



Edited by
Emanuela Arezzo • Gustavo Ghidini

Biotechnology and Software Patent Law

A Comparative Review of
New Developments

NEW DIRECTIONS IN PATENT LAW

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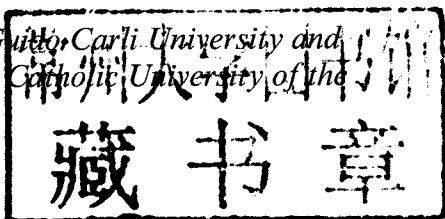
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NEW DIRECTIONS IN PATENT LAW

Edward Elgar

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Introduction

Emanuela Arezzo and Gustavo Ghidini

In the last and present century patent law has confronted itself with several critical issues. Emerging new technologies have seemingly shaken some of the very foundations of the system, modelled to accommodate the needs of the industrial sectors which emerged during the first industrial revolution. Thus, many commentators began to wonder whether it was still appropriate to maintain the traditional paradigm as it is, exclusively based on exclusive rights.

In the new millennium, not only have new sectors emerged but each one has developed its own features with regard to its own innovation process and the kind of output produced. Often the inventive process develops through a cumulative and incremental path, leading to small improvements built upon the knowledge entangled into previous innovations, rather than a sudden breakthrough innovation. Often, too, such inventive process leads to results which lie closer to pure knowledge than applied research. What is the role patent system plays in such a scenario? In particular, considering the different dynamics of innovation among ‘old’ and ‘new’ technological sectors – such as ITs and biotechnologies – should such a role be the same across all industries? Put another way, is the classical formula ‘one size fits all’ still appropriate for a twenty-first century patent system?

These questions have been posed and examined in the first two chapters of this book, respectively by Dan Burk and Mark Lemley, and by Valeria Falce.

In addressing such questions, it remains crucial not to lose track of the baseline assumption: patents are just a means to an end, which is the spurring of innovation. In sequence, ‘which innovation’ is worthy of patent protection is another fundamental issue that has recently re-emerged in both European and American jurisprudence. If patent protection is tailored to protect inventions, what is an ‘invention’ for the purpose of the patent system? In past years the concept of invention has been used to rule out some subject matters from the realm of patent law, this especially in the European patent tradition where that concept is intertwined with the

category of excluded subject matters listed in art. 52, 2° of the European Patent Convention. But what are the boundaries of patentable subject matter and how should they be construed? This intriguing issue has been deeply examined in the third chapter, devoted to the future of the requirement for – the existence of – an ‘invention’ in (European) patent law, by Justine Pila.

A proper construction of the concept of patentable subject matter obviously has an enormous impact on follow-on innovation. Drawing the line of what cannot be the subject of a patent appears of paramount importance as it outlines what room is left for other inventors to ‘take’, wholly or in part, the knowledge that has been used to make a previous patentable invention. In fact, not everything described and claimed in a patent document is excluded *tout court* from the public domain. The claims may contain reference to materials or tools which are widely known to technicians or whose protection has expired. However, thanks to the mandatory disclosure of patented inventions, even patented knowledge (i.e. the knowledge effectively claimed and embedded into a patent) should be, and actually is – albeit to varying extents related to specific different legal environments (just think of the EU and US) – at the disposal of other inventors for research purposes. What room exists – and should be preserved – for the application of the so-called ‘research use’ exemption is another crucial issue dealt with by one of the most fervent advocates of freedom of research, Vincenzo Di Cataldo.

The first part of the book ends with a contribution by Steve Anderman. While Justine Pila and Vincenzo Di Cataldo explore the pro-competitive ‘antibodies’, so to speak, built in within the patent system, Steve Anderman explores a second and ‘external’ source of pro-competitive limitations, namely: competition law. Although antitrust remedies have been mainly applied to cases involving copyright law, Steve Anderman argues that patents are well suited to be the next candidates.

The second and third parts of the book have been devoted to specific issues relating to the two sectors characterizing the contemporary stage of technological development: information technologies and biotechnological inventions.

Specifically, the second part of the volume concerns software and business methods inventions. Here, Reinier Bakels vividly challenges the idea that software patents really represent a category by itself. As is well known, patent protection of software *seems* to be banned in Europe by art. 52, 2°, lett. c) the European Patent Convention. Yet thousands of so called ‘software patents’ have been issued by the EPO since the end of the 1980s. So, what is a ‘software patent’ and how does it differ from other patents? Is software a product or a piece of technology used to make

products, hence just a means to build an invention? A tentative answer to this question is also provided by the contribution by Reto Hilty and Christophe Geiger, whose attention is devoted to verify to what extent software should be the subject of patent protection and whether the latter really is the most appropriate tool to promote innovation in such a field of technology. In particular, the authors also take into consideration copyright law, as alternative tool of protection initially chosen by American and European legislators to protect software instead of patents. The authors contend that although copyright rules have been specifically adapted to confront the needs of the information society, this tool of protection has proven to be unsatisfactory as it only works against mere unauthorized copying of the program. Is then patent law the right answer? Several European commentators are not satisfied with the 'technical contribution concept', as recently developed by the EPO. The authors try to work out what the most appropriate means of protection should be, taking into consideration the associated economic and social consequences.

This section ends with the chapter by Jay Thomas who brilliantly provides us with an American perspective on the debate. As in Europe with the recent decision of the EPO Enlarged Board of Appeal, in the United States the boundaries of patentable subject matter have been (or should have been) reassessed by a recent Supreme Court decision (*Bilski v. Kappos*, 2010). It seems, however, that the so much awaited judgment has not brought the clarity and guidance it was supposed to. In fact, while the decision sounds like a ban on the patentability of business methods and abstract ideas in general, it does not shed any lights on the test or methodology to be used to concretely rule out such subject matters from patent protection. The contribution is particularly interesting as the author uses his analysis of the *Bilski* case, framing it, in historical perspective, within the recent line of decision by the Supreme Court, hence eventually challenging the widespread idea that judicial decisions always provide the best mechanism to reform patent law in the United States.

The last part of this book has been devoted to the study of the most intriguing issues which have recently emerged in the field of biotechnology. This section opens with a chapter by Sven Bostyn, a critical review of the European biotech directive after its recent tenth anniversary. Bostyn elucidates lights and shadows of this highly controversial piece of legislation which, nonetheless, had the courage to set the basis for common provisions on the patentability of such critical subject matters as the biotech inventions.

The section continues with Chris Holman's chapter on the patentability of genes in the USA. Long before the adoption of the EU biotech

Directive, the United States' Supreme Court in the famous *Diamond v. Chakrabarty* case paved the way to the patentability of biotechnologies. Today, the PTO Guidelines of 2001 have taken the position – very close to the provisions of the EU Directive – that even the mere isolation of a naturally occurring DNA sequence can result in a patentable product insofar as it differs from the gene sequence as it exists in nature. Nonetheless, the issue of biotech patentability, especially with regard to gene patents, is far from being entirely settled. Several commentators and scientists still fervently oppose the patentability of such innovations, arguing that they impede rather than foster scientific progress. Holman takes the lead from the recent controversy brought by the American Civil Liberties Union (ACLU) against Myriad Genetics (exclusive licensee of the well known patents regarding genetic diagnostic testing for mutations in the BRCA1 and BRCA2 breast cancer susceptibility genes) to analyse the societal costs and benefits of gene patents, as well as their function in biotechnology research and innovation.

The third contribution of this section is focussed on the patentability of human stem cells. Patentability of human, and especially embryonic, stem cells has become a pivotal issue in biotechnology as such cells have proved to be crucial instruments in developing breakthrough research paths in the cure of several complex diseases. Unfortunately, this subject has been inconsistently dealt by the EU biotech Directive which on the one side does not address stem cells' patentability, and on the other side poses a strong veto on the patentability of inventions using human embryos for industrial or commercial purposes, leading interpreters to question whether embryonic stem cells may be covered by a patent. Paul Torremans' chapter analyses this topic, examining whether stem cells pose any patentability issues with regard to either the categories of patentable subject matter or their compliance with patentability requirements (this, even with regard to ethical considerations).

This section ends with Andrea Ottolia's chapter providing an in-depth study of the intersection between patent law and ethics which, in this area of technology, proves more problematic than ever. Many commentators feel that patent law does not represent the appropriate framework where ethical considerations should come into play. However, the discipline embedded in art. 6 of the biotech Directive and 53(a) of the EPC, together with rule 28 of its Implementing Regulation, has provided much of a leeway for Courts and Patent Offices to elaborate a test strongly influenced by ethical considerations. However, this kind of considerations is deeply intertwined with national cultures and values, as it is clearly reflected especially in the jurisprudence of the EPO Examining Divisions. Ottolia's chapter offers a critical analysis of the morality test developed by the

EPO jurisprudence from the *Oncomouse* case to the recent *Warf* decision, advocating that while exceptions to patentability rules might not be the right instrument to squeeze ethical considerations into patent law, they may nonetheless play, if properly interpreted and construed, a significant role in the harmonization of the system, even to the benefit of the internal market.

Emanuela Arezzo and Gustavo Ghidini
November 2011

PART I

General themes in patent law

1. Tailoring patents to different industries*

Dan L. Burk and Mark A. Lemley

INTRODUCTION

Patent law is our primary policy tool to promote innovation, encourage the development of new technologies, and increase the fund of human knowledge. To accomplish this end, patent statutes create a general set of legal rules that govern a wide variety of technologies.¹ In theory, we have uniform national patent systems that provide technology-neutral protection to all kinds of innovation.

Technology is anything but uniform, however, and it displays highly diverse characteristics across different sectors. A wealth of empirical evidence demonstrates deep structural differences in how industries innovate. There is no reason to assume that a unitary patent system will optimally encourage innovation in the wide range of diverse industries that it is expected to cover.

This seeming paradox – a monolithic legal incentive for wildly disparate industries – is resolved by the realization that, despite the appearance of uniformity, patent law is actually as varied as the industries it seeks to foster. A closer examination of patent law demonstrates that it is unified only in concept. In practice the rules actually applied to different industries increasingly diverge. As a practical matter, it appears that although patent law is technology-neutral in theory, it is technology-specific in application.

The differential application of patent standards to different industries correlates with a larger theoretical confusion in patent law. While most theorists agree on a general utilitarian framework of patent law – that is, they agree on the goals the patent statute is intended to achieve – they have offered radically different ideas for interpreting patent law to achieve

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¹ 35 U.S.C. §§ 100–212 (2000).

those goals. We suggest that none of these theories is entirely correct. Neither are they entirely wrong. Rather, like the blind men examining the proverbial elephant, theorists have approached patent law with the needs and characteristics of particular industries in mind, and have developed a general theory of patent law based on an understanding of innovation that is industry-specific and, therefore, necessarily incomplete.

The fact that economic evidence, patent doctrine and legal theory all vary by industry leads us to question whether patent law should explicitly attempt to tailor protection to the needs of specific industries, as many have suggested. We point out a number of risks inherent in such a technology-specific approach, particularly as it has been applied in the legislature. These risks suggest that policy-makers should be cautious about trading our uniform patent system for an industry-specific one.

Instead, there are other ways the law can take account of the needs of different industries. It makes sense to take economic policy and industry-specific variation into account explicitly in applying general patent rules to specific cases. Patent law leaves substantial freedom to do this by means of flexible legal standards we call 'policy levers' that can be applied by courts or in some cases by agencies to modulate an ostensibly uniform patent law to meet the needs of specific industries.

HETEROGENEITY IN INNOVATION AND PATENT LAW

In the last 20 years, legal and economic scholarship has provided valuable evidence about the complex process of innovation and how the patent system affects innovation. Rather than resolve debates over how well the patent system works, however, this evidence has painted a more complex picture.² For innovation, one size definitely does not fit all. This observation is graphically illustrated by examples from several industries.

The Industry-specific Nature of Innovation

The industry-specific components of innovation fall into several categories. First, the cost of R&D varies widely from industry to industry and from

² See generally Brett Frischmann, *Innovation and Institutions: Rethinking the Economics of U.S. Science and Technology Policy*, 24 *Vt. L. Rev.* 347, 351 (2000) (arguing that innovation is more complicated than traditionally understood by policy-makers).