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Giuseppe Andreoni
Massimo Barbieri
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Developing Biomedical Devices

Design, Innovation and Protection



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Preface

Innovation capability is one of the main indicators of the economic “health” and power of a nation and of a society. But inventive ability without its protection and exploitation is sterile. The success of the whole process can be achieved following a methodologically structured pathway, from the idea to the product. The knowledge about tools, strategies, time and cost is fundamental to identify the best solution. Too often this knowledge is absent in the inventors, whoever they are, both university researchers or industrial developers.

This book wants to address this lack of information providing a short but hopefully comprehensive description of the Intellectual Property forms of protection, and the methods and tools to be used in its management.

The protection of the innovation is the first choice that can also drive the exploitation. A correct first step is crucial and starts with the identification of the most suitable typology of Intellectual Property Rights (IPRs) to apply for. Coaching the innovators in this decision is the goal of this book.

It is addressed to different readers: Students, University Researchers and Professors, Designers and Industrial Researchers too, from Engineers in any discipline (mechanics, electronics, mathematics, ...) to Designers and Architects. Also, all the results of innovation should be considered: products, systems, fashion items, Information and Communication Technology (ICT), etc.

Each one of these applications can need different solutions to face their protection. But before protection it is necessary to properly understand what to protect and if it is possible. This means to codify the knowledge in the suitable form (mathematical formula, electronic circuit, drawings, ...) and to carry out a dedicated research into the corresponding databases and through the most proper codes and keywords. From this crosscheck arises the possibility to protect the creation in terms of patent, utility model or industrial design. Together with this opportunity and decision, the analysis of the options (for example and simply the designation of the territory where to apply for the protection, i.e. the national or international geographical area) and the related time scheduling and corresponding expenses is another key factor to consider. This leads to a reasonable and sustainable business plan that will drive the next steps of exploitation (licensing, spin-off/start-up company initiatives, ...).

At the beginning we defined Innovation as an index of the economic health of a society. Health is a human basic value, and for this reason we chose Biomedical devices used in healthcare as the case study in this book.

The text was updated in spring 2013: for new or more recent laws or determinations please consider also further readings.

Giuseppe Andreoni

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Chapter 1

Introduction

The protection and the exploitation of intellectual property are two of the main strategies to promote the renewal of the economic and entrepreneurial society. The expression “protection of Intellectual Property Rights” refers to the frame of rights, relating to:

- personal or moral right to be recognized as the author or creator of the work or the technical solution or brand, which is a personal and inalienable right;
- economic right related to the exploitation of the result of his/her creative activity, which is an available and transferable right.

By their very different nature and according to the rules defining them, the outcomes of human genius can be classified into three main categories:

- the results deriving from intellectual creativity, belonging to the world of art and culture (literature, organizational charts, theater and television shows, photographs, paintings, architectural projects, etc.), which are protected by those rules that are generally called copyright;
- those representing the distinctive marks or signs, such as brand, company, designations of origin, whose form of protection is registration;
- technical innovation and design, which relate to inventions, industrial designs, plant varieties, which are referred to the laws governing patent right.

Only about the last two categories, i.e. the intellectual property belonging to the world of science and technology, we can speak more properly of IPRs.

Today innovation is becoming more and more the crucial element for development and growth in all sectors of the economy. Thus the creative ability and the actions for the protection of inventive activity represent key factors for maintaining and increasing the level of competitiveness of an economic system. For this reason, in the last years we assisted to an “explosion” of patent application, in particular in those countries whose economy is rapidly growing (China, India, Brazil, ...). This phenomenon paired with a consolidation of IPR in the “traditional” western countries.

Universities and research institutes, but also multinational companies with large Research and Development (R&D) laboratories/departments, are the main sites of innovation. Feeding interaction and knowledge transfer between universities,