

Biotechnological Inventions

Revised Edition

Moral Restraints and Patent Law

OLIVER MILLS

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OLIVER MILLS

National University of Ireland, Galway



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Preface to the Revised Edition

The biotechnology industry is at the cutting edge of scientific research and innovation. The result is that communities, human and non-human, stand on the threshold of an extraordinary revolution that will have profound effects on their relationship with other creatures and the environment. This has resulted in much political debate because countries have fundamentally differing views about biotechnology. In addition, there are divergent views concerning the legal, moral, ethical and social problems connected with the technology. In order to orchestrate an informed debate among the public about the practice and application of biotechnology, scientists and non-scientists alike must work together in an effort to understand what biotechnology can and cannot do. While scientists are capable of identifying the potential advances in the fields of healthcare, agriculture and the food industry that might flow from the commercial application of the technology, only the public can decide their degree of importance and assess the benefits, hazards and impact. Such fundamental decisions can be made only within a properly constituted framework. Law can provide the mechanisms that facilitate the taking of necessary decisions about the nature and direction of both research and policy. In this regard, there are moral objections both to the technology itself and the patenting of biotechnological inventions. The patenting process stands at the confluence of science and technology, on the one hand, and law on the other. In several respects, the intertwining of two disciplines creates tensions not only at the national, but also the international, level. Problems arise because there are differences in matters such as: concepts justifying patent protection; patent law as a matter of economic policy; and patent law as an integral part of the general legal system of the country concerned.

Biotechnology has always been part of our heritage. However, it has been of special concern only since the novel use of organisms in the context of DNA structure was discovered. While developed initially in the area of lower organisms, modern genetic technologies are increasingly applied to more complex biological entities, giving rise to previously unknown, or little-known, concerns of a moral nature.

The advent of biotechnology has posed significant challenges for patent law. As in any legal system there are areas of contention and uncertainty as to the application of legal provisions to particular fact situations. The nature of the subject-matter gives rise to complex conceptual, theoretical and moral questions, particularly in regard to the application of exclusions to patentability of biotechnological inventions.

In its first edition, published in 2005, this book outlined the moral debate surrounding biotechnology and the patenting of biotechnological inventions. The aims of the European Patent Convention were examined and showed that a 'light' moral regime was intended. This compared favourably with the approach to the question of morality in the United States. The book also examined European Patent Office jurisprudence in the light of the policies underlying the exceptions to patentability; in regard to UK Patent Office jurisprudence the cases demonstrated that sufficient difficulties arise when traditional substantive patent law criteria are applied to new technologies without additional assessment of moral concerns. This was compared with protection available to innovators in the biological field in the United States. The Biotechnology Directive 1998 was outlined and assessed in order to determine the extent to which it allows the European Patent Office and national patent-granting authorities to interpret in the same way those provisions of patent law that apply to biotechnological inventions. In addition, the book examined why plant variety rights systems form a part of the critique of the Directive. In European states, developments showed an attempt by the European Union and European Patent Office to confine morality to commercial situations and to bring the European Patent Convention within the confines of the EU.

In such a fast-moving field as biotechnology there has been a plethora of new published material. Much of this emphasizes the higher public profile of debates associated with the technology and includes ethical and privacy issues surrounding the development of bio-banking, including cord blood banking and DNA profiling, and issues surrounding new therapeutic applications in regenerative medicines. Such subjects are undoubtedly interesting but are clearly outside the scope of this work, which is concerned with the legal framework associated with biotechnological inventions.

While there have been no radical changes to the law since publication of the first edition in 2005, there has been a steady accretion of the law. In this regard, the revised edition outlines developments and continues with a focused discussion of specific legal provisions. In particular, the Revised European Patent Convention 2000 (in force 2007) is important. It now incorporates the Biotechnology Directive 1998, and in this regard, Rule 28 EPC 2000 and Rule 29 EPC 2000 are examined to determine the extent to which harmonization of law has been facilitated. Public policy, and changes relating to Article 52(4) EPC 1973, now appearing as the new Article 53(c) EPC 2000, are examined. The revised edition reviews case law developments and examines, in particular, the application of Article 53(a) in relation to stem cells and human genetics. Additionally, new cases have been included to assess whether or not consistency of practice has been achieved by the courts in respect of more traditional patentability criteria. Monitored also through case law developments is how patent law reform in Europe, through the European Patent Office, is expanding; in contrast, patent law reform in the United States, through the Patent and Trademark Office, may now be curtailed. Also discussed are the most recent European Commission communications which highlight the importance of the link between patents and innovation. The European Commission

Proposal for a Regulation is aimed at creating a new unitary industrial property right, the Community patent. This, the Commission believes, is essential for eliminating the distortion of competition resulting from the territorial nature of national protection rights.

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Readers are advised that any shortcomings in the revised edition are solely my responsibility and that no liability will be accepted in respect of any reliance thereon.

List of Abbreviations

AIPPI	International Association for the Protection of Industrial Property
ASSINEL	International Association of Plant Breeders for the Protection of Plant Varieties
BIRPI	Bureaux internationaux réunis pour la protection de la propriété intellectuelle
CAFC	Court of Appeals for the Federal Circuit
CCPA	Court of Customs and Patent Appeals
CPVR	Community Plant Variety Rights 1994
ECHR	European Convention on Human Rights
ECJ	European Court of Justice
EEC	European Economic Community
EFTA	European Free Trade Area
EGE	European Group on Ethics in Science and New Technologies
EPC	European Patent Convention
EPO	European Patent Office
EPOR	European Patent Office Reports
EU	European Union
FSR	Fleet Street Reports
GAEIB	Group of Advisors on Ethical Implications of Biotechnology
OJ	<i>Official Journal</i> of the European Communities
PCT	Patent Cooperation Treaty 1970
PIP	1883 Paris Convention for the Protection of Industrial Property
PPA	1930 Plant Patent Act
PTO	US Patent and Trademark Office
PVPA	1970 Plant Variety Protection Act
RPC	Reports on Patent Cases
TRIPS	1994 Agreement on Trade-Related Aspects of Intellectual Property Rights
UPOV 1961	International Union for the Protection of New Varieties of Plants 1961 Act
UPOV 1991	International Union for the Protection of New Varieties of Plants 1991 Act
USC	United States Code
USPQ	United States Patent Quarterly
WIPO	World Intellectual Property Organization

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