1. Introduction

A GENERAL

This book will examine the scope of patent protection for methods of medical treatment, focusing on the exclusion of therapeutic, surgical and diagnostic methods in Europe, the United States of America and some Commonwealth countries. The focus on medical treatments is important in light of its exclusion from patent protection in most of the jurisdictions covered by this book, particularly in light of new developments in technology, including gene therapy, genetic diagnostic testing and stem cell therapy. Although the exclusion in the United Kingdom, for example, has been in existence for approximately 95 years, it was only in 1973, with the coming into force of the European Patent Convention (EPC), that the exclusion had a firm legal basis in most European countries. However, while in Europe the emphasis is on delineating the scope of the exclusion in decisions of the Technical Boards of Appeal (TBAs) and the Enlarged Board of Appeal (EBA) of the European Patent Office (EPO), other countries, for example, the United States, are still struggling with the issue of whether medical procedures are excluded from patent protection.

The question of whether patents should be granted for methods of medical treatment is still a live issue in some Commonwealth countries, in particular, in New Zealand where only six years ago, its Court of Appeal ruled that such methods are not patentable. However, in Australia, patent protection is available. In the United States, the issue of patentability was once thought settled and that methods of medical treatment were allowable was not questioned, especially in light of the Medical Procedures and Affordability Act 1996 (MPAA) which provided physicians with immunity from infringement suits relating to patent for methods of medical treatment. Recently, however, the question has arisen as to whether such treatments, in particular, diagnostic methods, are patentable and in 2006 the Supreme Court refused to rule on the issue. But, recently, the Federal Circuit has been examining the issue with inconsistent rulings on the

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1 The term ‘methods of medical treatment’ will be used interchangeably with ‘medical procedures’.

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question of whether methods of medical treatment are excluded from patent protection. It will not be long before the Supreme Court finally rules on the issue of patentability of methods of medical treatment, in particular, diagnostic methods.

Notwithstanding that the exclusion in Europe was etched in stone in Article 53(c) EPC 2000 (previously, Article 52(4) EPC 1973), some academics and judges in the United Kingdom have questioned the rationale and the logic of the exclusion. In 1999, for example, Jacob J., as he then was, stated that '[t]he thinking behind the exception [for methods of medical treatment] is not particularly rational: if one accepts that a patent monopoly is a fair price to pay for the extra research incentive, then there is no reason to suppose that that would not also apply to methods of treatment'. In 1971, 28 years earlier, Whitford J. in *Schering A G’s Application* stated that it was 'difficult to see any logical justification for the practice [of not granting patents] in relation to the processes for medical treatment, if the object of the system is in truth to give hope of a reward to people whose research and industry results in valuable products or processes.'

These statements create more problems than they solve. They do not identify why patenting methods of medical treatment would serve the public interest or whether there exist other public policy considerations that are stronger than those currently made against patenting methods of medical treatment. This book will seek to determine whether there is a coherent rationale for the exclusion of methods of medical treatment from patent protection and, in the process, outline the main arguments for and against patent protection for methods of medical treatment. A similar approach to, and consideration of, the issues relating to methods of medical treatment to be examined in this book was applied by Hammond J. in *Pfizer Inc v Commissioner of Patents*.

### B THE ARGUMENTS

The question of patenting methods of medical treatment is one that is multi-faceted because many arguments can be and are made either way for and against patent protection. The question of whether patent protection should be allowed or, in some jurisdictions, be removed is one that does not lend itself to an easy answer. This is evident in the different approaches of the Australian and New Zealand courts to the issue even when similar

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2 [1999] RPC 253 (emphasis added).
3 [1971] RPC 337 (PAT) 343.
statutory provisions were considered. In the United Kingdom, the then judicially-created exclusion is now in statutory form and is here to stay for the foreseeable future. This is so because the revision of the EPC in 2000 has kept the exclusion in its current form. An examination of the arguments made for and against patenting methods of medical treatment revealed that the question of which set of arguments should prevail cannot solely be answered at a theoretical level. Due weight must be given to empirical evidence, if any, of the impact of medical procedures on society in general, because without such evidence pointing in any particular direction, any attempt at coming to a firm conclusion on whether patents should be granted for methods of medical treatment would be unconvincing.

Where a change in the law would have serious implications for public health a cautious approach is needed. And, if there is to be any change in Europe, it should only be achieved if there are strong arguments (supported by empirical evidence) that that should be done. It has often been stated that the judicial branch is unable to accede to requests for changes in the law that have significant public policy implications. In the period before 1977, it was said that, if UK law were to change, it would be a matter for Parliament and not the courts, implying that such policy decisions were not the province of the courts. Similarly, in *Diamond v Chakrabarty*, where the issue was whether a live, human-made micro-organism was patentable subject matter, the Supreme Court stated that:

> What is more important is that we are without competence to entertain these arguments – either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution with the legislative process and after the kind of investigation, examination, and study that the legislative bodies can provide and the courts cannot. The process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed upon us should be addressed to the political branches of Government, the Congress and the Executive, and not to the courts.

This speaks directly to the issue that we are similarly confronted with here. The robust examination, investigation and study of the issue of whether patents should be granted for methods of medical treatment cannot be, and will not be, achieved within the pages of this book alone. The modest aim of chapters 2 and 3 is to outline and examine the various arguments that are

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6 Ibid, at 318.
made for and against patent protection for methods of medical treatment. This exercise is important since it will provide, among other things: (a) an insight into the various considerations (including ethics and morality) that the UK courts in the period before 1977 were hinting at but never fully explored; and (b) a more in-depth examination of the possible rationale for the exclusion of methods of medical treatment from patent protection.

To achieve this, the book will first consider, in chapter 2, the arguments that are made for patent protection for methods of medical treatment. Secondly, to ensure that the arguments are balanced, it will examine in chapter 3 the arguments that are made against patent protection of methods of medical treatment. Wilcox J. in *Anaesthetic Supplies v Rescare* observed that ‘[p]olicy arguments may be made, each way, upon the question whether the law should permit [patents for methods of medical treatment]’. The examination of these will show that the issue of patent protection for medical procedures is not as simplistic as it may initially seem and that a resolution of the various issues is only possible when evidence points directly to a certain impact on public health.

The arguments that are made against patent protection that will be examined include: (a) public health implications; (b) physician liberty and autonomy; (c) physician/patient relationship; (d) the Hippocratic Oath/sharing norm; (e) other incentive structures; and (f) breach of patient’s privacy. The arguments that are made for patent protection that will be examined include: (a) incentive to disclose; (b) incentive to invent/innovate; (c) prospect theory; (d) rent dissipation theory; (e) reward/desert; and (f) liberty/autonomy.

The arguments that are made for patent protection for methods of medical treatment may apply equally to pharmaceutical products. Therefore, no attempt will be made to analyse this aspect in this book. However, those who argue against patent protection for methods of medical treatment do not take into account that some of these same arguments equally apply to pharmaceutical products. Patent protection is available in most countries for pharmaceutical products and substances but not medical procedures. Why then is there a distinction between the two? When examining the arguments that are made against patent protection for methods of medical treatment, this book will attempt to highlight, where necessary, the differences between the two. The issue, as the Australian Federal Court in *Bristol-Myers Squibb Co v F H Faulding & Co. Ltd* saw it, was ‘the insurmountable
problem, from a public policy viewpoint, of drawing a logical distinction which would justify allowing patentability for a *product* for treating the human body, but deny patentability for a *method* of treatment.

It is arguable that the issue is one of direct control over the supply of the patented invention. In the case of pharmaceuticals, the patentee can limit supply and increase the price but, in most cases, it would not be in their interests to do so. Similarly, with methods of medical treatment, the patentee physician can also restrict supply of the necessary or potentially life-saving procedure by denying others the right to use it or by not performing it herself – which would be contrary to the public good. The consequences for the public seem to be worse in the case of the medical treatment since the procedure/process is unlike a drug which can be manufactured and distributed to millions of people. If licences are not readily made available by the patentee, one method by which this question of access to the medical treatment may be resolved is to subject it to a compulsory licensing regime. That approach also has limitations and, without empirical evidence concerning its economic impact on public health, one cannot come to a firm conclusion on whether it achieves an optimum balance.

C THE EPO JURISPRUDENCE

In exploring the issues to be resolved in this field, an examination of the jurisprudence of the European Patents Office (EPO) will be undertaken to assist in delineating the rationale for the exclusion of methods of medical treatment from patentability. This exercise will examine how the Technical Boards of Appeal (TBAs) and the Enlarged Board of Appeal of the European Patent Office (EBA) have interpreted the exclusion for methods of medical treatment in Europe, and, in the process, enable some conclusions to be made concerning how the exclusion came about, why, if at all, the exclusion should be maintained, and, importantly, what considerations the TBAs and the EBA have taken into account in making sense of the exclusion from patent protection of methods of medical treatment. Each method of medical treatment, namely, therapeutic methods (chapter 4), diagnostic methods (chapter 5) and surgical methods (chapter 6) will be examined in detail to determine: first, how they are each defined by the TBAs and the EBA; secondly, what limitations, if any, have the TBAs and the EBA accepted that would influence how each of the exclusions are to be

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defined; thirdly, what factors or considerations have the TBAs and the EBA taken into account in interpreting the exclusions; fourthly, whether there is any consistency in the broad approach to the interpretation of the exclusion by the TBAs and the EBA; and fifthly, whether a distinction is properly made in the jurisprudence of the TBAs and the EBA between treatment of animals and humans when interpreting the exclusion. This book will also examine the legislative history of the EPC in relation to each of the three exclusions to see what light, if any, it sheds on the rationale for the exclusion and, indeed, the manner in which they are to be interpreted.

Of critical importance too will be the examination in chapter 7 of the issue of second medical use patents under the EPC to determine: first, what do Articles 54(4) and 54(5) EPC 2000 really say; secondly, why was it necessary for the EBA to interpret Article 54(5) EPC 1973 to include second and further medical uses, contrary to its ordinary meaning; thirdly, what exactly did the EBA in *Eisai/Second medical indication* decide; and fourthly, whether the TBAs were correct in expanding this decision to other areas where, arguably, it was not intended. A related but important issue is that concerning patenting dosage regimes. Numerous issues are ripe for consideration, the first of which is whether the decision of the EBA in *Eisai/Second medical indication* compels the result in the recent decision of the EBA in *Abbott Respiratory/Dosage regime*; secondly, whether Articles 54(4) and 54(5) EPC 2000 can properly be interpreted to provide patent protection for dosage regimes; thirdly, whether such protection is justified as a matter of principle or policy.

The application of the principles derived from the interpretation of the exclusion by TBAs and the EBA by the UK courts will also be examined in chapter 9 in light of the requirement that UK courts should ensure consistency with the approach of the EPO. The pre-1977 law will be briefly compared to the position under the UK Patents Act 1977 (the 1977 Act), followed by an examination of how the UK courts have applied the principles emerging from the EPO in respect of the matters considered in chapters 4–7.

**D THE QUESTION OF PATENTABILITY**

The issue of whether patent protection was available for methods of medical treatment was still debatable in the United Kingdom until the early 1970s. Although the courts and the Patent Appeal Tribunal (PAT) were agreed that the exclusion existed, its jurisprudential foundations were very precarious. The jurisprudence in the United Kingdom prior to 1977 will be examined in chapter 8 to determine what light, if any, it sheds on the
subsequent UK interpretation of the 1977 Act, which incorporated the EPC 1973. The New Zealand and Australian approaches will also be considered in that section in light of their historical origins – s 6 of the Statute of Monopolies. However, although sharing a common ancestry, the courts in Australia have allowed patent protection for methods of medical treatment, whereas the courts in New Zealand have rejected such protection. These decisions will be examined to determine why this was the case. This chapter will also explore the issue of why the New Zealand Court of Appeal applied an EBA decision relating to second and further medical uses, notwithstanding that that decision originated from a totally different statutory framework than that which obtains in New Zealand.

The courts in the United States and the US Patent and Trademark Office (USPTO) were of the clear view that patents were available for methods of medical treatment. That this was so was evident by the fact that there was actual litigation relating to infringement of a medical procedure patent, which created a firestorm in a teacup in the United States. Swiftly following the litigation, Congress enacted the MPAA, which provided immunity to physicians when using medical procedure patents. Chapter 10 will consider the decisions of the USPTO, relating to exclusion, and also examine the legislative history and provisions of the MPAA. In addition, it will also consider whether the question of patentability of medical procedures, in particular, diagnostic methods, can be answered using Supreme Court jurisprudence relating to patentable subject matter, namely, *Benson, Flook* and *Diehr* and as recently rearticulated in *Bilski v Kappos*. In light of its decision in the latter case, the Supreme Court vacated two decisions of the Federal Circuit relating to diagnostic methods. However, since at least two decisions are making their way back to the Federal Circuit for reconsideration, and another for consideration, it is opportune that the book also examines the jurisprudence of the Federal Circuit and the Supreme Court to articulate an approach to resolve the issue of patenting diagnostic methods that are in line with Supreme Court jurisprudence.

**E THE FUTURE OF MEDICAL PATENTS**

It is apt that a book dealing with medical procedure patents should also examine the possible application of the exclusion of methods of medical treatment to the new technologies currently being applied to treat and diagnose illnesses. The medical treatment exception, as interpreted by the various TBAs and the EBA, will be examined to determine the extent to which it may limit the patenting of new treatments such as genetic therapy, stem cell therapy and genetic diagnostic testing. The complex nature of
such treatments and the technologies involved may implicate other areas, and the Biotech Directive will be evaluated in light of the issues to be discussed. Also important will be the examination of Article 53(a) EPC 2000 relating to morality and *ordre public* to determine to what extent the new treatments impact on that exclusion. In order to properly apply the relevant jurisprudence to the new medical treatments, these issues will be considered in the chapters dealing with the various methods of medical treatments, chapters 4–7.