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Panel 1

US/EU, A Transatlantic Gap?

Pharmaceutical Pricing and Markets: A European Union Enforcer's Perspective.

Webinar, 30 June 2020

*Interview with Paul Csiszar (EU Commission)
by Dr. Lisa Cameron (The Brattle Group)**



*Paul Csiszar (Director General, European Commission), has been interviewed by Dr. Lisa Cameron (Principal, The Brattle Group) in anticipation of the **Antitrust in Life Sciences** webinar, to be held on 30 June 2020. This webinar was originally a conference that would take place on 23 March 2020. However, due to the COVID-19 outbreak, it has been transformed into a webinar.*

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Dr. Lisa Cameron: In the past few years, we have seen a lot of media coverage on increasing prices of pharmaceutical markets, with significant public backlash both in

the US and in Europe (e.g., Pharma-Bro Shkreli or the price hikes in Epi-Pens). In Europe, these issues are often tackled in a competition framework of excessive pricing, with varying degrees of success. US competition law does not allow for this. Is it time for a change (both to the EU's existing method and maybe a US introduction of some way to deal with this)?

Paul Csiszar: In the EU, like in most other OECD countries, there are competition law provisions that aim to tackle “excessive pricing”, which after closer examination presents a number of complex legal and economic issues. In Europe, legal guidance in this field can be obtained from the judgments of the European Courts (eg, United Brands and AKKA-LAA judgments) and from the Commission’s own infringement (Deutsche Post) and commitment decisions (Gazprom, Rambus, Standard & Poor's) provide guidance.

These cases reveal that the competition agencies and courts in Europe often faced very different fact patterns in a variety of industries in dealing with “excessive prices” issues. With respect to pharmaceutical markets specifically, which are national given the national pricing and reimbursement systems that are in place in the European Union, the national competition authorities in Italy, the UK and Denmark have recently rendered several decisions finding excessive pricing in violation of competition law. These decisions, not surprisingly, all have all been appealed, and further guidance from the courts can be expected in this regard. Of course, after the conclusion of the Commission’s own Aspen investigation will also provide additional guidance to the market.

Given these pending cases, it would appear premature at this point in time to consider changing the EU's existing method and its approach to the issue. Article 102(a) TFEU gives us a clear mandate to tackle “unfair prices”; therefore, the question is not “whether” but “when” to tackle an allegedly excessive price. In other words, it is about balancing enforcement priorities and the analysis of the underlying facts and circumstances should determine whether enforcement action is warranted in a specific case. For instance, (i) is a timely and appropriate regulatory action still possible? (ii) can the market self-regulate? or (iii) would incentives to innovate and to invest be significantly stifled (notably in view of the high R&D failure rates in pharma). Only after considering these and other factors together can ensure sound and proportionate enforcement of excessive pricing cases in the pharmaceutical markets, such as, for example, tackling price gouging practices with off-patent niche pharmaceuticals.

In the US, I understand that many believe that charging excessive pricing for pharmaceutical products cannot be by itself a violation of US antitrust law. However, lasting high prices in cases of off-patent drugs may be indicative of anti-competitive conducts as well. We follow with great interest the recent litigation initiated by the FTC in this regard and the attempts of several US States that enacted legislation prohibiting price gouging and imposing financial penalties on drug manufacturers that significantly increase prices over a specified period of time.

The practice of parallel trade—in which medicines are purchased in low price countries for resale in high price countries—has been the subject of much debate in the EU. What

are your views on balancing the goals of facilitating free movement of these medicines throughout a single market with the risk of access limitations being imposed on low price countries?

Parallel trade within the European single market also raises many complex legal and economic issues in the pharmaceutical sector. It affects the interests of many stakeholders in a unique regulatory context. Notwithstanding the overarching policy objective to foster trade and free movement of goods within the EU, and the corresponding general legal prohibition to hinder parallel trade within the single market, one can reasonably point to some legitimate reasons to limit parallel trade of pharmaceutical products to some degree between Member States.

There could be lawful measures by Member States to channel parallel trade with a view toward preventing shortages of essential medicines if those measures fall under the protection of the public health exception of Art 36 TFEU, provided they are necessary, proportionate and effective. There could be steps taken also by pharmaceutical companies to channel parallel trade in furtherance of this objective. Those measures can be brought in line with EU law even by dominant companies protecting their own commercial interests [see, eg, ECJ judgment in *Lelos* (2009)]. The case law of the EU courts is firmly established on parallel trade for many years now. In addition, some Commission guidelines (eg, the Vertical Guidelines) also provide additional guidance to companies and the legal community in this field.

Last year, the EC issued a report analyzing pharmaceutical industry competitions between 2008 and 2017. The report's executive summary noted competition enforcement in the pharmaceutical sector remains a high priority but also noted that there was a clear limit to what could be achieved through competition law alone and that fostering and maintaining access to affordably priced medicines would require the combined efforts of various stakeholders. Can you provide further insight into the efforts by other stakeholders that the EC may have been envisioning?

The Commission's report you referring to is indeed an excellent overview of the European competition enforcement history in the sector in the past decade, and I can only recommend everybody with interest in the topic to read it. As I pointed out in the past, in my view the existence of lasting "excessive pricing" of off-patent drugs for example can be the sign not only of anticompetitive behaviour of private firms but a market and/or regulatory failure as well. More precisely, firms - and not only the pharma sector - sometimes take advantage of certain regulatory conditions to foreclose their rivals and increase their market power. A good example of this is the second offence set out in the *AstraZeneca* case (see the 2012 ECJ decision), where Europe's highest court cited with the Commission and ruled that *AstraZeneca* abused its dominant position through its misuse of the pharmaceutical regulatory system by selective withdrawal of certain marketing authorisations. In such cases, whether or not competition law tools are used first, often the more effective way to address the problem is to improve the regulatory landscape, as it was done in Europe after Commission decided to prosecute the *AstraZeneca* case.

Here I would mention the Commission's recent Regulation [2019/933] amending a Regulation [469/2009] concerning Supplementary Protection Certificate (SPC) for medicinal

products. This amendment concerns SPC manufacturing waivers whereby EU-based companies may manufacture a generic or biosimilar version of an SPC-protected medicine during the term of the SPC certificate, if done either for the purpose of exporting to a non-EU market, or for stock-piling during the final 6 months of the SPC ahead of entry in to the EU market. This new amendment removes a competitive disadvantage for EU-based manufacturers compared to manufacturers based in non-EU countries (where there is no SPC-type protection available or enforceable).

The Commission is also evaluating the legislation on medicines for children and rare diseases (Orphan Drugs Regulation). Given the lack or insufficient level of R&D by the pharmaceutical industry for diseases with low patient population, the Commission is assessing to which extent the current EU legislation is efficient and effective and it will consider whether it is fit for purpose in the light of developments in this area of pharmaceuticals. The Commission will look in particular into the impact of the incentives introduced by the legislation for research, development and marketing, for these specific medicines.

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