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Volume 20

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Patent Strategy in Pharmaceutical Industry: Are additional patents valuable?

Nomos

MIPLC Munich Intellectual Property Law Center
Augsburg
München
Washington DC

Die Deutsche Nationalbibliothek verzeichnet diese Publikation in der Deutschen Nationalbibliografie; detaillierte bibliografische Daten sind im Internet über http://dnb.d-nb.de abrufbar.

The Deutsche Nationalbibliothek lists this publication in the Deutsche Nationalbibliografie; detailed bibliographic data is available in the Internet at http://dnb.d-nb.de .

a.t.: Munich, Munich Intellectual Property Law Center, Thesis "Master of Laws in Intellectual Property (LL.M. IP)", 2012

ISBN 978-3-8487-0991-5

1. Auflage 2014

Preface

This thesis is the result of research and analysis of the patent portfolio regarding two commercially successful drugs of significant importance for public health. The investigation has sought to analyse the various motivations which are behind such patent portfolio as well as its potential value.

The research culminating in this thesis was carried out as part of the LL.M. Program at the Munich Intellectual Property Law Center (MIPLC). It has been generously supported by Dr. Heinz Hammann and Dr. Ulrich Kebekus of the Boehringer Ingelheim group's patent department, who provided access to some crucial data and also took time to make very helpful comments, for which I am very grateful.

I wish to thank my classmates and friends at the MIPLC LL.M. Program, for inspiring and supporting me, in particular Hyewon. Most importantly, I would like to thank my family. This dissertation would not have been possible without their support.

Munich in January 2014 *Monica Donghi*

Abstract

Lifecycle management is used by companies attempting to maximize the value of their product portfolio and it is often referred to by generic drug manufacturers as "evergreening". Lifecycle management arises in response to the increasing generic competition and to the constantly growing expenses necessary to develop new drugs. Between the various strategies being pursued this thesis analyses and evaluates two of them, namely product improvements and product line extensions. In particular, an evaluation of the patents that follow the basic one and that accompany the development of a drug from research to market is attempted.

Two "blockbuster" drugs, Taxotere and Xalatan, were randomly chosen to carry out such analysis. The patent portfolio of the originator companies is outlined and some important patents for each area of research (e.g. formulations, combinations, delivery devices) are shortly described. Moreover, the patent filing trends for the two drugs, both in regard of the originator and in regard of other competing companies (amongst these also the generics) are schematically shown.

The evaluation of the patent portfolio indicates in both case studies that the follow-on patents did not stop profit erosion after expiry of the basic patent. Various obstacles and drawbacks may be identified. In particular, many patent applications were withdrawn or did not result in a granted patent. Granted patents that covered valuable improvements of the characteristics of the two drugs, such for example a better formulation in the case of Taxotere, could not be maintained in some European countries and in the U.S. These follow-on patents tend to be weaker than the basic one and more difficult to defend for the originator, which appears to be due to a concomitant increase in knowledge as research moves forward, enhancing the basis of prior art to be considered.

Stronger patents are necessary to protect research that aims to improve a market drug. Such research is criticized by many and seen as deviating resources from the discovery of NCEs, nonetheless a benefit for the public arises in many cases from it. Innovation derives also from small incremental steps.

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