Abstract

The TRIPS Agreement and Patent Protection of Pharmaceuticals

The purpose of my thesis is to analyse the global system of pharmaceutical patent protection under the TRIPS agreement and to answer the question whether the specific character of these products and the need for their general availability is adequately addressed at present and, if possible, what are the changes needed in order to do so. The thesis is composed of four chapters.

Chapter One describes the philosophical background behind the patent protection of pharmaceuticals. It consists of two parts. Part One begins with an outline of the classical rational arguments in favour of the existence of patent protection as such. In order to describe the basic conflict of interests existing in the pharmaceutical industry, Part Two then continues with their application on the issue of patent protection and access to medicines.

Chapter Two presents a detailed analysis of the pharmaceutical patent protection standard under the TRIPS agreement from the perspective of access to medicines. Thus it focuses upon the possibilities that exist for securing greater availability of these essential products around the world. The chapter consists of four parts. Part One offers a brief history of the TRIPS agreement itself. Part Two continues with an analysis of the relevant parts of the general provisions and basic principles of TRIPS. Part Three focuses upon the different transitional periods offered by TRIPS. Finally, Part Four presents a thorough scrutiny of the specific institutes of medicines' patent protection, such as the unified length of the patent term, patentable subject matter and the rights conferred by a patent. Some recent developing country cases are analysed as examples.

Chapter Three illustrates certain additional instruments that can be used in the public interest. The chapter consists of two parts. Part One describes the options offered by different kinds of exceptions to the rights conferred under art. 30 TRIPS. As a

practical example, it uses the broadly accepted Bolar-type exception. Part Two continues with the now highly debated issue of compulsory licences under art. 31 TRIPS. It uses a recent Indian example to examine their use on general basis and then focuses on the so far very unsatisfactory use of the "paragraph 6" scheme of compulsory licences for export to countries with insufficient local manufacturing capacities.

Chapter Four looks at the role that subsequent bilateral and regional trade agreements play in the context of the main theme of the thesis. As such, the chapter consists of two parts. Part One looks at the issue of TRIPS-plus and their impact upon the global standard of patent protection in general. Part Two then shows several specific examples of the TRIPS-plus measures in relation to pharmaceuticals. To illustrate, it draws from 11 different bilateral agreements – with 9 of these having USA as a party and the remaining 2 being recent examples of similar EU activity.

There are two major conclusions drawn in the thesis. First, it can be said with certainty that, from today's point of view, the TRIPS agreement indeed offers a variety of options, which can be effectively used to secure greater access to medicines even in the developing world. However, the research of their actual use worldwide provides a rather gloomy picture. Therefore, as an addition to the primary conclusion, the thesis stresses the necessity of effective application.