Preface

The issue of patenting medical procedures (whether therapeutic, surgical or diagnostic) in the United States has been in a state of flux for over a hundred years. The uncertainty of an early district court decision was laid bare by the Board of Patent Appeals (BOPA), which decided in the 1950s that methods of medical treatments were patentable. This BOPA decision was also tenuous because it could easily be overruled by a district or higher court. Nonetheless, this decision was the foundation for the legal position in the United States for the next four decades. The spectre of physicians reaping monopoly profits from their patents on medical procedures on life-threatening illnesses prompted Congress to enact the Medical Procedures and Affordability Act (MPAA) in 1996. The MPAA provided immunity to physicians and health care entities from patent infringement suits.

These developments did not halt the tide of patenting medical and diagnostic treatments. With the mapping of the human genome in 2000, there was increased impetus to find genetic diagnoses of illnesses and patents on these have mushroomed. Methods of treating patients, dosage regimes, methods of determining the effectiveness of particular dosages, surgical methods and genetic diagnostic methods are now being patented. It was only a matter of time before the patentability of these came before the Supreme Court. Although missing an opportunity in 2006 (*Laboratory Corporation*), the Court in 2012 (*Prometheus*) finally determined that medical treatment and diagnostic methods are patentable under section 101 of the Patents Act, reversing decisions of the Federal Circuit that held the contrary. The issue of patenting genetic diagnostic methods is now on remand for reconsideration by the Federal Circuit, so the Court may soon have another opportunity to revisit the issue of patent protection for medical treatment and diagnostic methods and, consequently, finally decide on whether genetic diagnostic methods are patentable under section 101.

Chapter 1 provides an introduction. Chapter 2 considers the early decisions relating to patentability of methods of medical treatment in the United States, while Chapter 3 investigates the legislative history and provisions of the MPAA. Chapter 4 examines in detail the leading court authorities on patent-eligibility, namely, the *Benson*, *Flook* and *Diehr*

trilogy and *Bilski*. It proceeds to assess the post-*Bilski* Federal Circuit authorities to determine whether they have heeded the Court's mandate in *Bilski*. Chapter 5 analyses early and recent Federal Circuit authorities on medical treatment and diagnostic methods. Chapter 6 builds on this by exploring the dissenting judgment in *Laboratory Corporation* and the decision of the Court in *Prometheus*. It also examines a decision of the District Court applying *Prometheus* to similar medical diagnostic claims, and a decision of the Federal Circuit which seemingly eschewed many of the mandates of the Court in *Prometheus*. Chapter 7 concludes by providing some suggestions concerning how the issue of patent-eligibility of medical treatment and diagnostic methods under section 101 might be resolved.

This book is a completely revised and expanded version of Chapter 10 of my book, *Medical Patent Law: The Challenges of Medical Patents*, published by Edward Elgar in 2011. It follows themes I first addressed in my doctoral thesis at the University of Oxford between 2001 and 2004.