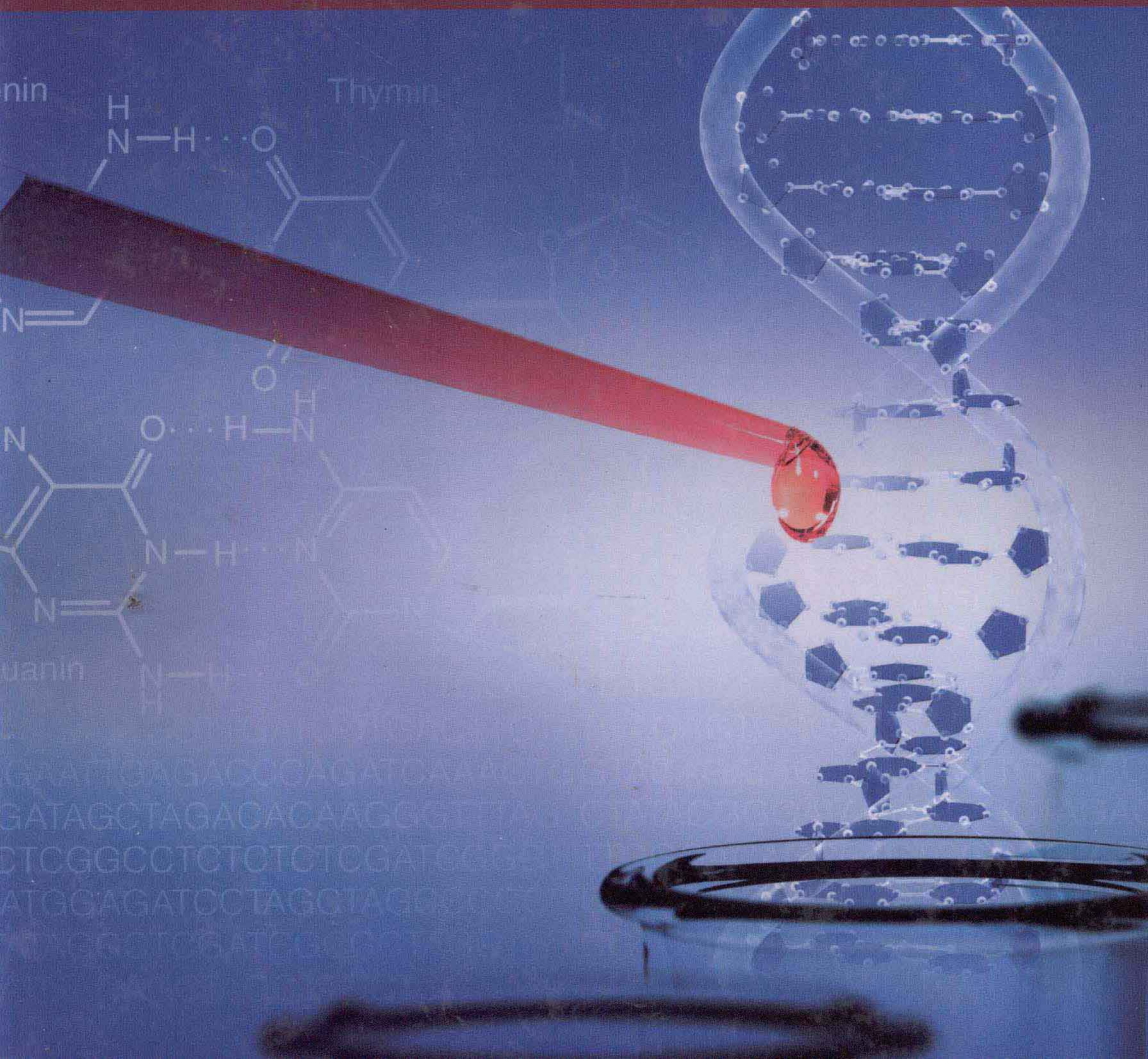
Medical Patent Law

- The Challenges of Medical Treatment

Eddy Ventose



Medical Patent Law – The Challenges of Medical Treatment

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List of abbreviations

Courts and Tribunals

Court of Appeal of England and Wales	CA
Enlarged Board of Appeal of the European Patent Office	EBA
Federal Court of Australia	FCA
High Court of Australia	HCA
High Court of England and Wales	HC
New Zealand Court of Appeal	NZCA
Patent Appeal Tribunal	PAT
Patent Office Board of Appeal (US)	POBA
Technical Board of Appeal	TBA

Legislation and Conventions

United Kingdom Patents Act 1977	1977 Act
European Patent Convention 1973	EPC 1973
Trade Related Aspects of Intellectual Property Rights	TRIPs
Medical Procedures and Affordability Act 1996	MPAA
Patent Convention Treaty	PCT
Genomic Research and Diagnostic Accessibility Act	GRDA

Organisations and Bodies

America Medical Association	AMA
European Patent Office	EPO
US Patent and Trademark Office	USPTO
World Medical Association	WMA

Others

Cornish, Llewellyn and Aplin, *Intellectual Property: Patents, Copyright, Trademarks and Allied Rights* (7th edn, Sweet and Maxwell, London 2010)	Cornish, Llewellyn and Aplin, *Intellectual Property*
Bently & Sherman, *Intellectual Property Law* (3rd edn, Oxford University Press, Oxford 2008)	Bently & Sherman, *Intellectual Property*
Base Proposal on the Revision of the European Patent Convention Munich (29 Nov 2000) MR/3/00 Rev	Base Proposal 2000
EC Directive on the Legal Protection of Biotechnological Inventions 98/44/EC of 6 July 1998, (1998) OJ L213/13	Biotech Directive

Foreword

Since its inception in the Statute of Monopolies, modern patent law has been remarkably adroit in adapting to the changing needs of inventors and industry. But changes in innovation and in the developed economies over the last 50 years have arguably put more acute pressures on the conceptual framework of the law than any it has encountered in its history. Those pressures have revealed how fragile are some of the distinctions – such as that between invention and discovery – that patent law has always taken for granted. They have pushed policy makers and lawyers back to the much contested, and often contradictory, justifications for the grant of the patent monopoly, even though those justifications have often had to be retrofitted onto the existing structures of the law.

One of the interesting things about those pressures is that they have often brought into the spotlight curious byways of the law; they have made issues that might once have been thought to be of merely scholarly interest commercially vital. It is in the consideration of these issues that the contradictions of patent law and policy have often become most plain.

In this way, enormous changes in the economics of the health system, in the way in which doctors regard their professional calling, and in patterns of healthcare innovation, together with contemporary expectations that all (or at least most) innovation should be rewarded, have put huge strain on the exclusion from patentability (however technically it may be achieved) of methods of medical treatment. The conceptual basis of that exclusion, while not robust, draws upon many other fundamental assumptions in the law of patents and, properly examined, opens up many of those assumptions themselves for further consideration.

This book is a careful, timely, and thorough treatment of what is therefore a question, not only of increasing commercial importance, but also of enormous intellectual interest. As its author teases out the policy underpinnings of the exception and the arguments against it, we get not only a helpful guide to this area of the law and its development, but a deeper understanding of patent law as a whole. I have no doubt that it will be of great interest not only to researchers and academics, but to practitioners and policy makers as well. Dr. Ventose is to be congratulated on a significant contribution to a growing and complex area of the law.

Dr. Michael Spence
The Vice-Chancellor and Principal
University of Sydney

Preface

The idea that the issue of excluding methods of medical treatment from patent protection could have generated enough material on which to write a thesis, let alone a book, would have startled anyone 10 or so years ago. But the question of patent protection for methods of medical treatment, which comprises therapeutic methods, surgical methods and diagnostic methods, has been debated and resolved with different results in Europe, the United States and some Commonwealth countries. The rationale for the exclusion from patent protection – one might say justifiably so – is to ensure that the activities of physicians when they treat their patients are not hampered by patents. The notion of a physician being able to secure a patent on a life-saving medical treatment has perhaps most potently put the idea of patent protection for such treatments beyond question. The exclusion for methods of medical treatments in Europe is seemingly here to stay, whereas in the United States the courts have revived the debate of whether they should be excluded from patent protection.

This book is divided into 11 chapters. Chapter 1 is the introduction. Chapters 2 and 3 examine the arguments of principle and policy that are usually made for and against patent protection for methods of medical treatment. What then marks the difference between the availability of patent protection in some countries and the lack thereof in others? Article 27(3)(a) of the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement provides that Members may exclude from patent protection diagnostic, therapeutic and surgical methods for the treatment of humans or animals. So either way, there would be compliance with this agreement. Sitting on the fence on this important issue is not comforting for those medical or veterinary practitioners, patients, inventors and pharmaceutical companies who all have a vested interest in the patentability or otherwise of methods of medical treatment. The arguments made in these two chapters put the debate in an appropriate context.

Chapters 4–6 deal with the exclusions from patentability under the European Patent Convention (EPC), namely, therapeutic methods, surgical methods and diagnostic methods respectively. It is in these three chapters that the fascinating legal framework for the exclusion of methods of medical treatment, which is found in a single provision, Article 53(c) EPC, is to be found. The scope of the exclusion and how it is to be

interpreted in light of competing considerations have, therefore, taken centre stage in Europe. The Technical Board of Appeal (TBAs) of the EPC have been delineating the scope of the exclusion in the last 38 years and the Enlarged Board of Appeal of the European Patent Office (EBA) has had to intervene in delineating the scope of the exclusion on four occasions: 1985 (second medical uses); 2004 (diagnostic methods); 2010 (surgical methods); 2010 (dosage regimes), with the effect that many of the troubling issues have been laid to rest by these decisions. Chapter 7 follows suit with an examination of the vexed question of patent protection for second and further medical uses, including that relating to dosage or treatment regimes under the EPC. Where appropriate, these chapters will also examine the exclusion in light of new technological advancements in medical treatments and considers other EPC exclusions that might be implicated in respect of these new technologies.

Chapter 8 considers the historical basis for the exclusion in the United Kingdom before 1977, examining its jurisprudential bases over the years, concluding with an examination of the position in New Zealand and Australia whose patent legislation is still based on pre-1977 UK patent law. Chapter 9 continues the examination of UK law by examining how UK courts have applied the decisions of the TBAs and the EBA relating to the exclusions (therapy, surgery and diagnosis), second and further medical uses and, most recently, dosage or treatment regimes. Chapter 10 considers the position in the United States of America, namely of the US Patent and Trademark Office (USPTO), legislative intervention and recent examination of the issue of patenting diagnostic methods by the Federal Circuit and the Supreme Court.

This book originated from my thesis completed as part of my doctorate at the University of Oxford between 2001 and 2004. The thesis has now been substantially expanded, revised and completely reworked to form this book. I wish to thank the Clarendon Fund Scholarship which funded my doctoral research. I am grateful for my supervisor, Dr Michael Spence, Vice-Chancellor and Principal of the University of Sydney, for his excellent supervision and my examiners, Dr Justine Pila and Dr Jenifer Davis, for their constructive comments. Special thanks to Chantal, Dimitrios, Faye, Gareth and Matt, for their unfailing support and encouragement throughout.

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March 2011

Table of cases

United States

European Patent Office

European Court of Justice