example, one issue raised by the manufacturers is that the period of effective patent protection is relatively short (even allowing for legal extensions such as supplementary protection certificates ("SPCs")) so that the ability to limit arbitrage between countries is an important factor in supporting efficient price discrimination to support recovery of fixed R&D costs.

The Advocate General's response to this was to say that, while there was not "any" evidence before the court, he nonetheless felt able to surmise that "the long delay was due to the internal cost structures of pharmaceutical undertak-

ings."[38] For good measure, he was also able to "hazard a guess" that the same was true in "other" unspecified "sectors."[39] This is not really high quality analysis. Also it's pretty obvious to most observers that a major contributory factor in shortened patent life is burdensome regulatory approval schemes. This is the main reason why we have, for example, the SPC regime in the EU.

It is also fair to point out that there are policy factors that may potentially go in the other direction. The pharmaceutical sector is said to be the single most profitable business sector in the economy,[40] with 15-25 percent plus margins being quite common.[41] Equally, it is striking that major pharmaceutical companies spend far more on marketing than they do on R&D—in many cases, by multiples.[42] This is a plausible explanation for why off-patent branded drugs still manage to maintain significant price premiums over generic products, i.e., marketing, not therapeutic innovation, sells. The oft-heard cry that regulatory or competition law interventions would rob the industry of essential funds for R&D must be seen in this context. Finally, the recent EU Commission sector inquiry and on-going US Federal Trade Commission enforcement in relation to patent settlements and impediments to generic entry raise at least a suspicion that an important parameter of competition has nothing to do with innovation but gaming various processes and legal settlements.[43]

On the other hand, advances in pharmaceuticals, biotechnology, and genetics (e.g., monoclonal therapies for cancer, HIV/AIDS treatments) make the economic and non-economic benefits of innovation undeniable and of profound importance to society. The costs of innovation are also staggering and success is fleeting. Bringing a new drug to market, for example, costs an average of $800 million in capitalized costs for pre-regulatory approval research and development and $95 million for post-approval research and development.[44] Only one in approximately every 435 drugs that are considered ever makes it to the market.[45] So the rewards for the few successes need to compensate for the many failures.[46]

In fairness to the ECJ though, its job is to decide the cases that come before it, not to make policy. These policy questions are also undoubtedly hard and may, in some respects, be too intractable to develop immutable legal rules. They are also questions that go far beyond the esoteric realms of competition law and raise fundamental questions of industrial and social policy for the EU economy (and others), as well as what type of public health policy it wants. A proper assessment also cannot ignore the industrial policy issues of whether the EU is content with relatively low levels of R&D based in the EU, with U.S.-based research being relied upon to a large extent. These are big questions and ones moreover than cannot, in an interdependent world, be looked at in terms of EU geography only. And very few of them will be answered in any satisfactory way as a result of the EU Commission's competition sector inquiry in the pharmaceutical sector,[47] which, to the extent any follow-up action results, will largely focus on agreements and practices that limit competition from generic and patent settlements.

But these questions are also unavoidably central to at least informing—and we would argue dictating—what sensible competition law and policy should be doing with questions like parallel trade. Of course the ECJ is a supreme court of law, not an enforcement agency or central planner. But this cannot lead to its abdicating a responsibility to examine the key policy issues in a serious, forensic, and measured way. Substituting all of this in favor of the pure pragmatism of imposing some upper limit on the duty to supply—"ordinary" supplies—is the legal equivalent of putting a Band Aid on a gaping wound.

III. Annex: *Syfait* and *Glaxo Greece* Compared

Issue	AG Jacobs in *Syfait*	AG Ruiz–Jarabo Colomer in *Glaxo Greece*	ECJ in *Glaxo Greece*
The uniqueness of the pharmaceutical market	"It is impossible, when assessing conduct of the kind at issue in the present proceedings, to ignore the pervasive and diverse regulation to which the pharmaceutical sector is subject both at national and Community levels, and which appears to me to set it apart from all other industries engaged in the production of readily traded goods." (¶77) "I think it is highly unlikely that any other sector would exhibit the characteristics which have led me to conclude that a restriction of supply in order to limit parallel trade is defensible in relation to pharmaceutical products." (¶102)	"We must rule out the idea that there are in this case objective reasons relating to State intervention in the market which would justify its conduct." (¶98)	The ECJ found that there are no grounds for treating restrictions to parallel trade in pharmaceuticals differently.
Economic justifications	"I consider that a restriction of supply by a dominant pharmaceutical undertaking in order to limit parallel trade is capable of justification as a reasonable and proportionate measure in defence of that undertaking's commercial interests.… Given the specific economic characteristics of the pharmaceutical industry, a requirement to supply would not necessarily promote either free movement or competition, and might harm the incentive for pharmaceutical undertakings to innovate." (¶100)	"Apart from the description of the 'horrors' caused by parallel trade, GSK does not indicate any positive aspect resulting from its restriction of supplies of medicinal products to the wholesalers, except that its profit margins recover, which is irrelevant for the purposes of classifying the conduct as an abuse, or for the purposes of justifying it." (¶118)	"Even if the degree of regulation regarding the price of medicines cannot prevent any refusal by a pharmaceuticals company in a dominant position to meet orders sent to it by wholesalers involved in parallel exports from constituting an abuse, such a company must nevertheless be in a position to take steps that are reasonable and in proportion to the need to protect its own commercial interests." (¶70)

Issue	AG Jacobs in *Syfait*	AG Ruiz–Jarabo Colomer in *Glaxo Greece*	ECJ in *Glaxo Greece*
Consumer benefit of parallel trade	"The fact that Member States have adopted radically different price levels for pharmaceutical products in their territories, and are themselves the main purchasers of pharmaceutical products, casts doubt upon the notion that parallel trade will in fact benefit the purchasers of such products." (¶88)	"Allowing preconceived and formalistic ideas on abuse of a dominant position to prevail would mask the fact that sometimes dominance can benefit consumers." (¶73)	"Even in the Member States where the prices of medicines are subject to State regulation, parallel trade is liable to exert pressure on prices and, consequently, to create financial benefits not only for the social health insurance funds, but equally for the patients concerned, from whom the proportion of the price of medicines for which they are responsible will be lower." (¶56)
Impact on R&D	"Innovation is an important parameter of competition in the pharmaceuticals sector." (¶89) "If low-price Member States were able to resist the pressure for price rises, and pharmaceuticals undertakings did not withdraw or delay products, the revenue generated by products in respect of which dominance was found would be cut. The incentive for a pharmaceutical undertaking to invest in research and development would to that extent be reduced, given the lower returns which such an undertaking could expect to enjoy during the period of its patent protection." (¶93)	"I cannot see that there is necessarily any causal link between any possible negative impact on R&D investment and parallel trade, since, in the first place, GSK and the writers in question have not provided any information relating to the reasons for the period during which the patent is not revenue producing." (¶109)	The ECJ declined to address the issue of a possible link between the losses incurred by pharmaceutical companies as a result of parallel trade and their ability to invest in R&D. (¶70)

1 Case C-53/03 *Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKline plc and GlaxoSmithKline AEVE*, [2005] ECR I-4609 ("*Syfait*").

2 Joined Cases C-468/06 to C-478/06, judgment of 16 September 2008, not yet reported. (*Glaxo Greece*)

3 Case T-168/01 *GlaxoSmithKline Services Unlimited v Commission* [2006] ECR II-2969, currently on appeal with an oral hearing scheduled in March 2009.

4 *Syfait*, *supra* note 1, per Advocate General Jacobs at ¶70.

5 *Glaxo Greece*, *supra* note 2, ¶35, 39.

6 *Id*.¶49, 50.

7 *Id*.¶57.

8 *Id*.¶56.

9 *Id*.¶62.

10 *Id*.¶63.

11 *Id*.¶67, 68.

12 *Id*.¶69.

13 The ECJ also held that the right to refuse to meet orders out of the ordinary answered the objection that a duty to supply parallel exporters could lead to shortages in the export country (which actually happened in Greece) (*Id*. ¶74).

14 *Id*. ¶77.

15 *See* J.S. Venit & P. Rey, *Parallel Trade and Pharmaceuticals: A Policy in Search of Itself,* Eur. L Rev 153 (2004).

16 *Glaxo Greece, supra* note 2, ¶70.

17 *Syfait, supra* note 1, ¶50 per Advocate General Jacobs:

> Given that any attempt by a producer to restrict supply in order to limit parallel trade is usually motivated by a concern to restrict intra-brand competition on the market of import, such a restriction is normally to be regarded as abusive. Partly, also, the Commission relies upon the market-partitioning object of the conduct at issue. The Court has consistently interpreted Articles 81 and 82 EC as prohibiting conduct aimed at dividing the common market.

18 GSK AEVE had delivered quantities of medicines corresponding to the monthly average sold in Greece during the first 10 months of 2000, while certain wholesalers asked for those quantities to be increased by a certain percentage, which was fixed by some of them at 20 percent (see *Glaxo Greece*, *supra* note 2, ¶72). The ECJ also held that the right to refuse to meet orders out of the ordinary answered the objection that a duty to supply parallel exporters could lead to shortages in the export country (which actually happened in Greece) (*Id.*, ¶74).

19 *Id*. ¶76.

20 Case 27/76, *United Brands Company and United Brands Continentaal BV v Commission* [1978] ECR 207.

21 Case 226/84, *British Leyland v Commission* [1978] ECR 207.

22 Case 26/75, *General Motors Continental v Commission* [1986] ECR 3263.

23 *Glaxo Greece, supra* note 2 ¶34.

24 *See* DG COMP Guidance on its enforcement priorities in applying Article 82 to abusive exclusionary conduct by dominant undertakings, official version published on February 9, 2009, *available at* http://ec.europa.eu/competition/antitrust/art82/guidance_en.pdf, (the "Article 82 Guidance Paper")

("The Commission will focus on those types of conduct that are most harmful to consumers", ¶5) (Section B, "Foreclosure leading to consumer harm"), and ¶19.

25 Another oddity of the ECJ's analysis is the focus on the manufacturer's dominance in the exporting market (here, Greece). But, surely, if the only plausible benefit of the parallel trade activity is to the importing Member State, the real issue is the state of competition in that market, not the market where the goods come from. It is perfectly possible that there could be much more inter-brand competition in the importing market such that a refusal to supply more products for intra-brand competition does not impact on effective competition overall.

26 *See*, e.g., Rule 3.4 of the Civil Procedure Rules in England & Wales.

27 *See*, e.g., *Chester City Council v. Arriva plc* [2007] EWHC 1373 (Ch), [2007] UKCLR 1582.

28 Matters are also complicated by the fact that it is not entirely clear from *Glaxo Greece* whether the dominant firm bears only an evidential burden (i.e., to put forward a *prima facie* case showing that the order is not "ordinary") or the entire legal burden of showing that its conduct is not abusive. One assumes the former, since this is how objective justification under Article 82 usually works and anything more would be contrary to the burden of proof rules in Council Regulation (EC) No 1/2003 of December 16, 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, OJ [2003] L 1/1.

29 *Glaxo Greece, supra* note 2 ¶65.

30 *Id*. ¶66.

31 *Id*. ¶111.

32 XXIIIrd Report on Competition Policy (1993), p. 1.

33 XXVIIth Report on Competition Policy (1997), foreword by the then Commissioner responsible for competition policy, Karel Van Miert.

34 *See* DG COMP Preliminary Report of November 28, 2008, *Pharmaceutical Sector Inquiry*, document available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf (last visited on February 28, 2009).

35 It is also striking how the EU institutions' policy in this regard has been selective. For example, the EU has a strict competition policy intended to promote parallel trade in automotive vehicles. But it has, at the same time, refused to take any action against national vehicle registration taxes and policies that, quite explicitly in some cases, are designed to off-set the savings made by purchasing the vehicle in another Member State. (Some might say, unfairly, that there is one rule for arbitrage that would offset disparities in national public fiscal policies and another where private interests such as pharmaceutical manufacturing are at issue.)

36 Case T-168/01 *GlaxoSmithKline Services Unlimited v Commission* [2006] ECR II-2969, ¶ 10.

37 In 1998, the Commission stated that "parallel trade creates inefficiencies because most, if not all, of the financial benefit accrues to the parallel trader rather than to the health care system or patient." *See* Commission Communication on the *Single Market in Pharmaceuticals*, COM (1998) 588. *See also* P.M. Danzon & A. Towse, Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents, AEI-Brookings Joint Centre Working Paper No. 03–7 (July 2003), pp. 13–14 and A. Towse, What are the Short and Long Run Implications for the UK of Parallel Trade in Pharmaceuticals?, Working Paper, 1997, London, Office of Health Economics, pp. 1–20.

38 *Glaxo Greece, supra* note 2 ¶111.

39 *Id*. ¶111.

40 *See,* e.g., data in *2002 Drug Industry Profits: Hefty Pharmaceutical Company Margins Dwarf Other Industries*, Congress Watch, June 2003, Figure 5, document available at http://www.citizen.org/documents/Pharma_Report.pdf.

41 *See* L. Davidson & G. Greblov, *The Pharmaceutical Industry in the Global Economy*, mimeo, Indiana University School of Business, Summer 2005, Table 2.8.

42 *Id*., Figure 3. *See also* M. Angell, *Excess in the Pharmaceutical Industry*, CMAJ 2004 December 7; 171(12): 1451–1453.

43 *Supra* note 34.

44 J.A .Dimasi, R.W. Hansen, & H.G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151–85 (2003).

45 Based on figures from H. Grabowski, *Patents, Innovation and Access to New Pharmaceuticals,* mimeo, Duke University, July 2002; and J.A. Dimasi, *Research and Development Costs For New Drugs by Therapeutic Category*, 7 PHARMACOECONOMICS 152–169 (1995).

46 *See generally* European Federation of Pharmaceutical Industries and Associations (EFPIA), *Article 82 EC: Can It Be Applied To Control Sales By Pharmaceutical Manufacturers To Wholesalers?*, Research Paper, November 2004.

47 *Supra* note 34.