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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