

A QUICK LOOK INTO THE PAST, PRESENT AND FUTURE OF COMPETITION ENFORCEMENT IN THE PHARMACEUTICAL SECTOR

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Good afternoon ladies and gentleman, it is a great pleasure to be here today. In my presentation, I have three ambitions, *i.e.* talk about the past, future and present.

I. The Past – A Reminder on the Interplay between Antitrust and the Pharmaceutical Industry

First, by way of introduction, I would like remind the audience of a basic, traditional principle that governs the interplay between competition law and pharmaceutical regulation. The pharmaceutical industry has nothing special for antitrust lawyers. More precisely, the heavy regulation that bears on the pharmaceutical sector does not insulate it, in part or in full, from the scope of EU competition law.

This is first true of the statutory protection of intellectual property (“IP”). The point is often made that in sectors where IP rights are granted *ex ante*, there should be a blanket *ex post* antitrust immunity. The underpinning argument is that both sets of rules seek to foster dynamic efficiency, *i.e.* innovation¹. Hence, competition agencies should defer to,² and at any rate never reverse – through for instance, compulsory licensing orders – decisions made by IP regulators.³ In short, the existence of IP rights should exhaust antitrust intervention.

Quite frankly, this argument is a no brainer. Competition law also promotes objectives alien to IP protection, such as *ex post* allocative and productive efficiency, *i.e.* price and costs reductions. The upshot of this is that *ex post* competition enforcement remains warranted even where IP rights are present, as soon as there is harm to allocative and productive

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¹ S. ANTHONY, “Antitrust and Intellectual Property Law: From Adversaries To Partners”, *AIPLA Quarterly Journal*, Volume 28, Number 1, Winter 2000, p. 1; US DOJ, *Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition*, April 2007, 220 p. ; G. GHIDINI, *Intellectual Property and Competition Law. The Innovation Nexus*, Cheltenham, Edward Elgar, 2006, p. 8.

² Commentators regularly stress the necessity to curtail antitrust interventions on IP to very rare instances of abuse, J. TURNEY, “Defining the Limits of the EU Essential Facilities Doctrine on Intellectual Property Rights: The Primacy of Securing Optimal Innovation”, 3 *Nw. J. Tech. & Intell. Prop.*, p. 179; R. GILBERT and C. SHAPIRO, “An economic analysis of unilateral refusals to license intellectual property”, *Proc. Natl. Acad. Sci. USA*, Vol. 93, November 1996, p. 12749.

³ A. FISCH, “Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem”, *Jurimetrics J.*, 34, 1993-1994, p. 295 (1993-1994).

efficiency. This is the rationale behind the well-known “*existence*”-“*exercise*” dichotomy,⁴ which entitles competition agencies to act where IP rights are used in ways detrimental to competition.

But this is also true of other types of regulations. For instance, drug manufacturers that attempt to dry out parallel trade, have claimed in defense that their conduct was caused by Member States’ distortions of trade flows through artificial price regulations. Under settled EU law, competition liability for anticompetitive infringements or abuse is only excluded if the conduct is “*required*” by legislation and the firm has no “*discretion*” to act differently⁵. As long as firms retain a margin of maneuver not to behave in anticompetitive ways, they can be found guilty of infringement. In this sense, the Court of Justice (“CJ”) noted in *Sot. Lelos kai Sia EE*, the Court held that “*the control exercised by Member States over the selling prices or the reimbursement of medicinal products does not entirely remove the prices of those products from the law of supply and demand*”.⁶ As a result, drug manufacturers should not seek to eliminate price competition across countries with restrictions to parallel trade.

The reason for antitrust orthodoxy is simple. Conceding derogations is a dangerous call, akin to a Trojan horse. If specific exemptions are created for the pharmaceutical sector, many interest groups representing other sectors will knock on the Commission’s door with exoneration claims. And, as a matter of fact, almost all industries are subject to intrusive *ex ante* or *ex post* regulatory frameworks at either and/or national level. Think of the financial sector, network industries or the agricultural sector.⁷

This notwithstanding, EU competition law pays some attention to the specificities of pharmaceutical markets. For instance, market definition responds to a specific methodology,

⁴ ECJ, 13 July 1966, *Consten and Grundig v. Commission*, Cases 56 and 58/64, ECR, 1966, p. 229, para 49-50 ; ECJ, *Deutsche Grammophon Gesellschaft mbH v Metro-SB-Großmärkte GmbH & Co. KG.*, Case 78/70, ECR, 1971, p. 487, para. 7-13.

⁵ ECJ, 11 November 1997, *Commission and French Republic v. Ladbroke Racing Ltd.*, C-350/95 P and C-379/95 P, ECR, 1997, p. I-6265, para 33.

⁶ ECJ, 16 September 2008, *Sot. Lélos kai Sia EE and Others v. GlaxoSmithKline*, C-468/06 and C-478/06, ECR, 2008, I-7139, para. 61. Nonetheless, it added at para. 67 that “*Although the degree of price regulation in the pharmaceuticals sector cannot therefore preclude the Community rules on competition from applying, ... it cannot be ignored that such State intervention is one of the factors liable to create opportunities for parallel trade*”.

⁷ See for example Regulation 924/2009 of the European Parliament and of the Council of 16 September 2009 on cross-border payments in the Community and repealing Regulation (EC) No 2560/2001, *OJ*, 9 October 2009, L 266/11; Directive 2002/19 of the European Parliament and of the Council of 7 March 2002 on access to, and interconnection of electronic communications networks and associated facilities (Access Directive), *OJ*, 24 April 2002, L108/7; Council Regulation 1184/2006 of 24 July 2006 applying certain rules of competition to the production of, and trade in, agricultural products, *OJ*, 4 August 2006, L 214/7;

based on the ATC 3 class, that is products with the same therapeutic indication⁸. Similarly, in the assessment of anticompetitive effects, competition authorities are well aware that exogenous factors aggravate the harm caused by restrictions of competition. For instance, the fact that patients, pharmacists and practitioners are not fully price-elastic as a result of price/reimbursement regulations, increases market power and exacerbates the effects of exclusionary conduct.⁹

II. The Present – An Overview of EU and National Cases on Life Cycle Management Practices

Turning now to the second stage of this short presentation, I would like to talk about the present. The idea is to take stock of the current enforcement practice of EU and national agencies.¹⁰ The first section deals with life cycle management practices (1).¹¹ The second section deals with other types of pharmaceutical cases (2).

1. Life cycle management practices

Back in 2009, the Commission had painted a gloomy picture of life cycle management practices. Its Provisional Report suggested that originators had resorted to a “*toolbox*” of unlawful practices that “*delayed or blocked the entry of generic medicines*”. In the Final Report, reference was made to practices such as (i) defensive patent strategies (patent clusters or filing of divisional patents); (ii) aggressive patent litigation; (iii) originators interventions before marketing authorities and pricing reimbursement authorities; (iv) and strategic launching of second generation and follow-on products, before entry of generic products.¹²

Now that three years have passed, it is time to take stock and to see what happened. To start with the EU level, first, the mountain has not (yet?) given birth to more than a mouse, so to say. There has been very little, if no enforcement, outside the realm of reverse payment settlements (and even there, where announcements were made, no decisions have been adopted). The only case related to unilateral life cycle management practices is *AstraZeneca*,

⁸ Commission Decision, 8 May 2000, Glaxo Wellcome / Smithkline Beecham, COMP/M.1846, para. 8 ff; Commission Decision, 27 February 2003, Pfizer / Pharmacia, Case No IV/M.2922, OJ, 8 May 2003, 110 p. 24, para. 14 ff; Commission Decision, 4 February 2009, Sanofi-Aventis / Zentiva, COMP/M.5253, para. 179 ff.

⁹ Hence, OTC and prescription products are often deemed to form separate relevant markets. Commission Decision, 27 May 2005, COMP/M.3751-Novartis/Hexal, p. 3; Commission Decision, 19 November 2004, COMP/M.3544, Bayer Healthcare / Roche (OTC Business), para. 13.

¹⁰ For more on recent developments in the pharmaceutical industry, see D. HULL, “The Application of EU Competition Law in the Pharmaceutical Sector”, *Journal of European Competition Law & Practice*, 2011, Vol. 2, No. 5.

¹¹ We do not deal here with patent settlements.

¹² EU Commission, DG Competition Staff Working Paper, *Pharmaceutical Sector Inquiry. Preliminary Report*, 28 November 2008, 426 p.

a case decided well before the sector inquiry.¹³ What is worth mentioning is that the decision was upheld in a lengthy 2010 judgment by the General Court (“GC”). In this case the Commission had found AZ guilty of abuse for (i) supplying misleading information to national patent offices in order to secure supplementary protection certificates; and (ii) deregistering specific marketing authorizations and introduction of new drugs.¹⁴ The case is pending under further appeal on points of law before the CJ.

This decision remains, however, the whole and sole enforcement initiative taken by the EU Commission against life cycle management practices since 2005. Whilst several cases involving abusive unilateral conduct had been opened following the sector inquiry, many were closed, including in recent weeks. In this context, *Boehringer* is a case in point. Here, *Boehringer* was suspected of having filed several un-meritous patent applications before the European Patent Office (“EPO”) and to have obtained patents by providing misleading information to the EPO. This was allegedly part of a move to foreclose a rival originator, *Almirall*, from the market. The Commission opened an investigation in 2009, but closed it in July 2011, following a commitment by *Boehringer* to remove the alleged blocking positions from Europe.¹⁵ Interestingly, the Commission suggested, or even “*encouraged*” the parties to find a mutually acceptable solution to their dispute.¹⁶

Of course, a bunch of cases are still in the Commission’s pipeline, awaiting decisional resolution. In *Servier*, the Commission is apparently at grips with suspicions of unilateral behavior and agreements which may have hindered entry on to the market of generic perindopril.¹⁷

¹³ Commission Decision, June 2005, COMP/A. 37.507/F3, *AstraZeneca*. D. HULL, “The AstraZeneca Judgment: Implications for IP and Regulatory Strategies”, *Journal of European Competition Law & Practice*, 2010, Vol. 1, No. 6.

¹⁴ GC, 1 July 2010, *AstraZeneca AB and AstraZeneca plc v European Commission*, T-321/05, not yet published.

¹⁵ EU Press release, Antitrust: Commission welcomes improved market entry for lung disease treatments, 6 July 2011, P/11/842.

¹⁶ In addition, two cases, i.e. *GSK* (Reuters, *EU regulator drops GSK antitrust investigation*, 2 March 2012 (Synthon)), and *AstraZeneca* (EU Press Release, *Antitrust: Commission closes investigation in pharmaceutical companies AstraZeneca and Nycomed*, 1st March 2012, IP/12/210) were recently dropped. But stays *J&J Novartis / Cephalon Teva* (EU Press Release, *Antitrust: Commission opens proceedings against Johnson & Johnson and Novartis*, 21 October 2011, IP/11/1228), as well as against *Servier* (see footnote below) and *Lundbeck*, see EU Press Release, *Antitrust: Commission opens formal proceedings against pharmaceutical company Lundbeck*, 07 January 2010, IP/10/8).

¹⁷ More generally, most settlement cases can in principle be dealt with under Article 102 TFEU. Yet, it is unclear if the Commission will treat them under Article 101, 102 or under both provisions. EU Press Release, *Antitrust: Commission opens formal proceedings against Les Laboratoires Servier and a number of generic pharmaceutical companies*, 8 July 2009, MEMO/09/322. A procedural case was closed in 2012: EU Press Release, *Antitrust: Commission closes procedural case against Servier*, 27 January 2012, IP/12/43.

Turning now to the national level, enforcement has been equally meager, contrary to what numbers suggest on face value. With reference to the above typology, we are indeed not aware of any case of unlawful (ii) aggressive patent litigation; (iii) originators interventions before marketing authorities and pricing reimbursement authorities.

As to the other types of practices, to date, there has been one case involving an unlawful patenting strategy. In the Italian *Xatalan* case, from February 2012, the ICA sanctioned Pfizer for abuse of dominance. It found that Pfizer had attempted to unduly prolong the patent protection of its drug Xatalan in Italy, through the filing of divisional patent application for Italy and the request for a SPC on this basis.¹⁸ The case looks like an offshoot of the EU *AstraZeneca* case. However, it goes slightly beyond, in sanctioning a pure patenting strategy.¹⁹

Besides this, most national cases concern practices seeking to prevent substitution to generics, post patent expiry. A raft of interesting cases concerns so-called denigration practices, post patent expiry. All of them are French cases. In *Arrow Generics v. Schering Plough*, *Ratiopharm v. Janssen Cilag* and *Teva v. Sanofi Aventis*, there were complaints before the FCA that patent originators tried to throw mud on the quality, efficacy, and/or bioequivalence of competing generic products.²⁰ Those practices included articles in the trade press, warning to pharmacists and practitioners, etc. Interestingly, the standard of what constitutes abusive denigration remains largely undefined in those cases. Most of those cases have indeed been dealt with under application for interim measures, and in only one case, they have been granted. A ruling on the substance is still awaited.

Similarly, in the 2011 *Reckitt Benckiser* case in the UK, a drug originator sought to prevent substitution to generics by practitioners. Some factual background is here in order. In the UK NHS uses a software platform which entitles practitioners to search for well-known branded product and its generic equivalent, so as to enable prescription substitution. In this case,

¹⁸ In essence, the ICA considered that the filing of the divisional patent, which did not cover a different invention to the parent patent, constituted double patenting. It also took objection with the fact that it had not told the Italian Patent Office that the patent was a divisional patent. Finally, it was concerned that this was a way, in Italy, to obtain protection where it had failed to obtain it on the basis of the original patent. "Italy: The Competition Authority fines anti-competitive Practices aimed at delaying Market Entry for generic Medicine", *ECN Brief*, 01/2012, p. 3.

¹⁹ T. GRAF, "Italian Competition Authority Challenges Patent Measures", Kluwer Competition Law Blog, 23 January 2012, available at: <http://kluwercompetitionlawblog.com/2012/01/23/italian-competition-authority-challenges-patent-measures/>

²⁰ M. VAN KERCKHOVE, "Dominance in the Pharmaceutical Sector: An Overview of EU and National Case Law", *e-Competitions*, N° 41059, December 2011, available at: http://www.concurrences.com/abstract_bulletin_web.php?id_article=41059

Reckitt Benckiser's patent over a branded drug called Gaviscon had expired. Reckitt Benckiser thus withdrew this drug from the NHS software, before a generic name was assigned to it. As a result of this, doctors looking for the branded Gaviscon drug could not find an equivalent generic. They only found another drug, found Gaviscon Advance Liquid, which was patent-protected, meaning no generic rivals were available. In April 2011, the OFT issued a decision finding an abuse of a dominant position and slapped a 10 million GBP fine on Reckitt Benckiser.²¹ And, the UK public administration is now seeking damages for a total amount of 90 million GBP.²²

Finally, a last interesting case, yet quite old, is the French GSK case from 2007. This case does not involve the strategic use of IP rights and/or procedures. Here, GSK had engaged into predatory pricing on a relatively small-sized hospital drug market, to build an aggressive reputation and send a "signal" aimed at intimidating and deterring small generic manufacturers from entering other peripheral, larger markets.²³ But GSK did not hold a dominant position on the market where the alleged abuse took place. In 2011, the French Supreme Court thus held that the FCA decision was unlawful. Predation in a non-dominated market is only abusive, if there is a close link with a dominated market, which was not obvious in this case.²⁴

2. Other cases

Besides practices involving life cycle management practices, there have been more conventional competition cases in the pharmaceutical sector. Again, there is little to report in so far as the EU level is concerned. In contrast, there has been more activity at the national level. In *Wyeth and Phadisco*, first, the Cyprus competition authority found that the free distribution of vaccines had no economic justification, and was thus abusive under national law.²⁵

²¹ OFT Press Release, *OFT issues decision in Reckitt Benckiser case*, 13 April 2011, 53/11.

²² "NHS Seeks Antitrust damages", *Ashurst Newsletter*, May 2011, available at : http://www.ashurst.com/publication-item.aspx?id_Content=5962.

²³ H. d'UDEKEM d'ACQZ, "The French Competition Council fines predatory pricing aimed at preventing entry of generic drugs in hospitals on the basis of both EC and national competition provisions, *e-Competitions*, n° 13613, 14 March 2007, available at: http://www.concurrences.com/abstract_bulletin_web.php3?id_article=13613.

²⁴ J. GOYER and S. JUDE, "The French Supreme Court confirms rebutting of an appeal against an NCA's decision sanctioning predatory pricing in the market for sodic cerufoxime (GlaxoSmithKline)", *e-Competitions*, N° 26440, 17 March 2009, available at: http://www.concurrences.com/abstract_bulletin_web.php3?id_article=41035.

²⁵ A. ANTONIOU, "The Cypriot Commission for the Protection of Competition holds two pharmaceutical companies as having abused their dominant position in the vaccines market through quantitative reductions and

Similarly, under Article 101 TFEU, some resale price maintenance cases have been dealt with. In Bulgaria, the public health service was found guilty of abuse for having imposed maximum retail margins to pharmacists for medicines sold under the NHS system.²⁶ The concerns, in this case, however appear unclear, and possibly misplaced. In Lithuania, there was also a RPM case, where suppliers had forced their distributors to report any unannounced public tender, and to pre-negotiate with them the conditions for participation to the tender.²⁷ As a result, the suppliers were suspected of trying to fix the price of distributors in public tenders. The case was, however, closed with commitments.

Finally, a number of parallel trade cases have also been dealt with. In Romania, for instance, four cases were opened following a sector inquiry.²⁸ Those cases mostly involved outright contractual export bans in distributors' contracts, outside of the Romanian territory. They were treated as restrictions by object and subject to fines. Similarly, there was in Spain a *Pfizer* case involving unlawful dual pricing allegations. Under a rather formal line of reasoning, the Spanish competition authority refused to consider that this case involved dual pricing. Pfizer charged a free price for its products, and the State regulated price for products dispensed in Spain. As a result, neither Pfizer, nor its distributors, were fixing the price for drugs sold on national territory. There was thus no dual pricing. The Spanish Supreme Court however quashed the ruling, and referred it back to the Spanish CA.²⁹

III. The Future – Speculations on Prospective Enforcement Trends

Coming to the close of this presentation, my last ambition is to look into the crystal ball to give some hints on what future competition cases in the pharmaceutical sector will look like. Or in other words, looking at the future, what can we draw from this?

free distribution of vaccines (Akis Panayiotou - Wyeth Hellas – Phadisco)", *e-Competitions*, No26651, 19 May 2009, available at: http://www.concurrences.com/abstract_bulletin_web.php3?id_article=41031

²⁶ I. SVETLICINII, "The Bulgarian Competition Authority fines the National Health Insurance Fund for imposing maximum retail margins for medicines sold under the national health insurance scheme (National Health Insurance Fund)", *e-Competitions*, No32776, 1 July 2010, available at: http://www.concurrences.com/abstract_bulletin_web.php3?id_article=41025

²⁷ "Lithuania: Competition Council accepts Commitments by pharmaceutical Companies", *ECN Brief*, 04/2011, p. 2.

²⁸ "Romania: Sector Inquiry Report on the Wholesale of Pharmaceutical", *ECN Brief*, 03/201, p. 23. Against Belupo and Baxter concerning prescription drugs and against Bayer for OTC medicines. See Press Release, The Competition Council finalized other two investigations on pharma market, available at: http://www.consiliulconcurentei.ro/uploads/docs/items/id7369/investigatii_pharma_english.pdf; Reuters, "Bayer AG Gets Fined by Romania's Competition Watchdog-Agence France Presse", 19 March 2012.

²⁹ L. BLANQUEZ PALASÍ, "The Spanish National Court applies the ECJ "dual pricing" ruling to quash a decision by the Spanish Competition Commission concerning prices imposed to wholesalers by pharmaceutical company (Pfizer)", *e-Competitions*, No39274, 13 June 2011, available at: http://www.concurrences.com/abstract_bulletin_web.php3?id_article=39274

First, looking at the track record of competition agencies, the low number of cases at both Commission and national level suggests Article 102 TFEU enforcement in relation to life cycle management practices will remain exceptional. The downside of this, however, is that market players are stuck with broad statements such as those found in the Final Report on the sector inquiry, or precedents such as *AstraZeneca* which involve very particular facts. Hence, the guidance offered to operators, and in turn the degree of legal certainty remains limited.

Second, and despite the low numbers, there are good chances that most enforcement against unilateral practices will take place at the national level. First, interim relief and damages are more readily available than at the EU level.³⁰ In addition, national agencies may be more attractive than the Commission, because national legislation on unilateral conduct can be stricter than EU competition law.³¹

Third, looking at the content of abusive life cycle management cases, such cases are built primarily on the basis of internal, documentary evidence of anticompetitive intent (as opposed to external, market based data of anticompetitive effects). In the *Xatalan* case, for instance, the ICA relied on many internal documents to show that there was an intention to delay generics entry. Similarly, in the *Reckitt Benckiser* case, internal documents leaked from Reckitt Benckiser revealed the existence of “*Project Eric*”, a secret plan by the company to manipulate doctors and regulators.³² Of course, this may be explained by the fact that it is difficult to prove exclusionary effects in such cases, which do not concern the exclusion of actual rivals, but the deterrence of hypothetical rivals that are not yet active in the market place.³³ Now, two predictions which run in opposite directions can be drawn from this. On the one hand, the optimistic interpretation is that given the well-known doubts surrounding the value of intent-based evidence in competition proceedings, such cases will remain rare, and unattractive to agencies. On the other hand, a possible Nostradamusque interpretation is that agencies have an easy route to craft abuse cases, out of internal documentary evidence of anticompetitive intent. In our opinion, whilst agencies may disregard effects in “*fraud*” cases

³⁰ T. FRAZER, L. GYSELEN, M. VAN KERCKHOVE, A. VARMA and B. WOOTTON, "Getting The Deal Through: Pharmaceutical Antitrust", *Global Competition Review*, 2008, p. 41.

³¹ See Article 3 (2) of Council Regulation 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, OJ, 4 January 2003, L1/1: “*Member States shall not under this Regulation be precluded from adopting and applying on their territory stricter national laws which prohibit or sanction unilateral conduct engaged in by undertakings.*”

³² D. LEIGH, “Company accused of cheating NHS”, *Guardian*, Friday 7 March 2008.

³³ More fundamentally, the reason for the intent route, rather than the economic route has to do with the particular setting of life cycle management cases. The theory of harm is that future entry is delayed. But given that entry has not happened, there is little to measure in terms of actual market competition, as compared to a case in which an actual competitor is foreclosed.

– i.e., cases where a firm deliberately provides misleading information to public authorities, such as the first abuse in *AstraZeneca* – they should be required to prove them in all other cases.

A fourth remark is that the above cases often involve what I call “*karate competition law*”.³⁴ Often, agencies have not taken objection with a stand-alone type of conduct that corresponds to a well-known type of abuse (*e.g.* a price increase or a price cut), but rather with a string of practices which cumulatively delay or block generic entry. This is comparable to Karate, where knockouts are often achieved through a complex combination of side-kicks and low kicks, rather than with a clean head shot. In *AstraZeneca*, for instance, it is not a stand-alone practice that was found abusive, but a combination of practices, such as the deregistration of marketing authorization and the introduction of a new drug; or the supply of initial misleading information, and the lack of accurate responses to requests for clarifications.

Surely, such types of infringements can be sanctioned, given that the list of abuses found in Article 102 TFEU is not exhaustive.³⁵ However, one may fear a lowering of the threshold of intervention in Article 102 cases, with authorities piling up shreds of practices that individually do not form abuse, but that altogether are abusive. More generally, this gives a lot of maneuver to competition authorities when it comes to crafting exotic, abusive life-cycle management cases.

Fifth, and to conclude on a touch of optimism, the scope of the efficiency defense in competition proceedings might increase in the years to come. By way of reminder, in the pharmaceutical sector, originators often seek to justify anticompetitive agreements and abuses on the basis of the necessity to protect their incentives to innovate and, in particular, their investments in R&D. Until now, this line of defense had received little attraction. Yet, in the *GSK* dual pricing judgments, the Court criticized the Commission for failing to sufficiently scrutinize the parties Article 101(3) TFEU allegations.³⁶ This judgment sends the signal that

³⁴ N. PETIT, “Microsoft v. Google – Karate Competition Law?”, Chilling'Competition, 7 April 2011, available at: <http://chillingcompetition.com/2011/04/07/microsoft-v-google-karate-competition-law/>.

³⁵ CJ, 17 February 2011, *Konkurrensverket v. TeliaSonera Sverige AB*, C-52/09, ECR, 2011, para. 26.

³⁶ CJ, 6 October 2009, *GlaxoSmithKline v. Commission*, C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, para. 118 and 120 : “*The Court of First Instance held that the Commission had not taken account of all the relevant evidence produced by GSK regarding the losses in efficiency associated with parallel trade or the gain in efficiency procured by Clause 4 of the agreement, and concluded that the contested decision was vitiated by a failure to carry out a proper examination (...) it does not follow from Verband der Sachversicherer v Commission, cited above, that the existence of an appreciable objective advantage necessarily supposes that all of the additional funds must be invested in R & D.*”

agencies cannot turn a blind eye on R&D efficiencies, not least because the case concerned a so-called restriction by object.³⁷

³⁷ Yet, only rarely do the Commission takes Article 101(3) TFEU decisions, and the Notice on Article 101(3) set a fairly high standard of proof. In Article 102 TFEU, the notion of objective justification is provided in a soft law instrument, yet it remains very abstract and devoid of case law illustrations. Now, on this, there is one particular issue that I would like to mention. It strikes me as odd, that pharmaceutical companies have not sought to argue on pure macro public policy grounds, and in particular on the issue of public health, as accepted by the Court of justice in many cases.