METODOLOGIA GIURIDICA E POLITICA DEL DIRITTO

8

METODOLOGIA GIURIDICA E POLITICA DEL DIRITTO

La collana accoglie monografie e contributi che, pur essendo ascrivibili a molteplici ambiti del diritto, risultano caratterizzati da un lato dalla comune attenzione alle problematiche metodologiche connesse — alternativamente ma non necessariamente disgiuntamente — ad un approccio gnoseologico al diritto e ad una riflessione sul concreto operare giuridico; dall'altro all'analisi delle modalità attraverso le quali le attività di produzione normativa e di applicazione del diritto si trasformano in orientamenti non solo giurisprudenziali ma anche sinergici (e per taluni versi anticipatori) rispetto alla declinazione attuativa delle politiche programmatiche nei vari ambiti di riferimento.

VICTORIA FORTINI

UNDERSTANDING THE VALUE OF TECHNOLOGY

LEGAL AND TECHNICAL REFLECTIONS ON TECHNOLOGY TRANSFER IN THE LIFE SCIENCES

Foreword by

MARIO DI GIULIO

With an introductory chapter by

CLARISSA CERUTI

aracne

ISBN
979–12–218–2120–8

FIRST EDITION
ROMA SEPTEMBER 1ST 2025

To my beloved little son,
who has amazed, challenged, encouraged,
embraced, and loved me,
and has taught me to love in a better way.
So that he may know.

And to my husband,
who has been by my side and supported me
every step of my career, patiently encouraging me
and challenging me when necessary.
He is not a lawyer, but he is the person
who understands every word, every emotion,
and every challenge of this work more deeply
than anyone else, because he has lived every stage
of my studies and professional journey with me, shar-
ing in every joy, every drop of sweat,
and every tear.
He has shared, and will always share, with me
the capacity for deep sensitivity and a restless soul,
which is the reason why we embrace the Night —
that Romantic yearning, that infinite longing
that keeps us from standing still and always pushes us
to seek more.
Because that is who we are.

The picture on the previous page shows the staircase of the Paris building where my dear friend Nunù currently lives. It's a way to remember the special times I spent visiting her and the precious moments we shared. One of the most valuable things she ever told me was to try to live in line with my truest desires. She is one of the rare souls with whom I've felt a profound and genuine affinity.

TABLE OF CONTENTS

FOREWORD

BY MARIO DI GIULIO[1]

The book offers an opportunity to reflect on the different and varied relationships that may occur between the law and the underlying reality (the reality that the law aims to govern).

In this framework, it is worth noting that this relationship can vary in different cases: sometimes it is the law that determines changes in reality, sometimes it is the ever–changing reality that determines the development of the law.

The starting point is each state's attempt to guide what happens based on what the legislator wants to happen. Experience and practice teach us that sometimes this desire remains just a wish.

Indeed, there are many areas of law (such as the law regulating family relations) that are only partially influenced by the reality during the law–making process, since the law can force or guide reality based on the opinions or religious convictions of the legislator (for example monogamous family versus polygamous family). On the contrary, there are other fields in which the rules are the result of needs that emerge from experience gained in the real field of human activities.

One of the latter cases occurs when the law regulates (or attempts to regulate) technology.

Here innovation indicates a direction and the law tries to govern it, often chasing something that is always one step ahead.

[1] Partner at the international law firm Pavia e Ansaldo. He serves as a university professor and participates in scientific committees. He is the author of numerous legal publications, contributing authoritatively to education and the development of the field.

In this case, the aim of the legislator and legal practitioners is first of all to understand what is happening, what are the interests at stake and then create or find the solution to the needs that emerge daily.

The Life science are one of the cases where the above run–back occurs most, with implications that go beyond the mere need to protect the parties from a transaction. In fact, there are many interests worthy of protection that go beyond the entities directly involved and are common to the entire society, so much so that life science also involve ethical and moral issues.

The book captures these connections and interactions well thanks to the combination of legal expertise and technical–scientific knowledge that informs its perspective.

The knowledge presented in this work is acquired through studies and enriched by experience in the fields, so that the analysis is not limited to an academic approach that could limit a fruitful reading without real implications, nor to a practical approach that could limit the reader to a partial vision of the matters.

Last but not least, the book opens readers' reflections to ethical considerations that legal practitioners normally limit only to theory when they study philosophy of law.

Thus, one more reason to read it.

PREFACE

BY VICTORIA FORTINI

In the commercial and M&A sector where I worked for many years as a legal professional, I engaged with a wide range of industries. Of course, you might specialize in a few, but the variety is part of the job. It took me some time to identify an industry I wanted to dive into with true passion. Eventually, I found that in the Life Science. After about a decade working in law firms, I transitioned to an in–house legal role in the MedTech sector. I immediately loved the field.

Thus I told myself, "Raise the game": it was time to step up. I decided to immerse myself in the Life Science world with the utmost dedication, approaching it from every possible angle. My goal was to elevate the intensity and quality of my expertise in this field. I worked on strengthening foundational hard skills, both legal and beyond — studying topics like human anatomy, market research, and policy frameworks. I also wanted to explore the topic of technology transfer in the Life Science in depth. The legal documents I had studied left me feeling incomplete and unsatisfied. At one point, I signed up for a course organized by a training company, featuring a renowned speaker in the field. Unfortunately, the course was canceled on the scheduled date. I try to embrace a mindset of serenity in accepting things I cannot change, but also the courage to act on the things I can. So instead of waiting for the course to be rescheduled, I decided to contact the speaker directly and ask if we could have a conversation about the topic anyway. She was a leading expert in the field — not a legal professional — but someone who could teach me the technical and scientific knowledge I needed to complement my legal expertise. This turned into a private course, where I learned so much. We discussed

technology transfer in the Life Science, combining our cross–disciplinary knowledge of the field. By the end of the course, I couldn't resist asking her if she would be interested in collaborating on a publication about technology transfer. Our discussions were far too stimulating to end there. To my delight, she agreed. That remarkable professional is Clarissa Ceruti, and today she is not only my co–author for this work but, with great joy, I can also call her a dear friend.

This work delves into technology transfer within the the life science, presenting a distinctive perspective. Technology transfer inherently connects multiple disciplines, especially in the life science, which draw upon a broad spectrum of fields and areas of expertise. Rather than creating confusion, this interplay of knowledge is viewed as a source of enrichment, providing a wide array of valuable insights. While a wealth of literature exists on the subject from different angles, this work introduces a fresh and innovative perspective.

Chapter I, authored by Clarissa Ceruti, provides a comprehensive introduction to Technology Transfer in Life Sciences, covering key concepts, evaluation criteria, and a brief overview of Open Innovation. This chapter lays the essential foundation for the legal analysis found in the following chapters.

Chapters II through VI, authored by Victoria Fortini, present a legal analysis of technology transfer in life sciences, combining rigorous legal insight with a creative and culturally informed approach. The work examines both technical–legal issues and broader cultural contexts, including historical and theoretical perspectives, while maintaining a strong focus on real–world applications. Law is portrayed not just as a system of rules, but as a living framework shaped by — and capable of shaping — history, economics, and culture. Inspired by the traditions of major European legal schools, the text positions legal science as a discipline that "cares for" the complexity of reality. By integrating theory with practice, this work weaves together key themes such as legal doctrine, the evolution of legal thought, statutory interpretation, and the economic dimensions of law. Designed for reflective and intellectually curious readers, it offers a stimulating and accessible exploration of legal thinking in action.

Enjoy the read!

CHAPTER I

TECHNOLOGY TRANSFER IN THE LIFE SCIENCE (NOT JUST AN) INTRODUCTION

BY CLARISSA CERUTI[1]

This introductory chapter provides a fundamental overview of Technology Transfer in the Life Science, presenting key concepts, evaluation criteria, and a concise look at Open Innovation. It lays the groundwork for the legal–focused chapters that follow, offering a preliminary understanding of essential notions that are further explored particularly from a legal standpoint.

1.1. Technology transfer process

Technology transfer (or tech transfer) is the process by which technology is transferred from an entity, usually an organization or one or more inventors that developed the technology, to another entity, usually a company, that should be responsible for advancing such technology to a point it becames a new product or service that benefits society.

Although the definition of technology is the use of scientific knowledge to create tools, techniques, and processes that solve problems, in this contest, technology has a broader meaning that indicates an invention, a patent application, a patent, or a technology that has the potential to solve a problem and ultimately benefits society.

[1] Clarissa Ceruti, with a PhD in biochemistry and an MBA, has bridged science and business across Italy and the US. She worked at Harvard, MIT, Abcam, Fox Chase, and BioIndustry Park. Now Executive Director of ISSNAF, and tech transfer advisor in Bugnion SpA, she consults in biotech and teaches innovation and tech transfer in Italian universities, with a passion for mentoring future entrepreneurs.

Technology transfer is mostly attributed to inventions generated in academia, but it can also occur in a company whether big or small.

The tech transfer is a complicated process that involves multiple steps and requires technical expertise, intellectual property familiarity, contract law knowledge, negotiation skill, business acumen as well as gathering information about the potential market, IP landscaping, and a valuation of the technology — to name a few.

The journey starts with an invention resulting from research. Often, research, invention, and innovation are used as synonymous, but they are not. Research is the result of a hypothesis. If the research has a practical application, then it becomes an invention, and the invention becomes an innovation once it is proven to have a market. An example to show this concept is the researcher who studies thermodynamics and the entrepreneur who sells the toaster. The principles of thermodynamics (research) have a practical application in heating food (invention), a phenomenon that can be exploited in developing the toaster (innovation), a product that has a market because it solves a need: heating and toasting the bread.

The invention is disclosed to the tech transfer manager, meaning the inventor or inventors have to fill a form describing the invention in great details and providing information about its technical features, benefits, limitations, technology readiness level (TRL), status of the IP, collaborations, and name of companies that might be interested in this invention.

TRL is a type of measurement system developed by the NASA and «used to assess the maturity level of a particular technology. Each technology project is evaluated against the parameters for each technology level and is then assigned a TRL rating based on the projects progress». The TRL scale has nine levels. TRL 1, the lowest, indicates that basic research is showing promising results and TRL 9, the highest, that the product is ready to be commercialized.

The levels in between grade the maturity of the technology up to its readiness for the market uptake. This system is also important to define what steps should be taken to bring the technology to the market and, in doing so, to determine the amount of investment needed in each step.

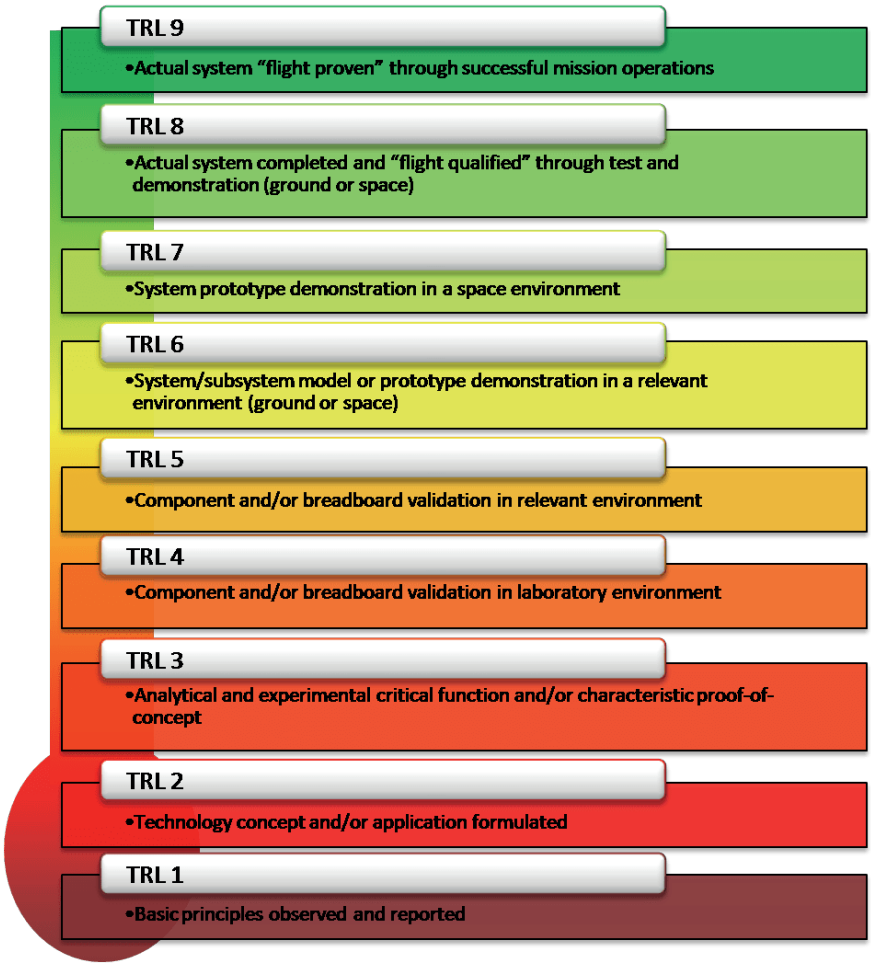

Figure 1.1. The Technology Readiness Level (SOURCE: https://www.nasa.gov/directorates/somd/space-communications-navigation-program/technology-readiness-levels/).

The TRL is an important metric to communicate to the entity interested in advancing the technology, namely investors, licensees, or startuppers.

Examples of the TRL steps for a drug are shown in Tables 1.1 and 1.2.

Table 1.1. Example of a TRL for a drug (SOURCE: https://euraxess.ec.europa.eu/career-development/researchers/manual-scientific-entrepreneurship/major-steps/trl).

+	TRL 1 Findings reviewed
+	TRL 2 Research idea
+	TRL 3 Design proof of concept
+	TRL 4 Demonstrate proof of concept
+	TRL 5 Pilot drug produced
+	TRL 6 Phase 1 clinical trials
+	TRL 7 Phase 2 clinical trials
+	TRL 8 New drug registration
+	TRL 9 Drug distributed and marketed

Table 1.2. Phases of R&D and TRLs in drug development (SOURCE: ÅRDAL C., BARALDI E., THEURETZBACHER U. *et al.*, *Insights into early stage of antibiotic development in small– and medium–sized enterprises: a survey of targets, costs, and durations*, «J of Pharm Policy and Pract», 11, 8 (2018). https://doi.org/10.1186/s40545-018-0135-0).

R&D Phase	Description	TRL
Research – Discovery activities, hit generation and testing	Generation of chemical starting points (hits) from screens or other drug discovery strategies	2
Research – Lead compound identification	Hits are evaluated and undergo limited optimization to identify promising lead compounds with meaningful activity against the target pathogens and possess the properties needed to make an effective and safe drug	3
Research – Lead compound optimization	Modifying and testing lead compound series to improve compound properties; selecting a candidate drug for further preclinical studies	4
Development – Preclinical testing	Conducting required toxicity and efficacy *in vitro* and *vivo* studies under good laboratory practice (GLP) protocols, and chemistry, manufacturing and control (CMC) studies	5
Development – Phase I clinical trials	Testing the candidate drug in healthy volunteers to determine pharmacokinetics, safe dose ranges and identify common toxicity; pharmacokinetic data feed into pharmacokinetic/ pharmacodynamic (PK/PD) models to determine the most appropriate doses for the next phase	6
Development – Phase II clinical trials	Testing the candidate drug in a small number of patients to obtain preliminary efficacy data and more short–term safety information; refining PK/PD models	7
Development – Phase III clinical trials	Testing on a larger number of patients to document efficacy, determine non–inferiority activity (or rarely superiority) and safety compared to other indicated drugs	8