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# The Technicality Requirement, Patent Scope and Patentable Subject Matter in Australia

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*The technicality requirement confines patentable subject matter to practical processes and products. It excludes theoretical knowledge and methods of conducting services as such from patentability. In a post-industrial age, there may be good arguments to abandon this limiting requirement, because innovation has become highly scientific and because services now form such an important part of industrial activity. However, because the underlying effect of the requirement is to limit the scope of patent claims, it should arguably be retained: patents of excessively broad scope have a negative aggregate welfare effect. In any case, even within the constraints of technicality, courts applying the NRDC principles retain sufficient flexibility to adapt the concept of "manner of manufacture" to rapid evolution in science and industry.*

## Introduction

In passing the *Patents Act 1990* (Cth) (*Patents Act*), Parliament chose not to constrain the broad and flexible power of the courts to decide what is suitable subject matter for the grant of letters patent.<sup>1</sup> The broad factors identified in *National Research Development Corporation v Commissioner of Patents*<sup>2</sup> (NRDC) thus continue to determine patentability. The High Court in the that

case was adamant that the courts' ability to adapt the notion of patentability to new scientific discoveries and technologies should not be fettered by artificial constraints. One of the factors identified in NRDC is the so-called "technicality" requirement,<sup>3</sup> elsewhere known as the requirement of industrial applicability.<sup>4</sup> A question arises whether, in a post-industrial age, that requirement itself *has now become an artificial fetter on patentability*, and should therefore be abandoned.

In examining this question, the author argues that the main effect of the technicality requirement is that it restricts the scope of patentable claims. Abandoning it would broaden the permissible scope of patents, thus shifting the demarcation line between appropriable and public domain

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<sup>1</sup> Other than by excluding human beings and biological processes for their generation from patentability: see *Patents Act*, s 18 (2).

<sup>2</sup> (1959) 102 CLR 252.

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<sup>3</sup> Also known as the practicality requirement, or requirement of industrial applicability; ie the requirement that a process or method to be patentable should result in an "artificial state of affairs" or "belong to the practical arts"; see further below.

<sup>4</sup> The European Patent Convention, s 52 provides:

"European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step."

knowledge.<sup>5</sup> The author proceeds on the basis that it is well accepted that the scope of patents is of vital importance to the overall effectiveness of a patent system. He concludes that aggregate public welfare flowing from a patents system will be adversely affected by allowing the kind of theoretical patents of broader scope that would result from abandoning the technicality requirement, and that there is thus good reason for it to be retained.

### Patentable subject matter in Australia: the NRDC rules

With the passing of the *Patents Act*, the Commonwealth Parliament chose to leave it to the courts to decide what is "suitable subject matter for the grant of letters patent".<sup>6</sup> Only human beings and biological processes for their generation were expressly excluded.<sup>7</sup> Retention of the archaic "manner of manufacture" terminology amounted to a legislative decision to endorse the courts' broad power to adapt the category of "patentable subject matter" in the light of evolving technology.<sup>8</sup> The enactment of the *Patents Act* supported the High Court's flexible and evolutionary approach as initiated in *NRDC*.

*NRDC* was a watershed case in Australian patent jurisprudence. Its general impact is similar to that of *Donoghue v Stevenson*<sup>9</sup> in the law of negligence. Previously disparate jurisprudence was synthesised into broad and general propositions that could be applied to any new technology, without necessarily

superseding all learning on specific categories of invention. *NRDC* did not represent an attempt to change the law, so much as to provide it with consistency through the stabilising force of broad principles.<sup>10</sup> The real importance of *NRDC* lies in the High Court's determination to ensure that the courts should be in a position to respond flexibly to new technological developments in the era of rapid scientific innovation that was unfolding.<sup>11</sup>

The Court stressed the risk inherent in attempting to impose a narrow fetter on the meaning of "manufacture", given the "excitingly unpredictable" nature of the pursuit of invention.<sup>12</sup> In other words, determining what is patentable subject matter could not be equated to an exercise in linguistic interpretation of the term "manufacture".<sup>13</sup> Therefore the right question was:

"Is this a proper subject of letters patent according to the principles which have been developed for the application of section 6 of the *Statute of Monopolies*?"

The question of patentability had to be addressed with an open mind, recognising that patents law must evolve in line with changes in scientific knowledge as well as economic development.<sup>14</sup>

<sup>5</sup> The distinction between the intellectual commons, and private knowledge subject to restrictive property rights, has considerable policy implications; see to that effect, P Drahos, *A Philosophy of Intellectual Property* (Dartmouth, 1996). The intellectual commons is often referred to as the "public domain".

<sup>6</sup> Parliament acted on recommendations made by the Intellectual Property Advisory Committee (IPAC) in its report *Patents, Innovation and Competition in Australia* (August 1984).

<sup>7</sup> *Patents Act*, s 18 (2).

<sup>8</sup> *Patents Act*, s 18 (1) states:

"[A] patentable invention is an invention that, so far as claimed in any claim: (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies."

While considering the scope of the intellectual property power in the Commonwealth Constitution (s 51 (xviii)), the High Court recently commented on the flexible content of the legislative power: see *Grain Pool of WA v The Commonwealth* (2000) 202 CLR 479.

<sup>9</sup> [1932] AC 562.

<sup>10</sup> In a remarkable paper presented during the IPSANZ Conference 2000, and also published at (2000) *Intellectual Property Forum* 43, entitled "Some Observations on the Requirement of Inherent Patentability in the Context of Business Methods Patents", Dr Andrew Christie suggested that *NRDC* revolutionised rather than synthesised the law. He notes (at 20):

"It might be said that *NRDC* is in fact a bombshell decisions, because it so generalised the concept of and test for inherent patentability that in practice the requirement has been annihilated."

<sup>11</sup> The *NRDC* decision is all the more remarkable for being unanimous.

<sup>12</sup> "It would be unsound to the extent of folly to attempt to do so now [ie to impose a narrow fetter on the meaning of the term 'manufacture'], when science has made such advances that the concrete applications of the notion which were familiar in 1623 can be seen to provide only the more obvious, not to say the more primitive, illustrations of the broad sweep of the concept": *NRDC* (1959) 102 CLR 252 at 271.

<sup>13</sup> "It is an inquiry not into the meaning of a word so much as into the breadth of the concept which the law has developed by its consideration of the text and purpose of the Statute of Monopolies": *NRDC* (1959) 102 CLR 252 at 269.

<sup>14</sup> On the facts of the case, the method for selectively exterminating weeds created an artificial state of affairs (greater than natural crop yield) which had "sensational" advantage in the area of cultivation, an economic endeavour. The new approach swept away all remaining vestiges of a so-called

In holding that a process (or method) invention that did not result in the production, improvement or repair of a vendible product was patentable subject matter,<sup>15</sup> the High Court formulated some *broad and flexible principles*.<sup>16</sup> First, the process must offer some advantage that is material, in the sense that the result of its application is of value in the field of economic endeavour; secondly, the method or process itself must belong to the practical rather than the fine arts; thirdly, the application of the method or process must have as its end result an artificial effect or a discernible artificial state of affairs. Rephrased, a post-*NRDC* definition of patentable subject matter other than a product, might therefore read:

“[A] process or method that does not belong to the fine arts, the application of which results in the production of an artificial state of affairs, and that is of economic significance.”

This leaves us with an important question: how does the general statement of principle in *NRDC* affect allegedly patentable subject matter that falls within a category traditionally excluded by case law?<sup>17</sup>

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agricultural and horticultural process exception, that had been based on a narrow linguistic interpretation of the term “manufacture”.

<sup>15</sup> Contrary to what had been thought before; the “production, repair or improvement of a vendible product” formula was expressed most strongly by Morton J in *Re GEC's Application* (1942) 60 RPC 1. The actual invention at stake in *NRDC* was a process to improve, by the application of known chemicals, the crop yield of arable land by selectively exterminating weeds without affecting the cultivated crop.

<sup>16</sup> In dealing with precedent, the Court essentially proceeded by way of a broad reinterpretation of the terms “vendible product” as meaning any economically significant result. The judgment quotes Evershed J in *Rantzen's case (Re Rantzen's Application)* (1946) 64 RPC 63) at 66 where—

“[H]e spoke of the expression ‘vendible product’ as laying proper emphasis upon the trading or industrial character of the processes intended to be comprehended by the Acts — their ‘industrial or commercial or trading character’ as Lloyd-Jacobs J himself described in *Re Lenard's Application* (1954) 71 RPC 190 at p 192.”

The judgment also quotes Evershed J in the *Cementation* case (*Re Cementation Co Ltd's Application* (1945) 62 RPC 151), where he said that a product meant “that which is produced by any action, operation or work; a production; the result”. The other commonly employed meaning of the word product, ie a thing, was not relevant in this context (*NRDC* (1959) 102 CLR 252 at 272).

<sup>17</sup> Such as, for instance, discoveries, laws of nature, methods of

The answer must be that the question cannot be resolved by categorising the invention and then automatically attaching the requisite consequence. Rather, reference should always be had to the general purpose underlying the doctrinal development of specific categories of exception, which is reflected by the general principles identified in *NRDC*. In some cases, the old category might be subverted by the *NRDC* principles to the extent that it should be swept away, such as the agricultural and horticultural “exception” under scrutiny in *NRDC* itself. In others, categorisation may be a useful guide but should not, without more, determine the outcome. As a result, subsequent to *NRDC*, categorisation-based misconceptions concerning patentability that have accumulated over time without clear jurisprudential support have been eliminated by the application of its general principles.<sup>18</sup>

### The *NRDC* rules in an era of “hyper-innovation”

When formulating its general principles, the High Court was conscious of the fact that it was operating in an era of rapid technological change. But it may not have foreseen quite how rapid and far-reaching scientific and technological change would become in the decades following on from the late 1950s. The same technological and scientific advances which the Court was so confident of being able to assess on the basis of technical legal principles, today attract considerable public controversy and give rise to far-reaching policy questions.<sup>19</sup> Nonetheless,

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calculation or theoretical schemes, plans, mathematical formulae, mere presentations of information and so on.

<sup>18</sup> See eg *IBM Corporation v Smith, Commissioner of Patents* (1991) 22 IPR 417, dispelling a long standing public misconception concerning patentability of computer implemented inventions; see also the rejection of the reasoning in *CCOM v Jiejing* at first instance by the Full Federal Court on the appeal in that case. About both cases, more further below.

<sup>19</sup> See, for instance, the introduction of a private member's Bill in the Senate, by Senator Stott-Despoja (Dem), that would have had the effect of rendering unpatentable naturally occurring genes; or naturally occurring gene sequences; or descriptions of the base sequence of a naturally occurring gene or a naturally occurring gene sequence (*Patents Amendment Bill 1996*). See also the deliberations and 1992 report of the House of Representatives Standing Committee on Industry, Science and Technology: *Genetic Manipulations: the Threat or the Glory?*. The Committee recommended against excluding organisms from patentability. See also the controversy surrounding the patenting

in 1990, the Commonwealth Parliament effectively gave the *NRDC* approach its stamp of approval.<sup>20</sup> It confirmed, rather than confined, the judicial power to adapt the concept of patentability to new and revolutionary advances in science and technology.

Since 1990, the courts have had to confront a number of important questions relating to new or intended developments. They have attempted to apply the general *NRDC* principles, but in the process it has become apparent that these are vague and embryonic. The difficulties inherent in applying them in a court of law are illustrated by the diverging conclusions of various judges deciding unresolved questions.

By way of illustration, this article focuses on two areas: patents for computer-implemented inventions and patents for methods of medical treatment. *IBM v Smith*<sup>21</sup> and *CCOM v Jiejing*<sup>22</sup> concern computer-implemented inventions; *Anaesthetic Supplies v Rescare*<sup>23</sup> and *Bristol-Myers Squibb v F H Faulding*<sup>24</sup> concern medical treatment methods.

### Applying *NRDC* to emerging technologies

#### *CCOM v Jiejing and IBM v Smith: computer-implemented inventions*

*CCOM v Jiejing* was concerned with a computer-implemented invention covered by a petty patent. The claims were effectively directed to process or method steps (although expressed as "means for" claims) for the production of Chinese characters on

a Visual Display Unit (VDU). The invention allegedly overcame a well-known practical word-processing problem in a language consisting of a very large number of individual characters.

In spite of the flexibility inherent in *NRDC*, prior to 1991 there was a common perception that Australian patents law (and in particular the *Patents Act 1952*) did not, or did only in a very restricted category of case, admit computer-implemented inventions as patentable subject matter.<sup>25</sup> However, the decision in *IBM v Smith* revealed that the attitude of the Patent Office had been too restrictive.<sup>26</sup> Burchett J held that the correct approach was *not* to start from the question whether the invention contained some theoretical knowledge, then to ask whether the rest of the claims were drafted in a manner that sufficiently limited the claim over that theoretical knowledge to a specific practical application. Rather, the invention should be looked at *as a whole*, whereupon the *NRDC* principles should be applied to it. In other words, did the process claimed result in the creation of an artificial state of affairs, being of significance to the economy, and did not belong to the fine arts?<sup>27</sup>

of genetically altered life forms, both in Australia and in Europe.

<sup>20</sup> That is not to say that the 1990 provisions did not import some changes in the approach to patentable subject matter, particularly in relation to the so-called threshold test of inventiveness on the face of the specification: see *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1995) 183 CLR 655 (*Philips*); *Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Ltd* (1998) 194 CLR 171.

<sup>21</sup> *IBM Corporation v Smith, Commissioner of Patents* (1991) 22 IPR 417.

<sup>22</sup> *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 27 IPR 577 (Cooper J); on appeal: (1994) 28 IPR 481 (Spender, Gummow and Heerey JJ).

<sup>23</sup> *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 28 IPR 383 (Lockhart and Wilcox JJ, Sheppard J dissenting); at first instance: *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 25 IPR 119 (Gummow J).

<sup>24</sup> *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) 97 FCR 524; 46 IPR 553.

<sup>25</sup> The Patent Office set restrictive guidelines for the examination of computer-related inventions, based on the US test in *Re Freeman* 197 USPQ 464 (1978), as modified or refined in *In re Walter* 205 USPQ 397 (1980), and in *Re Abele and Marshall* 214 USPQ 682 (1982). The test consisted of two steps: first, does the claim directly or indirectly recite an algorithm; secondly, if yes, then does the claim consist of more than the presentation and solution of the algorithm? If no, then no amount of post-solution activity or application will save the claim from being found not to recite patentable subject matter because it is no more than an idea or mathematical or mental process, a basic tool of scientific and technological work and thus not patentable. A claimed process that resulted in a number, even if that number can later be used in a practical application, was not patentable subject matter, but if it represented a physical thing, numerical representation was no bar to patentability. In other words a process that resulted in a number was only patentable if that number represented a physical reality.

The law in the US was for a long time rather confused (see L R Turkevich, "An End to the 'Mathematical Algorithm' Confusion?" [1995] EIPR 91), but now the US courts have overruled the old tests as well: see *AT&T Corp v Excel Communications Inc* US Ct of App, FC, 14 April 1999, cert den, USSC, 12 October 1999.

<sup>26</sup> Burchett J's decision reversed the decision of a delegate of the Commissioner of Patents to reject the patent application: see *Re International Business Machines Corporation* [1991] AIPC 90-781 (JI Welsh).

<sup>27</sup> In *IBM v Smith*, the process claimed a practical application:

The fact that the claims contained a theoretical element should not colour the inquiry from the outset. On the facts, the method of producing an improved curve on a VDU was relevant to the economy, resulted in the creation of an artificial state of affairs, and could not be said to belong to the fine rather than the practical arts.

In *CCOM*, the invention claimed was based on categorisation of Chinese characters by stroke type and by the pre-ordained order of applying the individual strokes to write a complete Chinese character. This was a well-known linguistic technique applied to ordinary writing.<sup>28</sup> The invention worked by the operator entering, on keys adapted for that purpose, stroke type categories in a specific order, whereupon the computer would retrieve and display characters from the database with the relevant stroke type applied in the relevant order and number. These might in fact be too numerous all to be displayed on screen, so that further research criteria might have to be entered to further limit the retrieved characters until the single desired character remained.<sup>29</sup> The claims of the invention were drafted in terms of relevantly constituted "data storage means", "display means", a "keyboard" and then by describing the operation of the whole by entering information (search criteria) by operation of the keys on the keyboard,<sup>30</sup> eventually to achieve the display of a set of desired Chinese characters.<sup>31</sup>

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the production of an improved curve on a computer VDU; this was an artificial state of affairs, of economic significance, and could not be said to belong to the fine arts.

<sup>28</sup> The normal way of finding a character in a Chinese language dictionary is by breaking it down into (brush-)strokes, and stroke count numbers, and further into so-called radicals, ie 214 basic character components not being strokes comprising the character.

<sup>29</sup> *CCOM* was in fact an action in infringement and counterclaim for invalidity. The allegedly infringing invention differed from the claimed invention in that it integrated further data concerning the frequency of occurrence of certain Chinese characters, thus reducing the need to input further search criteria, and increasing the efficiency of the system.

<sup>30</sup> Consisting of keys modified in a manner that was nonetheless not novel.

<sup>31</sup> The specification did not recite any algorithm, although indirectly algorithm(s) would form part of the claimed process, since it was to be executed on a computer. There is in fact no reason why, as far as the question of patentable subject matter is concerned, it should make any difference to the approach taken, that the claims and recite an algorithm (or, for that matter, some

In his decision in *CCOM* at first instance, Cooper J of the Federal Court first isolated the essence of the invention: the linguistic exercise whereby the Chinese characters were categorised by stroke type and stroke order, and the use of such criteria to retrieve (that is, find) a specific Chinese character. He separately considered the use of computer hardware to achieve the result, and categorised that as using a computer in a conventional manner to reproduce mental processes.<sup>32</sup> He then went on to say:

"[T]he formulation of such criteria and their use as rules to organise and process data stored in a database in a conventional computer are the product of human intellectual activity *lying in the fine arts and not the useful arts*" (emphasis added).

What was essentially claimed was a known intellectual task, executed on a computer, something that did not amount to patentable subject matter.<sup>33</sup>

The Full Court, in the appeal in *CCOM*, took a different line, more akin to Burchett J's approach in *IBM v Smith*. It applied *NRDC* principles to the invention as a whole. The specification effectively claimed a process that resulted in an artificial state of affairs, the generation of Chinese characters on a VDU; the ability to generate Chinese characters in that manner was obviously of enormous economic significance; and the process did not belong to the fine arts. What was in fact claimed (the process as executed in a specific manner on a computer) was a practical application that included some theoretical knowledge, but it was not the theoretical knowledge as such.<sup>34</sup> Pursuing a "holistic" method, and rejecting the approach that first isolates a theoretical element characterised as the essence of the invention,

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other theoretical or mental steps) or not.

<sup>32</sup> *CCOM* (1994) 27 IPR 577 at 593. As the Full Court pointed out (at 511) his Honour here may have failed to make a clear distinction between the question of patentable subject matter and obviousness; that the result is obtained on *conventional means* not being of any significance to the former question.

<sup>33</sup> *CCOM* (1994) 27 IPR 577 at 593. Cooper J derived some support from the decision of the German Federal Supreme Court in *Re the Computer Generation of Chinese Characters* [1993] FSR 315: there an application for a similar invention was dismissed on the basis that the invention was not of a technical nature. See also B Steckler, "Legal Protection of Computer Programs under German Law" [1994] 7 EIPR 293.

<sup>34</sup> In simple terms what was claimed was a practical solution to a well-known practical problem; that that solution contained some reference to theoretical knowledge or techniques that were akin to the fine arts was not a relevant concern.

the Full Court concluded that the claimed invention was:

“[P]roper subject matter for the grant of letters patent according to the principles which have been developed for the application of section 6 of the *Statute of Monopolies*.”<sup>35</sup>

The Full Court also filled out the broad parameters of *NRDC* with references to past cases; since there were virtually no Australian decisions on the relevant point, reference was had to certain UK decisions handed down on the basis of the (pre-1977) *Patents Act 1902* (UK), that did not expressly exclude computer programs as does the *Patents Act 1977* (UK).<sup>36</sup> Those decisions tended to support the point that more than a mental process was involved in claiming the process of application of certain

steps represented by a computer program on a standard computer, since the method as claimed was incorporated in the program and in apparatus in a physical form. The Court also highlighted the fact that whether the adaptation of a known process to a computer amounted to patentable subject matter should not be confused with the question whether it was novel or inventive to do so.

The Full Court in *CCOM* thus advocated a flexible, non-technical approach to a new category of invention,<sup>37</sup> entirely within the spirit of *NRDC*. The High Court in that case had issued a clear warning that the approach should not be based on a detailed linguistic analysis of the term “manner of manufacture”, nor on opposing the term “discovery” to the term “invention”, because the distinction between those two terms was “not precise enough to be other than misleading”.<sup>38</sup> The question must therefore be asked, not in relation to some isolated “essence (or essential feature) of the invention”, but in relation to the whole invention as circumscribed by its claims, and in light of what it attempts to achieve. Proposed new subject matters should be approached without artificial restrictions, taking into account that the courts are intended to respond to technological developments flexibly and with an open mind.

### *Anaesthetic Supplies v Rescare: human treatment methods*

*Anaesthetic Supplies v Rescare* (*Anaesthetic Supplies*) was concerned with the status of the so-called “(human) medical treatment exception” that purported to exclude methods for the treatment of human medical conditions from patentability,<sup>39</sup> either as not being subject matter suitable for the grant of letters patent, or because a patent would be “generally inconvenient”. The case starkly reveals a central policy dilemma of patents law. On the one hand, a patent encourages (so the theory goes) the diffusion of new and useful technologies by the grant of a temporary monopoly. On the other hand,

<sup>35</sup> The Full Court also emphasised that the concept of “manner of manufacture” is now fully distinct from any question of inventiveness; obviousness is a separate ground of invalidity and not one contained in the central concept of invention (*CCOM* (1994) 28 IPR 481 at 511). However, since the decision in *CCOM*, the judgment in *Philips* (1995) 183 CLR 655 may be seen as having cast some doubt on that proposition, since the High Court accepted that the term invention (including an alleged invention) in *Patents Act*, s 18 (1) did require reference to a threshold test of inventiveness; in that way, a claim for a new use of a known substance for which its known characteristics make it suitable, was not patentable subject matter for lack of obviousness. However, the High Court said only that if there was a prima facie lack of inventiveness, there could be no reference to an invention or alleged invention; is this a case where there is such a prima facie lack of inventiveness?

In *CCOM* the Full Court did consider an argument that the claim amounted to no more than the selection of desirable characteristics (“mere desiderata”) of a computer program (the ability to search a database of the type described in the manner described), then claiming all computers present and future possessing those characteristics, an argument that smacks of *Philips*. The Full Court rejected the argument since the objection did not fit into any category of requirement of patentability; they did not treat the argument as one addressing the question of “manner of manufacture” or the threshold concept of invention as put forward by the High Court in *Philips*. In fact the decision of the High Court in *Philips* was only handed down on 9 November 1995; the decision of the Full Court in *CCOM* was handed down on 22 June 1994, whereas the decision of the Full Court of the Federal Court in *Philips* was handed down on 26 August 1993 (see [1993] AIPC 91-025). Had the Full Court in *CCOM* had the guidance of the High Court decision in *Philips*, they would have had to consider the question differently, but would obviously have come to the same conclusion.

<sup>36</sup> *International Business Machines Corporation's Application* [1980] FSR 564; *Burroughs Corporation (Perkin's) Application* [1974] RPC 147.

<sup>37</sup> That is, new, not in a historical sense, but as far as the application of patents law to it is concerned.

<sup>38</sup> See *NRDC* (1959) 192 CLR 252 at 264.

<sup>39</sup> The status of this so-called exception under Australian law was unclear before *Anaesthetic Supplies*. For a comment on the case, see P Loughlan, “Of Patents and Patients: New Monopolies in Medical Methods” (1995) 6 AIPC 5.

it does this by restricting the right of a person who benefit from it to actually use it. This is true in every area of technology, but in terms of medical treatment, it means that the development of treatment methods is to be encouraged by granting the patentee the legal right to *deny a sick or injured person appropriate treatment*. The grant of a patent could obstruct a doctor's duty to make the optimal therapeutic decision for the treatment of a suffering patient.

Pharmaceutical substances claimed as products have long been patentable, despite the fact that much the same arguments that can be brought to bear against medical treatment patents could also be applied to drugs.<sup>40</sup> A question which arose in *Bristol-Myers Squibb v F H Faulding* reveals the potential inconsistency: can a process or method of administering a known drug, applied to the treatment of a disease for which it was previously not known to be effective, be claimed as patentable subject matter? Such an "invention" would have to be claimed as a method rather than a product, but would in a sense be very close to being a new product.

Are methods or processes of medical treatment of significance to the economy, ie concerned with, or part of, an economic activity, or are they of a different nature?<sup>41</sup> Prior to *NRDC*, it was thought that a process, to be patentable, had to result in the production of a "vendible product", which a (cured) human body strictly speaking was not. However, since *NRDC*, the question is whether the process resulted in an artificial state of affairs of significance to the economy; medical treatment could therefore

arguably qualify. Nonetheless, there was some reluctance to accept without demur that treating disease in human beings was an economic activity, although this much was asserted in some Australian cases.<sup>42</sup> Before *Anaesthetic Supplies*, one reason why the question had not been squarely addressed by an Australian court, was the judicial development of a distinction between prophylactic and cosmetic treatment of the human body, which allowed the courts to avoid the issue.<sup>43</sup>

But in *Anaesthetic Supplies* there was no avoiding it: the invention consisted of combined process/product claims for the continuous administration of oxygen, by means of a ventilation mask, to sufferers of obstructive sleep apnea, a potentially fatal medical condition that is not uncommon.<sup>44</sup> The difficulty related to those claims

<sup>42</sup> See for instance the (obiter) statement of Barwick CJ in *Joos v The Commissioner of Patents* (1972) 126 CLR 611 (*Joos*) to the effect that it was clear that medical treatment has economic effects, eg in time off work, insurance and so on. In *NRDC* itself, another obiter statement suggested that surgery or other processes for treating the human body may well lie outside the concept of invention "because the whole subject matter is conceived as essentially non-economic" (at CLR 275).

<sup>43</sup> Both in *Joos* (1972) 126 CLR 611, and in *Maeder v Busch* (1938) 59 CLR 684, the invention concerned was a method for cosmetic treatment of human hair. In NZ, on the other hand, the Appeal Court, in *Commissioner of Patents v The Wellcome Foundation Ltd* (1983) 2 IPR 156, felt itself bound by the authority of an English decision, *Re C & W's Application* (1914) 31 RPC 235, that set up a clear exception to patentability for human treatment methods. The Court did not feel that it could reverse such a clear position, since it would constitute a major shift between competing interests, which should be left to Parliament and not the courts.

Similar sentiments were expressed in two English cases of a later vintage than *Re C & W's Application*: *Eli Lilly & Company's Application* [1975] RPC 438, where the reason for the exclusion of methods of medical treatment was said to be based in ethics rather than in logic (at 445) and *Upjohn Company (Robert's) Application* [1977] RPC 94, where Russell LJ said that it was well established that a method of treatment of a human ailment with a known substance was not capable of being an invention under the Statute, and that if this should be changed, it should be done by Parliament (in fact the Parliament in the UK later expressly excluded medical treatment from patentability: see *Patents Act 1977* (UK)). The Federal Court in *Anaesthetic Supplies* did not see itself as similarly bound by the English decision, and found no binding authority in any Australian case.

<sup>44</sup> This condition, known as "OSA", is associated with extreme snoring and occurs when a patient suffers repeated near-choking on the tongue or soft palate while sleeping. In some cases the result can be fatal.

<sup>40</sup> A problem facing applicants who had invented a new use for a known drug (ie treatment of a disease for which the drug had not been known to be effective before) was that such an invention could only be claimed as a process, since the product was not new or inventive; but such drafting then ran the risk of falling foul of the human treatment exception; that is what happened in *The Wellcome Foundation Ltd v Commissioner of Patents* (1980) 145 CLR 520.

<sup>41</sup> As Cooke J pointed out in *Commissioner of Patents v The Wellcome Foundation Ltd* (1983) 2 IPR 156 (NZ AC), a case that was concerned with a patent for an invention which consisted of the use of a drug previously used for the treatment of malaria now claimed for the purpose of treating leukemia:

"[T]here remains a deep seated sense that the art of the physician or the surgeon in alleviating human suffering does not belong to the area of economic endeavour or trade and commerce": at 175.

that concerned the method or process of administering the oxygen. The Full Federal Court held by majority that methods of human treatment were patentable subject matter. The relevant claims were thus valid and enforceable.<sup>45</sup>

Lockhart J pointed out that there was little reason – the Court technically not being bound – to follow the approach exemplified by the English cases *Eli Lilly*,<sup>46</sup> *Upjohn*<sup>47</sup> and *Schering AG's Application*,<sup>48</sup> since they did not provide a satisfactory basis on which to halt the development of the law in this area. Furthermore, there was no difference in principle between the process invention considered in *NRDC* and the method of treatment of the human body at issue here. There was also no justification in law or logic for a distinction based on whether a substance produced a cosmetic or prophylactic result. *NRDC* had made it clear that it was essential that the law remain flexible. As Lockhart J put it:

“Australian courts must now take a realistic view of the matter in the light of current scientific development and legal process; the law must move with the changing needs and times”.<sup>49</sup>

The formulation of strict categories of exclusion was not consonant with such an approach. His Honour pointed out that in the debates leading up to the 1990 repeal of the *Patents Act 1952*, Parliament had had ample opportunity to exclude medical treatment processes from patentability and had not done so, having only excepted humans and biological processes for their generation.<sup>50</sup> It was not for the courts then to usurp Parliament's will and formulate such an exception. In the result, the claims disclosed patentable subject matter.<sup>51</sup>

To Wilcox J, the fact that Parliament had had the clear opportunity to exclude methods of human treatment in 1990 was also of vital significance; courts should be hesitant to introduce a gloss on Parliament's intention by reference to very general principles relating to the meaning of “manner of manufacture”.<sup>52</sup> *NRDC's* rationale had clearly swept away the “vendible product” limitations that had been imposed previously on the concept of “manner of manufacture” and which had inspired the decision in *Re C & W's Application*,<sup>53</sup> and an appeal court was therefore free to decide the issue. Having come to that conclusion, the way forward was clear: judges are ill equipped to make ethical or political judgments since they lack special expertise in that

conclusions to be drawn from the case, the fact that the few process claims were closely associated with product claims should be borne in mind. The main thrust of Lockhart J's argument was that a new use for an old thing could be patentable if there was ingenuity and novelty in discovering that the old thing may be used to produce a new effect; in such cases an old thing may be treated as new, its hitherto unknown potential being discovered by ingenuity. Such a new and useful effect was an artificially created state of affairs providing economic utility and thus a “manner of manufacture”.

<sup>52</sup> In some ways this is an argument that could easily be turned around: since Parliament did not provide a detailed list of exceptions to patentability, it demonstrated its clear intention that the courts continue the process of determining what is patentable subject matter on the basis of the very general terms “manner of manufacture”, and continue to interpret them in line with the general principles developed for that purpose. However, as the subsequent parts of his Honour's judgment demonstrate, he may rather have meant that no gloss on parliamentary intention should be imposed by reference to detailed exceptions to the very general principles relating to the meaning of “manner of manufacture”.

<sup>53</sup> (1914) 31 RPC 235. The invention concerned in that case was a method for the extraction of lead from the human body. Wilcox J explained in some detail why he felt free to decide the issue unconstrained by precedent. In Australia, *NRDC* swept away the “vendible product” limitation, only requiring that there be “some advantage which is material, in the sense that the process belongs to the useful art as distinct from a fine art – that its value to the country is in the field of economic endeavour” (*NRDC* (1959) 102 CLR 252 at 275). It thus swept away the rationale that had underpinned *Re C & W's Application*.

The UK courts, however, although accepting *NRDC*, took the view that the rule excepting medical treatment methods was so entrenched that its abrogation should be left to Parliament. The situation in Australia was the exact reverse, in that courts felt that they should not usurp Parliament's role by inserting such an exception, rather than by excising it. Once the rationale of the exception in *Re C & W's Application* disappeared, proper judicial policy required the courts to reconsider the issue.

<sup>45</sup> (1994) 50 FCR 1; 28 IPR 383; Wilcox and Lockhart JJ, Sheppard J dissenting. At first instance, Gummow J had held that the patent was valid and that there was no basis for distinguishing medical treatment methods: *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 25 IPR 119. The issue of patentability was considered upon a counterclaim for invalidity in an infringement action.

<sup>46</sup> [1975] RPC 438.

<sup>47</sup> [1975] RPC 94.

<sup>48</sup> (1971) All ER 177.

<sup>49</sup> (1994) 50 FCR 1 at 19.

<sup>50</sup> See *Patents Act*, s 18 (2).

<sup>51</sup> Although the general issue of patentability of human processes was canvassed, a necessary proviso which Lockhart J himself stressed was that the claims were mostly product claims in substance and form. It may be so that when considering the

area, and should therefore not entertain such arguments to add an exception to a statute that Parliament had had ample opportunity to consider. Arguments based in ethics and social policy rather than law, put forward by some other judges, were, in the opinion of Wilcox J, unpersuasive.

One of those "other judges", on the same Bench, was Sheppard J. He did canvass some of the broader issues at stake in formulating his dissenting opinion, although his ultimate decision that a medical treatment exception did exist was based on practicality rather than morality or social policy. His conclusions were based on an analysis of the question whether granting medical treatment method patents would be "generally inconvenient",<sup>54</sup> rather than whether they were drawn to patentable subject matter *sensu stricto*. Nonetheless, Sheppard J also focused on the nature of the profession of medicine, to determine whether it is an economic pursuit in the sense required by *NRDC*.<sup>55</sup> Medicine emphasises research and teaching, and:

"[T]here is a willingness on the part of the members [of the profession] to share information about new discoveries and new methods of treatment. This is particularly so in relation to surgical procedures of innumerable kinds and in relation to the management of people who are suffering from serious disease."<sup>56</sup>

There was wide dissemination of knowledge both nationally and internationally through teaching and publication, and:

"[T]he subject matter of all this, although it may have its commercial elements, is the treatment of human suffering. It has direct bearing on the well-being of the nation. Medical research and

treatment have a long history which is replete with distinguished examples afforded by a great many dedicated men and women".<sup>57</sup>

Sheppard J, however, did not make these points with a view to formulating a conclusion concerning the *NRDC* principles; rather, he considered them relevant to the issue of general inconvenience.<sup>58</sup> The arguments that led Sheppard J to exclude a patent on that basis were: first, that the grant of a monopoly in an invention may lead to the denial of its use and hence to unnecessary suffering or even death; and secondly, that this result would be contrary to the medical profession's essential nature, which is not the pursuit of economic gains.

"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 that proposition [ie that a patentee should be given the right to deny medical treatment]."

His Honour thus appeared to see the grant of a patent as a restraint on free dissemination and use of practical knowledge, in an area of human endeavour where such exchange, teaching and sharing of knowledge was essential to combating human suffering and disease. In so doing, he appeared to discount two professed policy aims of the grant of patents: first, the "incentive function", that is that the grant of monopolies encourages investment in the development of technologies beneficial to humankind, be it in medicine or in other areas; secondly, the information-diffusion function of patents through enabling disclosure. In contrast to the other two judges, Sheppard J accepted

<sup>54</sup> His Honour analysed the relevant cases and pointed out that Barwick CJ in *Joos* (1972) 126 CLR 611 and Somers J in *Wellcome Foundation* (1983) 2 IPR 156 had proceeded on the basis that the relevant question was that of "general inconvenience" ((1994) 50 FCR 1 at 40). In this context, he stressed that OSA was a potentially life-threatening disease ((1994) 50 FCR 1 at 41).

<sup>55</sup> Whether the correct approach is to ask what category of pursuit the invention belongs to, and whether that category is economically significant, is maybe not the approach envisaged by *NRDC*; a more precise reflection of the ratio in that case may be to ask whether the invention itself offers some material advantage the value of which lies in the field of economic endeavour. In other words, is the process of the practical arts; and is the result economically significant; although in the result the two approaches may differ little.

<sup>56</sup> (1994) 50 FCR 1 at 40.

<sup>57</sup> (1994) 50 FCR 1 at 41.

<sup>58</sup> Lockhart and Wilcox JJ did not pronounce themselves on the question of "general inconvenience". That the grant of a patent may logically lead to the denial of treatment appeared not to concern them. Maybe this was partly because of the close association between product and process patents in the invention concerned: it may seem unlikely that if the patented product is supplied, there would not be an implied or express licence to actually use it in the manner specified; whoever wanted to apply the method, would have to acquire the product first. It must be said that it would appear somewhat contrary to logic to grant a patent for a product (which may equally result in the denial of treatment with that product) without more ado, but not to grant a patent in the process to use that product. In adopting this approach he seemed to treat the two questions as alternatives, rather than seeing the question of general inconvenience as an issue only raised consequent upon a determination that an invention is a patentable "manner of manufacture".

competing arguments: "although it may have commercial elements", medical treatment was essentially aimed at the relief of human suffering, and thus not economic; at the very least, patenting such a method was inconvenient. Furthermore, the free exchange of information and free use of practical knowledge, were an essential element of medical treatment. His Honour's convictions concerning the relative merits of the arguments inevitably led him to conclude that the invention in suit did not concern patentable subject matter, within the context of the whole of s 6 of the *Statute of Monopolies*.

### *Bristol-Myers Squibb v F H Faulding: human treatment methods*

In *Bristol-Myers Squibb v F H Faulding (Bristol-Myers Squibb)*, the same issues were to the fore. The relevant claims were drawn to a new method of dosing and administering the known anti-cancer drug taxol. Black and Lehane JJ (on the appeal) followed the majority decision on appeal in *Anaesthetic Supplies*, favouring patentability of medical treatment methods. They stressed that the most cogent arguments leading to that conclusion were twofold:

"It is in those circumstances that we consider that we should adopt and apply the view of the majority in *Rescare*: a view reached after a close and persuasive analysis of principle and authority. In taking this course, we are fortified by two considerations. The first of these is what seems to us to be the insurmountable problem, from a public policy viewpoint, of drawing a logical distinction which would justify allowing patentability for a product for treating the human body, but deny patentability for a method of treatment ... This seems particularly the case where, as here, the claim is for an invention for the administration of a product.

The second compelling consideration is the very limited extent to which the Parliament dealt with patents with respect to the human body when it enacted the 1990 Act, bearing in mind, too, that it did so at a time when the long-standing practice in Australia was (as we are informed it still is) to grant patents for methods of medical treatment of the human body."<sup>59</sup>

As to the specific argument that methods of human treatment patents were "generally inconvenient", Black and Lehane JJ had this to say:

"It is perhaps tempting to posit a possible special area in which, for example, an entirely novel and simple procedure, capable of saving many lives by its application as first aid, might be denied patentability even though otherwise meeting the requirements for a valid patent. It may be that the 'certain methods of treatment of the human body' to which passing reference is made in *Ramset* (at 190) would fall into this category. Even here, however, although at first sight it is easy to see how it could be argued that it was 'generally inconvenient' for a simple, novel and dramatically life-saving method of treatment to be denied patentability on the footing that such a thing should be available universally and without restriction, the difficulty remains of drawing any logical distinction between a method of treatment and a patentable pharmaceutical product that produces the same beneficial results. More specifically, if (say) an antivenene for spider bite is patentable, on what ground can a new form of treatment for the same life-threatening bite be denied? The second consideration, referred to above, would also seem to remain as an obstacle."<sup>60</sup>

Finkelstein J in *Bristol-Myers Squibb* held that methods of human treatment clearly fell within the concept of manner of manufacture. The more relevant question was whether they were "generally inconvenient". His Honour said:

"[P]erhaps the most powerful argument against patenting is the idea that a patient may be denied medical treatment that she needs. It is certainly the most emotive of the arguments. It presumes that a medical practitioner may be unable to obtain the right to use a particular process, or may not be able to do so within due time, and therefore will be unwilling to undertake the process on her patients for fear of legal action."<sup>61</sup>

But on the other side of the argument was:

"[T]he underlying objective of patents, namely the promotion of science and the advancement of the arts for the general welfare of the State. As a

<sup>59</sup> *Bristol-Myers Squibb* (2000) 97 FCR 524 at 529-530.

<sup>60</sup> *Bristol-Myers Squibb* (2000) 97 FCR 524 at 530.

<sup>61</sup> *Bristol-Myers Squibb* (2000) 97 FCR 524 at 568.

general principle there can be no doubt that patent protection is desirable to encourage new medicines and surgical methods. It is an inescapable fact that inducement is necessary to encourage the great expense that is now required to evaluate and investigate the utility of many new medical processes and surgical methods.”<sup>62</sup>

But in the end his Honour rightly stressed that at the core of the debate lies the question of who should properly determine suitability for patenting, given the limited ability of a court of law to take evidence on the social and economic issues involved:

“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.”<sup>63</sup>

Interestingly enough, that is exactly what has happened in the US, where, since 1996, medical practitioners enjoy immunity from liability for patent infringement while performing a medical or surgical procedure.<sup>64</sup>

### NRDC's limitations in a post-industrial economy

Maybe the differences between the various judgments in *CCOM*, *IBM v Smith*, *Anaesthetic Supplies* and *Bristol-Myers Squibb* simply reflect the novelty of the questions involved. Certainly, the majority of the decisions reflect the courts' determination to respect the spirit of *NRDC*. The essence of the power bestowed by Parliament on the courts is to develop flexible rules that evolve with technological change. Each invention must be considered on its merits on the basis of the broad *NRDC* principles, and not on the basis of the question whether it fits into one or another rigidly

circumscribed category of invention or technology. Determining what is patentable subject matter is a process now shorn of artificial fetters and a priori limitations. In an era of rapid technological change this is a prudent approach; however, the differences between the judgments mentioned above reflect *the inherent difficulty of the task*, rather than simply its novelty.

There seem to be two main difficulties with the principles in *NRDC*. First, they are broad, and thus vague and uncertain; secondly, it is not clear that they are adequate and appropriate in an era of more rapid, more ubiquitous and more startling innovation than could have been envisaged in 1959. As to the first point, how does *NRDC* limit the subject matter suitable for the grant of a patent?

### The technicality requirement

Although *NRDC* completed a long judicial process of divorce from linguistic interpretation of the term “manufacture”, that term is still central in its implied limitation of patentability to a *practical process* and some *technical result*. In terms of *NRDC*, a process is one that

- “offers some advantage which is material, in the sense that the process belongs to a useful art as distinct from a fine art – that its value to the country is in the field of economic endeavour”;
- “has as its end result an artificial effect”;
- “[results in] an artificially created state of affairs. ... the significance of the product is economic: it provides a remarkable advantage ... for one of the most elemental activities by which man has *served his material needs*”;<sup>65</sup>
- “the result possesses its own economic utility”.

It would be fair to conclude that in *NRDC*, the grant of patents is still limited to *technological innovation*,<sup>66</sup> and does not extend to organisational, business, theoretical or scientific innovation as such.<sup>67</sup>

<sup>62</sup> *Bristol-Myers Squibb* (2000) 97 FCR 524 at 568.

<sup>63</sup> *Bristol-Myers Squibb* (2000) 97 FCR 524 at 569.

<sup>64</sup> (1996) *Public Law* 104-208. See also T Lithgow, “Patent Infringement Immunity for Medical Practitioners and Related Health Care Entities” (1997) *Jurimetrics Journal* 251; G Mossinghoff, “Remedies under Patents on Medical and Surgical Procedures” (1996) 78 *JPTOS* 789.

<sup>65</sup> *NRDC* (1959) 102 CLR 252.

<sup>66</sup> The *Merriam-Webster Online Collegiate Dictionary* definition of “technology” is:

“1a: the practical application of knowledge especially in a particular area; b: a capability given by the practical application of knowledge; 2: a manner of accomplishing a task especially using technical processes, methods, or knowledge.”

<sup>67</sup> The emphasis must be on the terms *as such*. Christie argues that the only requirement is that of implementation, and that “this requirement of implementation is of no practical

This was nicely illustrated by Heerey J in *Welcome Real-Time SA v Catuity Inc (Welcome Real-Time)*.<sup>68</sup> His Honour rightly rejected the attempted gloss on *NRDC* which would have required a “physically observable effect” rather than an artificial state of affairs to result from a patented process. The invention concerned did result in such an artificial state of affairs, namely the issuing of cards to consumers making available many different loyalty programs at retail outlets. The patent did not disclose a business method as such, ie a scheme or plan for carrying on a business (which would not be patentable), but a device and method *to be used* in a business. In other words, it was a technological innovation and not a business innovation.

In binding patentability to technological innovation, the courts perpetuate (admittedly they have only followed the lead of the legislator in the *Patents Act*) an historically-bound view of innovation. The patent system grew and developed in the golden age of manufacturing technology, and was aimed at promoting practical technological change in the context of value adding through manufacturing.<sup>69</sup> Neither the High Court nor any other court has as yet evinced any intention of moving beyond this view of innovation, ie of moving away from a requirement that there be some technical element to an invention, some reduction to a practical environment. But is this requirement no more than a pointless technicality in a post-industrial economy, a meaningless relic from a bygone age of industrial innovation? Or does it retain a solid theoretical foundation and significant purpose?

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significance” (see A Christie, n 10, at 10), certainly in an era where most business is conducted on or by means of computers.

<sup>68</sup> *Welcome Real-Time SA v Catuity Inc* (2001) 51 IPR 327.

<sup>69</sup> The concept of manufacturing has of course expanded through the ages, and thus also the area of applicability of patents (for instance, agriculture is now arguably an area of manufacture, as *NRDC* confirms). See, inter alia, E Walterscheid, “The Early Evolution of the United States Patent Law: Antecedents (Part I)” (1994) JPTOS 697; R Hauhart, “The Origin and Development of the British and American Patent and Copyright Laws” [1983] 5 Whittier L R 539; P Long, “Invention, Authorship, “Intellectual Property” and the Origin of Patents: Notes Toward a Conceptual History” (1991) *Technology and Culture* 32 at 846; G Mandich, “Venetian Patents (1450-1550)” (1948) JPTOS 30 at 166; G Mandich, “Primi Riconoscimenti Veneziani di un Diritto di Privativa agli Inventori” (1958) *Revista di Diritto Industriale* 1 at 101. More generally see Sherman & Bently, *The Making of Modern Intellectual Property Law* (CUP, 1999).

### *The technicality requirement in a post-industrial economy*

A number of differences between industrial and post-industrial economic structures are relevant to this debate.<sup>70</sup> First, manufacturing forms a less important part of most industrial activity, whereas services take an ever growing place. Secondly, in the post-industrial, or “information” or “knowledge” economy, the productive management of knowledge and information is a vital factor in the operation of markets and in the success of firms. Competition and innovation at firm-level are increasingly centred around the management of client relationships and service delivery. Thirdly, the rate of technological innovation, ie the rate of technological substitution<sup>71</sup> and of technological growth,<sup>72</sup> increases exponentially. Fourthly, the science quota of technology increases, ie technological innovation increasingly derives from theoretical study and scientific discovery, rather than from learning by doing. Fifthly, market structure is increasingly determined by technological “networks”, ie there is greater technological interdependence between firms, and between firms and clients. Lastly, in the context of factors three to five, firms attempt to establish and maintain market power by creating technological dependence (eg by standardisation based on proprietary technology or by exploiting first mover advantages through discount pricing and other pro-active marketing strategies).

The patents system has responded to these changes *to a degree*. If the management of knowledge and information is a crucial facet of the post-industrial age, and management of information is largely technological in the computer age, then it makes sense that computer implemented inventions and software inventions should be patentable. The courts, in Australia and elsewhere, have accepted this.

But other factors find less resonance in the evolution of patents law. For instance, the direct

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<sup>70</sup> The term “post-industrial” is used here, rather than “information” economy, because it gives a less restrictive ambit to the identification of factors that typify our present industrial context.

<sup>71</sup> The rate at which new technology is substituted for existing technologies.

<sup>72</sup> The rate at which new technologies are added to already existing technologies.

importance of scientific inquiry to technological innovation has greatly increased, yet scientific discoveries are not directly patentable *as such*, even where their *potential* useful applications have been identified and explained in theory. This is for two main reasons: first, science-related claims must be limited to a specific practical application which is described in an enabling disclosure; secondly, an element of inventiveness in the application of science to practical ends must be shown. These requirements exist irrespective of the size of the investment required in systematic scientific inquiry. As a result, a large fraction of that private investment in research remains unprotected by the property structures of patents.

A further example of the lack of responsiveness of patents law to new industrial structures relates to the relative growth of services as opposed to manufacturing. This has not resulted in service innovations being patentable *as such*. For example, the technicality requirement – or in terms of Australian law, the search for an “artificial state of affairs” – continues to stand in the way of patents over business methods *as such*. It is a misconception to think that the recent decisions of *State Street* in the US and *Welcome Real-Time* in Australia stand for anything else.

### *Abandoning the technicality requirement*

If the technicality requirement, whatever precise form it may take, is ill-adapted to a post-industrial, service-based economy, should it be abandoned? To take business methods *per se* as an example of service inventions in general, there is a number of arguments against allowing monopolies in such “inventions”. Are they warranted on the basis of the traditional incentive and publicity functions of patents law? Business method innovations may not require the same high levels of investment in research and development as does technology, nor similar levels of investment and risk in their implementation in business. There are also obvious difficulties in terms of usefulness (or “utility”), novelty and obviousness. Furthermore, there is a risk that the grant of business method patents could result in monopolies over whole sectors of the economy.<sup>73</sup>

<sup>73</sup> For a critique of business method patents, see R Merges, “As Many as Six Impossible Patents before Breakfast: Property

In other words, the grant of such monopolies may be *too broad in scope*. It is precisely in its impact on the scope of patent monopolies that the real and persistent usefulness of the technicality requirement lies.

The technicality requirement *limits* the scope of patent monopolies, and this in an era in which the expanding scientific content of new technologies encourages demands to allow more theoretical and thus broader patents. This effect is also well illustrated in the context of more “theoretical” patents, thus broader patents, ie patents that claim a monopoly over a large number of possible applications of a specific scientific breakthrough. The current *casus belli* in that regard is the scope of claims for applications of genetic information.<sup>74</sup> How should the courts operating under the flexible *NRDC* standards approach this issue? With considerable private investment in scientific research, and the increased scientific contents of technology, claims over known but unelaborated applications of scientific breakthroughs may appear justified. The real difficulty with such patents is again their scope, ie the effect they will have in interdicting investment in innovation by competitors, ultimately affecting public welfare. In this context as well, the remaining beneficial function that the technicality requirement fulfils is its *limiting effect on the scope* of patent monopolies.

So even though it is arguably an anachronism in a post-industrial economy, it may be reasonable to retain the technicality requirement as a limitation on

Rights for Business Concepts and Patent System Reform” (1999) *Berkeley Technology Law Journal* 577. See also R Dreyfuss, “Are Business Method Patents Bad for Business?”, unpublished paper referred to in Drummond J’s paper cited at the start of this article, presented at Fordham University School of Law, 8th Annual conference on International Intellectual Property Law and policy, April 2000, p 10.

<sup>74</sup> In general, see G Van Overwalle, *The Legal Protection of Biotechnological Inventions in Europe* (Leuven Law Series, Vol 10, Leuven University Press, 1997). The question is whether claims drawn to the application of genetic information (ie a gene sequence that codes for a certain characteristic) for any use in prevention of any disease disclose valid patentable subject matter. See also C Roberts, “The Prospects of Success of the National Institute of Health’s Human Genome Application” [1994] 1 *EIPR* 30; N Jones, “Biotechnology Patents: a Change of Heart” [1994] *EIPR* 37; T Roberts, “Broad Claims for Biotechnological Inventions” [1994] *EIPR* 371; R Nott, “The proposed directive on biotechnological inventions” [1994] *EIPR* 191.

patent scope. This equates to an argument that claims not limited to a technical application are too broad, and that overly broad monopolies have a negative aggregate welfare effect. Is that in fact so?

## Patent scope

It is almost commonplace that the *scope* of patent monopolies vitally determines whether a patent system as a whole has a positive aggregate welfare effect. In simple terms, a patent claim that is too broad will result in a monopoly that operates as a dead hand on innovative and competitive activity of competitors, but too narrow a patent will not provide a sufficient incentive to invest in the production of new inventions. Ideal, or at least "appropriate" patent scope will fall somewhere in between.

### *Patent scope and infringement*

Patent scope is a familiar concept in the construction of claims to determine infringement. Courts have accepted that to limit the scope of the monopoly to the exact wording of a claim would commonly render the patentee's monopoly illusory: a *literal* approach is thus not appropriate, although how closely the claims must be read will vary with their precise wording. Instead, the courts have adopted a *substantive* approach, finding infringement where the pith and marrow of an invention has been reproduced in all its essential integers. By so doing, courts have strengthened the position of the patentee by ignoring variations that are not material. The scope of the monopoly is arguably further widened by subjecting the specification to a *purposive* interpretation, ie by determining whether, in the opinion of a notional objective informed reader of the specification, some one or another element would require literal adherence or not.<sup>75</sup> These techniques are similar in effect to the application of the theory of equivalents in US patent law. They represent the courts' attempts to adjust the scope of patent claims to permit them to fulfil their function while not imposing excessive costs on society.

<sup>75</sup> Although the purposive approach can be read as a subset of the substantive approach rather than an extension of it.

### *Patent scope at the application stage*

While scope is central to infringement, it is only addressed *indirectly* in the context of validity, ie when examining whether claims disclose novel, inventive and useful patentable subject matter. The scope of patent claims is limited in various ways. First, as explained above, by requiring that an application must disclose some technical or practical element, effectively preventing the grant of more theoretical, and thus broader scope patents.<sup>76</sup> Secondly, by the requirement of enabling disclosure, ie that the description of the invention must be sufficiently precise to enable an informed reader of the specification to replicate it. Thirdly, by way of the requirements of novelty and inventiveness: if the scope of a patent is too broad, it will be difficult to escape an allegation of pre-emption or obviousness. Fourthly, by the requirement that the application disclose an invention on the face of the specification (the *Philips* threshold test).<sup>77</sup> Thus, appropriate patent scope is not an express factor determining patentability; but various technical legal devices indirectly affect the potential scope of patents. Should patent scope be so constrained, or should the constraints be abandoned to some degree, for instance by removing the technicality requirement?

## The economic effect of broad patents

### *The incentive theory*

Incentive theory posits that the market for information (of which patents are a sub-species, being information of a particular kind), is imperfect, because information is an inexhaustible public good with very low marginal costs of reproduction, and non-excludable. Less than optimal investment in the production of knowledge (ie, in this context, in research and development) results, since returns from innovation cannot be captured. The creation of property rights<sup>78</sup> allows the person generating new

<sup>76</sup> 32 IPR 449 at 451, as quoted from *Commissioner of Patents v Microcell Ltd* (1959) 102 CLR 232. As an example, the invention in *Philips* (see n 20) is apt: the Court found that that was "nothing but a claim for the use of a known material in the manufacture of known articles for the purpose of which its known properties make that material suitable."

<sup>77</sup> See n 20; and now also *Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Limited* (1998) 194 CLR 171.

<sup>78</sup> Patents are property rights of a kind; they are monopolistic in

knowledge or information to exclude others and drive up its marginal cost. This enables recovery of the sunk cost of research, and the generation of profits.

In this form, the incentive theory is rather reductionist. There may be under-investment in innovation in some areas of technology in the absence of property rights, but this may not be the case in others.<sup>79</sup> There are other factors that encourage innovation even in the absence of property rights, such as natural imitation lag; oligopolistic market structure; the structural advantage of being a market leader (so-called first mover advantage); availability of other methods of exclusion such as secrecy; network economic effects; natural monopolies (eg in rail technology) etc. Keeping this in mind, the effect of undifferentiated patents is hard to gauge. The grant of patent monopolies may in fact largely amount to an incentive to *reallocate* resources devoted to knowledge generation, rather than to *increase* such resources overall.

But the biggest difficulty is that whereas incentive theory may provide some support for the grant of patents as an incentive for innovation, it says little about the ideal size of the incentive. Nor does it identify at what stage along the discovery-invention-innovation-diffusion continuum a monopoly over knowledge should ideally be granted. These are two facets of one question: what is the ideal scope of a patent monopoly? A more subtle analytical framework is required to address this question.

### *Rent-dissipation and the race to invent*

Contemporary economic debate concerning the economics of patents has moved beyond a static reward/incentive analysis in a search for more subtle alternatives.<sup>80</sup> Rent-dissipation theory provides one

such alternative. Focusing on the rent-seeking behaviour that the grant of patent monopolies induces, it attempts to generate conclusions in relation to ideal patent scope. At its core lies the proposition that the aggregate public welfare effect of a patent system is critically dependent on the timing of the patent application.

The requirement of novelty (and thus pre-application secrecy), the absolute nature of the granted right, and the first to file structures of patents law all contribute to a race to invent and hence duplication of research effort. But patents law sets up a winner-take-all system: only the first to file obtains the prize of a patent monopoly. There is a consequent risk that the overall economic advantage gained by the use of property rights to encourage innovation is dissipated by the wastage resulting from duplication of research effort. Secrecy during the pre-application stage contributes to the wastage because there is imperfect information amongst competitors as to their respective positions in the race.<sup>81</sup> A patent system must take all this into account and provide an incentive whose overall cost to society (by duplication) does not outweigh overall benefit (by innovation). Critical in striking this balance is the scope of granted patents, ie the breadth of the monopoly reward; and critical to the scope of a patent is the timing of the patent application.

### *Striking a balance: timing of the application*

According to rent-dissipation theory, the more theoretical the inventions that can be patented, the earlier applications will be filed, and the broader the scope of the ensuing patents will be. Thus, the more theoretical the patented invention, the earlier the race to invent will cease, because the winner is known, with a consequent reduction of the wastage

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the sense that any person, even the independent developer, may be excluded from the use of an invention; they are also assignable; they grant the owner rights of action in enforcement; but they are limited in time and not guaranteed valid.

<sup>79</sup> This is reflected in the findings of studies that have investigated industry managers' attitudes towards patents; see eg RC Levin et al, "Appropriating the Returns from Industrial Research and Development" (1987) 3 *Brookings Papers on Economic Activity* 783.

<sup>80</sup> See in particular the rent-dissipation approach as explored by Grady and Alexander and others: see eg M F Grady and

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Jl Alexander, "Patent Law and Rent Dissipation" (1992) 78 *Virginia Law Review* 305; RP Merges, "Rent Control in the Patent District: Observations on the Grady-Alexander Thesis" (1992) 78 *Virginia Law Review* 359. See also DL Martin, "Reducing anticipated rewards from innovation through patent: or less is more" (1992) 78 *Virginia Law Review* 351, and the seminal article by EW Kitch, "The nature and function of the patent system" (1978) *J of L & Eco* 20 at 165. On the economics of patent scope in general, see R Merges and R Nelson, "On the complex economics of patents scope" (1990) *Columbia Law Review* 90 at 839.

<sup>81</sup> These criticism are based on Grady and Alexander, n 80.

from duplication. However, there is a countervailing effect: the broader the scope of the monopoly, and thus the size of the rent to be gained, the more firms will enter the race to be first and the more each entrant will invest in winning the race. In other words, although the duration of duplication may decrease with earlier filing, the volume of duplication may increase.

Thus, the focus of analysis becomes the timing of the patent application, which will be determined by how theoretical the law allows a patented invention to be. The filing decision can be expressed as a firm's choice between secrecy and publicity. The longer reliance on secrecy is extended and thus the decision to apply for a patent is put off, the later the moment the competitors in the race to invent receive the signal to desist, and the greater the wastage by duplication of research effort, and vice versa. The more theoretical claims are legally permitted to be, the earlier a firm will switch from secrecy to publicity by lodging a patent application. Were it not for the excessive incentive effect of higher rents to be derived from broad patents, more theoretical patents would be advantageous in terms of overall economic effect. But in fact, what is required is a patent with a scope that falls in between pure theory and narrow application, so that a balance is struck between reducing wastage by shortening the period of duplication and increasing wastage by increasing the incentive.

It may be that the present approach to patents, which does not allow purely theoretical patents, but requires some practical application of knowledge, crudely approximates this middle position. From this perspective, the technicality requirement as it is applied now helps to strike the balance between theory and application. Although a patented invention can incorporate theoretical knowledge (eg an algorithm) or scientific discovery (eg genetic data), it cannot consist of only that. The knowledge must be applied to a practical end that is technical in nature.

### *Coordination of R & D in the post-application stage*

To add another dimension to the analysis, the focus can be shifted to the potential role of the patentee as the coordinator of inventive and innovative activity.

In the pre-application (or pre-invention) stage, secrecy results in excess duplication and a lack of

coordination of research activity (ie a failure to direct all resources most efficiently to one goal). In the post-application stage, disclosure under the protection of property rights empowers the patentee as licensor to coordinate post-invention development, thus improving the efficiency of the overall innovation effort. This supports the grant of broad or more theoretical patents, since the patentee will then be able to adopt the role of an efficiency-enhancing coordinator of further developments at an earlier stage. There is a long lag time between invention and successful commercialisation. Many improvements and developments are required before a patent becomes the basis for a viable commercial product. The more effectively development activities are coordinated, the greater the overall welfare effect.

An early patent also enables others to use the information from the enabling disclosure in their own non-infringing research, which is of particular relevance in an increasingly scientific world. It allows the coordination of independent research groupings engaging in non-infringing research to occur more efficiently since it provides earlier knowledge about different research strands. This is all the more significant when so few firms are able to conduct all aspects of research themselves, ie they tend to be narrowly focused, but interdependent.

### *Doubts about coordination of R & D by the patentee*

But again there is the problem of the size of the rents gained from a broad patent. Even though early application (and thus grant of broad or theoretical claims) arguably improves innovation coordination, excessively broad (and thus early) patents may increase overall costs because of excessive investment in the pre-patenting stage with an eye to securing windfall rents (thus encouraging greater levels of duplication). Some of those rents would be derived not from commercialisation, but from an impost on the innovation activities of other researchers.

Also, whereas a broad patent may have an efficiency-enhancing effect in the post patent stage, in the pre-patent stage participants in the race to invent will arguably become less inclined to cooperate and exchange information as the size of the prize, and the potential losses from failure to win, increase.

Furthermore, very broad patents may in fact *deter* any inventing around or improvement-related research in the post-patent phase, leaving the patentee with nothing to coordinate other than his own research and development. But the patentee, having invested heavily in obtaining the potential windfall rents from the broad patent, may have insufficient resources to effectively carry on its own post-invention, innovation-orientated research. Since many of the most crucial breakthroughs in product development actually occur at the post-invention stage, this effect on the finding of improvements may be a particularly negative factor.

Because of the considerable lag between invention and return through commercialisation, investment in invention will remain unproductive for a long time, and should not be over-encouraged. Inventions should ideally be made when the market is ready for them, ie if there is a reasonable prospect of commercialisation (innovation) within a reasonable time lag; this favours *late* grant and thus narrow rather than broad patents. A related concern is that excessive emphasis (and investment) is placed on a section of the invention-innovation-commercialisation continuum which is not relevant to the other (and also capital intensive) stages of development.

In any case, and this is probably the most significant point, where the coordination theory emphasises the benefits flowing from the coordinating role of the patentee, it may be fundamentally flawed. One of its major premises, that the patentee will act as an efficiency-enhancing coordinator of research and development in the post-patent stage, is at best speculative. It may be that this coordinating activity is not likely to operate with any economic efficiency overall, since it will engender considerable transaction costs. It may also be that the principal interest of the patentee is not so much to coordinate the post-patent research effort, but to derive maximum short-term returns from it, or to *block* the research and development and investment in improvements that potential licensees might make.

### *Broad patents' effect on innovation*

From that perspective, aggregate welfare will be more effectively enhanced by encouraging the "follow-on" or "improvement" inventor, rather than

the initial inventor.<sup>82</sup> This will reduce the losses suffered by the losers in the race to invent, because much of the knowledge generated in the pre-invention stage may still be used autonomously even after grant of the patent. Wastage from duplication will be reduced, and entrants in the race to invent will be more able to continue to innovate even after the winner is known. It may be that the coordination occurs more effectively between *owners* of rights in narrow application patents rather than between the owner of a broad patent and those wanting to do research and development work in relation to the invention covered by that patent.<sup>83</sup>

Broad patents over certain kinds of technologies (eg basic research or diagnostic tools) may directly affect the research capacity, not only of commercial competitors, but also of not-for-profit research in universities and public institutions, constituting an unwarranted restraint on research rather than on commercial competition.<sup>84</sup> In other words, and this is of crucial importance, at least in some cases, it is clear that the impact of broad patents extends beyond *imitation*, not to coordinate but to restrain *innovation* by other researchers.<sup>85</sup>

Again, no "strong" conclusions can be drawn by analysing the effect of patent scope on post-application research activity. It is certainly not incontrovertible that broad patents will enhance the efficiency of post-grant innovation. In fact, in the author's opinion, on balance the arguments favour

<sup>82</sup> This blocking effect of broad patents is commented on in the literature: see eg J Barton, "Patents and Antitrust: a Rethinking in light of Patent Breadth and Sequential Innovation" (1997) *Antitrust Law Journal* 65 at 449. See also R Merges and R Nelson, "Market Structure and Technical Advance: the Role of Patent Scope Decisions", in T Jorde and D Teece (eds) *Antitrust, Innovation and Competitiveness* (1992), p 185.

<sup>83</sup> According to Scotchmer, broad patents will fatally decrease the incentive for firms other than the first innovator to invest in research and development in second generation products, and:

"[S]ince the first innovator might not have expertise in all applications, second generation products are likely to arise if more researchers have incentive to consider them."

This is an incentive that would be removed if the first innovator had too broad a patent: see S Scotchmer, "Standing on the Shoulders of Giants: Cumulative Research and the Patent Law", (1991) *Journal of Economic Perspectives* 5 at 29. See also M Lemley, "The Economics of Improvement in Intellectual Property Law" (1997) *Texas Law Review* 75 at 989.

<sup>84</sup> Barton cites a number of examples in biotechnology and computer programs: see n 82, at 449-450.

<sup>85</sup> This is the essence of the point that Scotchmer makes: see n 83.

narrow rather than broad scope patents, and hence retention of the technicality requirement as one method of limiting patent scope.

### *Regulatory advantages of early publication of broad patents?*

If it is accepted that more theoretical and thus broader patents will result in earlier filings and thus earlier public disclosure of new technologies, some advantages in terms of assessment and regulation of technology, and the early development of industry standards may flow from this. A regulatory framework may develop in a more timely fashion.<sup>86</sup> This is of particular relevance in the context of genetic modification patents, but is also relevant in other areas, the patent system functioning as a *partial* early warning system to regulators and public opinion.<sup>87</sup> Investment in further development can then occur in a clear regulatory context, and not subject to legality risks.<sup>88</sup> Early warning (through patent publication) about competing technologies could also promote determination of technological standards and prevent duplication in a race to appropriate industry-standard technology.

However, these are advantages that are tangential and indirect, and may only apply to a few technologies that have a high regulatory risk factor or are potential industry standards. In any case, the regulation of the use of technology should arguably remain a concern *outside* patents law.

<sup>86</sup> The patent system seems to sensitise public opinion concerning environmental, ethical and health issues surrounding new technologies, as was the case in Europe in relation to the patenting of genetically manipulated life forms (eg the so-called oncomouse).

<sup>87</sup> See eg concerning the tension between environmental reporting requirements and confidentiality in intellectual property law: N Atkinson, B Sherman, "Intellectual Property and Environmental Protection" [1991] 5 EIPR 165. See also N Hettinger, "Patenting Life: Biotechnology, Intellectual Property and Environmental Ethics" (1995) *Environmental Affairs* 22 at 267; A Wells, "Patenting New Life Forms: an Ecological Perspective" [1994] 3 EIPR 111; S Crespi, "Biotechnology Patenting: the Wicked Animal Must Defend Itself" [1995] EIPR 431; M Gollin, "Using Intellectual Property to Improve Environmental Protection" (1991) *Harvard J of L & Tech* 4, 193. See concerning the tension between administrative and liberal/neutral legal technical approaches to reward for innovation C Arup, *Innovation, Policy and Law* (Cambridge, 1993).

<sup>88</sup> For instance in relation to labelling requirements for GMO's.

### *Tentative conclusions about patent scope*

The arguments favouring grant of broad patents are not a sufficient basis for advocating divergence from the established legal factors that restrict patentable subject matter. The technicality requirement is one of these factors. Although arguably it is outdated in the present industrial context, strong arguments favour its retention as one of a constellation of well-established legal-technical instruments (such as also novelty; see above *Patent scope at the application stage*) that decision makers manipulate to shape patent monopolies of appropriate scope. Although its ultimate purpose may be economic in that it helps to mould a patent system with a positive aggregate welfare effect, the technicality requirement can be assessed by well-established methods of judicial reasoning and extrapolation from legal precedent. This avoids courts being required to hear and assess economic evidence as such.

It is true that in modern times patents law has never proceeded on the basis of a specific economic inquiry into the desirability of some proposed monopoly. Since the process of patent grant is ultimately legal rather than administrative, that is appropriate. However, this is not to say that there is never room to examine arguments related to the economics of patent scope *expressly* in the context of determining whether a patent should be granted or is valid in its proposed form. In the context of the present debate, it is arguable that, in a narrow category of case, empirical evidence should be admitted to establish that a proposed patent monopoly of broad scope will adversely affect *innovation* as opposed to *imitation* in a given industrial or research sector. Such an inquiry could proceed under the "general inconvenience" limb of s 6 of the *Statute of Monopolies*. It could result in a patent being rejected even where it otherwise meets all requisite legal standards.

### *Patents scope and general inconvenience*

In such cases, evidence would have to be called concerning the *concrete* effect that a monopoly in a claimed invention may have on the research and inventive activities of other researchers, whether in industry or the public sector. By this, the author means not general evidence concerning hypothetical effects on innovation or market conduct in relation

to nominal patents of the type proposed, but the effects of the actual patent on real research activity. A patent should be refused if the evidence establishes that patent grant would have an effect on innovation would have a measurable adverse effect on innovation in a given sector.

Such evidence will only be relevant if the effect of a proposed patent on the research and innovation activities of researchers in a certain sector goes beyond that of a patent of *appropriate* scope. In other words, a court will have to distinguish between the intended effect of a patent, ie to restrain *imitation* of the patented product or process for the term of the monopoly, and the undesirable effects of patents of excessive scope. No doubt there are many forms that evidence directly relevant to this issue could take; that question is best addressed in the context of a real case. Examples of areas of technology where the issue could arise are proposed patents over broad diagnostic or research tools in biotechnology; or proposed patents claiming potential uses of genetic data.

### Conclusion

The question of patent scope is of critical importance to a well-functioning patents system that has positive aggregate welfare effects for society as a whole. Patents with inappropriately broad scope will result in excess wastage because of duplication

of research investment and over-investment in a race to gain windfall profits, and stymie research and innovation by private and public sector researchers in the post-invention stage. This is not the intended effect of the patent system.

The courts in this country have the ability to adapt patentability requirements to changes in science and technology. *NRDC* sets out the basic factors that must be satisfied. One of these is the "technicality" or "practicality" requirement. Although this long-established factor is arguably out of step with the information economy, it deserves to be retained because it is one of a number of factors that have a limiting effect on the scope of patent monopolies. All these factors combined allow courts to fashion patents of acceptable scope over time, without having to address the arguments of economists overtly.

However, although in most cases appropriate patent scope is a matter that is properly addressed by the application of legal criteria, of which the technicality requirement is one, it may be that in some rare instances this is not so. In some cases, the question of patent scope could arguably be addressed by way of direct evidence of the potential effect of a patent on the research and inventive activity of other researchers in the public or private sectors. Such an inquiry could be undertaken under the "general inconvenience" limb of s 6 of the *Statute of Monopolies*.