

ered but should not be decisive in determining overall anticompetitive behavior.⁷³

Nevertheless, even the application of this more traditional view may in practice be biased in favor of (short-term) consumer benefits: As *Etro* argues, quantifying effects e.g. from excessive pricing, which can be observed and measured, is much easier than determining implications on incentives to innovate, which would require a deeper evaluation.⁷⁴ The pharmaceutical industry thus may find it harder in the future to argue the legitimacy of behaviors which show substantial anticompetitive effects today but at the same time significant procompetitive effects on innovation in the future.

This bias is also mirrored in the public healthcare debate, where many economic studies – more or less successfully – have tried to quantify drug pricing effects from generic competition,⁷⁵ whereas few works have successfully empirically argued the effects on incentives to create pharmaceutical innovation.

2.2.4. *The Sector Inquiry as an EU Competition Law Instrument*

The EU Commission's pharmaceutical sector inquiry has further increased legal uncertainty for the pharmaceutical industry. The legal basis for this instrument can be found in Art. 17 of Council Regulation EC 1/2003, which generally allows the EU Commission to investigate for a specific sector on its own motion or acting on a complaint.⁷⁶

In case of the pharmaceutical sector inquiry, the EU Commission “*suspected a potential systemic problem [with respect to] potential delays of market entry of generic companies*”.⁷⁷ Not surprisingly, the initiative was, *inter alia*, admittedly initiated by the European Generic Medicines Asso-

73 See Ulrich Gassner, Markteintrittsrelevante Vereinbarungen zwischen Original- und Generikaherstellern im Kreuzfeuer, 1 A&R 3, 9 (2010).

74 See Federico Etro, Competition, Innovation, and Antitrust, A Theory of Market Leaders and Its Policy Implications 186 (Pringer Verlag 2007).

75 See e.g. Michael C. Müller et al., Die Bedeutung der Generikaindustrie für die Gesundheitsversorgung in Deutschland (Accenture Management Consulting 2005), available at http://www.accenture.com/Countries/Germany/Research_and_Insights/Generikaindustrie.htm.

76 See *supra* note 74 at p. 172 and *supra* note 10 at pp. 508-510.

77 *Supra* note 28.

ciation (EGA).⁷⁸ The authors of the final report clarified that the sector inquiry's purpose was to assess pharmaceutical company's use of IP rights, mainly patenting behavior, which can in principle delay the market entry of others.⁷⁹ By that, authorities were supposed to gain a general understanding about potential anticompetitive behavior – quasi a fact-finding exercise as a basis for focusing further investigative priorities.⁸⁰ The final report is characterized by numerous disclaimers stressing that it does neither predetermine investigations of individual competition law cases, nor does it serve as competition law guidance.⁸¹

It surely is dissatisfying to the pharmaceutical industry that the report remains vague when it comes to practical implications – especially a frustrating experience considering the time, effort and uncertainty which was associated with it.⁸² This frustration may have even been increased by the EU Commission's preliminary view on French sector inquiry participant *Les Laboratoires Servier*, which was alleged to have provided “*misleading and incorrect*” information during the inquiry, which triggered a severe fine of over 35 million €. ⁸³ Some scholars, such as *Drexel*, criticize that the EU Commission has expressed concerns about certain company behavior without providing (sufficient) legal reasoning to justify these concerns.⁸⁴

But what relevance would legal reasoning have in the context of the EU Commission's sector inquiry? The sector inquiry's insights may suggest and drive legislative action.⁸⁵ Although the EU Commission does not have

78 See Thomas Porstner, Patienten müssen am ersten Tag nach Ablauf des Patents sofortigen Zugang zu bezahlbarer generischer Medizin erhalten, in *Sektoruntersuchung Pharma der Europäischen Kommission – Kartellrechtliche Disziplinierung des Patentsystems?* 3, 3 (Bardehle, Pagenberg, Dost Altenburg, Geissele eds., Carl Heymanns Verlag 2010).

79 Compare supra note 10 at p. 239 with supra note 11 at p. 61 (criticizing this focus on market participant behavior and arguing, that solving any generic delay issue would need to determine the relevance of company behavior vis-à-vis other potential sources for delays, such as in the regulatory system).

80 See supra note 7.

81 See e.g. supra note 10 at p. 245 and p. 278 and p. 508. The EU Commission for example has already issued guidelines on use of practices on IP rights in the regulation on the application of Art. 101.3 TFEU to categories of technology transfer agreements.

82 See supra note 78 at p. 8.

83 See Kevin Grogan, Servier could be hit with hefty fine for ‘misleading’ EU (PharmaTimes Online Jul. 28, 2010), available at, http://www.pharmatimes.com/Article/10-07-28/Servier_could_be_hit_with_hefty_fine_for_misleading_EU.aspx.

84 See supra note 68 at p. 25.

85 See supra note 28.

authority based on Art. 17 of Council Regulation EC 1/2003 to investigate for regulatory change, it is obliged to include any general insights gained into the political decision-making process.⁸⁶ When assessing implications for company behavior, it is therefore critical to understand that the EU Commission may believe it does not really need legal reasoning for justifying its concerns raised: Economic reasoning may be sufficient to trigger legislative change. The EU Commission acts, as *Etro* puts it, as a lawmaker, policy officer, investigator, prosecutor, judge and jury.⁸⁷

Besides policy setting, the EU Commission's power was already demonstrated by individual post-inquiry investigations against pharmaceutical companies *Les Laboratoires Servier* and *Lundbeck* based on Art. 11 of Council Regulation 1/2003 as well as Art. 2 of Commission Regulation 773/2004.⁸⁸ Moreover, any future investigation may rely on the sector inquiry's insights, empirical evidence and argumentation to render appropriate jurisprudence.

86 See supra note 59 at p. 31.

87 The Court of First Instance (CFI) has jurisdiction in all actions against the decision of the Commission, while ECJ decides on CFI appeal actions. See supra note 74 at p.172.

88 See Press Release IP/10/08, European Commission, Antitrust: Commission opens formal proceedings against pharmaceutical company Lundbeck (Jan. 7, 2010) and Press Release MEMO/09/322, European Commission, Antitrust: Commission opens formal proceedings against Les Laboratoires Servier and a number of generic pharmaceutical companies (Jul. 8, 2009) as well as Suzanne Rab and Bróna Heenan, European Commission Launches Monitoring of Patent Settlement Agreements, 15 Hogan & Hartson Life Sciences Competition & Antitrust Update 12, 12 (2010).