2. Governance Framework of Europe's Pharmaceutical Sector

Europe's pharmaceutical sector is a highly regulated one. On the one hand, undertakings have to adhere to a healthcare policy framework mainly influenced by patient safety and fiscal concerns. They however also benefit from opportunities to legally protect their products from product imitation. On the other hand, the behavior of pharmaceutical companies is governed by competition law. Although competition law doctrines are generally applicable to all industry sectors, they enjoy certain special considerations when applied in the context of the drug industry's characteristics. This chapter discusses important conflicts and opportunities of this governance framework relevant to analyze future implications on generic defense strategies.

2.1. Policy Objectives and Legal Protection

2.1.1. Conflicting Healthcare Policy Objectives

In line with initiatives of national member states,[16] the sector inquiry rearticulates the EU Commission's general policy objective of *"providing European patients with safe, effective and affordable medicines while at the same time creating a business environment that stimulates research, boosts valuable innovation and supports the competitiveness of the industry."*[17]

To promote these policy objectives, the EU Commission runs multiple programs, such as the DG Research's *Innovative Medicines Initiative* (IMI) for granting subsidies for integrated pharmaceutical industry's research activities.[18] Nevertheless, realizing all goals simultaneously represents a great challenge due to two fundamental conflicts:

16 See supra note 10 at p.132 regarding the common goals of the member states.

17 Supra note 10 at p. 10 and p. 478; see also Commission of the European Communities, Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector, COM (2008) 666 final (Dec. 10, 2008).

18 See Satish Sule and Dominik Schnichels, Die Untersuchung des pharmazeutischen Wirtschaftszweigs durch die Kommission, 20 EuZW 129, 129 (2009).

First, regulatory safety and efficacy requirements come at the price of increased drug development (transaction) costs for pharmaceutical manufacturers. Due to the scientific effort and high uncertainty involved, these costs are already naturally extremely high: Today, the development of an innovative drug from discovery to market can take 10-15 years and costs approximately 450 million US$ to 1 billion US$ - and these investments still not yet eliminate the substantial risk of product liability.[19] Regulatory requirements are thus targeted to protect European patients, but bear the risk of only fewer and/or more expensive products becoming available to these patients – especially in smaller/niche market segments.[20]

Secondly, promoting medical innovation requires incentives to increase the attractiveness for market participants to invest into complex, lengthy, expensive and uncertain research and development (R&D) projects.[21] As *Shapiro* argues, traditional approaches, such as granting IP rights, achieve this by allowing the owner of such a right to appropriate higher returns from its previous investments. This however typically *inter alia* leads to (temporarily) higher drug prices.[22] This conflict is often referred to as the 'innovation vs. access trade-off' or 'innovation dilemma'.[23] The fact that the EU Commission hereby explicitly stresses the promotion of (only) 'valuable' innovation may articulate its skepticism about whether all medical innovations currently rewarded really contribute additional benefits to patients.[24]

19 Compare Thomas C. Caskey, The Drug Development Crisis: Efficiency and Safety, 58 Ann. Rev. Med. 1, 1 (2007) and supra note 10 at p. 55 with Joseph A. DiMasi and Henry G. Grabowski, The Cost of Biopharmaceutical R&D: Is Biotech Different?, 28 Manag. Dec. Econ. 469 (2007) (estimating R&D average investments going even beyond 1 billion US$).

20 Higher transaction costs can lead to drug price increases to maintain profitability. Alternatively, it could also lead to lower profits assuming constant price levels. This bears the risk of drug manufacturing being a less attractive business to pursue. As a result, drug supply, especially in small market segments, may not be profitable, which may lead to lower availability of valuable medicine.

21 See supra note 13 at p. 1.

22 See Carl Shapiro, Antitrust Limits to Patent Settlements, 34 Rand J. Econ. 391, 391 (2003) as well as the in-depth discussion about static and dynamic efficiency in chapter 3.2.

23 See chapter 3.2 as well as William M. Landes and Richard A. Posner, The Economic Structure of Intellectual Property Law 20 (The Belknap Press of Harvard University Press 2003).

24 See supra note 10 at p. 10; as this concern is constantly – often implicitly – repeated throughout the final report of the sector inquiry, this paper addresses this topic thoroughly throughout subsequent chapters, especially in chapter 4.2.3.1.

At the end of the day, the EU legislator has to conduct a constant balancing exercise for all policy measures, i.e. the consideration of effects on drug quality, availability, price levels as well as the speed and quality of medical innovation. Thereby, a substantial part of the current healthcare system, especially pricing and reimbursement regulation, is not harmonized amongst EU member states and thus remains not under direct control of the EU legislator.

Over the last years, especially the issue of *price levels* and *affordability* has gained greater attention, as overall healthcare costs have substantially increased.[25] No surprise that healthcare spending on human pharmaceuticals is closely monitored, which today represents the third largest healthcare cost component across all OECD countries with disproportionately high growth rates.[26] As confirmed by the sector inquiry, policy priorities in many EU member states have therefore already shifted towards a more rigid regulation of pharmaceutical pricing and reimbursement.[27] Although the EU Commission proclaims that its concerns about the decreasing rate of new drug applications in Europe had been one of their main motivations to initiate the sector inquiry,[28] it seems that their true intention is rather driven by short-term considerations about "*how to lower prices and reduce the strain on national health-care budgets."*[29]

2.1.2. Legal Protection of Pharmaceutical Products

Besides the discussed restrictions derived from general policy concerns, the pharmaceutical industry on the other hand benefits from IP and other sui generis sector-specific exclusivity regimes. Although this being the cause for the above described 'innovation dilemma', pharmaceutical business models having such a heavy R&D burden, would simply not be possible without opportunities for legal protection of exclusivity.

25 Various factors have contributed to an increase in costs, e.g. the demographic development of Europe's population and additional costs per capita due to more costly innovative therapies.
26 See supra note 10 at p.19.
27 For examples see supra note 10 at p.61.
28 See Press Release MEMO/09/321, European Commission, Antitrust: shortcomings in pharmaceutical sector require further action – frequently asked questions (Jul. 8, 2009).
29 Supra note 7.

Innovative pharmaceutical companies primarily benefit from patent protection. Nevertheless, a complex set of additional pharma-specific exclusivities has been established to close incentive gaps of the patent system.[30] As the protection terms of some of these exclusivity instruments add to each other while others overlap and run in parallel, the concept of 'loss of exclusivity' (LOE) is critical: An innovative drug has reached LOE when the total term, during which the sales of product imitations are legally prohibited, has come to an end. After this date, bioequivalent product imitations may be legally manufactured and sold on the market – typically at substantially lower prices. One can distinguish three different layers of such drug exclusivities:

First, the exclusive rights conferred by patent law provide the basis of legal protection for a drug. As patents provide general incentives across all different technologies and industry sectors, they do not consider the specific characteristics of the pharmaceutical industry. In order to compensate for the time between patent filing and marketing authorization, which can be rather long due to necessary drug development and regulatory approval procedures, Supplementary Protection Certificates (SPCs) may – under certain conditions – complement patent exclusivity terms with additional protection of maximum five years.[31] SPCs therefore link a granted patent right with the independent regulatory regime of pharmaceutical marketing authorization – not without certain inconsistency problems and legally unclear situations.[32]

A major change in the patent regime was introduced by the so called 'Bolar exemption', which has provided much more leeway for the market entry preparation of bioequivalent product imitations.[33] Prior to its introduction, patent protection did not only make the third party manufacturing and sales

30 A full discussion about pharmaceutical protection regimes would go beyond the scope of this thesis. For a general discussion see e.g. supra note 13 at pp.222-283.

31 See Council Regulation 469/2009, 2009 O.J. (L 152); The patent system creates incentives to file an application as early as possible, which means that the point when such a patent is granted may still be many years before the corresponding pharmaceutical product receives marketing authorization and can be effectively launched on the market.

32 See, e.g., Case C-195/09, Synthon BV v. Merz Pharma GmbH & Co. KG, 2009 O.J. (C 193) (pending case as of reference for preliminary ruling from High Court of Justice, England and Wales).

33 The exception allows conducting experimentation on a patented invention, e.g. an originator's drug compound, during the term of protection, in order to prepare for marketing authorization. See Council Directive 2004/27, Art. 10.6, 2004 O.J. (L 136) 34, 40 (EC).

of a patented drug unlawful without a license, but also drug development experimentation as a mere preparation for fulfilling the abridged generic marketing authorization pathway. This effectively delayed the entry of product imitations beyond LOE of the reference drug. Interestingly, although the Bolar exemption was not in place during the sector inquiry's period of analysis, the final report did not refer to it as one potential source to explain such delays.[34]

Secondly, data exclusivity adds another layer independent from patent law. It serves as a reward for having invested substantially in demonstrating compliance with safety and efficacy requirements via long and complex clinical trials. As generic drugs per definition rely on originators' clinical trial data in the abridged generic approval pathway,[35] data exclusivity effectively blocks their market entry.[36] Although recently changed, data exclusivity did not only prohibit the commercialization of a generic product, but also its mere application for marketing authorization during the sector inquiry's period of analysis. Interestingly, also this fact did not find any recognition in the final report as one potential source of generic delay to market entry.[37]

Thirdly, the first two layers are complemented in specific cases, where the legislator had found it would be worth providing special incentives: Orphan and rare diseases as well as the pediatric use of drugs.[38] These instruments can extend drug's exclusivity on the market – their special and narrowly defined purpose however typically provides only incremental complementary value.

Based on the above, generic defense strategies therefore are defined as the tactics and activities pharmaceutical companies are able to perform to either

34 See supra note 11 at p. 57.
35 See Council Directive 2001/83, Art. 10, 2001 O.J. (L 311) 67, 75 (EC).
36 The so called '8+2+1 formula' is applied: Only eight years after the originator's marketing authorization, generic drugs can apply for marketing authorization themselves, while additional two years have to laps before such authorization is granted by authorities. In case the originator drug was extended to additional therapeutic indications in that first eight years on the market (which obviously constitutes additional effort), the protection is extended by one additional year; see supra note 33 at Art. 10.
37 See supra note 11 at p. 57.
38 See Council Regulation 141/2000, 2000 O. J. (L 18) 1 (EC) for orphan drug exclusivity and Council Regulation 1901/2006, 2006 O. J. (L 378) 1 (EC) for paediatric exclusivity.

postpone a product's LOE or to attenuate the effect of LOE on profitability.[39]

2.2. EU Competition Law and the Pharma Sector Inquiry

Besides healthcare specific policies and legal protection opportunities, the pharmaceutical sector – like any other industry – is subject to competition law, which is regulated and enforced at both EU and national member state level.[40] The likelihood of any potential limitation on generic defense strategies cannot be determined without a review of the critical doctrines and recent developments in EU competition law jurisprudence, to which this chapter is dedicated.

2.2.1. Legal Basis and General Art. 102 TFEU Principles

As outlined in Art. 3.1 (b) of the Treaty on the Functioning of the European Union (TFEU), competition law prohibits behavior and practices that restrict the functioning of the free internal market environment. More precisely, Art. 101 TFEU bans certain restrictive multilateral business practices, while Art. 102 TFEU makes the abuse of a dominant market position illegal. Cases under Art. 101 TFEU therefore require the involvement of at least two parties in contrast to cases under Art. 102 TFEU, which also apply to unilateral conducts. Very importantly however, Art. 102 TFEU cases require the addressee of the norm having a dominant position on the relevant market before the allegedly abusive practice is conducted.[41] As the application of Art. 101 TFEU generally is regarded to be easier, some words should be devoted to the assessment of Art. 102 TFEU infringements, which the sector inquiry seems to struggle with most:

39 Compare supra note 10 at p. 368, § 1053.

40 As outlined in the introduction, national competition law and policy in member states are outside the scope of this paper.

41 Compare Ulrich Schnelle, Missbrauch einer marktbeherrschenden Stellung durch Patentanmeldungs- und -verwaltungsstrategien, 8 GRUR-Prax 169, 169 (2010) with Dieter Stauder and Pascal Böhner, Bericht über die Diskussion, in Sektoruntersuchung Pharma der Europäischen Kommission – Kartellrechtliche Disziplinierung des Patentsystems? 73, 78 (Bardehle Pagenberg Dost Altenburg Geissler eds., 2010) (contrasting this doctrine to the 'monopolization' doctrine in US antitrust law).

The current European case law basis for applying Art. 102 TFEU to pharmaceutical companies' practices is small. Nevertheless, the EU Commission has initially addressed generic defense practices explicitly in the case of *AstraZeneca*.[42] Importantly, the decision has established the method to define the relevant pharmaceutical product market,[43] i.e. establishing the basis for any analysis of dominant position:[44] The court used the five-layered Anatomical Therapeutic Chemical Classification System ('ATC classification') by the World Health Organization (WHO) to separate relevant product markets, which is also used by the European Pharmaceutical Market Research Association (EphMRA). In contrast to its application in recent merger cases,[45] the *AstraZeneca* decision has established a narrower definition using the fourth instead of the third layer. This approach thus does not only consider a product's therapeutic indication, but also its mode-of-action.[46] The fact that also the sector inquiry analyzes data on a molecular level indeed indicates certain recognition for pharmaceutical product heterogeneity.

This narrower market definition has consequently lowered the threshold for market dominance.[47] Determining dominance by an undertaking's market share thereby is regarded to be only a rough initial proxy. Instead, dominance is defined by an undertaking's ability to appreciably influence the conditions of competition on the market, which the ECJ has established in its early *Hoffmann-La Roche* decision.[48] The abusiveness of a certain be-

42 See supra note 3; previous investigations in the pharmaceutical sector had only been focused on parallel trade and exhaustion of rights issues.

43 See also furthermore Josef Drexl, Deceptive Conduct in the Patent World – A Case for US Antitrust and EU Competition Law?, in Patents and Technological Progress in a Globalized World – Liber Amicorum Joseph Straus 137, 147 (Wolrad Prinz zu Waldeck und Pyrmont et. al. eds., 2009).

44 See also Case T-62/98, Volkswagen AG v. Comm'n, 2000 E.C.R. II-2707 (discussing the importance of the definition of the relevant market).

45 See e.g. Suzanne Rab and Daphne Monnoyeur, European Commission Inspections in the Pharmaceutical Sector – Antitrust Scrutiny Continues, 14 Hogan & Hartson Life Sciences Competition & Antitrust Update 10, 12 (2009) (referring to the merger cases Teva/Barr and Sanofi-Aventis/Zentiva).

46 See supra note 7.

47 This is in contrast to merger cases, where a narrow market definition may help the merging parties as it makes horizontal overlaps of businesses less likely. See supra note 45 at p. 12.

48 See Case 85/76, Hoffmann-La Roche & Co. AG v. Comm'n, 1979 E.C.R. 00461; See also Hanns Ullrich and Andreas Heinemann, in Wettbewerbsrecht Vol. 1 Part 2, 162 (Ulrich Immenga and Ernst-Joachim Mestmäcker eds. 2007) (providing an overview of relevant ECJ jurisprudence on that definition).

havior is assessed based on whether its actual or potential effects on the marketplace substantially harm (part of) intra-community trade. The assessment of both of these factors in a specific case involves thorough economic analysis, legal reasoning, substantial time and effort while still allowing a lot of leeway for a final judgment.[49] This in turn obviously is the source of high legal uncertainty – especially in the pharmaceutical industry due to its complex competitive forces (see chapter 3.2).

A controversially discussed issue in assessing Art. 102 TFEU abusiveness lies in the relevance of the underlying intent of a company's action. This is highly relevant for determining the legitimacy of generic defense strategies, as their objective – per definition – is to maintain or extend a company's competitive position in the marketplace: According to the *1998 World Cup*[50] and *Hoffmann-La Roche*[51] decisions, competition law evaluations of abusive conducts generally are supposed to be objective and neutral without considering the purpose or business rationale of a certain practice. Relevant is only the (potentially) resulting pro- and anticompetitive effects in the relevant marketplace. In contradiction to this, intent nevertheless can indirectly become relevant: According to the *Michelin II*[52] decision, intent easily proves or even presumes the existence of anticompetitive market effect in situations where the assessed conduct was designed for the sole purpose of excluding rivals. In those cases, no further evidence of an actual anticompetitive effect needs to be provided. This is also reflected in the EU Commission's guidance on Art. 102 TFEU enforcement priorities, according to which *"direct evidence of any exclusionary strategy [such as company-internal documents, will be considered insofar as this*] *may be helpful in interpreting the […] conduct"*.[53]

In any case, dominant firms do have special obligations when it comes to behavior in the marketplace.[54]

49 See supra note 9 at p. 585 referring to supra note 3.
50 See Commission Decision, Case IV/36.888, 1998 World Cup, 2000 O.J. (L 5) 55.
51 See supra note 48.
52 See Case T–203/01, Manufacture française des pneumatiques Michelin v Commission, 2003 E.C.R. II–4071.
53 European Commission, Competition DG, Guidance on the Commission's Enforcement Priorities in Applying Article 82 of the EC Treaty to Abusive Exclusionary Conduct by Dominant Undertakings, 2009 O.J. (C45) 7,10.
54 See Dieter Stauder and Pascal Böhner, Bericht über die Diskussion, in Sektoruntersuchung Pharma der Europäischen Kommission – Kartellrechtliche Disziplinierung des Patentsystems? 73, 78-80 (Bardehle Pagenberg Dost Altenburg Geissler eds., 2010).

2.2.2. The Intersection of IP and Competition Law

Assessing a pharmaceutical company's behavior under competition law requires an extraordinarily careful approach by the respective authorities due to the tradeoff between static and dynamic economic efficiency, which will be discussed at length in chapter 3.2.[55] Perfect static competition, where the equilibrium price would equal only the marginal costs of drug, would not allow innovative pharmaceutical companies to appropriate superior returns required to recoup their R&D investments.[56] Dynamic competition would consequently be eliminated. *Jones* and *Sufrin* therefore argue that a functioning free market competition may require a certain degree of temporary dominance by a firm as long as the market is not (fully) foreclosed from the entry of new incumbents, which would then compete via substitutes.[57]

The promotion of dynamic competition is *inter alia* ensured by the legal regime of IP rights (see chapter 2.1.2.). Although the sector inquiry stresses conflicts between IP and competition law, it is decisive to understand that the primary intention of IP rights is to complement rather than to exclude EU competition law.[58] This however is not achieved– as the sector inquiry may imply – through IP and competition law being *in pari materiae* in the sense that they would share the common goal of facilitating innovation. More so, IP rights in general and the patent system more precisely, should be regarded as a sub-system serving the overall market economy by achieving progress through innovation.[59]

55 Whereas static efficiency considers resource allocation and welfare effects from the equilibrium price and quantity at a certain point in time, dynamic efficiency considers economic progress and welfare effects of market participants' behavior over a certain period of time. The resulting policy conflict is predominantly strong in pharmaceuticals due to the 'innovation dilemma' as discussed in chapter 2.1.1.

56 See e.g. Alison Jones and Brenda Sufrin, EC Competition Law Text, Cases, and Materials 3-10 (3rd edition Oxford University Press 2008) (providing a general overview of fundamental economic theories and competition law).

57 See Id. at p.586.

58 See Frank L. Fine, The EC Competition Law on Technology Licensing 14 (Sweet&Maxwell 2006).

59 See Hanns Ullrich, Wahrung von Wettbewerbsfreiräumen innerhalb der Schutzrechtsverwertung – Die Regelung des Innovationswettbewerbs im und durch das Patentrecht, in Sektoruntersuchung Pharma der Europäischen Kommission – Kartellrechtliche Disziplinierung des Patentsystems? 29, 42 (Bardehle, Pagenberg, Dost Altenburg, Geissele eds., Carl Heymanns Verlag 2010).

In contrast to US antitrust law, the European understanding consequently does not see IP rights as an exclusionary zone not subject to competition law, but clearly as being fully in the scope of its regulation.[60] Nevertheless, the *Microsoft* decision[61] confirmed that the mere existence of IP rights does not automatically lead to a dominant market position. As *Ullrich* and *Heinemann* emphasize, the decisive criteria rather are under what circumstances the IP right holder becomes market dominant and what role the IP ownership plays in that respect.[62]

This perspective complemented the precedent cases of *Magill*[63] as well as *Bronner*,[64] where the ECJ concluded that the exercise of an IP right might indeed constitute an Art. 102 TFEU abuse, but only under 'exceptional circumstances'.[65] In these special situations, IP rights may be considered a 'bottleneck monopoly', or what the EU Commission calls an 'essential facility'. Thereby, access to a competitor's IP would be indispensable for the rival, as *'there is no actual or potential substitute'* for it.[66]

It therefore seems clear that there is nothing like an IP-induced general privilege in the application of Arts. 101 and 102 TFEU.[67] Nevertheless, *Drexl* observes that competition authorities are generally used to rather safeguard static competition and fight price cartels, whereas exactly this complex relationship between static and dynamic efficiency is what makes

60 Compare Commission Communication, Executive Summary of the Pharmaceutical Sector Inquiry Report 18-19 (Jul. 8, 2009) with Rainer Bechtold et al., EG Kartellrecht Kommentar Art. 81-86 EG, EG-Kartell-VO 1/2003 § 2009 (2nd edition, C.H. Beck 2009) (emphasizing that also restrictive business practices in the sense of Art. 101 TFEU do not constitute an exception to competition law).

61 See Case T-201/04, Microsoft Corp. v. Comm'n, 2007 E.C.R. II-03601, § 691.

62 See Ullrich & Heinemann, supra note 48 at p. 162.

63 See Case C-241/91 and C-242/91, Radio Telefis Eireann (RTE) and Independent Television Publications (ITP) v Comm'n, 1995 E.C.R. I-743, § 50.

64 See Case C-7/97, Oscar Bronner, 1998 E.C.R. I-7791.

65 See Joseph Straus, Patentanmeldung als Missbrauch der marktbeherrschenden Stellung nach Art. 82 EGV?, 2 GRUR-Int 93 (2009) (referring to the Magill decision).

66 See Irina Haracoglou, Competition Law and Patents – A Follow-on Innovation Perspective in the Biopharmaceutical Industry 133 (Steven D. Anderman et al. eds., Edward Elgar Publishing 2008) (referring to supra note 64 at § 38, 41 and 44).

67 See Press Release IP/04/382, European Commission, Commission concludes on Microsoft investigation, imposes
conduct remedies and a fine (Mar 24, 2004).

it so hard for them to apply competition law to cases in the IP-heavy pharmaceutical sector.[68]

2.2.3. The 'More Economic Approach' to EU Competition Law

The EU Commission has advocated for applying a 'more economic approach' to competition law. This is characterized by differentiated case-by-case decisions rather than strengthening per-se rules. Moreover, the approach calls for balancing pro- and anticompetitive effects of the conduct under investigation not on overall social welfare, but rather on consumer welfare.[69]

Central aspects of the 'more economic approach' stand in conflict with ECJ jurisprudence and previously articulated opinions by the EU Commission, which has substantially contributed to even further legal uncertainty for the pharmaceutical industry: A focus on consumer instead of overall social welfare implications is not supported by the ECJ, which has made clear that competition law is supposed to protect competitive market structures rather than competitors or consumers.[70] *Straus* interprets the EU Commission's discussion paper on the application of Art. 82 of the EC Treaty (now Art. 102 TFEU) as also supporting this more traditional perspective: In the paper, the EU Commission would articulate the objective of protecting competition, not competitors.[71] The more traditional perspective is also supported by *Gassner*, who concludes with reference to the *GlaxoSmithKline* decision[72] that negative effect on consumer welfare should be consid-

68 See Josef Drexl, Pay-for-Delay – Zur kartellrechtlichen Beurteilung streitbeilegender Vereibarungen bei Pharma-Patenten, in Sektoruntersuchung Pharma der Europäischen Kommission – Kartellrechtliche Disziplinierung des Patentsystems? 13, 22 (Bardehle, Pagenberg, Dost Altenburg, Geissele eds., Carl Heymanns Verlag 2010).

69 See Dieter Schmidtchen, Der „more economic approach" in der europäischen Wettbewerbspolitik – Ein Konzept mit Zukunft, in Internationalisierung des Rechts und seine ökonomische Analyse 473, 473 (Thomas Eger et al. eds., 2008).

70 See e.g. Joint Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, GlaxoSmithKline Services Unlimited v. Comm'n (under appeal – not published yet, see Case T-168/01, GlaxoSmithKlineServices Unlimited v. Comm'n, 2006 E.C.R. II-2969.

71 See supra note 65 at p. 100.

72 See supra note 70.

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 *Drexl*, 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).