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Intellectual Property Related Generic Defense Strategies in the European Pharmaceutical Market

Implications of the EU Commission's Sector Inquiry from an IP, Competition Law and Economic Perspective

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Abstract

This thesis discusses the implications of the 2009 EU Commission's Pharmaceutical Sector Inquiry on originator's opportunities to apply Intellectual Property related measures in defending against generic competition. It argues that on the one hand recent developments in EU competition law do indeed impose potential limitations on an originator's ability to block or delay generic market entry. On the other hand, the thesis calls for a differentiated assessment of the rather broad allegations made by the sector inquiry. The thesis thereby presents and thoroughly analyzes six key issues identified by the EU Commission in the inquiry's final report: Blocking/ defensive patenting, patent thickets, patent-related disputes and litigation, follow-on innovation, authorized generic entries and patent settlement agreements as well as interventions into generic marketing authorization. The analysis aims at reducing legal uncertainty by providing a clearer picture of legal boundaries between legitimate and problematic conduct under Arts. 101 and 102 TFEU. An evaluation framework called PACE is developed and serves as the structure for the assessment, which consists of four dimensions, i.e. **P**riority, **A**bility, **C**hangeability and **E**nforceability. The thesis also puts the sector inquiry's findings into a forward-looking perspective by highlighting industry trends with the potential to transform traditional originator and generic business models. Based on a holistic trilateral approach of IP, economics and competition law, the thesis concludes that originator companies are well advised to follow a 5-step approach for revisiting and fine-tuning their IP-related generic defense strategies for the Europe market.

Key words: *Intellectual property, competition law, antitrust, EU Commission, pharmaceutical sector inquiry, generic competition, defense strategies, innovation.*

Table of Contents