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).