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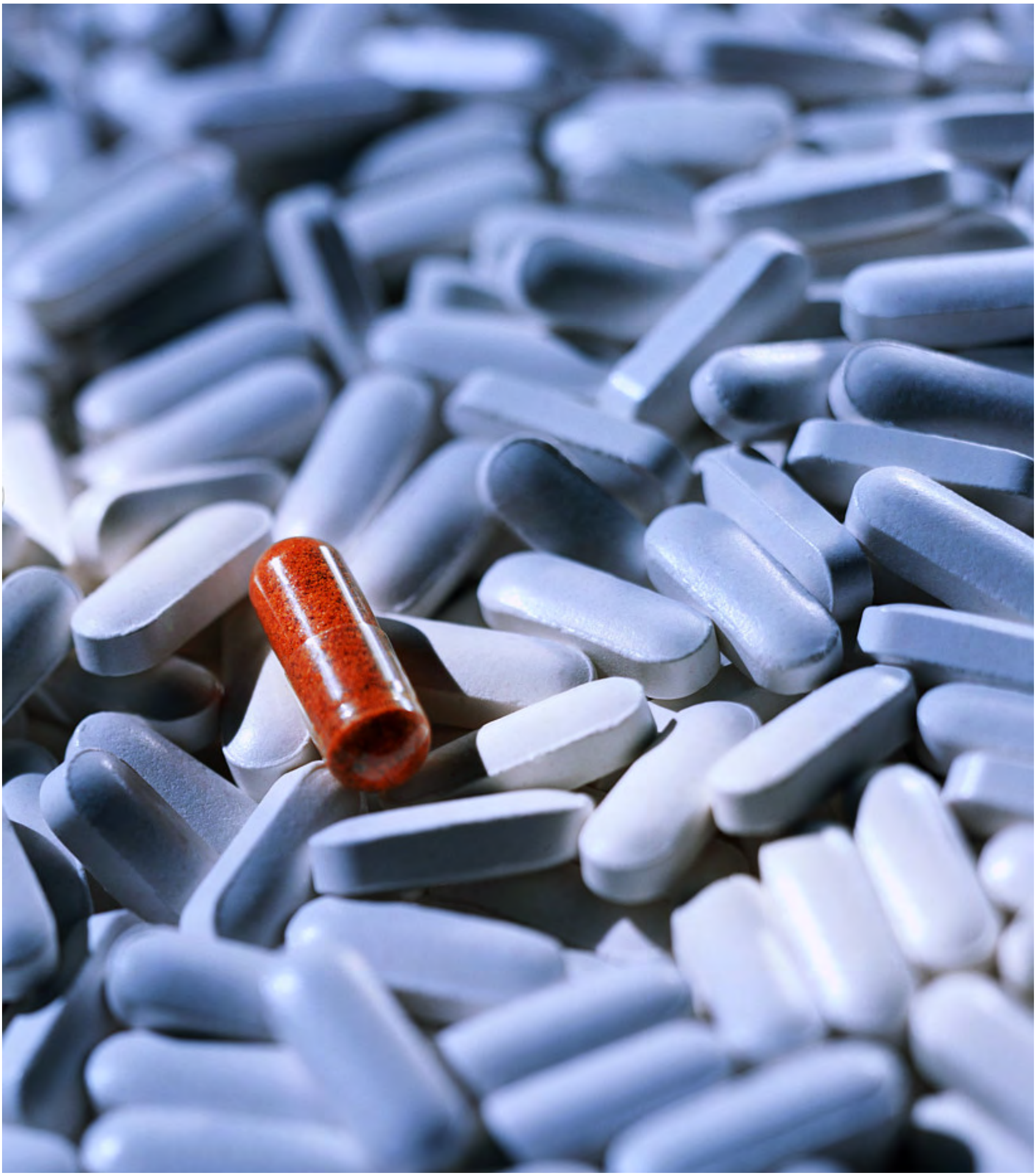

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Abuse of dominance in pharmaceutical products cases concerning parallel trade: should the Lelos decision of 2008 be revisited in the present Greek era?

By Despina Samara

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In 2001, following complaints of 16 associations of pharmacists, the Pan-Hellenic Association of pharmaceutical warehouses, the Pan-Hellenic Association of pharmaceutical wholesalers and 41 pharmaceuticals wholesalers against the policy applied by GlaxoSmithKline SA and its parent company for the distribution system of three of its pharmaceutical products in Greece. The legality of a dominant pharmaceuticals company's behaviour in trying to restrict parallel trade of its products was put under scrutiny both by national and European courts as well as the National Competition Commission. After almost 14 years, the final episode to the so-called Glaxo saga has not been played as yet; on the contrary, the two opinions delivered by two Advocate Generals on the said case, the decision of the European Court of Justice (now Court of Justice of the EU (aka, CJEU)) taken back in 2008, as well as some recent decisions of the Greek courts published in light of the decision of the CJEU, have all highlighted the fact that the issue is far from a clear and unambiguous closure. This is even more the case when taking into account the recent regulatory developments in the Greek pharmaceutical market.

In more detail, back in 2003, Advocate General Jacobs relied on sector-specific features to justify a dominant company's conduct to refuse supply with the intention to restrict parallel trade. Deviating clearly from the view taken by the European Commission on the said matter, Advocate General Jacobs concluded that the specific characteristics of the pharmaceutical industry do not ensure that a requirement to supply would necessarily promote either free movement or competition; on the contrary, to the opinion of AG Jacobs, it might harm the incentive for pharmaceutical undertakings to innovate after all. In 2008, a new opinion was delivered on the same factual and legal circumstances by Advocate General Colomer. Advocate General Colomer moved directly opposite Advocate General Jacob's opinion into refusing in effect the special characteristics of the pharmaceutical sector as sufficient justification grounds for a dominant pharmaceutical company's conduct intended to restrict parallel trade. When ruling on the case, the European Court was not as clear as the two Advocate Generals in its decision. While not rejecting the specific characteristics of the pharmaceutical market and their relevance in addressing a dominant company's behaviour in intending to restrict or limit parallel trade of its products, the Court tried to define the lines of such behaviour by adhering to the basic community principle of free movement of goods and the respective protection to parallel trade. In compromising these two ends, the Court essentially produced a somehow ambiguous ruling which shall eventually be revisited especially given the new regulatory environment that has emerged following the financial crisis of the recent years in Greece with a view to controlling public expenditure for health care.

In more detail, Law 4052/2012 as amended by Law 4093/2012, introduced a number of changes affecting predominantly the pricing and reimbursement of pharmaceutical products: promotion of generics via compulsory prescription by active substance; e-prescription for almost all medicines; a claw back and a rebate mechanism in effect retrospectively; consecutive reductions in the maximum prices for both original and generic pharmaceuticals; reductions in profit margins for pharmacists; e-procurement for the supply of medicines to public hospitals; an one-off special payment by marketing authorisation holders for the inclusion of prescription medicines in the positive list to name but the main changes adopted. All these measures, coupled with the considerable "haircut" of the state bonds the pharmaceutical

companies had acquired in settlement of overdue hospital debts have taken their toll in the national pharmaceutical market. Great concerns have thus arisen both in terms of the availability of products in the market as well as an emerging explosion in parallel exports as prices got even lower. A new environment has been created for pharmaceutical companies in Greece - one which should in itself be considered as possessing unique and special characteristics. The national Ministry of Health and Solidarity seems to argue in favour of such a finding as it has adopted the following disclaimer: "the current Greek pricing system is based on the exceptional and harsh economic, social and medical factors that are specific to Greece. The Greek Ministry of Health asks competent Authorities in other Countries not to refer to those prices in their national pricing and reimbursement decision-making process".

In light of the above, it is difficult to see how a judge or a competition commission in this regard could escape addressing the particular new features of the pharmaceutical market in case of an alleged violation of competition law rules by a pharmaceutical company in Greece. First of all, it should be noted that an approach which takes into account sector-specific features as justification for an anti-competitive conduct is not a "novelty" for the European Court. On the contrary, the Court itself accepted in another Glaxo-related case (Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, GlaxoSmithKline v Commission of the European Union) that Article 81 (3) (now 101 (3) TFEU) is the appropriate forum to consider the particular features of the pharmaceutical sector. More significantly, in the said case, the Court found that the Court of First Instance (CFI) was correct in criticizing the European Commission for not taking into consideration the "specific structural features" of the pharmaceutical sector as an assessment of the exemption under Article 81 (3) (now 101 (3) TFEU) "may require" the nature and the specific features of the sector concerned by the agreement to be taken into account if its nature and those specific features are decisive for the outcome of the analysis" (para.103 of the decision). Second, although the degree of price regulation in the pharmaceuticals sector cannot preclude the Community rules on competition from applying, the fact none the less remains that, when assessing, in the case of Member States with a system of price regulation, whether the refusal of a pharmaceuticals company to supply medicines to wholesalers involved in parallel exports constitutes abuse, it cannot be ignored that such State intervention is one of the factors liable to create opportunities for parallel trade. Furthermore, in the light of the Treaty objectives to protect consumers by means of undistorted competition and the integration of national markets, Community rules on competition are also incapable of being interpreted in such a way 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. One could argue that if pharmaceutical companies cannot negotiate a price increase in low-price Member States, dominant undertakings would respond to an obligation to supply parallel traders within a given Member State by removing existing products from the market in that State, if they were able to do so, and by delaying the launch of new products there. Price differentials would be replaced by a greater fragmentation of the market, with a differing range of products available from State to State.

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Dr. Despina Samara is a senior associate at Calavros & Partners Law Firm since 2006. She specializes in EU and Greek competition law and regulation, as well as general EU law (free movement of goods and services, intellectual property law, harmonisation of laws and public procurement). She advises and assists clients in procedures before both national and community authorities and courts in cases involving abuse of sole and collective dominance, state aid and public procurement, horizontal and vertical agreements (joint ventures, agency and distribution networks, supply contracts and licensing), private antitrust litigation matters and cartel-related work, with particular emphasis on pharmaceuticals related matters. She also provides antitrust compliance advice and sectoral inquiry related expert counseling. The corporations she acts for are active across a wide range of industry sectors including oil, pharmaceuticals, telecommunications, energy, consumer goods and retail sales. Dr. Samara also has extensive experience in drafting and revising commercial agreements and private contracts. She has acted as an advisor to Greek state controlled companies and the Greek Government in relation to privatization initiatives.

Dr. Samara has also completed a stage with the Industrial Property Unit of the Directorate General of Internal Market, European Commission, while she has acted as research assistant at the Department of Health and Social Care of the London School of Economics and Political Sciences.