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BOOK REVIEW

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Patent Portfolios and Pharmaceuticals: A European Perspective

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I. Introduction

The book deals with a complex subject, although far from new, which is the intersection between intellectual property (“IP”) and competition law. Indeed, exclusive rights confer market power and restrict competition temporarily. Along these lines, Emanuela Arezzo, Associate Professor of Commercial Law at the Faculty of Law of the University of Teramo (Italy) and winner of the Jean Monnet Chair in EU Innovation Law & Policy (2023-2026), focuses on the pharmaceutical sector, mostly from the point of view of European Union Law and its Institutions (as opposed, in particular, to the regime of the United States of America). The book highlights recent behaviour trends in this sector, specifically, the building and exploration of patent portfolios.

II. Description¹

The book has seven chapters, being the first introductory and the last a conclusive one. In chapter one, Arezzo addresses the significant increase in patent filings in recent years, which she describes, quoting J. Masur, as “patent inflation”. While this could mean that innovation is growing, the author points out that only a small percentage of these patents is put to use. The author then discusses the possible factors for this trend, such as

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¹ The description of the chapters focuses on key points, and not necessarily in the same order presented by the author.

the coverage of a certain technological trail or the strategic value of patent portfolios to create leverage against rivals. In this context, the chapter distinguishes between two sets of technological sectors (discrete and complex) and two kinds of patent portfolios, in terms of size (large or small number of patent applications) and composition (a portfolio related to complementary, substitutive, or derivative technologies). The author concludes the chapter by exploring what she considers to be three significant transversal competitive advantages of patent portfolios (to be used by undertakings against other competitors): (i) increase of the strategic information asymmetries; (ii) raise of the bargaining power in order to force rivals to accept unfavourable licensing arrangements or enter into (anticompetitive) patent settlements; and (iii) safeguard of several innovation trails and respective profit possibilities.

In chapter two, the author analyses IP law and doctrines' evolution (namely, the European Patent Convention, including its implementing regulation, guidelines, the European Patent Office's case-law, and the Agreement on a Unified Patent Court), with regard to the so called "derivative or follow-on patents" as tools to build patent portfolios. In this respect, it would have been useful if the references to scholars and courts' doctrines had been more equal, with the book giving the former prominence. Nevertheless, the author explores with detail various subcategories of derivative patents, such as improvement, combination, translation, second use and selection inventions, as well as its practical relevance in terms of assessment of novelty in the chemical sector.

The third chapter of the book focuses on one of the subcategories of derivative patents mentioned above: second use, in the medical field. According to the author, this is the only type of derivative invention expressly recognised by the aforementioned legislation (and, therefore, by the national laws of its signatories' countries). This chapter is more practical than the previous ones. It links an allegedly permissive/open interpretation by the jurisprudence to the phenomenon of patent proliferation. The author's choice of the topic of the application of these concepts to the field of medicine is very pertinent, since, as Arezzo points out, the rationale of protecting research through exclusive rights had to be balanced, by the legislator, against a possibly greater public social interest: access to the best medical care and medicines or substances used in medical treatments, such as vaccines. Indeed, if the patenting of therapeutic, diagnostic, and surgical methods was banned by the legislator, the patenting of products

(in particular, substances or compositions) to be used in these methods was not. Having this in mind, the author went through recent legislative and case-law developments regarding the possibility of extending patentability to different types of second-use (medical) inventions, such as new therapeutic applications, changes to the original form of administration or new dosage of a certain pharmaceutical substance.

In chapter four, Arezzo explores the construction of patent portfolios through a particular patent procedure, used to claim derivative patents, named “divisional application”. She analyses the procedural patent provisions and rules invoked by undertakings for that purpose. It is worth noting the author’s stance on artificiality dissection of the same invention concept (*i.e.*, of the same technical contribution due to the same technical characteristics), contrary to the principle of unity.

Chapter five begins, in a way, a second part of the book, focussing more on the implications of the above concepts, such as the difficulties that multiple patents filing cause competitors in terms of identifying the exact contours of protection offered by the whole portfolio (especially regarding follow-on inventions, within which the boundaries of protection remain, according to the author, uncertain). Pursuing this hook, the author deeps the issue of potential infringements of first (or second) medical use patents by subsequent second therapeutic use patents. Since the patentability of this further therapeutical use patent normally results in the distribution of two identical medicinal products simultaneously in the market (even though for different purposes), the author explores the example of generic companies/products, as opposed to original companies/products – that is, those that introduced the innovative medicinal products in the market. Usually, the former enters the pharmaceutical market after the patent that protected the original compound expires, restoring price competition. However, as Arezzo points out in this chapter, other uses, patented at a later stage, can still be protected, and it is in these cases that actions based on infringement of IP rights are filed. Then, the book explores the different types of problems related to generic competition in terms of patent infringements, exposed by case-law. Once again, we would have liked to have seen the author’s opinion expressed more explicitly, namely regarding the existence (or not) of infringement in the various cases described. Even so, the author addressed the problem completely, also covering the different approaches of national courts and not leaving aside complex issues such as the potential liability (that Arezzo considers to be to ward off) of intermediary actors – such as

doctors who write blank prescriptions or pharmacists who make verbal suggestions to the consumers for cheaper drugs.

In the penultimate chapter, the book finally brings fully together patent portfolios and competition law, by studying, this time from the point of view of the latter, forms of exploitation – individually (via abuse of dominant position) or by anticompetitive agreements between undertakings (for instance, “reverse payment settlement agreements”) – of the protection granted by exclusive IP rights to exclude other competitors from the market. The author begins this sixth chapter with considerations about the potential tensions between the goals pursued by IP and competition law, highlighting the capability of the competition authorities to assess whether an anticompetitive conduct, caused by the strategic use of patents, can be justified, namely through innovation gains. To develop this issue, which as the author emphasizes must be assessed on a case-by-case basis, the book essentially explores the 2009’s European Commission (“EC”) Pharmaceutical Sector Inquiry and the EC and the Court of Justice of the European Union case-law (as well as some national decision-making practice, such as of the Italian Competition Authority). From classic cases, such as *Astrazeneca* (T-321/2005), to more recent ones, such as *Generics* (C-307/18) or even *Teva* (AT.40588, with Statement of Objections issued in 2022), the book focuses, for the purposes of applying competition law, on the issues of, on the one hand, the irrelevance of the compliance with other branches of law and, on the other hand, of the relevance of the undertakings’ anti-competitive intention. Finally, the book covers both refusal to deal and strategic patent filing cases, agreeing with the competition authorities’ approach of linking the theory of harm to the rationale of the patent system and its purpose of spurring innovations.

In the seventh and final chapter, the author highlights the main conclusions drawn from of the analysis carried out throughout the book, and suggests solutions, particularly legislative ones, to overcome some of the complex scenarios exposed.

III. Critical Analysis²

The book deals with recent trends and, to that extent, it is very pertinent. That being said, there were already several essays on the subject, both inside and outside academy.

² To ease contextualization, some of the critics were made in the previous parts.

As it became clear from the previous parts, the book is more about IP than competition law. The author makes references to competition law throughout the work but there are, in fact, two distinct parts to this book, with the first part, IP, deserving much more attention. Although the competition law section takes a smaller part of the book, from the point of view of a competition law scholar and practitioner (the only point of view we can speak from) reading this book was extremely instructive, contributing for understanding the legal contours of these IP phenomena and how they can restrict competition.

Curiously, while the first part of the book sometimes prioritises too much, in our opinion, literature over practice, as well as description – we would have liked to see more critical views from the author –, in the last chapters, which link IP to competition law, she focuses more on case-law and gives her opinion/contribution more often, making the reading more enjoyable and fruitful.

In addition, it would have been useful for the reader to have brief sub-conclusions at the end of each chapter. Indeed, since the subject is so dense and complex, a summary at the end of each chapter with its main ideas/conclusions would have helped the reader to retain them before moving on to the next chapter.

We also believe that there were useful contributions to the discussion that were not covered in the book, such as the Report on Competition Enforcement in the Pharmaceutical Sector, published in 2019 by the EC's Pharmaceutical Committee.

Finally, it is to be praised that the author did not limit herself to making an overview of the book's conclusions but suggested concrete solutions to the subsisting problems.

In the end, the main idea that remains from this work is that, while patent law textbooks still seem to tell the tale of the ground-breaking invention – one-innovation/one-patent model –, practice has radically changed, even in sectors where innovation exhibits a more unitary feature, like the pharmaceutical sector. While the cluster of patents rights in one undertaking is legal from the point of view of IP law, and even advisable to protect investments and research avenues, exploiting the competitive advantages granted by the patent portfolio to restrict competition may infringe competition law.

Concluding, this is a highly recommended book, especially for scholars and competition law practitioners who want to understand the complex scenarios that patent portfolios create.