# 1. Introduction

While European countries carved out an exception for methods of treatment of the human or animal body by therapy, surgery and diagnostic methods practised on the human or animal body (Article 52(4) European Patent Convention (EPC) 1973 (later confirmed in Article 53(c) EPC 2000)), no legislative change dealing with medical methods/procedures occurred in the United States until 1996. However, the Board of Patent Appeals of the United States Patent Office (USPTO) (BOPA) and the courts, namely, the Federal Circuit and the Supreme Court of the United States (Court), did have occasion to consider the issue of patent protection for methods of medical treatment.

This book examines the scope of patent protection for methods of medical treatment and genetic diagnostic methods in the United States. Since the question of patent protection has not been finally decided legislatively, the issue is still a live one for the courts in the United States. The jurisprudence considered will mainly examine the central issue of whether medical and genetic diagnostic methods are patent-eligible under section 101 of the Patents Act. An in-depth consideration of the issue is important in light of the continued uncertainty medical patents might have on public health, investment by pharmaceutical companies in research and development, and the impact that uncertainty might have on medical and veterinary practitioners.

The book first considers how the Board of Patent Appeals (BOPA) and the courts in the United States had to deal with the issue as it arose previously. One of the seminal cases, *Morton v New York Eye Infirmary*,[1] will be considered in detail to determine whether it is in fact authority for the unpatentability of medical treatment methods, as is widely assumed. In addition, much needed guidance on this issue will be provided by the decisions of the various courts which applied or referred to *Morton*. Of equal significance too in this historical exegesis is an examination of the decisions of the BOPA, which have addressed this issue. Two important decisions will be explored fully, namely, *ex parte Brinkerhoff*[2] (which seemingly held

[1] (1862) 17 F Cas 879.
[2] (1883) reprinted in 27 JPOS 797 (BOPA (1945)).

that methods of medical treatment were not patentable subject matter) and *ex parte Scherer*[3] (which overruled *ex parte Brinkerhoff* to the extent to which it held that medical treatment methods were not patent-eligible). While *ex parte Brinkerhoff* might have settled the question, other decisions had applied *ex parte Brinkerhoff* and *Morton*, holding that medical and diagnostic methods were unpatentable. These early decisions are explored to determine what was the status of the patentability of medical and diagnostic methods before the Federal Circuit, at least initially, joined in the debate on patent-eligibility.

Before that is considered, the book takes an important but necessary diversion from an examination of the case law in this area to consider the legislative intervention, which was precipitated by potential infringement liability of medical and veterinary practitioners who treat their patients. As will be seen, the courts and the USPTO oscillated on the issue of patent protection for methods of medical treatment. Medical procedures were initially excluded from patent protection, but, in 1954, the BOPA in *ex parte Scherer* decided affirmatively that such procedures were not outside the scope of patent protection. The patenting of medical treatments continued unhindered, without posing any serious threat to the medical profession and health care, after the decision in *ex parte Scherer*. The issues only climaxed in the aftermath of the *Pallin v Singer*[4] litigation, where one physician sought to enforce a patent for a method of medical treatment against another physician. The publicity given to this case in the media alerted the public to the possibility of patents negatively impacting health care. The legislators were quick to respond to what was perceived to be an upsurge in patents for methods of medical treatment. The Medical Procedures and Affordability Act (MPAA) was the resulting compromise that provided immunity to physicians and related health care entities against suits for patent infringement. The legislation, the drafters thought, achieved a proper balance between, on the one hand, the public health considerations and, on the other hand, the economic incentive of the patent system. This book examines comprehensively the numerous drafts and the debates surrounding the passage of the MPAA, including the various versions of House Bills and Senate Bills that dealt with similar subject matter. This provides cogent evidence for the rationale for the enactment of the MPAA. A detailed examination of the provisions of the MPAA is also undertaken in order to properly determine its scope and the manner in which it was expected that the immunity provision would work.

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[3] 103 USPQ 107 (BOPA (1954)).
[4] 36 USPQ 2d 1050 (US DCDY 1995).

Even before considering the decisions of the Federal Circuit dealing directly with medical treatment and diagnostic methods, it is important to consider the controlling precedents of the Court on the question of patent-eligibility under section 101 of the Patents Act. This is important because many of the earlier Federal Circuit decisions applied the Court's precedent to decide those issues relating to medical patents. Since the Court precedent is not static, this book considers the main Court precedents, which articulate the first principles by which section 101 is to be construed, namely, *Gottschalk v Benson*,[5] *Parker v Flook*[6] and *Diamond v Diehr*.[7] These seminal decisions provide the backdrop against which the issue of patent protection for medical treatment and diagnostic methods are considered. As such, it is necessary to consider them in some detail. Additionally, the recent Court decision in *Bilski v Kappos*,[8] which has also reconsidered that trilogy, is also examined to the extent that it sheds any light on the way section 101 is to be construed, in particular, with advancements in technology and the information age – a point which was repeated by the Court in *Bilski*. Since the Federal Circuit is burdened with interpreting the Court's decisions to provide answers to the myriad of section 101 issues that usually confront it, decisions of the Federal Circuit that have applied *Bilski* are considered, especially since, in *Bilski*, the Court stated categorically that, '[i]n searching for a limiting principle, this Court's precedents on the unpatentability of abstract ideas provide useful tools' and that if the Federal Circuit 'were to succeed in defining a narrower category or class of patent applications that claim to instruct how business should be conducted, and then rule that the category is unpatentable because, for instance, it represents an attempt to patent abstract ideas, this conclusion might well be in accord with controlling precedent'.[9]

The Federal Circuit lost no time in heeding the words of the Court and, in approximately seven decisions, since the Court's decision in *Bilski* in June 2010, unrelated to medical treatment or diagnostic methods, it has attempted to interpret the Court's precedents, including *Bilski*, to provide a workable test or method by which to determine which claims fall within the Court's exceptions for the laws of nature, natural phenomena and abstract ideas. An examination of the post-*Bilski* Federal Circuit's jurisprudence in this area, particularly, *Research Corp Technologies Inc. v*

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5 409 U.S. 63 (1972).
6 437 U.S. 584 (1978).
7 450 U.S. 175 (1981).
8 130 S. Ct. 3218; 177 L. Ed. 2d 792 (2010).
9 Ibid. at 805.

*Microsoft Corp*.,[10] is important. In these decisions, the Federal Circuit is trying to carve out a consistent theme in its section 101 jurisprudence and this has implications for its consideration of patents for medical treatment and genetic diagnostic methods. The manner in which the Court and the Federal Circuit interpret section 101 determines, to a considerable extent, the scope of protection for medical and diagnostic method patents.

The Federal Circuit, therefore, is a filtering mechanism for decisions on section 101 of the Patents Act. By having a unified court dealing with patents it was hoped that, to a large extent, its jurisprudence would be mainly uniform. However, since the Federal Circuit sits in panels, there are sometimes diverging views on some issues, which is usually resolved by using an *en banc* panel, as happened in the *Bilski* litigation. More importantly, though, is that many of the decisions on section 101 are resolved at the Federal Circuit. The Supreme Court seldom forays into section 101 jurisprudence. Since the trilogy of decisions of *Benson* (1972), *Flook* (1978) and *Diehr* (1981), it took the Court approximately 30 years before it next considered a section 101 case: *Bilski* (2010). The Federal Circuit, therefore, provides the bulk of such cases, so it was not surprising that even as early as 1982, in *In re Meyer*,[11] and in 1989, in *In re Grams*,[12] the Federal Circuit was already dealing with related medical patents. These early decisions provide some insight into the way in which the Federal Circuit considered the issue of medical treatment and diagnostic method patents. The book considers what the Federal Circuit had to say about the Court's decision in *Laboratory Corporation v Metabolite Labs*,[13] which dealt with a medical diagnostic method. It also examines the District Court and Federal Circuit decisions in the recent trilogy of decisions dealing with treatment regimes, diagnostic methods and genetic diagnostic methods in *Classen Immunotherapies Inc. v Biogen Idec*,[14] *Prometheus Laboratories Inc. v Mayo Collaborative Services*[15] and *Association for Molecular Pathology v U.S. Patent & Trademark Office* (*AMP v USPTO*).[16] These decisions provide the basis for recent Federal Circuit opinion on the issues considered in this book.

This upsurge in decisions relating to methods of medical treatment and

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10 627 F.3d 859 (Fed. Cir. 2010).
11 688 F.2d 789 (CCPA 1982).
12 888 F.2d 835 (Fed. Cir. 1989).
13 548 U.S. 124, 126 S. Ct. 2921, 165 L. Ed. 2d 399 (2006).
14 659 F.3d 1057 (Fed. Cir. 2011).
15 628 F.3d 1347 (Fed. Cir. 2010), cert. granted (June 20 2011). See the Federal Circuit's first decision in this case: 581 F.3d 1336 (Fed. Cir. 2009).
16 653 F.3d 1329 (Fed. Cir. 2011).

diagnostic methods reaching the Federal Circuit did not go unnoticed by the Court. After delivering its judgment in *Bilski*, the Court remanded both *Prometheus* and *Classen* for reconsideration by the Federal Circuit. The two decisions had applied the 'machine or transformation test' and had provided different conclusions on broadly similar claims. On further reconsideration, the *Prometheus* case was first to get back onto the Court's docket, with a unanimous decision by the Court handed down in March 2012. The Court missed its first opportunity to consider patent-eligibility of medical and diagnostic patents in 2006 in *Laboratory Corporation* when it dismissed the writ as improvidently granted, causing Breyer J to pen a vigorous dissent. However, his dissent, which did not find favour with most of the decisions of the Federal Circuit in *Prometheus*, *Classen* or *AMP*, anticipated the unanimous decision of the Court in *Prometheus*.[17] Not surprisingly, Breyer J wrote the decision of the Court. *Prometheus*, although not deciding that methods of medical treatment, including diagnostic methods, are not patent-eligible, provides much needed guidance on the scope of section 101 of the Patent Act in relation to medical and diagnostic methods in the United States. This book: first, explores the rationale for the dissent in *Laboratory Corporation*; second, examines the decision of the Court in *Prometheus* to determine how it sheds light on the issue of patent protection for medical treatment and diagnostic methods in the United States; and third, examines a recent District Court decision in *SmartGene Inc v Advanced Biological Laboratories SA*[18] that has already applied the Court's decision in *Prometheus* to medical patent claims.

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17 Supreme Court decision dated 20 March 2012.
18 212 U.S. Dist. LEXIS 44138 (March 30 2012).