

METHODS OF MEDICAL TREATMENT WITHIN AUSTRALIAN AND UNITED KINGDOM PATENTS LAW

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I INTRODUCTION

The accommodation of methods of medical treatment within Australian and United Kingdom ('UK') patents law has been controversial since the first patent applications in respect of such methods were filed in the early 20th century. For the last 30 years that controversy has been accepted as having a moral¹ basis, the issue being whether the public interest in encouraging research and innovation in the medical arena through the provision of patent-related incentives for creators of new and useful therapeutic methods on the one hand is outweighed, on the other, by the various public policy objections to permitting the monopolisation of such methods. Those objections include fears that the monopolisation of medical methods would:

- (a) hinder medical research by restricting the free availability of knowledge;
- (b) be inconsistent with the teaching of medical students and practitioners;
- (c) expose medical practitioners and patients who use and accept the use of a patented method without a licence to liability for patent infringement; and
- (d) enable patentees to exact unreasonable payments for life-saving or potentially life-saving techniques.²

The controversy regarding the patentability of methods of medical treatment has not always been understood as an ethical one. Prior to 1971 the inherent patentability of methods of medical treatment was expressly regarded by both

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1 Throughout this article the terms 'morality' and 'ethics' are used interchangeably in accordance with their common language meanings (see *The Macquarie Dictionary* (3rd ed, 1997)). Note however the changing pattern of usage of those terms within patents law from 'morality' to 'ethics' without any apparent change in intended meaning (see, eg, below ns 66, 74, 130, 155 and accompanying text). The most recent view of the courts has been that references to 'morality' and 'ethics' in the context of patents law are misplaced and should be replaced by references to 'public policy' (see below n 215).

2 See further Anna Feros, 'Patentability of Methods of Medical Treatment' [2001] *European Intellectual Property Review* 79, 84-5; below n 195 and accompanying text.

Australian and UK decision makers as turning on the essentially black letter law question of the nature of an 'invention', a question that only arose in those jurisdictions after the introduction of modern³ patents legislation.⁴ Reconceptualisation of the issue from 1971 in moral terms can be attributed to a number of possible causes, including the recovery by decision makers from the initial shock caused by the prospect of allowing patents for potentially life-saving treatment, and the general increase in community (and judicial) interest in the morality of science and its implications for patents law. However, it can also be viewed as a recognition by the judiciary of the questions that have always lain at the heart of the issue concerning methods of medical treatment and patents law – namely, whether methods of medical treatment *should* be patentable and, as a precursor to that question, to what extent (if any) legal constructions of the term 'invention' and patent eligibility generally can legitimately and openly accommodate ethical and other public policy considerations.

There is a great deal of literature concerning the specific public policy arguments for and against the patenting of methods of medical treatment,⁵ and it is not the purpose of this article to review such arguments nor to argue for their resolution along particular lines. Rather, the purpose of the article is to consider by historical analysis the relationship between decision makers' responses to medical method patents and their conceptions of inherent patentability generally. The thesis advanced in the course of such consideration can be summarised as follows. First, for the last 100 years much of the important jurisprudence relating to inherent patentability in the UK and Australia has derived from cases involving methods of medical treatment. Secondly, those cases are distinguished by the failure of decision makers to resolve convincingly or consistently: (a) the basis for the exclusion from patentability of methods of medical treatment; and (b) the extent (if any) to which legal constructions of inherent patentability can legitimately accommodate ethical and other (non-commercial) public policy considerations. And thirdly, this failure is largely responsible for the unduly restrictive legal principles that governed inherent patentability in Australia and the UK until 1959 and methods of medical treatment until the 1970s. It is also responsible for the ongoing uncertainty on the part of Australian decision makers concerning the relevance of morality and public policy generally to inherent patentability.

Central to this thesis are the issues noted above concerning what an 'invention' is and whether patents law, in its various 20th century guises, permits

3 Whilst the patents legislation of 1883 (*Patents, Designs & Trade Marks Act 1883* (UK) 46 & 47 Vict, c57 ('1883 Act')) was preceded by two other 19th century statutes (*An Act to Amend the Law Touching Letters Patent for Inventions 1835* (UK) 5 & 6 Wm IV, c83 ('1835 Act'); *Patents Law Amendment Act 1852* (UK) 15 & 16 Vict, c83 ('1852 Act')), it is the 1883 Act that is generally considered to have ushered in the era of modern patents law, principally by reason of its extensive procedural reforms: see generally Neil Davenport, *The UK Patent System: A Brief History With Bibliography* (1979) 20-1.

4 Whilst the word 'invention' has been used to denote inherently patentable subject matter in patents legislation since 1835, it was not expressly defined until 1883.

5 See, eg, Joel J Garris, 'The Case for Patenting Medical Procedures' [1996] *American Journal of Law and Medicine* 85, 90-100; Beata Gocyk-Farber, 'Patenting Medical Procedures: A Search for a Compromise Between Ethics and Economics' [1997] *Cardozo Law Review* 1527.

decision makers to consider moral issues when determining a subject matter's prima facie eligibility for patent protection. At a time of increasing public and legal debate regarding both the ability of certain new technologies to be treated as inventions and the moral implications of such treatment,⁶ an historical account of the development of decision makers' responses to these issues has never been more important. That account serves, among other things, as a reminder of the potential consequences for law of dressing public policy decisions in black letter principle, or of otherwise assuming inherent (un)patentability without proper consideration of the foundations for that assumption.

II THE PATENTABILITY OF METHODS OF MEDICAL TREATMENT IN AUSTRALIA AND THE UK TO 1959

Inherent patentability under Australian and UK law has been the subject of legislation since 1623. Analysis of the development of inherent patentability must therefore begin with a description of its contemporary and historical legislative basis.

A Legislative Definitions of Inherent Patentability

1 Australia

Inherent patentability under Australian law depends on the existence of an inherently patentable subject matter or, as such subject matter has traditionally been denoted, on the existence of an 'invention' within the meaning of contemporary patents legislation. The current legislative definition of 'invention' is contained in sch 1 of the *Patents Act 1990* (Cth) ('1990 Act') and remains essentially unchanged since the introduction of the first federal Australian patents legislation in 1903.⁷ Pursuant to that definition, an 'invention' is 'any manner of new manufacture ... within section six of the *Statute of Monopolies* [including] an alleged invention'.⁸ Section 6 of the *Statute of Monopolies 1623* (Eng) ('*Statute of Monopolies*')⁹ in turn provides as follows:

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- 6 The new technologies that have attracted the most attention in this regard are biotechnological subject matter such as recombinant DNA technology and its various applications and products. The literature relating to the legal and moral implications raised by the patenting of such subject matter is vast, but includes: Rebecca S Eisenberg, 'Re-examining the Role of Patents in Appropriating the Value of DNA Sequences' (2000) 49 *Emory Law Journal* 783; David Keays, 'Patenting DNA and Amino Acid Sequences – An Australian Perspective' (1999) 7 *Health Law Journal* 69; Karinne Ludlow, 'Genetically Modified Organisms and their Products as Patentable Subject-matter in Australia' [1999] *European Intellectual Property Review* 298.
- 7 *Patents Act 1903* (Cth) ('1903 Act'). Note that the same definition was contained in the colonial patents legislation of the late 19th century, which replicated the provisions of the UK 1883 Act. Throughout this article references to Australian statutory law are confined to federal legislation.
- 8 *Patents, Designs & Trade Marks Act 1883* (UK) 46 & 47 Vict, c57 s 46; *Patents and Designs Act 1907* (UK) 7 Edw 7, c29 ('1907 Act') s 93; *Patents Act 1949* (UK) 12, 13 & 14 Geo 6, c87 ('1949 Act') s 101; *Patents Act 1903* (Cth) s 4; *Patents Act 1952* (Cth) ('1952 Act') s 6; *Patents Act 1990* (Cth) sch 1.
- 9 21 Jac I, c3.

Provided also, and be it declared and enacted, that any declaration, before-mentioned, shall not extend to any letters patent and grants of privilege for the term of fourteen years, or under, hereafter to be made, of the sole working or making of any manner of new manufactures within this realm, to the true and first inventor and inventors of such manufactures, which others at the time of making such letters patent and grants shall not use, so as also they be not contrary to the law, nor mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient. The said fourteen years to be accounted from the date of the first letters patent of grants of such privilege hereafter to be made, but that the same shall be of such force as they should be, if this act had never been made, and of none other.

Thus an invention for the purposes of Australian law is 'any manner of new manufactures ... not contrary to the law, nor mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient' within the meaning of the 1623 *Statute of Monopolies*.¹⁰

2 *The UK*

Before the introduction of the current patents legislation in 1977,¹¹ inherent patentability had the same statutory form in the UK as in Australia and thus depended on the existence of a 'manner of new manufacture' within the meaning of s 6 of the *Statute of Monopolies*. This common legislative basis makes it appropriate to view the jurisprudence of Australia to date and the UK prior to 1977 as forming one 'Anglo-Australian' jurisprudence; a view that is supported by the historical reliance of Australian decision makers in this area on UK decisions. Despite this, differences in the interpretation of the *Statute of Monopolies* and of patentability generally by decision makers in both jurisdictions do exist, and are reflected in the case law involving methods of medical treatment. In the following historical analysis of Anglo-Australian jurisprudence those differences are highlighted as they arise and in so far as they relate to inherent patentability. The effect of the changes to the legislative definition of inherent patentability introduced in the UK in 1977 is also discussed, both for the sake of completeness and as a point of comparison with contemporary Australian law.

Before considering the patentability of medical methods under Anglo-Australian law some description of the legal background to that issue is necessary. This is particularly so given the central thesis of the article regarding the inadequacy of decision makers' responses to medical method patents and its consequences for inherent patentability generally. Hence the purpose of the following section, which is to give an overview of inherent patentability prior to the emergence of medical methods as an issue for Anglo-Australian law in the early 20th century.

10 For a detailed discussion of the nature of an invention within the meaning of the *Statute of Monopolies*, see Justine Pila, 'The Common Law Invention In Its Original Form' [2001] *Intellectual Property Quarterly* 209.

11 *Patents Act 1977* (UK) ('1977 Act').

B Inherent Patentability in Anglo-Australian Law Prior to the Emergence of Methods of Medical Treatment as a Patents Law Issue

Before the introduction of the first modern patents legislation in the UK in 1883 there was very little detailed consideration by Anglo-Australian decision makers of the concept or requirements of inherent patentability. This is perhaps not surprising given the general confusion that resulted from the first attempt at such consideration in the late 18th century case of *Boulton v Bull*,¹² and is likely a reflection of the courts' reticence to revisit the issues at the centre of that confusion. Those issues and their resolution in *Boulton v Bull* are a recurring theme in the 20th century debates concerning inherent patentability generally, and medical methods specifically.

1 *Inherent Patentability Before the Enactment of Modern Patents Legislation: Boulton v Bull and Beyond*

(a) Background to *Boulton v Bull*

In 1795 the law of inherent patentability was still in its infancy. Whilst legislation codifying the common law principles of patentability had existed for over 150 years (in the form of s 6 of the *Statute of Monopolies*), for a variety of mainly political reasons the patents system saw little use from the introduction of that legislation in 1623 to the mid-18th century.¹³ The result was that in 1795, such principles and the *Statute of Monopolies* itself had still not received the sustained attention of the courts.¹⁴ It is largely for this reason that *Boulton v Bull* has acquired so much significance, as it is the first case in which inherent patentability under UK law was considered in detail.

(b) The Decision in *Boulton v Bull*

Boulton v Bull involved a challenge to a patent for a new method of using an old steam engine in a more beneficial way that was described in the specification¹⁵ as consisting of certain principles applied in a particular mode to the purposes of the invention.¹⁶ The question for the Court was whether the alleged invention so described was a method or principle and, if so, whether this rendered the patent invalid for lack of patentable subject matter. The Judges'

12 (1795) 126 ER 651.

13 See generally Christine MacLeod, *Inventing the Industrial Revolution: The English Patent System, 1600-1800* (1988) 34; Edward C Walterscheid, 'The Early Evolution of the United States Patent Law: Antecedents' (Pt 4) (1996) 78 *Journal of the Patent and Trademark Office Society* 77, 80.

14 The only reported case from 1623-1794 in which inherent patentability was considered in any detail was *R v Arkwright* (1785) 1 Web Pat Cas 64, in which additions to existing machinery were held to be inherently patentable, reversing the earlier authority of *Bircot's case* (1573) Co 3rd Inst 181. For an account of the law of inherent patentability prior to 1623, see generally Pila, above n 10.

15 For a detailed account of the patent in issue in *Boulton v Bull* in its social and economic context, see generally E Robinson and A E Musson, *James Watt and the Steam Revolution* (1969); J P Muirhead, *The Origin and Progress of the Mechanical Inventions of James Watt* (1854).

16 The principles of the invention concerned the nature of steam, the particular mode involved keeping the steam vessel in the engine as hot as the steam during the time the engine was at work, and the purposes were to lessen the engine's consumption of fuel: *Boulton v Bull* (1795) 126 ER 651, 651.

decisions differed greatly in method and conception, ultimately producing a split of 2:2 on the question of the patent's validity. The implications of those decisions for inherent patentability can be considered in terms of three related points.

The first point concerns methodology. Three of the Judges – Eyre CJ, and Buller and Heath JJ – treated the inherent patentability of the alleged invention as depending upon its classification as a 'manufacture' within the meaning of s 6 of the *Statute of Monopolies*.¹⁷ The fourth Judge, Rooke J, also relied on the *Statute of Monopolies* but for its 'spirit' and not its concept of manufacture.¹⁸ According to his Honour, the spirit of s 6 supported the patent – there being a new and useful improvement in fire engines sufficiently described in the specification¹⁹ – and arguments of invalidity moving from classification of its subject matter as a method or principle not within the scope of 'manufacture' were merely verbal.²⁰ Implicit in this approach was a view of inherent patentability as encompassing any new and useful technological advance adequately represented in the specification.

The second point concerns the widely divergent results of the other three Judges' reliance on the concept of manufacture for the purposes of determining the alleged invention's inherent patentability. According to Heath J, 'manufacture' meant vendible machine or substance,²¹ with the result that an invention for patentability purposes required a definite physical form.²² Excluding the requirement of vendibility Buller J agreed,²³ confirming the restriction of inherent patentability to mechanical and chemical objects.²⁴ This view of the invention was, however, not shared by Eyre CJ, who considered judicial exposition of the *Statute of Monopolies* to have bestowed a much wider meaning on 'manufacture' than ordinary language would support.²⁵ Whilst not quite conceding its co-extensiveness with the phrase 'any thing' in s 1 of that statute, the Chief Justice did consider 'manufacture' to be of extensive signification, applying not only to things made but also to practices of making, ways of operating, and principles carried into practice in a new manner or to

17 *Boulton v Bull* (1795) 126 ER 651, 660-1 (Heath J), 663 (Buller J), 665-7 (Eyre CJ).

18 *Ibid* 658: Rooke J was inclined to support the patent on the basis of its conformance to the 'spirit' of the *Statute of Monopolies* 'provided it may be supported without violating any rule of law'. In considering whether the patent did violate any rule of law his Honour did not refer to s 6 of the *Statute of Monopolies*.

19 *Ibid*.

20 *Ibid* 659.

21 *Ibid* 660-1.

22 Interestingly, the view of the invention as requiring some physical form was inconsistent with the nature of the post-specification invention as an abstract conception and of the pre-specification invention as a working device or trade, which had a tangible existence but (in the case of trades at least) no necessary physical form (see generally Pila, above n 10).

23 *Boulton v Bull* (1795) 126 ER 651, 662-3.

24 Note, however, the inconsistency of Justice Buller's conception of the invention as physical object with his statement that additions were inherently patentable provided the relevant patent 'be for the addition only, and not for the old machine too': *ibid* 664.

25 *Boulton v Bull* (1795) 126 ER 651, 666.

produce new (including non-physical) results.²⁶ Ultimately for the Chief Justice, an invention for patentability purposes included any specific human action producing effects of use or benefit to the public. This understanding of the invention was sympathetic to the view of inherent patentability supported by Rooke J.

The third point about *Boulton v Bull* of present relevance concerns the limitations recognised by each Judge as to the scope of inherent patentability. All agreed that principles were inherently unpatentable and, with the exception of Heath J, understood 'principle' in this context to mean an abstract notion²⁷ or elementary truth of the arts and sciences.²⁸ For Heath J principles extended beyond such elementary principles to encompass methods of production, which were therefore also inherently unpatentable in his view.²⁹ Buller J agreed with this conclusion regarding methods of production, but rationalised it by reference to the nature of a method as a 'double use' rather than a principle per se.³⁰ Thus, uses constituted a third category of subject matter identified in *Boulton v Bull* as inherently unpatentable.

The overall conclusion to be drawn from *Boulton v Bull* is that in 1795 the common law principles concerning inherent patentability were in a state of confusion. Such confusion centred on two central issues: first, how subject matter for which a patent had been granted was to be construed and defined; and second, how the inherent patentability of subject matter so defined was to be determined. Central to this second issue was the importance of the initial classification of the subject matter itself. In particular, was the inherent patentability of an alleged invention to depend upon its classification as a 'manufacture' and, if so, what did 'manufacture' mean?³¹ The polarised responses to these issues in *Boulton v Bull* define to a large extent the post-18th

26 The Chief Justice also noted that a patent for a method involving no new mechanism and producing no new result would necessarily be for the method itself; ie, for the 'method detached from all physical existence whatever': *ibid* 667.

27 *Boulton v Bull* (1795) 126 ER 651, 667 (Eyre CJ).

28 *Ibid* 659 (Rooke J), 662 (Buller J).

29 *Ibid* 661. Despite the argument of Heath J to the contrary, it is clear that his Honour's conclusion that methods of production were inherently unpatentable contradicted the position established by pre-1795 authorities, which overwhelmingly supported the ability of such methods to support a patent. This was recognised by Eyre CJ, who commented (*ibid* 667) that

we should well consider what we do in this case, that we may not shake the foundation upon which these patents stand. Probably I do not over-rate it when I state that two-thirds, I believe I might say three-fourths, of all patents granted since the [*Statute of Monopolies*] passed, are for a method of operating and of manufacturing, producing no new stances and employing no new machinery. If the list were examined, I dare say there might be found fifty patents for methods of producing all the known salts, either the simple salt, or the old compounds.

30 *Boulton v Bull* (1795) 126 ER 651, 663.

31 The confusion surrounding the construction of patented subject matter and the determination of its inherent patentability was further reflected four years later in the decision in *Hornblower v Boulton* (1799) 101 ER 1285, in which the issue in *Boulton v Bull* was re-litigated. All four judges in that case affirmed the validity of the patent, two without substantive reasoning and two adopting the reasoning of Buller J in *Boulton v Bull* by focusing on the need for some physical 'manufacture' accurately described in the specification.

century debates regarding inherent patentability, including those in respect of methods of medical treatment.

(c) *Inherent Patentability Post-Boulton v Bull*

The innate difficulty of the issues raised in *Boulton v Bull* is reflected in the case law of the following 100 years. This case law contains virtually no express judicial consideration of inherent patentability,³² reflecting instead a struggle on the part of the courts and other decision makers to understand that concept sufficiently to deal with the individual subject matter before them. Despite this, some conclusions can be drawn from the decisions of this period in relation to the nature and scope of inherent patentability. Principal amongst them is that decision makers overwhelmingly supported the approach of Eyre CJ and Rooke J in *Boulton v Bull* by acknowledging that any product or method could support a patent, subject only to its inherent ability to satisfy each of the secondary patentability requirements of novelty, utility, and sufficient description in the specification.³³ The only subject matter incapable of doing so (and therefore incapable of supporting a patent) were statements of abstract principle having no specified practical utility³⁴ and, for innate lack of novelty (and later inventiveness),³⁵ uses and collocations of known objects, the working or underlying principle of which was identical to that of an existing invention.³⁶ With the exception of these three subject matter,³⁷ no other exclusions from inherent patentability were recognised during the 19th century. In addition, patented inventions during this period were routinely construed in liberal and

32 Cf *R v Wheeler* (1819) 106 ER 392.

33 See generally *Cartwright v Eamer* (1800) G 112; *Bainbridge v Wigley* (1810) 1 Carp Pat Cas 270; *Manton v Parker* (1814) 1 Carp Pat Cas 274; *Bovill v Moore* (1815) 47 ER 1048; *Wood v Zimmer* (1815) 171 ER 161; *Cochrane v Smethurst* (1816) 171 ER 448; *Macfarlane v Price* (1816) 171 ER 446; *R v Cutler* (1816) 171 ER 495; *Hill v Thompson* (1817) 36 ER 239; *R v Wheeler* (1819) 106 ER 392; *R v Fussell* (1826) 1 Carp Pat Cas 449; *Sturtz v De la Rue* (1828) 38 ER 1048; *Lewis v Davis* (1829) 1 Web Pat Cas 488; *Lewis v Marling* (1829) 1 Web Pat Cas 490; aff'd (1829) 1 Web Pat Cas 493; *Jupe v Pratt* (1837) 1 Web Pat Cas 145; *Househill Iron Co v Neilson* (1843) 1 Web Pat Cas 673. Note that the same exclusive concern with novelty, utility and adequacy of specification is also reflected in the pre-1795 case law.

34 The rule that abstract principles lacked the practical utility necessary for inherent patentability was implicit in the judgment of Eyre CJ in *Boulton v Bull* 126 ER 651, 667, and was not revisited during the 19th century.

35 In respect of the emergence of inventiveness as a requirement distinct from novelty, see generally *Brook v Aston* (1857) 120 ER 178; aff'd (1857) 28 LJ QB 175; *The Patent Bottle Envelope Company v Seymour* (1858) 141 ER 65, 69; *Harwood v Great Northern Railway Co* (1862) 9 ER 1488; *Calvert v Ashburn* (1862) JPM 84; *Horton v Mabon* (1862) 142 ER 1213; *Thompson v James* (1863) 55 ER 224; *Willis v Davison* (1863) 1 NR 234; *Ralston v Smith* (1865) 11 ER 1318; *Jordan v Moore* (1866) LR 1 CP 624; *Parkes v Stevens* (1869) LR 5 Ch 36; *Tatham v Dania* (1869) 1 Gr 213; *Rushton v Crawley* (1870) LR 10 Eq 522; *Bamlett v Picksley* (1875) 1 Gr 40; *Hill v Tombs* (1881) JPM 82.

36 See generally *Losh v Hague* (1838) 1 Web Pat Cas 202; *Kay v Marshall* (1839) 2 Web Pat Cas 71; aff'd (1841) 2 Web Pat Cas 79; *R v Cutler* (1847) Macr 124; *Bush v Fox* (1852) Macr 140; aff'd (1856) 10 ER 1080; *ibid*.

37 A fourth subject matter denied inherent patentability during the 19th century was working directions or instructions concerning the use of a known product or process: see, eg, *Patterson v The Gas Light and Coke Company* (1875) 2 Ch D 812, 834; aff'd (1875) 3 App Cas 239. That subject matter can, however, be viewed as an instance of analogous use.

abstract terms, as practical manifestations of an underlying or working principle, the novelty of which derived either from such principle itself or its particular manifestation.³⁸ It was against the background of this very liberal understanding of inherent patentability that modern patents law and the question regarding the position of medical methods within it emerged.

2 The Modern Law of Inherent Patentability

(a) Legislative Reform

As has been noted, the modern era of Anglo-Australian patents law began with the introduction of the *Patents, Designs and Trade Marks Act 1883* (UK) ('1883 Act'),³⁹ which was reflected in Australian colonial legislation soon after. The principal significance of that Act for inherent patentability derived from its effect in focusing the attention of decision makers on the literal terms of patents legislation, including s 6 of the *Statute of Monopolies* by reference to which inherent patentability was now expressly defined.⁴⁰ This identification of inherent patentability as a discrete concept and issue was facilitated by the Act's recognition of a distinction between the existence of an invention on the one hand and its novelty on the other.⁴¹ An equivalent distinction between an invention and the need for inventiveness and utility was introduced in the second quarter of the 20th century, when each of the threshold and secondary criteria of patent protection was given explicit statutory expression as a ground for opposing a patent application or seeking revocation of a patent grant.⁴² The

38 See generally *Jones v Pearce* (1832) 1 Web Pat Cas 123; *Morgan v Seaward* (1836) 1 Web Pat Cas 170 (rule nisi subsequently obtained on unrelated point: (1837) 150 ER 874); *Jupe v Pratt* (1837) 1 Web Pat Cas 145; *Kay v Marshall* (1839) 132 ER 1189; aff'd (1841) 8 ER 96; *Neilson v Harford* (1841) 1 Web Pat Cas 331; *Walton v Bateman* (1841) 1 Web Pat Cas 613; *Walton v Potter* (1841) 1 Web Pat Cas 585; aff'd (1842) 1 Web Pat Cas 597; *Househill Iron Co v Neilson* (1843) 1 Web Pat Cas 673; *Muntz's Patent* (1846) 2 Web Pat Cas 113 and accompanying commentary; *Newton v Vaucher* (1851) 155 ER 794.

39 46 & 47 Vict, c57.

40 The effect of the insertion of an express definition of the term 'invention' into Anglo-Australian legislation in focusing attention on the literal terms of s 6 of the *Statute of Monopolies* is also reflected in the contemporary academic writings of the time regarding inherent patentability: see, eg, Courtney Terrell, *Thomas Terrell, The Law and Practice Relating to Letters Patent for Inventions* (4th ed, 1906) 39; H Fletcher Moulton, *The Present Law and Practice Relating to Letters Patent for Inventions* (1913) 15; T M Stevens, *Lewis Edmunds, The Law and Practice of Letters Patent for Inventions* (2nd ed, 1897) 18-19.

41 *Patents, Designs & Trade Marks Act 1883* (UK) 46 & 47 Vict, c57 s 11.

42 Before 1883, a patent was revocable by writ of *scire facias* for failure to satisfy the common law requirements of patentability (*An Act to Amend the Law Touching Letters Patent for Inventions 1835* (UK) 5 & 6 Wm IV, c83 s 3; *Patents law Amendment Act 1852* (UK) 15 & 16 Vict, c83 s xv). In 1883 the *scire facias* action was abolished in the UK and replaced with a statutory revocation procedure, which could be instituted on any of the grounds of the original action: *Patents, Designs & Trade Marks Act 1883* (UK) 46 & 47 Vict, c57 s 26. The same change was effected in Australia by s 86 of the *Patents Act 1903* (Cth). In the UK, the grounds for revoking a patent were first given explicit legislative form in 1907 (*Patents and Designs Act 1907* (UK) 7 Edw 7, c29 ss 25, 26), and were expanded to include lack of an 'invention' within the meaning of the statutory definition in 1932 (*Patents and Designs Act, 1932* 22 & 23 Geo 5, c32 ('1932 Act') s 3(d), amending *Patents and Designs Act 1907* (UK) 7 Edw 7, c29 s 25). In Australia, the grounds for revoking a patent were individually explicated by s 100 of the *Patents*

effect of such expression was to require decision makers from the mid 20th century, and earlier in the case of novelty, to treat inherent patentability as a discrete concept independent of inventiveness, utility and novelty in order to distinguish between the various grounds for statutory action.

In addition to the entrenchment by modern patents legislation of the need for an 'invention' as a discrete and threshold requirement of patentability, two other turn-of-the-century developments of significance for inherent patentability should be noted. The first is the centralisation of the patents system in Australia following federation⁴³ and, in particular, the conferral of original jurisdiction in respect of patents matters on the newly established High Court.⁴⁴ Such conferral created an additional source of patents decisions to supplement those of the UK and Australian Attorneys- and Solicitors-General, the State Supreme Courts and the High Court of England. This development was of particular significance given the seniority of the High Court within Australia's judicial hierarchy compared with that of the UK decision makers having equivalent patents law jurisdiction.

The second significant development around 1900 was a change in the types of technologies for which patents were sought and, in particular, the emergence of a range of new subject matter and their demand for accommodation within traditional patents jurisprudence. Two such subject matter to be considered in the UK and Australia were abstract schemes and methods of facilitating a natural

Act 1952 (Cth), and included by s 100(1)(d) 'lack of an invention' within the meaning of the statutory definition. In the UK, an action for opposing the grant of a patent was first introduced in 1883, and was limited to the ground of lack of novelty (*Patents, Designs & Trade Marks Act 1883* (UK) 46 & 47 Vict, c57 s 11). In Australia the same action was introduced by s 56 of the *Patents Act 1903* (Cth) (see generally the decisions of the High Court of Australia in respect of this section in *Dunlop v Cooper* (1908) 7 CLR 146; *Gum v Stevens* (1923) 33 CLR 267). In the UK the grounds for opposition were extended in 1907 to include insufficient description of the invention in the specification (*Patents and Designs Act 1907* (UK) 7 Edw 7, c29 s 11) and again in 1949 to include (among other things) lack of inventiveness and lack of an 'invention' within the statutory definition: *Patents & Designs Act 1949* (UK) 12, 13 & 14 Geo 6, c 62, s 7; *Patents Act 1949* (UK) 12, 13 & 14 Geo 6, c87 s 14. In Australia they were extended in 1952 to include (among other things) the same grounds (*Patents Act 1952* (Cth) s 59). Inherent patentability remains both a threshold requirement for patentability and a ground for opposition and revocation of a patent in current Australian legislation: *Patents Act 1990* (Cth) s 18(1), s 59(b), s 138(3)(b). Note, finally, that in both the UK and Australia the Comptroller and Commissioner of Patents respectively have always had the power to refuse an application and specification for a patent for failure to claim and disclose an 'invention' within the meaning of the statutory definition. In respect of the UK, see *Re an Application for a Patent by Compagnies Reunies des Glaces et Verres Speciaux Du Nord De La France* (1930) 48 RPC 185 ('*Compagnies' Application*') (in respect of the 1907 Act and, by inference based on the relevant equivalence of its provisions, the 1883 and 1949 Acts). In respect of Australia, see *Patents Act 1903* (Cth) ss 4, 33, 47; *Patents Act 1952* (Cth) ss 6, 35 (particularly after the insertion of s 35(1)(aa) by *Patents Act 1969* (Cth) No 34, s 7), 52; *Patents Act 1990* (Cth) ss 18, 29, 49, 50, sch 1.

43 The Federal Parliament's power to legislate with respect to patents derives from s 51(xviii), (xxix), (xxxi) of the *Australian Constitution*. Note that the right to apply for a patent under the State Patent Acts was not revoked until 1952: *Patents Act 1952* (Cth) s 9.

44 *Patents Act 1903* (Cth), ss 47(1), 59, 86(2). Whilst the Supreme Courts of the States also had original jurisdiction under these provisions, such jurisdiction was rarely exercised. Note that the Federal Court of Australia has been the principal Court for patent matters in Australia since 1976 when it was created and Part XVII was inserted into the *Patents Act 1952* (Cth).

process.⁴⁵ The early response of decision makers to those subject matter can be viewed in hindsight as precursory to the reception of methods of medical treatment.

(b) Signs of Judicial Reform: The Exclusion from Patentability of Abstract Schemes and Methods of Facilitating a Natural Process

The first case to consider in detail the inherent patentability of abstract schemes,⁴⁶ and one of the earliest cases to consider in detail the scope of inherent patentability under modern legislation was *Re Cooper's Application for a Patent* ('*Cooper's Application*'),⁴⁷ decided in 1901. That case involved a patent application in respect of an improved form of newspaper page featuring a blank space along which the page could be folded without disrupting the line of its text.⁴⁸ Allowing an appeal from a decision of the Comptroller-General, Sir Robert Finlay A-G affirmed the inherent patentability of the subject matter on the ground that it involved 'invention with reference to a manufacture' resulting in a material artificial product.⁴⁹ The requirement advanced by the Attorney-General for production of a material artificial product was not justified by reference to any authorities and, indeed, was advanced primarily to support the 'tolerably obvious' proposition that '[y]ou cannot have a Patent for a mere scheme or plan'.⁵⁰ Regardless of the correctness of that proposition itself, the need for a material artificial product had no evident basis in contemporary UK patents law. In addition, it went against the 19th century view of inherent patentability as encompassing any practical manifestation of an idea regardless of physical form, conforming instead to the more restrictive principles of Heath and Buller JJ in *Boulton v Bull*. The same trend was signaled nine years later in the first reported case to consider the patentability of a method of facilitating a natural process. That case was *Rogers v Commonwealth*,⁵¹ and was a decision of the High Court of Australia.

Rogers v Commonwealth involved an opposition to a patent application in respect of a method of burning timber that involved causing a self feeding slow fire to act continuously against the side of a tree. The main contention of the opponent was that the method was not an invention within the meaning of the

45 The subject matter most alike abstract schemes and methods of facilitating a natural process, the inherent patentability of which was considered before the 20th century, were methods of producing a negative or non-physical result: see, eg, *Hartley's Patent* (1777) 1 Web Pat Cas 54 (method of securing buildings and ships against the calamities of fire, described by Eyre CJ in *Boulton v Bull* (1795) 126 ER 651, 666 as having as its purpose the production of 'a mere negative quality, the absence of fire' as distinct from any 'stance or composition of things'); see further *Boulton v Bull* 126 ER 651, 661 (Heath J), 663 (Buller J); *Electric Telegraph Company v Brett* (1851) 138 ER 331 (improvements in giving signals and sounding alarms in distant places by means of electric currents); *Newton v Vaucher* (1851) 155 ER 794 (improvements in method of packaging machines to render them air and fluid tight).

46 See also *Re Brown* (1899) 5 ALR 81.

47 (1901) 19 RPC 53.

48 *Ibid* 54.

49 *Ibid*.

50 *Ibid*.

51 (1910) 10 CLR 701.

statutory definition. That contention was accepted by the two-Judge majority, albeit for different reasons. For Griffiths CJ, the alleged invention was ‘a [mere] direction how best to use materials in everyday use to achieve an everyday object’⁵² equivalent to an inherently unpatentable analogous use. For O’Connor J, in contrast, the alleged invention was unsuited to patent protection because it involved neither the production of any vendible article nor the inventive application of any mechanical contrivance or chemical substance.⁵³ His Honour stated:

The proposition [articulated by Tindal CJ in *Crane v Price*⁵⁴] that a patent may be granted for a new method of producing an old result in a more efficient and more economical manner must be qualified by the condition that *the new method must either produce some vendible article or must be carried out by some mechanical contrivance or some substance* the use or adaptation of which for the purpose of working the new method is part of the invention.⁵⁵

Whilst not expressly supported by reference to *Cooper’s Application* – or for that matter any other decision – this requirement for the production of a vendible article or use of a mechanical or chemical object was reminiscent of that case with two qualifications. First, the requirement for production of a physical article was expressed by O’Connor J as applying only in respect of methods not involving the use or adaptation of a mechanical contrivance or substance, and was thus not absolute. But second, to the extent that production of a physical article was required the article had to be ‘vendible’, consistent with the judgment of Heath J in *Boulton v Bull*.

The ultimate significance of Justice O’Connor’s decision lies in its reflection (with *Cooper’s Application*) of an emerging trend during the early 20th century of restrictively interpreting the scope and requirements of inherent patentability in order to exclude subject matter not involving the production or treatment of vendible and/or artificial products. Whilst it is difficult to view the decision of Griffiths CJ in *Rogers v Commonwealth* as having supported or undermined this trend, the minority view of Isaacs J in the same case was clearly against it. In a judgment reminiscent of the decisions of Eyre CJ and Rooke J in *Boulton v Bull*, his Honour rejected both the contention of law proposed by O’Connor J and the interpretation of the subject matter suggested by Griffiths CJ, arguing in respect of the former that any subject matter could on current authority support a patent if it involved a new and useful combination of idea and *modus operandi*.⁵⁶ As has been seen, this conception of the invention as ‘applied idea’ was consistent with the approach of UK decision makers throughout the 19th century.

Despite their lack of supporting authority, the judgments of O’Connor J in *Rogers v Commonwealth* and the Attorney-General in *Cooper’s Application* were largely vindicated in 1914 by the recognition, in the UK, of a general

52 Ibid 709.

53 Ibid 712.

54 (1842) 134 ER 239, 248. Note the subsequent reliance by the High Court of Australia on the decision of Tindal CJ in *Crane v Price* to justify a broad conception of inherent patentability: see below n 104 and accompanying text.

55 *Rogers v Commonwealth* (1910) 10 CLR 701, 712 (emphasis added).

56 Ibid 718.

requirement that a subject matter to be patentable must involve the production or treatment of a commercial product. The case in which this requirement was formulated is *Re C & W's Application for a Patent* ('*C & W's Application*'),⁵⁷ which is the first reported case in the history of Anglo-Australian law to consider the inherent patentability of methods of medical treatment.

C The Emergence of Medical Methods as an Issue for Anglo-Australian Patents Law

1 C & W's Application

In *C & W's Application* a method of extracting lead from human bodies was held ineligible for patent protection because of its lack of association with the manufacture or sale of a 'commercial product', and consequential inability to be regarded as an 'invention' within the meaning of the applicable patents legislation.⁵⁸ In reaching his conclusion, the Solicitor-General relied on the original statutory context of the phrase 'manner of new manufacture'⁵⁹ – including, in particular, the exclusion from patentability by s 6 of the *Statute of Monopolies* of subject matter 'contrary to the law []or mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient' – to support a conception of the invention as a new or improved thing or substance, or 'a machine or a process that can be used in making something that is, or may be, of commercial value'.⁶⁰ Whilst a human being could be considered a working organism that would be improved by the method in question, this was not sufficient in the Solicitor-General's opinion to make that method one of relevance to 'manufacture or trade'.⁶¹ The result was the acceptance by the Solicitor-General of a general exclusion from patentability covering methods of medical treatment.

Three comments can be made in relation to that exclusion and its rationalisation by the Solicitor-General. The first concerns the Solicitor-General's reliance on the proviso in s 6 of the *Statute of Monopolies*. Such reliance was consistent with the emphasis of decision makers during the late 19th and early 20th centuries on the literal language of modern patents legislation, and with their related concern to justify in terms of that language the historical exclusions from patentability. One consequence of this trend was a practice during this period of invoking the s 6 proviso to support a particular conclusion regarding a subject matter's inherent patentability.⁶² To the extent that it reflected this trend *C & W's Application* was not unusual. Reliance on the proviso in the context of methods of medical treatment was, however, significant in establishing a doctrinal link that would become important later in the 20th century.

57 (1914) 31 RPC 235.

58 *Patents and Designs Act 1907* (UK) 7 Edw 7, c29 s 93; see above n 8 and accompanying text.

59 *C & W's Application* (1914) 31 RPC 235, 235.

60 *Ibid* 235-6.

61 *Ibid* 236.

62 See, eg, *Morgan v Windover* (1890) 7 RPC 131; *Thierry v Riekman* (1895) 12 RPC 412; *Wood v Raphael* (1896) 13 RPC 730; *Schwer v Fulham* (1910) 11 CLR 249.

The second comment in respect of *C & W's Application* is that no authorities were cited by the Solicitor-General in support of his decision generally or the exclusion of medical methods from patentability specifically. This is partly explicable by reference to the absence of reported decisions involving methods of medical treatment, but also reflects the lack of precedential support for the vendible product requirement itself. Indeed, the only reported decision expressly in favour of a vendible product requirement was that of Heath J in *Boulton v Bull* – which, as has been seen, was discredited by the approach of decision makers during the 19th century. Whilst the decisions of Buller J in the same case, the Attorney-General in *Cooper's Application* and O'Connor J in *Rogers v Commonwealth*⁶³ all came close, they ultimately fell short of stipulating that all inherently patentable methods must involve the production or treatment of a vendible object and remained, in any case, anomalous reflections of a very restrictive understanding of inherent patentability.⁶⁴ For these reasons *C & W's Application* is best explained as the third in a line of early 20th century Anglo-Australian cases to support an increasingly narrow interpretation of inherent patentability. Similarly the commercial product requirement articulated in *C & W's Application* – which manifested the trend represented by those cases – is best explained as a useful expedient to support the exclusion from patentability of methods of medical treatment.

This raises the third point concerning *C & W's Application*, which is that if as contended the commercial product requirement was a means of justifying ex post facto the denial of patents for methods of medical treatment, the question remains as to the reason for that denial. Put differently, why were methods of treating humans considered by the Solicitor-General to be ineligible for patent protection? Whilst the express reason offered by the Solicitor-General was that such methods have no relevance to 'manufacture and trade', exactly how or on what basis that reason was reached is unclear. Consideration of his decision as a whole suggests as its likely basis an unwillingness to treat humans as objects of commercial exploitation. In addition, it appears from the Solicitor-General's judgment that such unwillingness was fuelled by his view that doctors should not, on moral grounds, seek commercial monopolies in respect of their professional skills. This is despite the Solicitor-General's express statement that morality was not a consideration in his finding of unpatentability:

63 Note however that even Justice O'Connor's test of inherent patentability would have encompassed methods of medical treatment to the extent that they involved the use of a physical object: see above n 55 and accompanying text.

64 Cf *Cornish v Keene* (1837) 132 ER 530, 536; *Hornblower v Boulton* (1799) 101 ER 1285, 1287-8 (Lord Kenyon CJ).

It has been urged, and I think quite rightly, that the question of humanity ought not to affect the decision in such a case as this ... Of course, it is well known that the medical profession do all in their power to discourage members of their body from obtaining protection for any discovery that has for its object the alleviation of human suffering, and it is impossible to speak too highly of such conduct, but it cannot affect my judgment in arriving at a conclusion upon the terms of the Section of the Act of Parliament, and I have altogether excluded such consideration from my mind.⁶⁵

Ultimately, the Solicitor-General's success in not allowing his views regarding the morality of monopolizing medical methods affect his legal judgment must be doubted given the absence of any convincing alternative justification for his decision. In addition the Solicitor-General's assertion that morality was not relevant to inherent patentability, apart from being gratuitous, was inconsistent with the thrust of contemporary UK patents legislation which implicitly acknowledged such relevance in its conferral of power on the Comptroller to 'refuse to grant a patent for an invention ... of which the use would, in his opinion, be contrary to law or morality'.⁶⁶ It was also arguably inconsistent with the historical prohibition, reflected in s 6 of the *Statute of Monopolies* (and thus incorporated into modern Anglo-Australian legislative definitions of 'invention'), against the monopolisation of subject matter considered 'generally inconvenient'⁶⁷ which, at least in theory,⁶⁸ provided the Crown and Privy Council with an unfettered discretion to deny patentability on any public policy ground.⁶⁹

The overall impression created by *C & W's Application* is that the Solicitor-General's eschewal of the relevance of morality to inherent patentability, and his recognition of a commercial product requirement as the basis for a general exclusion from patentability in respect of methods of medical treatment, were the combined result of his refusal: (a) to engage openly with the moral issues purportedly raised by the patenting of medical methods; and (b) to concede that, morality or other public policy aside, there was no sound legal basis for denying patentability to such methods. This impression is borne out by the subsequent history of the medical methods exclusion. Interestingly, it is also consistent with the only other case during the early 20th century in which the relevance of morality to inherent patentability was expressly considered. That case, *A & H's*

65 *C & W's Application* (1914) 31 RPC 235, 236.

66 *Patents, Designs & Trade Marks Act 1883* (UK) 46 & 47 Vict, c57 s 86. This provision was replicated in the *Patents and Designs Act 1907* (UK) 7 Edw 7, c29 s 75 (sequently expanded by s 11 of the *Patents and Designs Act, 1932* 22 & 23 Geo 5, c32), but was removed from UK patents legislation in 1949. No equivalent provision was ever introduced in Australia.

67 The historical prohibition against the monopolisation of 'generally inconvenient' subject matter derived from the 16th century Crown practice of including in letters patent clauses enabling their revocation for 'inconveniency': see D Seaborne Davies, 'The Early History of the Patent Specification' (1934) 50 *Law Quarterly Review* 86, 102.

68 Note however that in practice the 'general inconvenience' provision had historically been invoked for the exclusive purpose of protecting local employment: see Davies, above n 67, 102-4. The main way a patent would threaten the interests of local workers was by encouraging their replacement with machines: see *Re an Application for a Patent by T S* [1924] 41 RPC 530, 538.

69 See MacLeod, above n 13, 13.

Application,⁷⁰ involved an appeal from a decision by the Assistant-Comptroller to refuse a patent application in respect of a contraceptive device on the ground that use of such device was ‘contrary to ... morality’ within the meaning of the applicable patents legislation.⁷¹ On appeal, the patentee disputed this finding by contending that use of a contraceptive device was contrary neither to law nor to morality, and that the application should therefore be permitted to proceed as relating to an ‘invention’. Interestingly given his first instance decision, the Assistant-Comptroller when responding to this contention avoided the ‘morality’ issue and urged the Solicitor-General instead to ‘refuse the Grant of a Patent for articles which it would not be fitting to sell as being protected by Royal Letters Patent’.⁷² The Solicitor-General complied, thereby also avoiding discussion of the device’s morality. He said:

The question ... arises whether, quite apart from Section 75,^[73] the Crown in the exercise of its prerogative could possibly be expected to exercise its discretion to grant a patent for an article designed as an apparatus for the prevention of contraception ... I decline to be any part to the grant of a patent for this class of article ... Even if, as to which I express no opinion, its use as a contraceptive is consistent with morality, I am not prepared to exercise on behalf of the Crown the Crown’s discretion in favour of the grant of a patent in respect of it ... I express no opinion as to whether the use of these articles is consistent with morality, because I am not aware that the law has laid down what the exact standards of morality are. I am a Court of Law, and not a Court of Morality. All I say is I think these are not articles for which, whether the specification be amended or not, the Crown can be expected to exercise its discretion by way of granting a patent. I therefore dismiss the Appeal.⁷⁴

Thus, and as in *C & W’s Application*, the Solicitor-General’s suggestion that morality could not be considered when determining inherent patentability left him with the task of finding another legal basis on which to justify rejection of the patent application before him. The fact that the device was a physical object and not a method meant that the ‘commercial product’ requirement of *C & W’s Application* was not available to this end. Rather than deriving an equivalent restriction based on the necessary characteristics of an invention, the Solicitor-General relied instead on his role as delegate of the Crown, and on the ‘inappropriateness’ of exercising the Crown’s prerogative in respect of articles of dubious moral status. In so doing he avoided the need to engage openly with the moral issues concerning the patenting of a contraceptive device, whilst also avoiding the admission and conclusion that, morality aside, there was no obstacle to allowing the device to be patented. In method this decision was very similar to that of *C & W’s Application*, and supports the conclusions reached in respect of that case above. In both cases a new principle of black letter law masqueraded as public policy.

70 *A & H’s Application* (1927) 44 RPC 298.

71 *Patents and Designs Act 1907* (UK) 7 Edw 7, c29 s 75 (see above n 66).

72 *A & H’s Application* (1927) 44 RPC 298, 298.

73 See above n 71.

74 *A & H’s Application* (1927) 44 RPC 298, 298.

2 C & W's Application Before the High Court of Australia: Maeder v Busch

The instability of the legal foundation of *C & W's Application* was acknowledged in the only other Anglo-Australian decision prior to 1959 to consider methods of medical treatment in detail, which was the decision of the High Court of Australia in *Maeder v Busch*.⁷⁵

Maeder v Busch concerned a patent application for a method of forming permanent waves in human hair that was opposed, among other things, for its alleged failure to involve an 'invention' on the principles of *C & W's Application*. Of the four Judges to hear the opposition, two offered tentative support for *C & W's Application*⁷⁶ and two expressed reservations about its correctness.⁷⁷ None however was prepared to decide the matter finally, and only Dixon J was prepared to consider it in any detail. In the course of such consideration his Honour cast doubt on the limits of the exclusion recognised in *C & W's Application*, articulating the problem as follows:

To be patentable an invention must relate to an art. Perhaps the widest statement is one of the earliest [referring to the statement of Eyre CJ in *Boulton v Bull*]. But the ultimate end in view is the production or treatment of, or effect upon, some entity. Applications of old things to a new use, accompanied by the exercise of inventive power, are often patentable though there be no production of a new thing. But in every case the invention must refer to and be applicable to a tangible thing.

In the present case there is nothing to be affected but the hair. The chemical compounds already exist. The use of them, the application of heat and the method of treatment constitute nothing but method, procedure, treatment or process. Can the hair growing upon the human head be regarded as satisfying the condition that the process shall in some way relate to the productive arts?⁷⁸

His Honour's answer to this question was ambivalent. On the one hand a method of treating hair was not, he suggested, aimed at producing or helping to produce any article of commerce; no substance or thing forming a possible subject of commerce or contribution to the productive arts being brought into existence by it or with its aid.⁷⁹ On the other hand, however, the method could be considered to be 'embodied in a manual art or craft' on the ground that its purpose was the treatment of an object of purely mechanical utility.⁸⁰ Thus the patentability of the method depended in his Honour's view on whether a process to be an invention had to involve the production or treatment of a commercial product (as had been held in *C & W's Application*), or merely the production or treatment of some object of mechanical utility so as to reflect a manual art or craft.⁸¹ According to Dixon J, however, even the latter view would not save from unpatentability methods of treating or manipulating a vital part of the human

75 (1938) 59 CLR 684.

76 *Ibid* 699 (Latham CJ), 708 (McTiernan J).

77 *Ibid* 706-7 (Dixon J), 707 (Evatt J).

78 *Ibid* 706.

79 *Ibid*.

80 *Ibid*.

81 *Ibid*.

body which, he held, would always lack the artificial or mechanical element of an invention.⁸²

The effect of Justice Dixon's reasoning was two-fold. First, it challenged the breadth of the existing scope of the medical methods exclusion beyond methods having a therapeutic purpose. But second, it added new weight to the exclusion so restricted by identifying as its underlying justification the inherent inability of methods of treating a vital part of the human body to possess the artificiality required of an invention. That justification was not affected by the question raised by Dixon J concerning the correctness of the commercial product requirement, and suggested as the critical distinction for methods of medical treatment the distinction between 'natural' and 'artificial' subject matter. Exactly why a method of treating a living thing such as a human being should not be considered 'artificial' was not explicated by Dixon J and is difficult to understand. Specifically, it is difficult to see how the 'naturalness' of the object of a method can be viewed as affecting the artificiality or otherwise of the method itself; a point implicitly acknowledged by Evatt J in the following passage from the same case:

[I]t was suggested that, under the *Patents Act*, assuming that every other element necessary to establish a valid patent is present, the mere fact that the curls are to be produced on the head of a living person precludes a valid grant. The question whether this one fact – that curls are to be made on the head of a living person – prevents the issue of a grant need not here be decided; but I am inclined to the opinion that providing all the other elements of patentability are present, it cannot be laid down as an absolute rule that although the making of artificial curls for subsequent use on the human head can be protected by a patentable process, doing very much the same thing with the hair that is already on the head cannot be protected.⁸³

Ultimately, the justification offered by Dixon J for a continued medical methods exclusion independent of any vendible product requirement is unconvincing, and reflects the same concern as in *C & W's Application* to entrench that exclusion without proper consideration of its underlying basis. Unlike the Solicitor-General in *C & W's Application*, however, Justice Dixon's decision appears genuinely not to have been motivated by any moral concerns regarding the patenting of medical methods; his Honour having expressly (and convincingly) stated that the purpose for or vocation in which the alleged invention was to be used could not in logic be relevant to its patentability.⁸⁴ Exactly why Dixon J was so adamant in affirming the exclusion, despite his otherwise cautious and well-reasoned decision, is unclear. The fact remains, however, that his decision in this regard reflected for the second time in as many

82 *Ibid.*

83 *Ibid* 707.

84 *Ibid* 706 (Dixon J):

It is difficult to base any legal distinction on the motive or purpose of the operator or manipulator or on the vocation he pursues. It can hardly matter whether he acts in the exercise of a profession or art or trade or business. The purpose of the patentee and those intended to employ the process may be entirely commercial. The process may be intended for use in ordinary trade or business such as that of hairdressing, manicure, pedicure. The purpose, on the other hand, may be the relief of suffering by surgical or manipulative means.

decisions the adaptation of first principles of patents law to support an unconvincing view of medical methods as lacking the characteristics required of inventions.

3 *The Commercial Product Requirement and Medical Methods Exclusion After Maeder v Busch*

Justice Dixon's questioning of the commercial product requirement and reformulation of the legal basis for the medical methods exclusion had no effect on the approach of UK decision makers for the two decades following *Maeder v Busch*. Indeed, four years after that case the commercial product requirement was approved and entrenched in the UK by the decision of the Patents Appeal Tribunal ('PAT') in *G E C's Application*.⁸⁵ The alleged invention in *G E C's Application* was somewhat similar to that of *Rogers v Commonwealth*⁸⁶ and, in a judgment reminiscent of the judgment of O'Connor J therein, was denied a patent for its failure to involve the production, improvement, restoration or preservation of a vendible product.⁸⁷ In support of the requirement for such involvement the PAT in *G E C's Application* confirmed the inherent unpatentability of 'processes or methods of treating diseases in human beings';⁸⁸ its reasoning in this regard being somewhat ironic given the original justification of the medical methods exclusion by reference to the vendible product requirement itself.⁸⁹ Put differently, it is ironic that the medical methods exclusion was now being relied on to support the restrictive conception of inherent patentability from which that exclusion was itself originally said to derive.

The circularity of the reasoning in *G E C's Application* belied the ongoing instability of the legal foundation on which the vendible product requirement and the (purportedly related) rule against patenting medical methods rested, even in the UK. Some acknowledgement of that instability was reflected almost immediately during the 1940s, when Evershed LJ attempted to relax the vendible product requirement in order, his Lordship held, that it not restrict the common language meaning of 'manner of new manufacture'⁹⁰ and through it the statutory definition of 'invention' per se.⁹¹ The initial focus of Evershed LJ in this regard was on the word 'product' which he stated could only be reconciled with 'manner of new manufacture' if it was understood as having been used by Morton LJ as

85 (1942) 60 RPC 1.

86 The subject matter in *G E C's Application* was a method of extinguishing fires using a known chemical stance.

87 *G E C's Application* (1942) 60 RPC 1, 4.

88 *Ibid* 6.

89 See above n 60 and accompanying text.

90 *Re Two Applications for Patents by The Cementation Company Ltd* (1945) 62 RPC 151, 153 ('*The Cementation Company's Application*'), where Evershed LJ construed the common language of 'manufacture' as embracing '(a) the action or process of making by hand (b) the making of articles or material ... by physical labour or mechanical power and (c) a branch of productive industry'.

91 *Ibid* 153-4.

a convenient and compendious term to indicate the article or material resulting from the activity, and [not as] intending to limit by reference to what may be the common acceptance to-day of the word 'product' that which results from a manufacture.⁹²

The immediate effect of this clarification was to concede as inherently patentable methods involving the treatment of any (vendible) tangible matter regardless of its physicality or artificiality.⁹³ Whilst a human body is clearly a 'tangible matter', the problem remained of the more restrictive aspect of Lord Justice Morton's rules which required that the product of a patentable process be 'vendible'. That requirement was also elucidated by Evershed LJ during the 1940s, when his Lordship held in *Re an Application for a Patent by Rantzen*⁹⁴ that a 'vendible product' was not confined to something that could be passed from one man to another upon a transaction of purchase or sale, but rather encompassed anything that might 'fairly be regarded as the outcome of a process of manufacture'.⁹⁵ Even had this liberal interpretation of the vendible product requirement been supported by his Honour's contemporaries (which it was not),⁹⁶ it would still have precluded the patenting of methods of medical treatment. Thus, by 1959, methods of treating the human body remained inherently unpatentable both in the UK (by operation of the vendible product requirement) and in Australia (by operation of the same requirement and/or the need for production or treatment of an artificial product). In that year the rift between UK and Australian law, already evident in *Maeder v Busch*, widened with the important⁹⁷ decision of the High Court of Australia in *National Research Development Corporation v Commissioner of Patents* ('NRDC').⁹⁸ The effect of this decision was to demolish both the vendible product requirement and the requirement recognised by Dixon J for the production or treatment of an artificial product. Amazingly, however, the exclusion from patentability of

92 Ibid 154.

93 See, eg, *The Cementation Company's Application* (1945) 62 RPC 151; *Re an Application for a Patent by Rantzen* (1946) 64 RPC 63; *Re Philips Electrical Industries Ltd's Application for a Patent* [1959] RPC 341; compare *Re an Application for a Patent by Bovingdon* (1946) 64 RPC 20, 21. See further *Re the Dow Chemical Company's Application for a Patent* [1956] RPC 247; *Re American Chemical Paint Company's Application* [1958] RPC 47; *British Petroleum Coy Ltd's Application for a Patent* [1958] RPC 253.

94 (1946) 64 RPC 63.

95 Ibid 66.

96 With the exception of Lloyd-Jacob J (as illustrated by the decisions in *Re an Application for a Patent by Lenard* (1954) 71 RPC 190 and *Elton and Leda Chemical Ltd's Application for a Patent* [1957] RPC 267), Lord Justice Evershed's contemporaries applied Lord Justice Morton's rules to justify the exclusion from patentability of two main types of process from 1942-1959. The first involved the production or treatment of ephemeral matter (see, eg, *Re an Application for a Patent by C M* (1944) 61 RPC 63; *Re F's Application for a Patent* (1954) 72 RPC 127; *Re Huber's Application for a Patent* [1956] RPC 50; *Re Philips Electrical Industries Ltd's Application for a Patent* [1959] RPC 341; *British Petroleum Co Ltd's Application for a Patent* [1958] RPC 253), and the second involved the treatment of soil to improve its crop-bearing capacity (see, eg, *Standard Oil Development Company's Application* (1951) 68 RPC 114; *Re the Dow Chemical Company's Application for a Patent* [1956] RPC 247; *Re American Chemical Paint Company's Application* [1958] RPC 47).

97 The importance of the decision in NRDC has frequently been acknowledged by Australian and overseas courts (see, eg, *Joos v Commissioner of Patents* (1972) 126 CLR 611, 616 (Barwick CJ); *Swift and Company v Commissioner of Patents* [1960] NZLR 775, 779 (Barrowclough CJ)).

98 (1959) 102 CLR 252.

methods of medical treatment that had previously rested on those requirements continued intact.

III THE PATENTABILITY OF METHODS OF MEDICAL TREATMENT IN AUSTRALIA AND THE UK FROM 1959

A Revision of the Vendible Product Requirement and its Implications for Methods of Medical Treatment

NRDC involved a method of using a known chemical substance to treat soil in order to eradicate and control weeds from crop areas without affecting the crops themselves.⁹⁹ The issue it raised was whether such a method was precluded from patentability because, among other things, of its failure to result in any new or improved vendible product. In a unanimous decision the High Court held that it was not so precluded on the ground that it was a proper subject of letters patent according to the historically developed principles governing application of s 6 of the *Statute of Monopolies*; its purpose being to create a 'vendible product' in the sense of an artificially created end of practical utility.¹⁰⁰

There are two aspects, to the High Court's finding on this point. The first concerns the question to be posed by decision makers in determining the existence of an 'invention' within the meaning of modern patents legislation, and the second concerns the essential attributes of an invention so defined. In respect of the first of these aspects the Court held that the right question is not "Is this a manner (or kind) of manufacture?", but rather "Is this a proper subject of letters patent according to the principles which have been developed for the application of s. 6 of the *Statute of Monopolies*?"¹⁰¹ By emphasizing the spirit of the *Statute of Monopolies* over its literal terms, the Court vindicated the approach of *Rooke J* in *Boulton v Bull* more than 150 years earlier.

In respect of the second aspect of the *NRDC* decision concerning the essential attributes of an invention, the Court's reasoning proceeded as follows. First, the Court noted the comment by the Chief Justice in *Maeder v Busch* that a widening conception of the invention had been a characteristic of the growth of patents law,¹⁰² and cited as examples of the accuracy of that statement the conceptions of the invention articulated by *Eyre CJ* in *Boulton v Bull*¹⁰³ and *Tindal CJ* in *Crane v Price*.¹⁰⁴ It then described, as the central unresolved issue concerning such conception, 'whether it is enough that a process [to be patentable] produces a useful result or whether it is necessary that some physical thing is either brought into existence or so affected as the better to serve man's purposes',¹⁰⁵ before reviewing the early 20th century Anglo-Australian case law in respect of that

99 The claims in issue in *NRDC* are extracted at *ibid* 260-1.

100 *NRDC* (1959) 102 CLR 252, 276-7.

101 *Ibid* 269.

102 *Ibid* 270.

103 126 ER 651, 666; see above n 26 and accompanying text.

104 134 ER 239, 248; see above n 54 and accompanying text.

105 *NRDC* (1959) 102 CLR 252, 270.

issue including, in particular, *G E C's Application* and the line of cases in which the rules there articulated were subsequently applied.¹⁰⁶ Such review was concluded by the Court with the statement that the rules of *G E C's Application* could only be upheld as 'wide enough to convey the broad idea which the long line of decisions on the subject has shown to be comprehended by the Statute'¹⁰⁷ if the word 'product' in those rules was understood 'as covering every end produced',¹⁰⁸ and the word "vendible" as pointing only to the requirement of utility in practical affairs'.¹⁰⁹ The effect of this conclusion was to bring *NRDC's* method within the scope of those rules, as a method '[having] as its end result an artificial effect falling squarely within the true concept of what must be produced by a process if it is to be held patentable'.¹¹⁰ The Court extrapolated:

This view is, we think, required by a sound understanding of the lines along which patents law has developed and necessarily must develop in a modern society. The effect produced by the appellant's method exhibits the two essential qualities upon which 'product' and 'vendible' seem designed to insist. It is a 'product' because it consists in an artificially created state of affairs, discernible by observing over a period the growth of weeds and crops respectively on sown land on which the method has been put into practice. And the significance of the product is economic; for it provides a remarkable advantage, indeed to the lay mind a sensational advantage, for one of the most elemental activities by which man has served his material needs, the cultivation of the soil for the production of its fruits.¹¹¹

Thus, in the view of the High Court, any method resulting in an objectively discernible and artificially created state of affairs of economic significance would be a proper subject of letters patent within the meaning of the *Statute of Monopolies*; a subject matter of this type being a method producing an end of utility in practical affairs. The effect of this view was to bring inherent patentability back into line with 19th century authorities, and to undermine the two historical reasons expressed for denying patents to medical methods. Such effect was not however recognised by the High Court – or at least was not recognised as being sufficient to permit the patenting of methods of medical treatment. Hence the Court's rather tentative¹¹² suggestion that

[t]he exclusion of methods of surgery and other processes for treating the human body may well lie outside the concept of invention because the whole subject is conceived as essentially non-economic.¹¹³

This suggestion that the exclusion from patentability of methods of medical treatment could be justified on the basis of their non-economic value is unconvincing. Indeed, it is difficult to see how medical methods could be devoid of 'economic significance' in the broad sense in which that phrase was understood in *NRDC* when they are routinely performed for commercial profit.

106 *Ibid* 271-6.

107 *Ibid* 276.

108 *Ibid*.

109 *Ibid*.

110 *Ibid* 277.

111 *Ibid*.

112 The tentative nature of the Court's finding in respect of methods of medical treatment is reflected not only in the language in which it is expressed but also in its appearance in parentheses.

113 *NRDC* (1959) 102 CLR 252, 275 (footnotes omitted).

As with the decision of Dixon J in *Maeder v Busch*, the High Court's apparent refusal to concede the implications for methods of medical treatment of its own principles of inherent patentability reflects an unchallenged assumption that such methods were an inappropriate subject matter for patent protection. The result in *NRDC*, as for Dixon J in *Maeder v Busch*, was the dubious adaptation of first principles of inherent patentability to justify perpetuation of the medical methods exclusion.

During the 1960s, the High Court's continued recognition of an exclusion in respect of methods of medical treatment was welcomed in the UK as vindicating the result of *C & W's Application*. The High Court's justification of that exclusion by reference to the 'essentially non-economic' nature of such methods was, however, largely ignored. This left decision makers in the (no longer novel) position of having a recognised exclusion that they were keen to perpetuate but no recognised legal basis on which to do so. Their response was to borrow from the emerging jurisprudence regarding another subject matter involving living matter – biotechnology – and in so doing to revert to the reasoning of Dixon J in *Maeder v Busch*.

B 1960-70: Methods of Medical Treatment as Insufficiently Artificial

The only reported cases to involve a patent application in respect of a method of medical treatment in the decade following *NRDC* were decided in the UK. Each of those cases upheld the historical exclusion of medical methods¹¹⁴ and many relied in doing so on *NRDC*.¹¹⁵ The central reason offered for that exclusion was not however that such methods lacked commercial value as had been held in *NRDC*, but rather that they lacked the artificiality required of inventions. In addition to supporting the approach of Dixon J in *Maeder v Busch*, this reason reflected contemporary decisions in which agricultural and biotechnological subject matter had been denied patentability on the basis of their dependence upon the physiological functions of a higher life form, and consequential inability to be regarded as controllably responsive to human operation.¹¹⁶ That reason was first articulated in *Swift & Company's*

114 Cf *Swift & Company's Application* [1962] RPC 37, discussed below n 117.

115 See, eg, *United States Rubber Company's Application* [1964] RPC 104; *London Rubber Industries Ltd's Patent* [1968] RPC 31 ('*London Rubber*').

116 Biotechnological subject matter was treated after *NRDC* as inherently patentable, subject only to the requirement that it manifest a sufficient level of human involvement to take it out of the realm of nature and into the realm of (artificial) invention; the difficult question in such cases being the construction and application of the nature-artifice divide itself. See generally *General Electric Co Ltd's Application (Patent)* [1961] RPC 21; *American Cyanamid Company (Dann's) Patent* [1971] RPC 425; *Ranks Hovis McDougall Limited* (1976) 46 AOJP 3915; *American Cyanamid Company v Berk Pharmaceuticals Limited* [1976] RPC 231; *Kiren-Amgen Inc v Board of Regents of University of Washington* (1995) 33 IPR 557. For a general discussion of this issue see Ludlow, above n 6. Note the similarity of the legal justification for the medical methods exclusion during this period with the legal justification for the same exclusion recognised under 19th century US law: *Morton v New York Eye Infirmary* 17 Fed Cas 879, 884 (1862).

*Application*¹¹⁷ in respect of a method of treating live animals, and was adapted during the 1960s to support the exclusion from patentability of methods of treating humans.¹¹⁸ Thus in *Neva Corporation's Application* ('*Neva*')¹¹⁹ a method of inducing a state of reduced awareness in humans (and animals) by means of sounds generated by a known apparatus was held to be an unpatentable method of medical treatment on the ground that its utility depended upon the reception and interaction of the sounds with the human brain. This was consistent with *London Rubber Industries Ltd's Patent* ('*London Rubber*'),¹²⁰ where a method of controlling female ovulation through the prescribed oral administration of known hormones was refused a patent on the ground, implicitly, that the utility of such method depended upon the physiological response of the person treated and for this reason fell outside the realm of useful arts in which inventions exist.¹²¹ In one of the very few early decisions that expressly considered the reason for the exclusion of methods of medical treatment from inherent patentability, the PAT in *London Rubber* reconciled its decision with *NRDC* as follows:

[In *NRDC* i]t was suggested that the justification for excluding from the concept of invention methods of surgery or other processes for the treatment of the human body might well rest upon the fact that they are essentially non-economic and the reference in the judgment to *Maeder v Busch* (1938) 59 C.L.R. 684 at 706 shows that by this is meant that: (a) the object is not to produce or aid in the production of any article of commerce; (b) no substance or thing forming a possible subject of commerce or a contribution to the productive arts is to be brought into existence by means of or with the aid of the process ...

[T]he improvisation of a method of treating a human being cannot in reason be regarded as affording proper subject matter for letters patent. If for the purposes of argument the oral administration of specific pills in a controlled manner be taken to be a method or constitute a process, it still cannot be asserted with any reality that the human response to the ingredients so administered falls within any category of the useful arts.¹²²

In this passage the *Swift & Company's Application* emphasis on human control is reconciled with the *NRDC* emphasis on results of commercial significance by positing as the results of medical methods, the human response to them which, in *NRDC* terms, was considered 'essentially non-economic'. It was not long however before this rather tortuous explication of the two decisions was rejected, and the reconception of the medical methods exclusion on public policy grounds began.

117 [1961] RPC 129. Whilst the decision in *Swift & Company's Application* was overruled on appeal by the High Court of Justice on the basis of the Court's 'reasonable doubt' as to its correctness (*Swift & Company's Application* [1962] RPC 37), UK decision makers throughout the 1960s supported in stance the approach of the SE and PAT over that of the High Court of Justice: see, eg, *Neva Corporation's Application* [1968] RPC 481 ('*Neva*'); *London Rubber* [1968] RPC 31.

118 See in this context *Puharich and Lawrence's Application* [1965] RPC 395. Note that detailed reasons were not always provided for the exclusion of methods of medical treatment from patentability during the 1960s (see, eg, *United States Rubber Company's Application* [1964] RPC 104).

119 [1968] RPC 481.

120 [1968] RPC 31.

121 *Ibid* 35.

122 *Ibid* 34-5.

C Developments in Australia and the UK Since 1970

1 *The Reconception of the Medical Methods Exclusion in the UK and Australia From 1970-77*

(a) Cracks in the Façade of *London Rubber*

Cracks in the façade of *London Rubber* were already evident in the 1970 case of *Palmer's Application*.¹²³ In that case, a Superintending Examiner's finding of inherent unpatentability in respect of a method of treatment that depended for its efficacy upon the physiological response of the persons treated was overruled on appeal, on the basis that a method so depending could still involve the practical employment of a person's art and skill so as to constitute an invention.¹²⁴ The effect of such recognition was to remove yet again the primary legal obstacle to the inherent patentability of surgical and therapeutic methods. Whilst that effect was acknowledged the following year in *Schering AG's Application* ('*Schering*'),¹²⁵ its acknowledgement was still not sufficient to secure a reversal of the historical rule against the patenting of such methods, with the PAT in *Schering* once again finding a new justification for that rule's perpetuation. While consistent with the trend of past cases in this respect, in another respect the PAT's judgment represented a radical departure from those cases. Such departure came with its concession that morality both *should* and *could* provide a basis for denying patents to medical methods; a concession that constituted an important step in the reconception of the medical methods exclusion.

(b) The First Step in Reconceiving the Medical Methods Exclusion: *Schering*

The subject matter in *Schering* was a method of female contraception almost identical to that in *London Rubber* but, contrary to the decision in *London Rubber*, was allowed to proceed to grant in the face of opposition for patent ineligibility. At first instance,¹²⁶ the Superintending Examiner ('SE') focused on distinguishing *Palmer's Application* in order to preserve the historical position regarding methods of medical treatment, the correctness of which, he noted, was confirmed in *NRDC*.¹²⁷ On appeal, in contrast,¹²⁸ the PAT avoided discussion of *Palmer's Application* opting instead for a first principles analysis that led it to the following four central observations: 'The method in question was the result of considerable research effort, and represented a novel and important contribution to the techniques of contraception'.¹²⁹

123 [1970] RPC 597. But note the decision of the High Court of Justice in *Swift & Company's Application* discussed above n 117, and the New Zealand case (*Swift and Company v Commissioner of Patents* [1960] NZLR 775) on which that decision was based.

124 *Palmer's Application* [1970] RPC 597, 601.

125 [1971] RPC 337.

126 *Ibid* 338.

127 *Ibid*.

128 *Ibid* 339.

129 *Ibid*.

Whilst it was plainly arguable upon ethical grounds that there should be no patent protection in the medical field at all, the patentability under UK law of pharmaceutical substances and curative devices had long been recognised, and had resulted in an enormous investment in the field of medical research.¹³⁰ Such patentability was subject to certain legislative safeguards against unwarrantable exploitation.¹³¹

If the practice of awarding patents for medical substances and devices in order to encourage further investment in medical research was approved – and if the object of the patent system was in truth to give hope of a reward to people whose research and industry resulted in valuable products or processes – there could be no logical basis for not extending that practice to medical methods, subject to extension also of the legislative safeguards applicable in respect of medical substances and devices.¹³²

Whilst the denial of patents to methods of medical treatment had historically been considered axiomatic, the demise of the need for any treatment or production of a commercial object made the logic of such denial unclear.¹³³

Despite these observations, the PAT concluded that the absence in contemporary patents legislation of safeguards against the unwarranted exploitation of processes for medical treatment, as existed for medical substances and devices,¹³⁴ reflected a clear assumption by Parliament that methods of medical treatment could not be patented.¹³⁵ This raised the question as to the meaning of ‘method of medical treatment’ in this context and as to whether that meaning included methods of contraception such as that in issue.¹³⁶ The PAT held it did not, ‘medical treatment’ denoting treatments to cure or prevent disease.¹³⁷

The overall significance of the decision in *Schering* is four-fold. First, it confirmed as the primary justification for the conferring of patents the rewarding of inventors for their introduction within the jurisdiction of new and useful objects through the expenditure of skill, effort and expense.¹³⁸ Secondly, it confirmed the applicability of this justification in respect of methods of medical treatment, thereby removing any first principle policy objections to the patenting of such methods and affirming generally the non-discriminatory bias of inherent

130 Ibid 340.

131 Ibid.

132 Ibid 341.

133 Ibid 342.

134 The relevant legislative safeguards against unwarranted exploitation of medical stances and devices were contained in s 41 of the *Patents Act 1949* (UK) 12, 13 & 14 Geo 6, c87, which provided for compulsory licences in respect of such stances and devices consistent with s 38A of the *Patents and Designs Act 1907* (UK) 7 Edw 7, c29 (inserted by *Patents and Designs Act 1919* (UK) 9 & 10 Geo 5, c80, s 11(1)).

135 *Schering* [1971] RPC 337, 343.

136 Ibid.

137 Ibid 344. Note the similarity between the definition of ‘methods of medical treatment’ adopted in *Schering* and that supported by Dixon J in *Maeder v Busch*, focusing on methods of treating or manipulating vital parts of the human body (see above n 81 and accompanying text).

138 The justification for patents offered by the PAT in *Schering* was consistent with the emphasis of 19th century decision makers on novelty, utility and sufficient description as the only real restrictions on the scope of patentability: see above n 33 and accompanying text.

patentability central to the decision in *NRDC*.¹³⁹ Thirdly, it confirmed the absence of any relevant distinction for patentability purposes between methods of medical treatment on the one hand and medical substances and devices on the other, and conceded the absence of any logical basis for treating the former as a 'fine art' and the latter as an invention or 'useful art'. The effect of this concession was to confirm the inherent patentability of methods of medical treatment pursuant to the principles of *NRDC* and emphasise – for the second time¹⁴⁰ – the illogicality of intuitive objections to the patenting of such methods given the absence of similar objections in respect of medical products.

This raises the fourth point regarding *Schering*, which concerns the PAT's suggestion that, express legislative provision aside, the only legitimate ground on which methods of medical treatment could be denied inherent patentability was that of ethics. This reconception of the medical methods exclusion in moral terms reflected two things. First, it reflected yet another attempt by an Anglo-Australian decision maker to find a legitimate basis for perpetuating that exclusion. And secondly – in a radical departure from existing jurisprudence – it reflected an admission that the only such basis that existed was morality. The foundation for that admission, however, remained unclear. Specifically, the PAT in *Schering* offered no legal justification to support its view of morality as relevant to inherent patentability, let alone any policy justification to support its view of morality as requiring the exclusion from patentability of methods of medical treatment. In respect of the first of these points there remained the historical principle against the relevance of morality to inherent patentability; a principle that, as has been seen, was established in the context of medical methods themselves.¹⁴¹ In respect of the second, the PAT merely accepted without critical discussion that moral objections to the patenting of medical methods not only existed, but were such as to require prima facie the exclusion from patentability of all medical subject matter, whether method or product.¹⁴²

One final point of interest about *Schering* should be noted, and that is the absence of any suggestion by the SE or PAT that the alleged invention should be denied patentability on the basis of the immorality of its contraceptive purpose, which was the approach in *A & H's Application* nearly 50 years earlier. It is clear from such absence that whatever the view regarding the ethics of patenting

139 In *NRDC* the High Court expressly rejected an argument that 'agricultural' or 'horticultural' processes should prima facie be excluded from patentability (*NRDC* (1959) 102 CLR 252, 279), and supported a conception of inherent patentability as not discriminating between different kinds of subject matter or fields of technology.

140 See above n 83 and accompanying text.

141 See above n 65 and accompanying text. Note the irony of the fact that the PAT's apparent departure from this principle came only after the removal from UK legislation of the very provision that had originally undermined it (see above n 66 and accompanying text).

142 The PAT's acceptance that the ethical issues relating to the patenting of medical methods applied equally in respect of medical products undermined the illogicality of the differential treatment of medical methods and products within patents law; the reason being that, unlike those to the patenting of medical methods, the moral objections to the patenting of medical products were rebutted by the existence of compulsory licencing provisions: see above n 134 and accompanying text.

methods of medical treatment generally, societal prejudices regarding the morality of contraceptive devices and processes had changed by the 1970s.

(c) Reconception of the Medical Methods Exclusion in Moral Terms by the High Court of Australia in 1972: *Joos v Commissioner of Patents*

It took only two years and two cases¹⁴³ for the import of *Schering* to be taken up at a higher judicial level. Thus, in the 1972 High Court of Australia case of *Joos v Commissioner of Patents* ('*Joos*')¹⁴⁴ Barwick CJ held that a method of cosmetic treatment was inherently patentable by reason of its commercial significance (consistent with *NRDC*), and suggested that any general exclusion from inherent patentability of methods of medical treatment – which his Honour defined narrowly as methods 'for medical treatment of human disease, malfunction, disability or incapacity of the human body or any other part of it'¹⁴⁵ not including methods of cosmetic treatment such as that in issue¹⁴⁶ – could only be justified at common law on 'public policy [grounds] as being, in the language of the *Statute of Monopolies*, "generally inconvenient"¹⁴⁷. The implication of this suggestion was that the only legitimate basis on which the inherent patentability of medical methods could be denied was public policy and that, public policy aside, medical methods were 'inventions' within the meaning of *NRDC* and the *Statute of Monopolies*.¹⁴⁸

Two points were central to the decision in *Joos*. The first concerns the effect of *NRDC* which, his Honour held, was to establish as inherently patentable any process having economic value, whether or not 'directly supplied by the nature of the activity which would utilise the process';¹⁴⁹ a finding that directly undermined the treatment of medical methods in that case as 'essentially non-economic'. And the second concerns the phrase 'general inconvenience' in s 6 of the *Statute of Monopolies* which, the Chief Justice suggested, could provide a general public policy basis for the exclusion of subject matter from inherent patentability.¹⁵⁰ This suggestion recognised for the first time a legal basis for opposing inherent patentability on moral grounds. The Chief Justice's reliance to

143 The intervening cases involving methods of medical treatment are *Bio-Digital Sciences Incorporated's Application* [1973] RPC 668 and *Calmic Engineering Company Limited's Application* [1973] RPC 684.

144 (1972) 126 CLR 611.

145 *Ibid* 622.

146 The definition of 'methods of medical treatment' supported by Barwick CJ in *Joos* was consistent with that of the PAT in *Schering* (see above n 137 and accompanying text).

147 *Joos* (1972) 126 CLR 611, 622.

148 *Ibid* 623-624.

149 *Ibid* 624. The implications of this test for the cosmetic method in issue in *Joos* were stated as follows:

In this case, the processes are to be used in what cannot be described otherwise than as a commercial activity of hairdressing, a sector of activity that accounts, I imagine, for a great deal of employment. I could not assign the skill of the hairdresser to the area of the fine arts and have little difficulty placing it in the area of the useful arts. In my opinion, it is an activity in the field of economic endeavour and has commercial significance as those expressions ought to be understood in relation to the grants of patents. Therefore, it could not be said, in my opinion, that the application should not be allowed to proceed because clearly it had no commercial significance in the relevant aspect.

150 *Joos* (1972) 126 CLR 611, 623.

this end on general inconvenience was consistent with two (then) recent decisions of the UK PAT and SE.¹⁵¹ Whilst his Honour referred to neither of those decisions, the effect of his judgment was to support their interpretation of 'general inconvenience' and to confirm the existence under Australian patents law of a general discretion permitting decision makers to deny patentability to any subject matter on public policy grounds.¹⁵² It is interesting that the source of this discretion – the proviso to s 6 of the *Statute of Monopolies* – was the same as that relied on by the Solicitor-General in *C & W's Application* to support the vendible product requirement from which the medical methods exclusion was (then) said to derive.¹⁵³

(d) The Acceptance of *Joos* in the UK to 1977

After *Joos* it was generally accepted by UK decision makers that any historical reason in principle or logic for the denial of patent protection to methods of medical treatment was removed by the test of inherent patentability articulated in *NRDC*, despite the apparent confirmation in that case that medical methods could not support a patent.¹⁵⁴ It was also accepted however that methods of medical treatment could, in theory, still be legitimately regarded as beyond the scope of s 6 of the *Statute of Monopolies* – and therefore beyond the definition of 'invention' in contemporary patents legislation – on ethical grounds which, it was assumed, were accommodated within the concept of 'general inconvenience' contained in that section.¹⁵⁵ This had the effect of reducing the question of the inherent patentability of methods of medical treatment to a question of public policy and, more specifically, to the question of whether

151 See *Rolls-Royce Ltd's Application* [1963] RPC 231 ('Rolls-Royce') and *Hiller's Application* [1969] RPC 267 concerning, respectively, a method of operating a known engine to improve its performance and an improved plan for subterranean utility distribution schemes. The effect of those cases was to permit an opposition to a patent application on the basis of the 'general inconvenience' that permitting the patent would in each case have caused to the public. (See further *Application by Fluid Energy Systems Pty Ltd* [1991] APO 40.) In *Rolls-Royce*, the source of the 'general inconvenience' was the additional burden that would be imposed on pilots – whose responsibility in carrying passengers was held to be sufficiently onerous already – should they be required to '[avoid] infringement of a statutory monopoly in the operation of [their] standard engine controls': *Rolls-Royce* [1963] RPC 231, 256. The same reasoning was adopted in *Hiller's Application* in respect of those responsible for providing utility services: see *Hiller's Application* [1969] RPC 267, 268. Whilst leaving the question open, the PAT on appeal in *Hiller's Application* indicated that objection to the patent on the ground of general inconvenience 'may well be ... fatal': *Hiller's Application* [1969] RPC 267, 270. Interestingly, the decisions in *Rolls-Royce* and *Hiller's Application* were inconsistent with the only other case since the *Statute of Monopolies* to have considered expressly the phrase 'generally inconvenient': *Re an Application for a Patent by T S* [1924] 41 RPC 530.

152 See above n 69 and accompanying text.

153 See above n 60 and accompanying text.

154 See, eg, *Eli Lilly & Company's Application* [1975] RPC 438; *The Upjohn Company (Robert's Application)* [1977] RPC 94 ('Upjohn'); *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 25 IPR 119 ('Rescare'); *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 ('Rescare appeal'); *Laboratories Prographarm v F H Faulding & Co Ltd* [1988] APO 63; *Bristol-Myers Squibb Company v F H Faulding & Co Ltd* (1998) 41 IPR 467 ('Bristol-Myers'); *Bristol-Myers Squibb Company v F H Faulding & Co Ltd* (2000) 46 IPR 553 ('Bristol-Myers v FH Faulding'); cf *Application for a Patent by N V Organon* (1974) 44 AOJP 4503.

155 *Ibid.*

allowing patents for such methods would be unethical or otherwise 'generally inconvenient' within the principles developed in respect of that concept under the *Statute of Monopolies*.

Despite this, the issue of the ethics of permitting patents for methods of medical treatment continued to elude the direct attention of UK decision makers. This is notwithstanding the shift reflected in post-*Joos* cases in the intuitive response of decision makers to that issue, as evidenced by the following statement of the PAT in *Eli Lilly & Company's Application* ('*Eli Lilly*').¹⁵⁶

The reasons for such exclusion [of methods of medical treatment from patentability] appears to us to be based in ethics rather than logic but if there is to be a change of policy, which would appear to us to be sensible, this ought in our view to be effected by legislation rather than by interpretation.¹⁵⁷

Two things are interesting about this statement. The first is the PAT's suggestion that the policy against allowing patents for medical methods on ethical grounds should be changed, and the second is its suggestion that effecting such change is a matter for the legislature and not the courts. Thus, whilst recognizing the ethical basis of the medical methods exclusion, the PAT questioned the courts' competency to reconsider that basis in order to displace the exclusion and permit patents for methods of medical treatment.¹⁵⁸ In addition to vindicating the view of the Solicitors-General in *C & W's Application* and *A & H's Application* 50 years earlier regarding the inappropriateness of considering morality when determining inherent patentability, the PAT's approach in *Eli Lilly* showed the ongoing intransigence of the medical methods exclusion even after judicial support for its perpetuation had declined.

2 *Methods of Medical Treatment in the UK from 1977: Explication of Section 4(2) of the Patents Act 1977 (UK)*

(a) Statutory Reform

The PAT's call for legislative action in respect of medical methods was answered in 1977 with the introduction of a new patents system in the UK mirroring that of the *Convention on the Grant of European Patents* ('EPC').¹⁵⁹ Amongst other things, the *Patents Act 1977 (UK)* ('1977 Act') replaces the express definition of 'invention' by reference to s 6 of the *Statute of Monopolies* with a list of specific exclusions from patentability including, by s 4(2), the exclusion of 'method[s] of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body'.¹⁶⁰ The express legislative basis of this exclusion is not public policy or inherent patentability per se, but rather the inability of medical (and veterinarian) methods to satisfy the secondary patentability requirement of industrial applicability.¹⁶¹ That the

156 [1975] RPC 438.

157 Ibid 445.

158 See also *Upjohn* [1977] RPC 94, 98.

159 Opened for signature 5 October 1973, 13 ILM 268 (entered into force 7 October 1977).

160 *Patents Act 1977 (UK)* s 4(2). The EPC provision corresponding to s 4(2) is art 52(4).

161 The requirement for industrial applicability under the *Patents Act 1977 (UK)* (ss 1(1)(c), 4) and the EPC (arts 52(1), 57, 52(4)) is equivalent to the requirement for utility under Australian law.

exclusion has a public policy justification is, however, recognised by the courts, although – and consistent with the stirrings of the PAT in *Eli Lilly* – that justification is no longer accorded the respect shown by the Solicitor-General in *C & W's Application* and the PAT in *Schering*. This is reflected in the following passage from the judgment of Jacob J in the 1998 case of *Bristol-Myers Squibb Co v Baker Norton Inc* ('*Bristol-Myers v Baker Norton*'):¹⁶²

[T]he limited purpose of the [s 4(2)] exception ... is not so broad as to stop doctors using whatever they feel they need to treat patients. If that were the purpose then one would not allow patents for medicines or medical implements at all. The purpose of the limitation is much narrower, merely to keep patent law from interfering directly with what the doctor actually does to the patient. Patent monopolies are permitted to control what he administers to, or the implements he uses on, the patient. The thinking behind the exception 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 apply also to methods of treatment. It is noteworthy that in the U.S. any such exception has gone, and yet no-one, so far as I know, suggests that its removal has caused any trouble.¹⁶³

The irony of the UK legislature's entrenchment of the medical methods exclusion – which for the first time removes any doubt as to the legal basis for that exclusion – at precisely the time when decision makers were starting to question its public policy basis cannot be ignored. Not surprisingly, the shift away from viewing the patenting of methods of medical treatment as contrary to public policy has not been confined to the UK, but rather is reflected amongst decision makers in most jurisdictions around the world.¹⁶⁴ In the following section the impact of that global shift on the scope of s 4(2) to date will be considered. The conclusion from such consideration is that the loss of judicial support for the medical methods exclusion entrenched by that section is unlikely to have the same impact in the UK as in other countries faced with the same exclusion and shifting judicial perspectives regarding the ethics of medical method patents.

(b) The Liberalisation of the UK Approach to Medical Method Patents

The relaxation of judicial attitudes to methods of medical treatment discernible in the 1970s is also reflected in the earliest cases involving s 4(2) of the 1977 Act, which go some way to limiting the impact of that section on the availability of patent protection for medical methods in the UK. For example, in the 1980 case of *Blendax-Werke's Application* ('*Blendax*'),¹⁶⁵ Graham J of the Patents Court approved the principle – which he himself had articulated 10 years earlier in *Organon Laboratories Limited's Application* ('*Organon*')¹⁶⁶ – that the inventor of a method of medical treatment involving a novel and inventive means of administering known drugs could obtain 'back-door' protection for such method by patenting the form in which the drugs are packaged. The reason

162 [1999] RPC 253.

163 *Ibid* 274.

164 See generally *Bristol-Myers v FH Faulding* (2000) 46 IPR 553, 594 (Finkelstein J).

165 [1980] RPC 491.

166 [1970] RPC 574.

offered in *Organon* for this principle was that there would be 'no reason why [anyone] should want to [use the packaging] except for the new treatment';¹⁶⁷ a fact that also precluded the argument that permitting the patent would cause 'general inconvenience'.¹⁶⁸

Both the conclusion and reasoning of *Organon* were upheld in *Blendax* as a legitimate means of circumventing s 4(2) of the 1977 Act. In the words of Graham J,

I do not ... see why the applicant, who has invented a valuable process which, owing to the law as it stands at present, he cannot claim as a process, should not be able, as far as he can, to get a monopoly for packs or other articles which are useful in that process, so that he can in effect rely on the value of his discovery in claiming something which otherwise people might think had no subject matter.¹⁶⁹

A similarly liberal approach to s 4(2) is reflected in the second of the post-1977 Act cases to involve a method of medical treatment, which is *Stafford-Miller Ltd's Applications* ('*Stafford-Miller*').¹⁷⁰ The patent in that case was for a method of controlling extoparasites or their ova on humans,¹⁷¹ and the issue turned on whether such method fell within the scope of s 4(2) as a 'method of treatment of the human ... body by ... therapy'. Overruling a decision of the SE that it did so fall, the Patents Court upheld the Court of Appeal's decision in *Upjohn*, restricting operation of the medical methods exclusion to 'method[s] of treatment of a human ailment'.¹⁷² The Patents Court concluded that 'a treatment involving the destruction of parasites which are to be found on the body or in the hair' was not such a method.¹⁷³ The reason given by Whitford J for this conclusion was that the object of the treatment was outside the body, and that whilst the distinction for s 4(2) purposes between treating organisms outside and inside the body

may well be somewhat strange ... a line has to be drawn somewhere and I am not sufficiently satisfied that these claims fall on the wrong side of the line as to justify saying at this stage in their life that these patents are incapable of providing a good basis for a sound claim.¹⁷⁴

Overall, the decisions in *Blendax* and *Stafford-Miller* go some way to limiting the impact of s 4(2) on the scope of patentability by means of principles formulated in the 1970s. The liberal approach reflected in those decisions reached its limit, however, in the 1980s, when a new genre of patent claims aimed at defeating that section emerged.

167 Ibid 579.

168 Ibid.

169 [1980] RPC 491, 506.

170 [1984] FSR 258.

171 Whilst the principal claim of the *Stafford-Miller* patent application was directed to the method when used in respect of any substrate, it was conceded by the applicants to have as its particular focus human beings.

172 [1977] RPC 94, 98.

173 [1984] FSR 258, 261.

174 Ibid.

(c) Limits to the Liberalisation of the UK Approach to Medical Method Patents: Swiss Style Claims

So-called 'Swiss style' claims are claims for the 'use of substance or composition X for the manufacture of a medicament for a specified new and inventive therapeutic application'.¹⁷⁵ Whilst claims described in this manner do not on their face involve methods of medical treatment, they do involve uses of a known substance and are thus *prima facie* unpatentable for lack of novelty under s 2 of the 1977 Act. An issue arises however by virtue of s 2(6) of that Act, which provides an express exemption from the novelty requirement for certain uses of known substances in methods of medical treatment, as follows:

In the case of an invention consisting of a substance or composition for use in a method [excluded from patentability by s 4(2)], the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art.

When initially considered, this provision was held in the UK not to cover Swiss style claims on the ground that its application was limited to the *first* use of a known substance in any method of medical treatment.¹⁷⁶ This interpretation was supported by the legislative intent underlying that provision and, it was said, by the intent underlying the equivalently worded art 54(5) of the *EPC*.¹⁷⁷ A problem arose, however, when the Enlarged Board of the European Patent Office ('EPO') disagreed with this construction of art 54(5).¹⁷⁸ According to the Board, the novelty of any second or subsequent medical use of a known substance derived, for the purposes of art 54(5), from that second or subsequent use itself; the claims envisaged by article 54(5) being purpose-limited product claims to a known substance or composition when used in a particular medical method.¹⁷⁹ This finding formed the basis of a second decision by the Enlarged Board in *Mobil/Friction Reducing Additive* ('*Mobil*').¹⁸⁰ In that case it was held that the use of a known compound in a known method to achieve a new technical effect would only be invalid for lack of novelty if such effect had previously been made available to the public. In considering whether an effect had 'previously been made available', the Board emphasised the need to draw 'a line ... between what is in fact made available, and what remains hidden or otherwise has not

175 Claims directed to a second medical use of a known stance or composition are referred to as being of 'Swiss form' in recognition of their original allowance by the Swiss Patent Office: see 'Statement of practice regarding "use claims" issued by the Swiss Federal Intellectual Property Office' [1984] EPOR 581.

176 *Sopharma S A's Application* [1983] RPC 195, 197-8; applied *Bayer A G (Meyer's) Application* [1984] RPC 11, 12.

177 [1983] RPC 195, 198-9.

178 See generally *Re Eisai Co Ltd* (Decision G 5/83 (1985)) [1985] EPOR 241 ('*Eisai*').

179 *Ibid* 248-9.

180 (Decision G02/88) [1990] EPOR 73. In relation to the connection between *Mobil* and *Eisai* see generally *Bristol-Myers v Baker Norton* [1999] RPC 253, 277, where Jacob J held it 'arguable that there is no logical or reasonable distinction between [the decision in *Mobil*] and the decision in *Eisai*', and stated that 'to try and ... steer a course between accepting *Eisai* and yet holding *Mobil* wrong' would 'at best ... involve more Byzantine logic'; cf *Mobil* [1990] EPOR 73, 84-5.

been made available';¹⁸¹ noting that the mere fact of an effect having 'inherently taken place in the course of carrying out what [had] previously been made available' was not sufficient to destroy the use's novelty.¹⁸² The effect of this reasoning is to emasculate the medical methods exclusion contained in art 52(4) by enabling any method of medical treatment involving the use of a known substance to be protected as a 'second medical indication' or 'purpose-limited product', provided only that such substance has not previously and knowingly been used for the same purpose in the same medical treatment.¹⁸³ The result is that medical methods involving the use of a substance can support a patent under the *EPC* if described in Swiss style form.

The impact of the EPO's acceptance of Swiss style claims on UK law has been decisive. Having had their patents system pegged to that of the *EPC*,¹⁸⁴ UK decision makers have been forced to adopt the EPO position in relation to those claims in the interests of doctrinal conformity¹⁸⁵ and despite their clear rejection of its correctness.¹⁸⁶ Since this adoption, however, the same decision makers have been working to find paths around the EPO principles. To date two such paths have been identified. The first involves recognition of a more rigorous 'supporting description' standard in respect of Swiss style claims, under which full disclosure is required not only of the substance, but also of the means by which that substance is to be used in the medical treatment (including dosage amounts and forms of administration).¹⁸⁷ This requirement for detailed supporting description has been relied on several times already to strike down a second medical use patent,¹⁸⁸ despite objections by some applicants that it cannot reasonably be satisfied until full and proper testing has been undertaken, which itself cannot occur until after a patent has been granted.¹⁸⁹

The second means by which UK decision makers have avoided the effect of EPO authorities regarding Swiss style claims has been to distinguish them on the facts of individual cases. This was the approach adopted more recently by the Patents Court in *Bristol-Myers v Baker Norton*,¹⁹⁰ where Jacob J – after almost

181 [1990] EPOR 73, 88.

182 *Ibid* 89. The implications of the reasoning in *Mobil* for the subject matter in issue was to establish as novel the addition of a known compound to lubricating oil for the purpose of reducing friction, even though the same compound had previously been added to lubricating oil for the purpose of preventing rust. See also *Plant Genetic Systems/Glutamine Synthetase Inhibitors* (T356/93) [1995] EPOR 545.

183 See above n 180.

184 *Patents Act 1977* (UK) s 130(7); *John Wyeth & Brothers Ltd's Application*; *Schering A G's Application* [1985] RPC 545, 565 ('Wyeth; Schering'); *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd* [1996] RPC 76, 82 ('Merrell Dow'); *Bristol-Myers v Baker Norton* [1999] RPC 253, 272-3.

185 *Wyeth; Schering* [1985] RPC 545, 567; *Bristol-Myers v Baker Norton* [1999] RPC 253, 272, 276-7. Note also the extra-curial views expressed by Jacob J of the Patents Court in relation to the EPO's application of novelty principles to Swiss form claims in Sir Robin Jacob, 'Novelty of Use Claims' (1996) 27 *International Review of Industrial Property and Copyright Law* 170.

186 See, eg, *ibid*.

187 A rigorous supporting description standard for Swiss style claims was first recognised in *Hoermann's Application* [1996] RPC 341, 345.

188 See, eg, *ibid*; *McManus's Application* [1993] FSR 558; *Consultants Suppliers Ltd's Application* [1996] RPC 348.

189 See, eg, *Hoermann's Application* [1996] RPC 341, 347.

190 [1999] RPC 253.

lamenting his inability to declare such authorities 'bad law'¹⁹¹ – proceeded to strike down a second medical use patent on the ground that it was not a case of a second or other medical use at all, but rather 'a case of a mere discovery about an old use'.¹⁹² The effect of his Honour's decision is to undermine *Mobil* by providing a means for excluding from patentability uses of a known compound previously used in the same manner but for the purpose of achieving a different technical effect.¹⁹³

(d) Conclusion

It is tempting to view contemporary UK law regarding methods of medical treatment as vindicating the decision of the Solicitor-General in *C & W's Application* nearly 90 years ago, in which the exclusion from patentability in respect of such methods was first recognised. However, whilst the existence of that exclusion has never been doubted, the fact of such existence remains the only consistent and reliable theme in the history of medical method patents in the UK to date. Indeed, so intransigent has the exclusion been that it has survived the discrediting of its various legal bases and the shift in judicial attitude to the public policy issues underlying them. Whilst such intransigence has not been shown in Australia, the development of the principles governing medical methods since 1977 continues to chart the same general course there as in the UK. The purpose of the following and concluding section is to consider this development.

3 *Methods of Medical Treatment in Australia Since 1977*

It is a remarkable fact, given the length of time that had passed since the PAT's initial suggestion in *Schering* that morality was a legitimate basis for the exclusion of medical methods from patentability, that the nature and force of the moral issues raised by the patenting of such methods were not considered in detail until 1992. Less surprising, given the historical trend of decision making in this area, is that when they were so considered it was by an Australian and not a UK court. Also unsurprising in light of this trend – and in light of the shift in judicial attitudes to the patenting of medical methods generally – is that when considered, morality was deemed insufficient to justify the denial of patentability to such methods at all. The case in which that consideration was undertaken is *Rescare*.¹⁹⁴

191 Ibid 277. Aside from the persuasiveness of decisions of the Enlarged Board of the EPO, there remained the UK case of *Merrell Dow* [1996] RPC 76 in which 'the House of Lords ... given the opportunity to say that *Mobil* was bad law, clearly declined to take it' (ibid 277).

192 Ibid.

193 Ibid 278-9.

194 (1992) 25 IPR 119.

(a) Analysis of the Public Policy Considerations Relating to Medical Method Patents: the *Rescare* Litigation of the 1990s

Rescare involved methods for treating obstructive sleep apnoea, more commonly known as snoring. In a strong judgment, Gummow J confirmed the inherent patentability of the methods on the test set by Barwick CJ in *Joos*, resolving the public policy question at the heart of that test as follows:

Counsel for the respondent ... submitted that [the method claims were] 'generally inconvenient' within the *Statute of Monopolies* because: (i) modern medicine depends on technological innovation and it is in the public interest that this should be published and freely available; (ii) to grant a monopoly in respect of methods of treatment of disease would be 'inconsistent' with the teaching of medical students and practitioners of such methods; (iii) if such grants were permitted the medical practitioner who applied the treatment without a licence and the patient who authorised the treatment would be infringers; and (iv) the dissemination of the description of the method by a teacher or medical writer might amount to exploitation of the invention within the meaning of the definition of 'exploit' in Sch 1 of the 1990 Act and thus to infringement; and (v) the patentee would be able to refuse to license the invention or to charge substantial licensing fees, subject only to the operation of the compulsory licence and Crown use provisions in chs 12 and 17 of the 1990 Act.

Counsel for the applicant responded to point (v) that the position was no different with patents for pharmaceutical products. As to the other points, it was most unlikely that the patient who authorised the use of the process upon his or her person would be held to infringe or that a medical teacher or writer would either exploit the invention or authorise such exploitation within the meaning of the 1990 Act.¹⁹⁵

By this reasoning, his Honour rejected the respondent's argument that the methods of treatment should be denied a patent for general inconvenience, thereby overruling the medical methods exclusion for the purposes of Australian law.¹⁹⁶ That decision was upheld on appeal by a divided Full Court.¹⁹⁷ Whilst the three Judges constituting the Court agreed with Justice Gummow's conception and resolution of the issue in terms of 'general inconvenience' and public policy, only two – Lockhart and Wilcox JJ – held the public interest to favour patentability. In the principal judgment of the Court, Lockhart J relied heavily on a 1979 decision of Davison CJ of the Supreme Court of New Zealand¹⁹⁸ to reason as follows:

195 *Ibid* 150-1.

196 Note that the decision of Gummow J that methods of medical treatment were inherently patentable put Australia in conflict with almost every other jurisdiction to have considered the patentability of medical methods, including Europe, Japan, the UK and New Zealand. See *EPC* art 52(4) (Europe); *Patents Act 1977* (UK) s 4(2) (UK); *Pharmaceutical Management Agency Ltd v Commissioner of Patents* (1999) 46 IPR 655 – in respect of surgery and methods of preventing or treating disease only (New Zealand); cf *Ex parte Scherer* 103 USPQ 107, 110 (1954).

197 *Rescare* appeal (1994) 50 FCR 1.

198 *Wellcome Foundation Ltd v Commissioner of Patents* (1979) 2 NZLR 591 ('Wellcome'); overruled on appeal by unanimous decision of the New Zealand Court of Appeal in *Commissioner of Patents v The Wellcome Foundation Limited* (1983) 2 IPR 156 ('Wellcome appeal'). Note also the decision of the New Zealand Court of Appeal in respect of methods of medical treatment in *Pharmaceutical Management Agency Ltd v Commissioner of Patents* (1999) 46 IPR 655.

The statement by the court in [*Eli Lilly*] that in dealing with the exclusion of a process for medical treatment from patent protection 'the reasons for such an exclusion appear to us to be based in ethics rather than logic' was criticised, correctly in my respectful opinion, by Davison CJ ... The original basis which was reaffirmed in the *C and W* case in 1914 was not ethics, but that a process for medical treatment was not 'an art of manufacture' or was not a form of manufacture or trade. As Davison CJ observed ... now that the foundation for the decision in the *C and W* case has been removed by subsequent decisions, the courts have been grasping for some other ground on which to base a refusal to exclude processes for medical treatment from patent protection. The Chief Justice found no warrant in the law for grounding such refusal on ethical considerations. He said that the law permits the granting of a patent for a drug, the inventor has rights to it, and it can be employed in medical treatments only if made available to the medical profession by reason of licensing or compulsory licensing. If a process for medical treatment is invented, it can be licensed in the same way ... As members of the public are not currently deprived of the use of drugs under the existing law, Davison CJ saw no reason why the public would be deprived of the use of patented methods of medical treatment ...

Davison CJ said that on the other hand there were sound grounds for granting patent protection for processes of medical treatment which by research result from discovery of the fact that new properties and new uses exist for known chemicals. There would be reduced incentive to expend time, effort and money, often necessary to make such discoveries, if no financial return was to be available. Drugs have long been recognised as patentable subject matter. I respectfully adopt the Chief Justice's comments. Once the notion of the necessity for a 'vendible product' is eliminated there is no distinction in principle between a product for treating the human body and a method of treating the human body.¹⁹⁹

Two points are implicit in this reasoning. The first is that the reliance by UK decision makers on ethics to support a medical methods exclusion following the abolition of the vendible product requirement was a reflection of ex post facto justification rather than sound legal reasoning. And the second is that any ethical arguments against the patenting of medical methods were outweighed by the need to encourage medical research and by the long-standing acceptance of the patentability of medical products.²⁰⁰ Justice Wilcox agreed. In addition, his Honour distinguished the line of UK authorities in favour of the medical methods exclusion as 'not so deeply embedded in Australian law as to preclude an appellate court departing from it'.²⁰¹ Indeed, according to Wilcox J, it was obvious that the High Court of Australia had, in each of the three cases in which the issue was raised (*Maeder v Busch*, *NRDC* and *Joos*), assumed rather than decided the existence of a medical methods exclusion.²⁰² The result, his Honour suggested, was that methods of medical treatment were not only inherently patentable under Australian law, but had never been declared by an Australian Court to be otherwise.²⁰³ In this way, Wilcox J relied on the dubiousness of the High Court's reasons for affirming the medical methods exclusion as evidence of

199 *Rescare* appeal (1994) 50 FCR 1, 18.

200 As Lockhart J noted in his reasons (*ibid*), the arguments raised in *Schering* in relation to the limited availability of compulsory licences for medical subject matter under UK legislation were inapplicable in Australia by reason of its different licensing system (see *Patents Act 1990* (Cth) s 133).

201 *Rescare* appeal (1994) 50 FCR 1, 44.

202 *Ibid*.

203 *Ibid*.

its lack of genuine support for that exclusion. Whilst this view is arguable in relation to Chief Justice Barwick's decision in *Joos*, and even in relation to *NRDC*, it is a less convincing explanation of Justice Dixon's decision in *Maeder v Busch*, in which the unpatentability of medical methods was more clearly asserted.

Challenging the view of the majority in the *Rescare* appeal was Sheppard J, who delivered a strong dissent against patentability. Central to his Honour's decision was the view that the need not to impede the work of those engaged in the alleviation of human suffering outweighed the need to encourage medical research and, more specifically, that permitting the monopolisation of means of treating potentially life-threatening illness would be 'generally inconvenient' within the meaning of the *Statute of Monopolies*.²⁰⁴ In his Honour's words:

It is not going too far, I think, to say that the Court should not contemplate the grant of letters patent which would give to one medical practitioner, or perhaps a group of medical practitioners, a monopoly over, for example, a surgical procedure which might be greatly beneficial to mankind. Its denial might mean the death or unnecessary suffering of countless people. I cannot think that this is really what the medical profession as a whole would seek to achieve. Its whole history is a denial of the proposition.²⁰⁵

Although in dissent, the decision of Sheppard J was upheld and applied by Heerey J of the Federal Court at first instance in *Bristol-Myers*, the next (and most recent) case to consider the medical methods issue in Australia.²⁰⁶ Not surprisingly, however, given the weight of authority against that decision, Justice Heerey's judgment in *Bristol-Myers* did not survive on appeal to the Full Court, which unanimously affirmed the inherent patentability of methods of medical treatment on the principles expressed by Lockhart and Wilcox JJ in the *Rescare* appeal.²⁰⁷ Whilst the Full Court's decision in *Bristol-Myers* offers no new insight to the public policy issues on which the division of opinion in the *Rescare* litigation turned, it does reignite the historical issue concerning the legal basis for denying patentability on moral grounds and, in so doing, casts doubt over the ability and willingness of Australian judges to engage with moral issues when determining inherent patentability.

204 *Ibid* 41.

205 *Ibid*.

206 *Bristol-Myers* (1998) 41 IPR 467. In *Bristol-Myers* Heerey J held a patent for administering the drug taxol in the treatment of cancer to be invalid on the ground among others that it claimed a method of medical treatment which, his Honour held, was not a proper subject matter for a patent. His Honour's reasoning emphasized three main points. First, such obiter as existed tended against the patentability of methods of medical treatment of the human body (*Bristol-Myers* (1998) 41 IPR 467, 479). Secondly, the New Zealand Court of Appeal had decided against patentability (*Wellcome* appeal (1983) 2 IPR 156, overruling the decision of Davison CJ affirmed by Lockhart J in the *Rescare* appeal), and it was desirable that Australian and New Zealand commercial laws be consistent (*Bristol-Myers* (1998) 41 IPR 467, 479). And thirdly, the exclusion of methods of medical treatment was required by the same public policy considerations outlined by Sheppard J in the *Rescare* appeal, including the nature and objectives of the medical profession (*Bristol-Myers* (1998) 41 IPR 467, 480). Finally, Heerey J noted that any illogicality in the distinction created by his decision between medical products (which his Honour conceded were patentable) and medical processes was explicable by the nature of the life of the law which, he noted, had been experience and not logic (*Bristol-Myers* (1998) 41 IPR 467, 481).

207 *Bristol-Myers v FH Faulding* (2000) 46 IPR 553.

(b) *Bristol-Myers* and the Relevance of Morality to Inherent Unpatentability

Bristol-Myers involved a patent for a method of administering the drug taxol in the treatment of cancer. Two judgments were delivered on appeal; the first by Black CJ and Lehane J, and the second by Finkelstein J. The question of inherent patentability was resolved swiftly in the first judgment by reference to the weight of past judicial opinion.²⁰⁸ More detailed consideration of the issue was offered in the decision of Finkelstein J.²⁰⁹

Justice Finkelstein began by affirming the general approach of Anglo-Australian decision makers since *Rescare*, viewing the exclusion of methods of medical treatment from patentability under Australian law as supportable on public policy grounds only and, in particular, on the ground that permitting patents for such methods would be 'generally inconvenient' within the meaning of the *Statute of Monopolies*.²¹⁰ He then proceeded to consider the public policy arguments for and against the patenting of methods of medical treatment, concluding as follows:

How is a court able to resolve these competing contentions? None of them is supported by evidence. Some may not even be capable of proof. Even if evidence was called to make good the unsubstantiated assertions, on what basis is the court to decide how the public interest will best be served? I do not believe that in a controversial issue such as is raised by the present argument, I would be abandoning my responsibility as a judge to follow this approach and to hold that if public policy demands that a medical or surgical process should be excluded from patentability, then that is a matter that should be resolved by the parliament.

It is likely that few of the arguments admit of a definitive answer. The area of controversy is great. Public interest groups, medical and professional associations, medical scientists and the pharmaceutical industry, among others, would need to be approached and their views ascertained before a court could ever hope to arrive at a reasoned conclusion, if it could ever do so. Indeed a court might well be asked to take account of ethical and moral considerations to arrive at a decision. This is not the function of a court on an issue such as this. In my opinion, medical treatment and surgical process [*sic*] are patentable under the legislation and, if public policy requires a different result, it is for the parliament to amend the 1990 Act.²¹¹

Thus, in Justice Finkelstein's view, the fact that resolving the public policy question raised by medical method patents might require the consideration of

208 In their joint judgment, Black CJ and Lehane J deferred expressly to the preponderance of Australian appellate opinion which, they held, was represented by the majority's decision in the *Rescare* appeal. In so doing they noted two additional considerations as providing additional support for the position represented by that opinion. The first of those considerations was the public policy problem of distinguishing between products and methods of treating the human body, and the second was the failure of Parliament to exclude such methods from patentability ten years earlier, when the 1990 Act was introduced. See generally *ibid* 558.

209 Note that Finkelstein J ultimately decided the question of inherent patentability on another basis (not relevant to the present discussion), with the result that the aspect of his Honour's decision herein discussed is strictly *obiter dictum*.

210 *Rescare* (1992) 25 IPR 119, 148-9; affirmed by Finkelstein J after considering the history of the proviso to s 6 of the *Statute of Monopolies* (*Bristol-Myers v FH Faulding* (2000) 46 IPR 553, 589).

211 *Ibid* 595-6.

moral or ethical issues made that question an inappropriate one for the courts;²¹² the result being that medical methods should remain inherently patentable unless and until Parliament legislates to the contrary. This view receives some support from the decision of Wilcox J in *Rescare*²¹³ and reflects also the approach of the UK PAT in the 1970s' cases of *Eli Lilly* and *Upjohn*.²¹⁴ Ultimately, however, it goes beyond those decisions in its suggestion that any public policy question having a moral or ethical dimension is beyond the competency of the courts. Exactly how the line between public policy and morality is to be drawn is unclear, with Finkelstein J himself having implicitly conceded that the very nature of a public policy exception is, in some cases at least, synonymous with an exception based on ethics.²¹⁵

In addition, whilst historically very few patented subject matter have raised ethical issues, this is rapidly changing with the biotechnological revolution of the last 20 years. This revolution has given rise to a range of new and developing subject matter that are seeking accommodation within traditional patents jurisprudence in exactly the same way as occurred with methods of medical treatment in the early 20th century. The difference in respect of such subject matter, however, is that the legal and ethical issues raised by their patenting is the subject of a wide-ranging public debate. Whilst much of this debate concerns the logic and morality of treating biotechnology as 'inventions' capable of monopolisation,²¹⁶ it also raises questions regarding the rights of patients versus those of pharmaceutical companies which increasingly represent the primary source of ownership of patents for recombinant and other medicinal products.²¹⁷ However the ethical issues concerning individual biotechnological subject matter are ultimately resolved, it is clear that if they are to be resolved judicially and on a case by case basis, the courts will first need to answer the question raised by Finkelstein J regarding the extent to which decision makers are competent to consider ethical issues when determining a particular subject matter's eligibility for patent protection. Interestingly, in casting doubt over such competency, Finkelstein J undermined the distinction drawn by Sheppard J in the *Rescare* appeal between the approaches of Australian and New Zealand judges to the medical methods question (as, indeed, did the other Full Court Judges in *Bristol-Myers*). According to Sheppard J, whilst the Judges of the New Zealand Court of Appeal in the (then) leading case in that jurisdiction²¹⁸ had felt bound or led by existing authority to conclude that medical methods were not patentable and had viewed any decision to the contrary as the responsibility of the legislature

212 In respect of the inappropriateness of courts determining moral or ethical issues see further *ibid* 586.

213 *Rescare* appeal (1994) 50 FCR 1, 42-3.

214 See above n 156 and accompanying text.

215 Justice Finkelstein noted that the references by Graham and Whitford JJ in *Schering* [1971] RPC 337 and *Eli Lilly* [1975] RPC 438 to the 'ethical grounds' justifying the exclusion of medical processes from patent protection should be understood as references to 'public policy grounds': *Bristol-Myers* (1998) 46 IPR 553, 591.

216 See above n 6.

217 See generally Ray Moynihan, 'Saving patients or protecting patents?', *The Australian Financial Review Weekend* (Sydney), 7-8 April 2001, 30.

218 *Wellcome* appeal (1983) 2 IPR 156.

and not the courts, the Judges of the High Court of Australia in *NRDC* had 'regarded the matter as one which the Court was free to decide' – the reason it had not been conclusively decided in that case being that the matter had not been raised for decision.²¹⁹

Whether the High Court of Australia will regard the inherent patentability of methods of medical treatment as one it is 'free to decide' when the issue next comes before it remains to be seen, although Justice Gummow's first instance decision in *Rescare* suggests that he, at least, is likely to do so. In the meantime, however, the Judges of the Full Federal Court in *Bristol-Myers* have each opted for the approach ascribed by Sheppard J to the New Zealand Court of Appeal in *Wellcome*, albeit with the opposite result. Thus Black CJ and Lehane J were led by existing authority to conclude that methods of medical treatment were patentable, and Finkelstein J renounced the competency of courts to decide to the contrary. Ultimately this approach is a further reflection of the historical unwillingness of Anglo-Australian decision makers to deal substantively with the relationship between inherent patentability and morality. In addition, however, it demonstrates that such unwillingness is not of itself conclusive of a particular result, the Federal Court having obtained the opposite result in *Bristol-Myers* to that obtained by the New Zealand Court of Appeal in *Wellcome*, and the UK PAT in *Eli Lilly* and *Upjohn*, even though it adopted the same approach.

IV CONCLUSION

As has been noted, the existence of an exclusion from patentability in respect of methods of medical treatment has been the only consistent and reliable theme in the history of medical method patents in the UK to date. Whilst the same cannot be said of Australia (where such methods are now accepted to be inherently patentable), what can be said is that Australian judicial thinking has charted and continues to chart the same general course as judicial thinking in the UK. This is reflected not only in the shifting judicial perspectives regarding the public policy issues raised by medical method patents, but also in the changing views regarding the relevance of such issues to conceptions of inherent patentability per se. Hence the assumption by decision makers in both jurisdictions until the 1970s that any exclusion from patentability in respect of medical methods could only be justified by reference to their failure to possess the essential tangible characteristics of an invention. Hence also the (continued) instability of the medical methods exclusion following its reconception in ethical terms after the 1970s, caused in the UK by the unwillingness of decision makers to consider ethical issues and (more recently) in Australia by the same emerging unwillingness. The exclusion's entrenchment by Parliament has not stabilised it in the UK, even though such entrenchment relies on grounds other than inherent patentability and public policy. Perhaps ironically however, particularly given the general lack of support for a medical methods exclusion amongst

219 *Rescare* appeal (1994) 50 FCR 1, 40.

contemporary decision makers, courts in the UK have resisted the recent trend in Europe of supporting clever drafting techniques aimed at allowing such methods to be patented. Whether the legislature will enter the fray in Australia remains to be seen. If it does, it will be interesting to see how Australian judges interpret any future legislative exclusion of methods of medical treatment from patentability.

The overall conclusion to be drawn from the history of medical methods in Australian and UK law is that the rudderless nature of decision makers' responses to medical method patents has been to the detriment of 20th century patents law in its precipitation of at best unclear, and at worst unconvincing, legal principles. Whilst historically the main focus of such principles has been inherent patentability, and the role therein of morality and other public policy considerations, the secondary requirement of novelty has also more recently been implicated in the UK. Inevitably such principles have had – and in Australia particularly look set to continue to have – implications for a wide range of subject matter beyond methods of medical treatment.