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).