I. Introduction

In 2011, the world pharmaceutical market was worth an estimated 614.6 billion € at ex-factory prizes. The European share of this market is estimated to be around 26.8% (or 157.3 billion €), with an annual market growth of ca. 2.6% for the five major European markets.[1] The world's fastest growing markets are the Brazilian and Chinese markets with an estimated growth of more than 20%.[2]

In Europe, the researching pharmaceutical industry (constituting the so-called "originator companies") is the leading high technology industry in terms of investment in research and development. An estimated 27.8 billion € has been invested in the year 2010 (a year of global economic downturn) into research directed towards new chemical and biological entities (drugs) and their development to bring forth new innovative cures for diseases.[3] This figure has more than doubled in the past ten years, and is over ten times more than the figure in 1980. The cost of pharmaceutical research has been increasing dramatically over the years for several reasons.[4] First, with the increasing knowledge acquired through the various genome projects, science has become much more complex. Not only have become known much more potential targets to be addressed by a drug to treat a given disease, but also much more is known about potential collateral targets which need to be avoided in order not to cause undesired side reactions.[5] As a further consequence of the increased knowledge, also

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1 European Federation of Pharmaceutical Industries and Associations (hereinafter 'EFPIA'): The Pharmaceutical Industry in Figures, 2012 Edition, found at: http://www.efpia.eu/sites/www.efpia.eu/files/EFPIA_Figures_2012_Final-20120622-003-EN-v1.pdf (last visited Aug 2, 2012).

2 *Id.* at 4.

3 *Id*. at 9.

4 *Id*.

5 G. Emilien, M. Ponchon, C. Caldas, O. Isacson and J.-M. Maloteaux, 5 *Impact of genomics on drug discovery and clinical medicine*, 93 QJM. Int. J. Med. 391, 394 (2000).

regulatory obligations in preparation of the data package to obtain market approval become more and more stringent. This results in ever larger and lengthier clinical trials and an enhanced rate of failure.[6] The increased regulatory obligations have consequently reduced the period of time where the originator companies have market exclusivity and the number of drugs which arrive to the market.[7] This situation has led the pharmaceutical industry to pay more attention to the patent portfolio and to invest into research connected with already marketed products (such as development of combination therapies).

The climate in which the pharmaceutical industry operates can be characterized as lacking acceptance of the business model and critical regarding the value it creates for society. The critics deny any fair analysis of achievements of commercial pharmaceutical research and focus on failures – disregarding the industries commitment to supply the market with safe and efficacious drugs.

This thesis will start by giving a short overview on the different phases of pharmaceutical drug research and a summary of the European Medicines Agency (EMA) regulations which deal with the approval of new and generic drugs. Next, this thesis will seek to describe different kinds of subject matter (e.g. salts, formulations, combinations, delivery devices) pursued by the patent protection. These patents that accompany the development of a drug from research to market are referred to as follow on patents and are often considered by generic companies as "evergreening".

In particular, it will compare the originators' patent portfolio built to protect drugs for two selected pharmaceuticals. It will attempt to analyse the various motivations which are behind such patent portfolio, whether follow up patents are of value and if not the reasons leading to this conclusion. This thesis will also highlight challenges that

6 Jack W. Scannell, Alex Blanckley, Helen Boldon, Brian Warrington, *Diagnosing the decline in pharmaceutical R&D efficiency*, 11 Nat. Rev. Drug Disc. 191, 193 (2012).

7 Ronald D. Fitzmartin, *The challenge of global electronic submission standards in the biopharmaceutical industry*, 32 Drug Inf. J. 745 (1998).

this current patent strategy could encounter in the future especially as far as competition law is concerned.