IV. Discussion

A. Lifecycle Management: Criticism and Supports

It has been reported that "[o]ver the next few years, patent exclusivity will expire for drugs with combined annual sales of $140 billion."[108] With increasing generic competition and constantly growing expenses for developing new chemical entities (NCEs) into successful drugs, drug companies are forced to maximise the value of their product portfolio. To deal with this challenge, active lifecycle management represents a response and comprises the efforts of improving return from R&D investments.[109] Various strategies are being pursued and among these figure product improvements and product line extensions.[110]

Members of the generic industry argue that "[...] such practices are anticompetitive and result in higher cost of healthcare to the patient and government bodies [...]".[111] The strategies employed are oftentimes pejoratively called "evergreening" strategies.[112, 113, 114] This negative connotation stems from the impression, that the originator drug companies have the ability to obtain multiple patents on a drug which in turn leads to an effective extension of the patent term. Such

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108 Angelo DePalma, *Patent expiration: Innovate or die,* Eyeforpharma, Feb. 3, 2011, available at http://social.eyeforpharma.com/.

109 John Fraher, *Life-Cycle Management: The Link to Drug Delivery*, 2 Drug Deliv. Tech. 158, (2002).

110 Leighton Howard, *Use of patents in drug lifecycle management*, 4 J. generic medicines 230, 236, (2007).

111 *Id.*

112 Kate S. Gaudry, *Evergreening: a common practice to protect new drugs*, 29 Nat. Biotechnol. 876, (2011).

113 C. Scott Hemphill, Bhaven N. Sampat, *Evergreening, patent challenges, and effective market life in pharmaceuticals*, 31 J Health Econ. 327, (2012).

114 Gaurav Dwivedi, Sharanabasava Hallihosur, Latha Rangan, *Evergreening: A deceptive device in patent rights*, 32 Technology in Society 324, (2010).

strategy is seen as impeding entry of generic drugs to the market. In this context, one cannot fail to observe that the term "evergreening"[115] in itself is entirely incorrect and inappropriate as it implies that the same invention is repeatedly protected. However, the patents obtained are generally different from one another and are directed to various aspects. The patenting strategies employed generally conform to the letter of the law. GlaxoSmithKline took publicly position on this issue. The innovator company argues that no evidence has ever been produced that those practices coined "evergreening" have an impact on patients or markets.[116] Furthermore, GlaxoSmithKline pointed out three key issues. First, improvement patents are available only if they meet the normal requirements of patentability. Second, it is disputed "that improvements subject to later patents are not medically important and should not be encouraged." The patent system provides an incentive to improve products and "the importance of such improvements is assessed by the market and clinical demand." Third, there is no motivation why patented improvements should delay generic competition, because the patent systems allow and foster competition.[117]

The generic industry holds against the point of view that in their opinion a multitude of low-quality patents is granted which to be revoked and worked around binds a considerable amount of resources and of money.[118] The same issue of quality of late secondary patents was also considered by the EU Commission in its recent sector inquiry.[119] The Commission recognized the importance of subsequent

115 *Id.*

116 GlaxoSmithKline Briefings, *Evergreening*, (March, 2007), found at http://www.gsk.com/policies/GSK-and-evergreening.pdf. (last visited, July 25, 2012).

117 *Id*.

118 See Howard s*upra* note 110.

119 Research Paper in Law Cahiers juridiques, Nicoleta Tuominen, Patenting Strategies of the EU Pharmaceutical Industry Crossroad between Patent Law and Competition Policy No 1 (2011), at 16.

improvements made to the initial invention.[120] They agreed that such contributions, if inventive, merit patent protection but they call for a closer scrutiny of patent applications.[121]

Patents that try to protect improvements of a drug incorrectly are deemed to prolong the life of the basic patent. First, they do not impede the commercialization of the drug, whose patent is expired. Second, everyone is free to invest into research and identify (incremental as well as substantial) improvements to existing inventions by building on the existing knowledge. The only advantage the originator initially has over a competitor is the know-how generated on the way to the first patent and finally the marketed drug. However, this know-how came at a price (the investment into research) to the originator company, this price being generally orders of magnitude higher than the one paid for later increments. As some authors observed the use of the clinical know-how gained can lead to cheaper and faster development of novel applications, offering a benefit for both industry and patients.[122]

Given the continuous advances in science and the consequent gain of knowledge the inventive step disclosed in some of these applications is smaller than in a pioneering patent. Notwithstanding the fact that such patents are considered weaker and of low quality, an inventive step may oftentimes be identified. The gain from such incremental improvement is to the benefit of all. If no protection would be available for these improvements identified during the lifecycle management and if all researching industry would focus only on providing "blockbuster" drugs, which then however would not be refined into the best possible formulation or made with the most economic process, then it may be expected, that due to reduced revenue less drugs

120 European Commission, *Communication from the Commission – Executive Summary of the Pharmaceutical Sector Inquiry Report*, (July 8, 2011) at ¶1323, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf, (last visited Aug. 1, 2012).

121 *Id.* at ¶1324.

122 Christian Sternitzke, *Knowledge sources, patent protection, and commercialization of pharmaceutical innovations*, 39 Research Policy 810, 812, (2010).

will reach the market in the end, and fewer medical needs will be addressed.

B. Further Filing Strategy: Commercial Value

Further research to improve properties of a drug and to address unmet needs benefit not only the industry but also the public. Such research needs incentives but it is debatable whether the strategy of further filing is of any value in this context. The further filing connected with a blockbuster drug might present various problems also on the side of the originator. Such problems can be highlighted through the analysis of the case studies reported in this work. First, innovation tracks such as formulation, combination, new uses and process have many shortcomings for the originator; second, the patent strategy pursued by an originator in a dominant position can fall under scrutiny of competition law.[123]

It is also important to underline that such strategy *per se* does not preclude competition but on the contrary can foster it both in regard of innovation (as this work will try to evidence) and of price. On this point it has been shown in the past that 80% of the new entrants to an existing class (follow-on drugs) were launched in the U.S. with a price discount and the discount rate was on average 26%.[124]

Furthermore, inventions whose patent have expired can be marketed by a generic competitor, since improvement patents are narrower in scope.[125]

123 E.g. Xalatan: see AGCM *supra* note 96.

124 Joseph A. DiMasi, Cherie Paquette, *The Economics of Follow-on Drug Research and Development*, 22 Pharmacoeconomics 1, 12 (2004).

125 See GlaxoSmithKline *supra* note 116.