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.