EUR on an ex-factory basis.[103] Interestingly, only one European generic company, i.e. Germany's *Ratiopharm*, is represented within the Top-50 pharmaceutical companies. Beyond this, only four other non-EU generic companies appear on the list, i.e. *Teva*, *Mylan*, *Watson* and *Actavis*. Except for *Teva*, all of them generate global annual sales significantly below 5 billion US$. This confirms the sector inquiry's finding of generic companies being generally smaller and more localized compared to originators.[104] One should however not forget that approximately 40% of the total worldwide generic sales in 2007 was generated by two market leaders: Israel's *Teva* as well as *Sandoz,* originator *Novartis'* own generics division.[105]

3.2. Dimensions of Competition

Originator and generic companies compete within Europe's common market. However, available legal protection instruments for innovative drugs as outlined in chapter 2.1.2 require a more differentiated consideration of existing competitive forces in order to effectively analyze the sector inquiry's findings.[106] Before the discussion turns towards potential limitations of generic defense strategies, this chapter therefore discusses the difficulties involved with dynamic competition on the one and static competition on the other hand.

3.2.1. Dynamic Competition for Substitution by Innovation

Dynamic competition is what the traditional originator business model is all about: Different market participants compete for product substitution by inventions, not by imitation of the same invention. Originator business strategies therefore 'race for innovation' to launch a first-in-class patent protected product with effectively no substitutability ('first to discover, first to patent').[107] *Etro* calls this a 'winner-takes-all' race. In contrast, patent

103 See supra note 11 at p. 59.
104 See supra note 91 at pp. 70-78 as well as supra note 10 at p. 37.
105 See Eyal Desheh, Chief Financial Officer, Teva Pharmaceuticals and Bill Marth, President and Chief Executive Officer, Teva North America, Presentation at the 27th annual JP Morgan Healthcare Conference: Introducing the World Leader in Generic Pharmaceuticals (Jan. 12, 2009).
106 See supra note 10 at p. 25.
107 See Id. at p.25 and 379.

protected drugs in areas where treatment already exists need at least to be 'best-in-class' by providing superior treatment profiles in order to be commercially successful.[108] Demand for such products can however be attracted away by alternative patent protected products as well as by already existing generic versions of such alternative therapies. This illustrates why *"[p]atents grant a legal monopoly that cannot necessarily be equated with an economic monopoly."*[109] In the vast majority of cases, innovative drugs are in direct competition with different patented and generic products for the same treatment even prior to LOE.[110] The maximum time for a new drug's successful commercial exploitation thus is less determined by the term of protection prior to LEO, but rather by the degree of dynamic competition.

Originator products (i.e. innovative pharmaceuticals) are nevertheless predominantly defined by their ability to meet patentability requirements in major jurisdictions: A new patentable active ingredient protecting a drug not marketed before clearly is the result of dynamic competition. A rather grey and undefined area relates to products which are (only) able to provide additional (medical) use or a more beneficial application over existing reference products, but are not able to enjoy patent protection.[111] A broader definition of innovation and dynamic competition would also include products complementary to already existing reference products, which competing firms develop or would want to develop.[112] In contrast to this, a product which only achieves a lower price level on the market without any other additional therapeutic value over an existing reference product can be clearly regarded as static competition for imitation.

This distinction is critical when it comes to alleged anticompetitive effects associated with generic defense strategies: The foreclosure of static competition via IP rights (during the term of protection) has to be considered legitimate.[113] Competition law governing the patent system normally also accepts loss of competition in case of true dependencies between main in-

108 See supra note 74 at p. 26.
109 Supra note 66 at p. 120.
110 See supra note 10 at p.25.
111 This may be the case for example due to lack of inventive step, which would make the invention obvious.
112 See supra note 41 at p. 169.
113 See supra note 13 at p. 416.

vention and incremental inventions.[114] As *Schnelle* argues, EU competition law may however consider practices of dominant IP right holders abusive where they have a substantial limiting effect on dynamic competition for innovation. Such competition, which is based on specific techniques, technologies or standards, thus is also safeguarded by competition law even against exclusive IP rights.[115] As *Drexl* puts it: *"'Successful' innovation is allowed, and is even expected, to override inferior technology and to win market dominance. However, such dominant positions in a competition-oriented IP system should remain contestable."*[116]

The boundaries of such cases obviously depend on the underlying definition of pharmaceutical product innovation. This general issue is indeed substantially more complex for drugs than for other goods, as some drugs may not be able to achieve patent protection, but still provide incremental therapeutic improvements, which is a classical line of argumentation by generic companies.

3.2.2. Static Competition for Imitation of In-Market Products

In contrast to dynamic competition, static competition optimizes the allocative efficiency of resources at a certain point in time by driving down prices to marginal costs. Although this is what theoretically happens at a drug's LOE, in reality, a certain minimum level of static inefficiency is system-immanent. The reason lies in the European public healthcare system being built around the principle of solidarity. This system is faced by a typical principal-agent dilemma: While physicians and patients decide about a specific therapy, associated costs are borne by others, i.e. the health insurance.[117] The health insurance as the principal thus is unable to control the necessity of drug prescription and consumption by the agents, i.e. physi-

114 This is because a refusal to license an invention to a dependent patent holder generally is legitimate (however with exceptions as outlined in chapter 4.2.1.); see supra note 59 at pp. 43-44.

115 See supra note 41 at p. 169.

116 Josef Drexl, Responding to the Challenges for Development with a Competition-Oriented Approach, in 1 International Centre for Trade and Sustainable Development, Views on the Future of the Intellectual Property System 17, 19 (John H. Barton et al. eds., 2007).

117 See supra note 68 at p. 17 and supra note 10 at p. 28 and p. 46.