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Mixed Messages in the "By Object" vs "By Effects" Saga: The Enigma of *Lundbeck*

By Peter Alexiadis and Pablo Figueroa (Gibson, Dunn & Crutcher LLP)[1]

Edited by Anna Tzanaki (Competition Policy International) & Juan Delgado (Global Economics Group)

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I. Introduction

It is well understood that Article 101(1) TFEU prohibits concerted practices or agreements which have the "*object or effect*" of restricting competition. Once it has been established that the *object* of an agreement is to restrict competition, it is irrelevant, for the purposes of determining whether an infringement of Article 101(1) has occurred, whether the concerted practice or agreement in question actually had an anti-competitive effect in the marketplace.[2] In other words, for the purpose of applying Article 101(1) TFEU, no actual anti-competitive effects need to be demonstrated where the agreement constitutes a restriction of competition "by object".[3]

Ever since its inception, EU competition law has been the subject of criticism from a broad spectrum of the antitrust Bar for interpreting the notion of "restriction of competition" too broadly, especially as regards restrictions of competition that are deemed to be "by object".[4] As far back as 1966, Advocate General Roemer criticised the Commission for "*not being wholly consistent*" in its approach.[5] Over the years, the scope of the by object offence has incrementally broadened and it now includes, when it comes to agreements between competitors, most agreements to fix prices, to exchange information that reduce uncertainty about future behaviour, to share markets, to limit output, including the removal of excess capacity, to limit sales, collective exclusive dealing and, after *Lundbeck*, to pay competitors to delay the launch of competing products.[6] This broadening has often been criticised as leading to "false positives" and "over-deterrence", with European competition law risking to become, in the words of one academic, "*just sands in the gears of the European Economy*".[7]

The accurate legal characterisation of the alleged restriction of competition is not immaterial, since it will inevitably affect whether or not an agreement between entities without market power can be characterised as a restriction of competition *and* the likely chances of an Article 101(3) TFEU justification applying with respect to that agreement. As such, the legal characterisation of a

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[1] Peter Alexiadis and Pablo Figueroa are, respectively, a Partner in and Senior Associate in the Brussels office of Gibson, Dunn & Crutcher LLP. The views expressed herein are personal, and may not reflect the views of clients of Gibson Dunn.

[2] For example, because of the lack of market power of the contracting parties. *See* Case 56/64 *Consten and Grundig* [1966]. *See* also Case C-226/11 *Expedia* ECLI:EU:C:2012:795.

[3] Though a defence based on the 'efficiencies' of any given practice may arguably be raised under Article 101(3) TFEU irrespective of whether the practice is *prima facie* problematic either under a by object of by effect analysis, the European Commission does not hide its scepticism as to the low likelihood of a successful efficiencies defence being raised in relation to a restriction of competition by object.

[4] For the classic criticism, *see* Joliet, R., *The Rule of Reason in Antitrust Law: American, German and Common Market Laws in Comparison*, Springer, 1967 and Korah, V., "EEC Competition Policy – Legal Form of Economic Efficiency", (1986) *Current Legal Problems*, 85. The nature of the criticism has arguably changed over time. Originally, it focused on the Commission adopting an overly formalistic and broad approach to the notion of restriction of competition generally (*i.e.*, whether by object or effect), treating restrictions on conduct as always leading to restrictions of competition pursuant to traditional German ordo liberalism. That changed, at least to some extent, with the impact of the EU enforcement modernisation regime and the wave of Commission guidance available since 2000. In recent years, the criticism has focused more on the Commission's approach as to whether the scope of the so-called "object box" (*i.e.*, the list of practices which are considered to constitute restrictions of competition by object, see Whish, R. and Bailey, D., *Competition law*, Eigth Edition, Oxford, 2015, at p. 123) is inappropriately wide. The latest development is the Ruling of the ECJ of 23 January 2018 in Case C-179/16 *F. Hoffmann-La Roche Ltd and Others v Autorità Garante della Concorrenza e del Mercato*, where the ECJ considered a certain practice (namely, alleged collusion to differentiate between two drugs which were differently priced and which many doctors considered to be substitutable in their functionality, despite the fact that the applicable regulatory framework prescribed otherwise), to constitute a restriction by object in the limited factual circumstances of that case.

[5] *See*, Case 56/64 *Consten v Grundig*, Opinion of Advocate General Roemer of 27 April 1966.

[6] *See* Whish, R., and Bailey, D., *Competition law*, Oxford 2015 at page 132. For some NCAs, the "box" is arguably broader, which raises problems of compatibility of their practice in this domain with Article 3 Regulation 1/2003.

[7] *See* Alfaro, J., "The Question is not whether 'a more economic approach' is dead or alive. The question is that it has reached its limits", 28 January 2011, *available at*: http://derechomercantilespana.blogspot.fr/2011/01/question-is-not-whether-more-economic.html. The discussion arose also in the context of the application of US antitrust law as regards the scope of the "per se" rule under § 1 Sherman Act (see Bork, R. H., "The Rule of Reason and the Per Se Concept: Price Fixing and Market Division", 74 *Yale L.J.* (1965) and Ehrlich, I., and Posner, R., "An Economic Analysis of Legal Rulemaking", 3 *J. Legal Stud.* 257, 268 (1974)).

competition law infringement as one by object results in a significant short-circuiting of the investigatory role of the Commission, suggesting also that fine levels will be high and less likely to successful challenge before the courts, and placing defendants in a compromised position when defending damages claims before national courts.

In September 2014, it seemed that this trend was being reversed when the European Court of Justice ("ECJ") issued its Ruling in the *Groupement des Cartes Bancaires* Case, in which it was indicated that an essential legal criterion of a by object offence is whether the coordination between undertakings reveal a sufficient degree of harm to competition. Moreover, the ECJ warned that the concept of a restriction of competition by object should not be interpreted too broadly. Rather, the ECJ identified the policy imperative that the concept is to be interpreted narrowly, as "*otherwise the Commission would be exempted from the obligation to prove the actual effects on the market of agreements which are in no way established to be, by their very nature, harmful to the proper functioning of normal competition*".[8]

In its *Lundbeck* Decision of 2013, which preceded the *Cartes Bancaires* Ruling, the Commission had ended its ten year investigation into so-called reverse payment settlements[9] by concluding that the Danish pharmaceutical company Lundbeck and four manufacturers of generic drugs had concluded anti-competitive agreements in violation of Article 101 TFEU.[10] According to the Commission, these agreements would have allowed Lundbeck to delay the entry of cheaper medicines into the EU, thereby sustaining artificially the price of its drug citalopram.[11] This paper explores how the analysis conducted by the Commission in *Lundbeck*, and the subsequent endorsement of that approach by the General Court, has thrown into disarray the implications that might otherwise arise from the adoption of the approach endorsed in the *Cartes Bancaires* Ruling.

II. The Commission Decision

From the late 1970s, Lundbeck developed and patented an anti-depressant medicinal product containing the active ingredient "citalopram".[12] After its basic patent for the citalopram molecule had expired, Lundbeck only held a number of *process* patents which, according to the Commission, provided "*a more limited protection*".[13] In particular, Lundbeck had applied for a process patent to produce citalopram by way of salt crystallisation.[14]

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[8] *See* respectively, Case C-67/13 P *Groupement des Cartes Bancaires*, at para. 58 and T-491/07 *Groupement des Cartes Bancaires*, at paras. 49 ff, 124 and 146.

[9] Under reverse payment settlement agreements, an original pharmaceutical manufacturer, or "originator", settles an IP challenge from a manufacturer of generics by paying the latter to stay out of the market for a designated period of time.

[10] Commission Decision C(2013) 3803 of 19 June 2013, Case AT.39226 — *Lundbeck* (the "Lundbeck Decision").

[11] *See* European Commission Press Release IP/13/563, of 19 June 2013, *available at*: http://europa.eu/rapid/press-release_IP-13-563_en.htm?locale=en. Since 2009, the Commission has been continuously monitoring patent settlements in order to identify settlements which it regards as "potentially problematic" from an antitrust perspective, namely, those that limit generic entry against a value transfer from an originator to a generic company. The latest Commission Report on the practice was published in December 2016. *See*, European Commission, "7th Report on the Monitoring of Patent Settlements (period: January-December 2015)", 13 December 2016, *available at*: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report7_en.pdf.

[12] *See* T-472/13 *Lundbeck v. Commission* [NYR] (the "Lundbeck Ruling"), at para. 16.

[13] *See* European Commission Press Release IP/13/563, 19 June 2013, *available at*: http://europa.eu/rapid/press-release_IP-13-563_en.htm?locale=en. It should be recalled, in this regard, that, according to Article 27 of the TRIPS (WTO) Agreement, "*patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application*".

[14] *See Lundbeck Ruling*, at para. 20.

According to the Commission, Lundbeck concluded six agreements in 2002 concerning citalopram with four manufacturers of generic drugs (namely, Merck KGaA / Generics (UK), Alpharma, Arrow and Ranbaxy). Lundbeck paid substantial consideration in cash in return for the commitment of these generic producers not to enter the citalopram market.[15] These cash payments were linked to the profit or turnover which the manufacturers of generics expected to make during the duration of the agreements at issue.[16] Moreover, according to the Commission, Lundbeck had a strategy to delay generic entry and thus to create a "window of opportunity" in which to convince general practitioners to transition to its new (IP-protected) drug, *escitalopram*.[17]

In its Decision of 19 June 2013, the Commission found that the agreements constituted restrictions of competition *by object*, in breach of the prohibition of anti-competitive agreements under Article 101 TFEU.[18] The Commission's theory of harm can be summarised as follows:[19]

First, Lundbeck and the generic undertakings were "*at least*" potential competitors.[20]

Second, the generic undertakings committed in the agreements to limit, for the duration of the agreement, their independent efforts to enter one or more EEA markets with their generic products.

Third, the agreement related to the transfer of value from the originator undertaking, which reduced substantially the incentives of the generic undertaking to pursue independently its efforts to enter one or more EEA markets with a generic product.

The Commission imposed a total fine of €93.7 million on Lundbeck and €52.2 million on the generic undertakings. The defendants appealed the Decision to the General Court, where they sought its annulment. On 8 September 2016, the General Court confirmed that certain pharmaceutical reverse payment settlements can constitute a breach of the EU competition rules, dismissing the actions brought on appeal and confirming the fines imposed.

After *Lundbeck*, the Commission implemented the logic of that case and imposed fines, in both 2013 and 2014 respectively, on companies in two other investigations characterised as reverse payment settlements concerning fentanyl (a pain-killer)[21] and perindopril (a cardiovascular medicine).[22] The *Fentanyl* Case is perhaps more accurately characterised as involving a co-promotion agreement involving the alleged delay of generic entry, since it does not appear to have involved an actual settlement. The *Fentanyl* Decision was not appealed, while several appeals against the *Perindopril Servier* Decision remain pending before the General Court.[23] In the *Lundbeck*, *Fentanyl*, and *Servier* Decisions, the Commission again characterised the agreements in question as restrictions of competition by object, without enquiring further as to their actual effects on the market.

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15 *See Lundbeck Ruling*, at paras. 26; 35; 39; 42-43 and 47-48.
16 *See Lundbeck Ruling*, at para. 362.
17 See *Lundbeck Decision*, at Section 6(2).
18 See *Lundbeck Decision*, at paras. 647 ff.
19 See *Lundbeck Decision*, at para. 661. Paragraph 662 sets out various additional factors that were also taken into consideration, such as the fact that the value which Lundbeck transferred took account of the turnover or the profit the generic undertaking anticipated if it had in fact successfully entered the market, *etc.*
20 See *Lundbeck Decision*, at paras. 610 ff.
21 *See* European Commission Press Release IP/13/1233*, Commission fines Johnson & Johnson and Novartis € 16 million for delaying market entry of generic pain-killer fentanyl*, 10 December 2013, *available at*: http://europa.eu/rapid/press-release_IP-13-1233_en.htm. *See* further Commission Decision C(2013) 4955 of 9 July 2014, Case AT.39685 — *Fentanyl*.
22 *See* European Commission Press Release IP/14/799, 9 July 2014, *Commission fines Servier and five generic companies for curbing entry of cheaper versions of cardiovascular medicine, available at*: http://europa.eu/rapid/press-release_IP-14-799_en.htm. *See* further Commission Decision C(2014) 4955 of 9 July 2014, Case AT.39612 — *Perindopril (Servier)*.
23 *See* Case T-147/00 *Laboratoires Servier v Commission.*

At the national level, the UK's Competition and Markets Authority ("CMA") adopted infringement Decisions in February 2016 in relation to a number of companies regarding "pay-for-delay" agreements over the supply of paroxetine, another anti-depressant.[24] These agreements were found to constitute a competition law infringement both by object *and* by effect. By March 2017, the CMA had also issued a Statement of Objections relating to an agreement allegedly aimed at delaying the entry into the market for the supply of Hydrocortisone tablets, although it has yet to adopt its final Decision in the matter.[25]

III. Appeal to the General Court

In analysing upon appeal whether the Commission was entitled to conclude that the agreements at issue constituted a restriction of competition by object, the General Court in its *Lundbeck* Ruling made a number of findings.

First, there are certain patent settlements which can legitimately be considered to be *compatible* with Article 101 TFEU. This proposition would be true, noted the General Court, while purporting to follow the Commission's Decision, in the case of settlements where: "*(i) payment is linked to the strength of the patent, as perceived by each of the parties; (ii) [the payment] is necessary in order to find an acceptable and legitimate solution in the eyes of two parties* ***and*** *(iii) [the payment] is not accompanied by restrictions intended to delay the market entry of generics*".[26] (Emphasis added.)

In its particular context, the inclusion by the General Court of the disjunctive "and" is potentially problematic. In our view, the requirements described in the quoted text should be set out in the *alternative*, rather than being *cumulative* conditions. Otherwise, in order for a settlement to be lawful, it must never be capable of delaying entry. (A delayed entry by generics would otherwise be sufficient, in and of itself, to satisfy alleged antitrust concerns.) In addition, the action must be necessary (*i.e.*, it is probably required to satisfy the requirements of a defence based on the ancillary restraints doctrine). Finally, the payment should be linked to the strength of the patent "*as perceived by each of the parties*". This latter condition requires that intrinsically subjective evaluations be made and, as such, appears to be prone to an unnecessary degree of complexity in its application.

A further inconsistency in approach seems to arise when the General Court indicates that "*in certain cases, the conclusion of a patent settlement is not anticompetitive, particularly where it is based on the assessment of the strength of the patent made by each of the parties to the agreement* ***or*** *where it provides for a reverse payment, without however delaying the market entry of generics*".[27] Accordingly, while we can safely conclude that the satisfaction of all three cumulative criteria will bring a patent settlement agreement outside the reach of Article 101(1) TFEU, it should follow that the satisfaction of at least a few of the criteria might be sufficient for the arrangement to be deemed to outside the Article 101(1) TFEU prohibition .

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[24] *See* Case CE/9531-11 *Paroxetine*, 12 February 2016. For a comment on the case, see Ezrachi, A., *EU Competition Law: An Analytical Guide to the Leading Cases*, 5th Edition, Bloomsbury, 2016, 396. The decision is under appeal to the UK Competition Appeal Tribunal (see *GlaxoSmithKline v CMA*, information on the case available at: http://www.catribunal.org.uk/237-9158/1252-1-12-16-GlaxoSmithKline-PLC.html).

[25] See CMA Press Release of 3 March 2017, available at: https://www.gov.uk/government/news/cma-alleges-anti-competitive-agreements-for-hydrocortisone-tablets.

[26] *See Lundbeck Ruling*, at para. 350. Please note that the Court is here summarising the *Lundbeck Decision*. However, this does not render the text less relevant, on the contrary, it could be argued that this is how the General Court reads a Decision whose precedential value is, if anything, enhanced by the blurriness of the Ruling of the General Court.

[27] *See Lundbeck Ruling*, at para. 431.

Second, the arrangement might fall outside the Article 101(1) TFEU prohibition where the ancillary restraints doctrine would justify the competitive restraints. In other words, the General Court envisages the existence of circumstances in which the parties to the settlement indeed might be able to demonstrate they are objectively necessary and proportionate in order to defend their IP rights.[28] However, by entertaining this a possibility in such wide forms, the Court tends to undermine its own endorsement of the Commission's "by object" analysis.

Third, while there are certain patent settlements which are likely to be considered *incompatible* with Article 101 TFEU as restrictions of competition by object, the Ruling is not particularly clear as to the circumstances which will govern such a legal categorisation. For example, a literal reading of paragraphs 332 to 334 of the *Lundbeck Ruling*, which more accurately summarise the Commission's Decision rather than analysing it, could potentially render problematic all patent settlements which "*[provide] for the exclusion from the market of one of the parties, which was at the very least a potential competitor of the other party, for a certain period, and where they were accompanied by a transfer of value from the patent holder to the generic undertaking liable to infringe that patent ('reverse payments')*." By contrast, a more holistic reading of *Lundbeck* would confine the Commission's findings solely to the facts of that case.

Even though it is difficult to identify systematically these factors considered to be decisive when determining whether a reverse payment settlement constitutes a restriction by object, the following have been considered to be relevant considerations in the Commission's analysis:[29]

- The "*disproportionate nature*" of such payments, when "*combined with other factors, such as the fact that the amounts of those payments seemed to correspond at least to the profit anticipated by the generic undertaking*".[30] This reasoning echoes the US Supreme Court's *Actavis* Ruling,[31] which, the General Court indicated, supports the proposition that "*the size of a reverse payment may constitute an indicator of the strength or weakness of a patent [...] the presence of a significant reverse payment in a patent settlement agreement can provide a workable surrogate for the weakness of a patent, without a court having to carry out a detailed analysis of the validity of the patent*".[32] However, the General Court tends to overlook the fact that the US Supreme Court was conducting an analysis of the scale of the payment within the context of a full "rule of reason" analysis (in other words, the US equivalent of an effects-based approach under EU law competition practice). Such an analysis, by its very nature, is more detailed than the more limited analysis which takes place under EU competition rules in the context of a review of a restriction of competition by object. Despite this, the General Court drew the sweeping conclusion that "*the higher the originator undertaking estimates the chance of its patent being found invalid or not infringed, and the higher the damage to the originator undertaking resulting from successful generic entry, the more money it will be willing to pay the generic undertaking to avoid that risk*". While one cannot ignore the fact that such a presumption might materialise in many circumstances, the nexus being drawn between high payments and foregone profits might not be true universally.[33]

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[28] *See Lundbeck Ruling*, at paras. 451 *ff*, in particular, at paras. 458 and 460.
[29] *See Lundbeck Ruling*, at para. 354.
[30] *See Lundbeck Ruling*, at paras. 354 and 355.
[31] *See Federal Trade Commission v. Actavis*, 570 US (2013).
[32] *See Lundbeck Ruling*, at para. 353.
[33] *See Lundbeck Decision*, at para. 640.

- The correspondence between the amount of the payment and the anticipated profit to be made by the generic producers on the assumption they had entered the market.[34] According to the Commission, "*the value which Lundbeck transferred, took into consideration the turnover or profit the generic undertaking expected if it had successfully entered the market*".[35]

- The absence of provisions allowing the generic producer to launch its product on the market upon the expiry of the settlement agreement, without fear of an infringement action being brought by Lundbeck[36] (*i.e.*, in the words of the General Court, without "*resolving the underlying patent dispute*").[37]

- The link between the payments and the profits which generics manufacturers expected to make during the life of the agreements.[38]

- The presence in those agreements of restrictions going beyond the scope of Lundbeck's patents, such as those regarding citalopram products that could have been produced in a non-infringing manner.[39]

As a consequence of the anti-competitive nature of the agreement allegedly satisfying the factors listed above, the Commission found (and the General Court confirmed) that generics manufacturers no longer had an incentive to continue their independent efforts to enter the market.[40]

IV. Conclusions

The overarching criticism that can be made of the General Court's *Lundbeck* Ruling is that it purports to introduce into the assessment of patent settlement schemes what might unkindly be referred to as "known unknowns", namely, *things we know we do not know*[41]. At the same time, the General Court purports to endorse the Commission's "by object" analysis in a manner that suggests that the Court is unwilling to challenge any of the Commission's working assumption, and indeed arguably dues little more than paraphrase the Commissions conclusions without subjecting them to any meaningful reviews.

As a result, the legal standard set forth by the General Court as regards when a reverse payment settlement constitutes a restriction of competition by object is anything but clear. There are a myriad of reasons why reverse payments and patent settlements might be perfectly legal, or indeed illegal. The US Supreme Court referred to such reasons in its *Actavis* Ruling, where it stated that: "*[t]he reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement. That payment may reflect compensation for other services that the generic has promised to perform, such as distributing the patented item or helping to develop a market for that item*".[42] In the light of these observations and the fact that the parties to

[34] *See Lundbeck Ruling*, at paras. 354; 383 and 414.
[35] *See Lundbeck Decision*, at paras. 6; 788; 824; 874; 962; 1013; 1087.
[36] *See Lundbeck Ruling*, at paras. 354; 383; 410.
[37] *See Lundbeck Ruling*, at para. 360.
[38] *See Lundbeck Ruling*, at para. 362.
[39] *See Lundbeck Ruling*, at paras. 354; 383.
[40] *See Lundbeck Ruling*, at para. 336.
[41] *See* Rumsfeld, *D., Known Unknown: A Memoir, Sentinel*, 2011.
[42] *See Federal Trade Commission v. Actavis*, 570 US (2013).

such agreements are often, at best, only potential competitors at the time of its conclusion, one would have thought that the best means of analysing such arrangements from an antitrust perspective would be *not* to treat them as a restriction of competition by object at all, but rather to take due account of all the relevant economic circumstances underpinning such arrangements. Yet the General Court arguably confuses matters further more by purporting to apply a "by object" test when setting forth a long list of conditions which actually seem to sit much more comfortably with the application of a "by effects" analysis.

If that ambiguity in approach were not enough, the General Court expressly indicated in *Lundbeck* that the Commission was under no obligation to analyse the counterfactual situation in relation to a case built around an allegation of a restriction of competition by object.[43] One might indeed argue that a counterfactual should be considered in every case involving an alleged restriction of competition: where there is no competition, there is no competition to be restricted. On the other hand, it could be argued that, in a true "by object" case, the pernicious effect of the practice is self-evident and there is consequently no need to conduct any further analysis which explores the counterfactual scenario, as this would risk an analysis of effects being brought in through the proverbial back door. Even if one were to defer to the General Court that this position might be correct as a strict matter of law,[44] a thorough analysis of the counterfactual scenarios would inevitably be required in relation to an action based on the restriction of competition *by effect*.[45] If the effect is ambiguous or even beneficial, an analysis of the counterfactual situation assumes even greater importance.[46] Indeed, given the fact that an allegation based on a by object offence is little more than the establishment of a presumption about legality, it would seem inappropriate for that presumption to be anything other than rebuttable if economic circumstances so justify.[47]

In addition, the failure of the Commission in its *Lundbeck* Decision to conduct a formal analysis of the effects of the impugned practice leaves open the question of whether there exist patent settlements which may be considered to be incompatible with Article 101 TFEU as restrictions of competition *only* after an analysis of their effects on the relevant market. The answer is probably in the affirmative. However, given that none of the pay-for-delay Decisions before the Commission have thus far been subject to an *effects* analysis, we are left without effective guidance as to how that analysis will be conducted, other than in weighing up the criteria supposedly forming part of the *by object* analysis.

Perhaps we can legitimately draw upon the findings of the US Supreme Court in *Actavis* in relation to the criteria to be taken into consideration when reviewing reverse payment settlements against a "*rule of reason*" standard. According to the Supreme Court, "*the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payer's anticipated future litigation costs, its independence from other services for which it might represent*

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[43] *See Lundbeck Ruling*, at para. 473. A counterfactual situation is one where the competitive situation is assessed by reference to how it would appear in the absence of the allegedly anti-competitive conduct. Thus, if the market would result in the same characteristics irrespective of whether the improper conduct materialised, there is unlikely to be an anti-competitive 'effect' which could have been generated by that conduct.

[44] Compare the Opinion of Advocate General Roemer with the Ruling of the Court in Case 56/64 *Consten v Grundig*. See also Ibañez, P., "GC Judgment in Case T-472/13 *Lundbeck v Commission*: on patents and Schrödinger's cat", *Chillin' Competition*, 13 September 2016, *available at*: https://chillingcompetition.com/2016/09/13/gc-judgment-in-case-t-47213-lundbeck-v-commission-on-patents-and-schrodingers-cat/.

[45] *See* Case T-328/03 *T-Mobile Deutschland / O2* [2006], ECR II-1231.

[46] *See*, *e.g.*, High Court Ruling in *Arcadia & Ors v. MasterCard* [2017] EWH93 (Comm).

[47] As to the ongoing debate about the value of presumptions under EU competition rules, refer to Ritter, Cyril, Presumptions in EU Competition Law (July 10, 2017). Available at SSRN: https://ssrn.com/abstract=2999638

payment and the lack of any other convincing justification. The existence and degree of any anticompetitive consequences may also vary among industries".[48]

It is unfortunate that neither the European Commission nor the General Court have sought to shed light on how one is to conduct an effects-based analysis under an Article 101(1) TFEU investigation into reverse payment settlement, despite having spent the best part of a decade having evaluated such reverse payment settlements under an "by object" analysis – a legal standard of review which seems to be forever dwindling in importance in the evaluation of most other commercial practices involving the exercise of market power.[49]

One cannot but wonder whether the Commission's administrative resources would have been better spent analysing the actual effects of the practices on competition rather than defending this legal categorisation of the practices in question, which the ECJ has otherwise indicated should be interpreted restrictively when applied to new practices. If the end result of the *Lundbeck* litigation is to be that commercial practicing will be opposed on a *by object* begins irrespective of whether multiple factors need to be examined before any conclusions as to anti-competitive effect can be drawn, such a result sits very uncomfortably with the idea that the "by object" categorisation is designed to inject legal certainty into a competition analysis. A legal presumption riddled with exceptions is, after all, not much of a legal presumption.

With the *Lundbeck* appeal pending before the ECJ and the *Servier* appeal pending before the General Court, the Commission might be in for a, not surprisingly, bumpy ride which hopefully would bring us back to the more coherent logic of the ECJ's *Cartes Bancaires*.

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[48] *See Federal Trade Commission v Actavis* 570 US 2013.

[49] In this regard, refer to the Commission's enforcement priorities expressed as far back as 2009, where it expressed the clear policy guidance that the competition law analysis under Article 102 TFEU should be driven by an effects-based approach. (*See Communication from the Commission, Guidance on its Enforcement Priorities in Applying Article [102 TFEU] to abusive exclusionary conduct by dominant undertakings*, OJ C 45, 24.2.2009, pp. 7-20.)