HIGH COURT OF AUSTRALIA

FRENCH CJ,
HAYNE, CRENNAN, KIEFEL AND GAGELER JJ

APOTEX PTY LTD APPLICANT/APPELLANT

AND

SANOFI-AVENTIS AUSTRALIA PTY LTD & ORS RESPONDENTS

Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd
[2013] HCA 50
4 December 2013
S219/2012 & S1/2013

ORDER

Matter No S1 of 2013

Appeal dismissed with costs.

Matter No S219 of 2012

1. *Special leave to appeal on ground 3 of the Draft Notice of Appeal filed on 10 September 2012 granted.*

2. *Appeal allowed with costs.*

3. *Set aside the orders of the Full Court of the Federal Court of Australia made on 18 July 2012 and, in their place, order that:*

   (a) *the appeal be allowed in part;*

   (b) *orders 2, 3 and 6 of the Federal Court made on 18 November 2011 be set aside;*

   (c) *order 1 of the Federal Court made on 24 February 2012 be set aside; and*

(d) so much of the Amended Application dated 22 September 2009 as made in paragraphs 14 to 22 be dismissed.

4. Remit the matter to the Full Court on the questions of the costs of the appeal to that Court and the costs of the trial (which latter question may, at the discretion of the Full Court, be remitted to the primary judge).

On appeal from the Federal Court of Australia

Representation

D K Catterns QC with N R Murray for the applicant/appellant (instructed by Herbert Smith Freehills)

D F Jackson QC with C Dimitriadis for the respondents (instructed by Jones Day)

Reports.

CATCHWORDS

Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd

Intellectual property – Patents – Patent claimed administration of pharmaceutical substance as method of preventing or treating medical condition – Whether method of medical treatment of human body is patentable invention within meaning of s 18(1)(a) of *Patents Act* 1990 (Cth) – Whether product or process is manner of manufacture within meaning of s 6 of *Statute of Monopolies* – Whether novel therapeutic use of known substance is patentable invention.

Intellectual property – Patents – Infringement – Construction of claim – Patent claimed use of pharmaceutical substance for preventing or treating medical condition – Whether person who supplies drug and indicates use for treatment of different condition infringes patent under s 117(1) of *Patents Act* 1990 (Cth).

Words and phrases – "manner of manufacture", "patentable invention".

Patents Act 1990 (Cth), ss 13(1), 18(1)(a), 18(2), 117(1), 119A, 138(3)(b), Sched 1.
Statute of Monopolies 1623 (21 Jac I c 3), s 6.
Therapeutic Goods Act 1989 (Cth), s 16(1).

FRENCH CJ.

Introduction

1. The primary question in this case is whether methods of medical treatment of human beings, including surgery and the administration of therapeutic drugs, can be the subject of patents. This Court has not had to decide the question until now. For the reasons that follow, in particular so that the law may be logically coherent, the question ought to be answered in the affirmative. The appellant, Apotex Pty Ltd ("Apotex"), which was sued by the respondents for infringement of their patent for a method of using a known drug to prevent or treat psoriasis, therefore fails in its challenge to the validity of the patent. However, for the reasons given by Crennan and Kiefel JJ, Apotex's application for special leave to appeal against the finding in the Federal Court that it infringed the patent should be granted and its appeal on that matter allowed.

Factual and procedural history

1. It is sufficient to outline briefly salient features of the factual and procedural history, which are dealt with in more detail in the judgment of Hayne J and the joint judgment of Crennan and Kiefel JJ.

2. The drug Leflunomide, the preparation and composition of which were the subject of an expired Australian patent, is used for the treatment of psoriatic and rheumatoid arthritis. A method of using Leflunomide is the subject of a current Australian Patent No 670491 entitled "Pharmaceutical for the treatment of skin disorders" ("the Patent"). The Patent has a priority date of 31 March 1993 and expires on 29 March 2014. It has a single claim:

> "A method of preventing or treating a skin disorder, wherein the skin disorder is psoriasis, which comprises administering to a recipient an effective amount of a pharmaceutical composition containing as an active ingredient a compound of the formula I or II".

The formulae are then set out. A compound of the formula I is Leflunomide. The validity of the Patent is in issue in this appeal. Apotex contends that it relates to a method of medical treatment and cannot be a patentable invention under the *Patents Act* 1990 (Cth) ("1990 Act"). In the alternative, Apotex contends that the claim in the Patent is for a second or subsequent medical use of a previously known product involving the purpose of its use as an element and that on that ground, it does not disclose a patentable invention.

1. The second respondent, Sanofi-Aventis Deutschland GmbH, is the registered owner of the Patent. The first respondent, Sanofi-Aventis Australia Pty Ltd, supplies Leflunomide in Australia under the trade names "Arava" and "Arabloc". Apotex obtained registration of generic versions of Leflunomide (collectively, "Apotex Leflunomide Products") on the Australian Register of Therapeutic Goods in or about July 2008. Its intention was to supply the products and offer them for supply in Australia as treatments for psoriatic arthritis and rheumatoid arthritis. The respondents initiated proceedings against Apotex in the Federal Court of Australia on 23 October 2008. They alleged that Apotex's proposed supply of the Apotex Leflunomide Products for the treatment of psoriatic arthritis would infringe the Patent. Other causes of action not material to this appeal were also asserted.

2. In support of their infringement claim, the respondents alleged, inter alia:

- Apotex intended to supply and offered to supply in Australia the

Apotex Leflunomide Products for the treatment of active psoriatic arthritis.

- The use by a person of the Apotex Leflunomide Products for the treatment of active psoriatic arthritis would infringe claim 1 of the Patent.

- That use would be in accordance with instructions for the use of the products given by Apotex to such a person.

- Each supply or offer to supply made by Apotex of any of the Apotex Leflunomide Products for the treatment of active psoriatic arthritis would infringe claim 1 of the Patent pursuant to s 117 of the 1990 Act.

Apotex cross-claimed for revocation of the Patent on a variety of grounds, none of which succeeded.

1. On 18 November 2011, the primary judge dismissed the cross-claim and made a declaration that Apotex had threatened to infringe claim 1 of the Patent "by threatening to import, market, take orders for, sell, supply and offer to supply products containing leflunomide … in Australia for the treatment of psoriatic arthritis." Her Honour granted injunctive relief restraining Apotex from infringing claim 1 and from supplying or offering to supply products containing Leflunomide for the treatment of psoriatic arthritis. Apotex appealed to the Full Court of the Federal Court. On 18 July 2012, the Full Court (Keane CJ, Bennett and Yates JJ) dismissed the appeal and ordered that Apotex pay the respondents' costs of the appeal.

2. On 14 December 2012, this Court (French CJ and Kiefel J) granted special leave to Apotex to appeal from the judgment of the Full Court in relation to the validity of the Patent and referred the application for special leave in relation to infringement to an enlarged Bench for further consideration so that it could be argued as if it were on an appeal.

Patentability of medical treatments — A "common law" question?

1. The single ground upon which special leave was granted was that the Full Court erred in finding that the claim of the Patent claimed a manner of manufacture within the meaning of s 18(1) of the 1990 Act. The first question raised by Apotex in support of that ground is whether a method of medical treatment of human beings is capable of being a patentable invention. That question directs attention to the relevant statutory language and the body of case law which has informed its application.

2. Section 18 of the 1990 Act lists necessary conditions for an

invention to be a patentable invention for the purposes of a standard patent. One of those conditions, set out in s 18(1)(a), is that the invention, so far as claimed in any claim:

> "is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies".

Despite the classificatory character of the criterion, the question whether it is to be met in respect of a claim for an invention is not answered simply by asking whether such a claim is "a manner of manufacture". As this Court said in *National Research Development Corp v Commissioner of Patents* ("*NRDC*"):

> "The right question is: 'Is this a proper subject of letters patent according to the principles which have been developed for the application of s 6 of the *Statute of Monopolies*?'"

It is relevant to that inquiry that the term "manner of manufacture" originated as part of a statute which was seen as declaratory of the common law. Its application in various statutory embodiments since the *Statute of Monopolies* 1623 ("the Statute") was enacted has evolved according to common law processes. It has always been applied:

> "beyond the limits which a strict observance of its etymology would suggest, and ... a widening conception of the notion has been a characteristic of the growth of patent law."

1. The Statute was a response to the abuse of grants of monopolies in the purported exercise of the royal prerogative. It declared all monopolies void, subject to the proviso in s 6:

> "Provided also That any Declaration before mentioned shall not extend to any Letters Patents and Grant of Privilege for the term of fourteen years or under, hereafter to be made of the sole working or making of *any manner of new Manufactures* within this Realm, to the true and first Inventor and Inventors of such Manufactures, which others at the time of making such Letters Patents and Grants shall not use, so as also they be not contrary to the Law nor mischievous to the State, by raising prices of Commodities at home, or hurt of Trade, or generally inconvenient …" (emphasis added)

The Statute did not alter the common law. It did not confer rights upon inventors. Coke said of it:

> "[T]his act maketh them [patents] no better, than they should have been, if this act had never been made".

The objectives of s 6, as Cornish, Llewelyn and Aplin observed in the 8th edition of their textbook on *Intellectual Property*, "were the encouragement of industry, employment and growth, rather than justice to the 'inventor' for his intellectual percipience."

1. Legislation enacted in the United Kingdom after the Statute provided machinery for the grant and enforcement of patents but left unaffected the central requirement for their grant in s 6. The source of power to grant patents remained the prerogative. It seems that between the enactment of the Statute and the mid-18th century the patent system was little used. The decision of the Court of Common Pleas in *Boulton v Bull* was the first case in which so-called "inherent patentability" received close consideration. That case apart, there was little accumulated authority on inherent patentability in the United Kingdom before the first consolidation of patent laws in the *Patents, Designs, and Trade Marks Act* 1883 (UK) ("1883 UK Act").

2. The 1883 UK Act defined "invention" as "any manner of new manufacture the subject of letters patent and grant of privilege within section six of the Statute of Monopolies". Its effect was to confer upon an inventor "the right to a patent under certain conditions". Subject to various amendments it remained in place for 24 years and provided a model for patents legislation in the Australian colonies prior to federation and for the first Commonwealth patent law, the *Patents Act* 1903 (Cth) ("1903 Act"). The 1883 UK Act was superseded by the *Patents and Designs Act* 1907 (UK) ("1907 UK Act"), which continued the definition of "invention" by reference to the Statute. Both the 1883 and 1907 UK Acts preserved the prerogative to grant letters patent. In the 6th edition of *Terrell on the Law of Patents*, published in 1921, the effect of the successive UK statutes, up to and including the 1907 statute, was described as:

> "declaratory of the limits within which that [the royal] prerogative should be exercised, and of the method of procedure to be adopted in obtaining letters patent for inventions."

1. The 1907 UK Act and subsequent amending legislation was repealed by the *Patents Act* 1949 (UK) ("1949 UK Act"). That Act also defined "invention" in terms of "any manner of new manufacture" within s 6 of the Statute. Like its predecessors, it preserved the prerogative of the Crown. The 1949 UK Act was superseded by the *Patents Act* 1977 (UK) ("1977 UK Act"). The term "manner of manufacture" and reference to the Statute were replaced in the 1977 UK Act with a codification of the requirements of patentability. Those requirements were set out in ss 1(1) to 1(4), which were based on and intended to have, as nearly as practicable, the same effect in the United Kingdom as Arts 52 to 57 of the European Patent Convention of 1973. Methods of treatment of the human body were

excluded from patent protection by s 4(2) of the 1977 UK Act as not capable of industrial application. The patent law of the United Kingdom was thereby aligned with the exclusion derived from Art 52(4) of the European Patent Convention. The *Patents Act* 2004 (UK) repealed s 4(2) and introduced a new s 4A into the 1977 UK Act, excluding methods of treatment of the human body from patent protection without reference to industrial applicability, subject to "an invention consisting of a substance or composition for use in any such method." That amendment implemented changes brought about by the revision of the European Patent Convention in 2000. Apotex and the respondents debated in their written submissions whether the exclusion in the 1977 UK Act was based on policy grounds or reflected pre-existing United Kingdom case law relating to inherent patentability. It is unnecessary and unhelpful to explore the factors which may have influenced the introduction of a statutory exclusion in the 1977 UK Act. There is, however, no doubt about the existence of the exclusion prior to its express enactment.

2. In the Report of the Banks Committee, which preceded the enactment of the 1977 UK Act, examples were given of matter which had never been considered to be an "invention" as defined, including "treatment of human beings". The Committee observed that a process consisting of using a known compound for treating a human being medically had never been held to be patentable because the courts had consistently expressed the opinion that a process for medical treatment of a human being was not a proper subject for a patent monopoly. The Committee expressed doubt whether the grant of such patents would accord with the requirements of the Strasbourg Convention that protection should be granted for inventions susceptible of "industrial application".

3. The *Patents Act* 1952 (Cth) ("1952 Act"), which replaced the 1903 Act, was based upon the 1949 UK Act. It was enacted following the Report of the Dean Committee in 1952. A point made in the Report was that "in the matter of patents for inventions, there should be as close a correspondence as possible between the two Acts." The Committee did not recommend any change to the definition of "invention" under the 1903 Act.

4. Following a Report of the Industrial Property Advisory Committee in 1984, the 1952 Act was repealed and the 1990 Act was enacted. The criterion that an invention must be a "manner of manufacture within the meaning of s 6 of the Statute of Monopolies" was retained. In recommending its retention, the Committee said:

> "We consider that the existing concept operates quite satisfactorily. It has the advantage of being underpinned by an extensive body of decided case law which facilitates its application in particular circumstances."

The Committee rejected the alternative of a codified definition. The rationale for retaining the existing criterion was reflected in the Explanatory Memorandum for the Patents Bill 1990, which said of the proposed definition of "invention":

> "The requirement in paragraph 18(a) ... invokes a long line of UK and Australian court decisions. It means little more than that an invention must belong to the useful arts rather than the fine arts. The Government accepted the Industrial Property Advisory Committee's recommendation that this flexible threshold test of patentability be retained in preference to adopting a more inflexible codified definition."

The legislative purpose reflected in s 18(1)(a) of the 1990 Act is that the "manner of manufacture" criterion for a patentable invention ought to continue to be applied on a case-by-case basis.

1. The processes for the ascertainment, application and development of the principles determining whether a claimed invention is a "manner of manufacture" can appropriately be described as common law processes. They accord with the fourth and fifth senses in which the term "the common law" is used, as described by Professor AWB Simpson in the *New Oxford Companion to Law* and referred to in the joint majority judgment of this Court in *PGA v The Queen*. According to those senses of the term, the common law is "law based on cases, or law evolved through adjudication in particular cases, as opposed to law derived from the analysis and exposition of authoritative texts." Particularly apposite is the paraphrase in *PGA* of what was said by six members of this Court in the *Native Title Act Case*:

> "the term 'common law' might be understood not only as a body of law created and defined by the courts in the past, but also as a body of law the content of which, having been declared by the courts at a particular time, might be developed thereafter and be declared to be different."

1. Case-by-case decision-making and associated development of the law is a process characteristic of the common law. It is also a characteristic of the application by courts of broadly stated statutory provisions, the interpretation, fleshing out, and application of which the legislature has left to the courts. The prohibition of misleading or deceptive conduct in trade or commerce is one example. Such a provision sets out broad textual parameters within which principles of law are to be ascertained, applied and developed. The boundaries between the common law process detached from a statutory context and analogous processes in a statutory setting are not firm and fixed. Indeed there are many examples of statutes which incorporate, by reference, common law concepts.

2. The respondents submitted that, having regard to existing practice and case law in Australia, which accepts the patentability of methods of medical treatment, the omission of the legislature to provide for the express exclusion of such claims was inconsistent with "an implied exclusion that was plainly never intended." That submission should not be accepted. As appears from the shifting history of the understanding of "manner of manufacture", legislative silence in this field is an unsure guide to the development of principle. Its invocation in this context attracts the kind of caution, only with greater emphasis, associated with the invocation of the maxim *expressio unius exclusio alterius*. In any event, as explained above, s 18(1)(a) of the 1990 Act was enacted on the basis that within the framework of the case-by-case common law process, the continuing exposition and application of the criterion which it embodied would be left to the courts.

3. The term "manner of manufacture" has long been given a wide application, which was widened by the decision of this Court in *NRDC*. In *Boulton v Bull*, four Judges of the Court of Common Pleas divided equally on whether a patent granted to James Watt for an improved steam engine was void. It was conceded by counsel in that case that the word "manufacture" was "of extensive signification" and that it applied "not only to things made, but to the practice of making, to principles carried into practice in a new manner, to new results of principles carried into practice." The elaboration by Eyre LCJ of that concession was described by Dixon J in *Maeder v Busch* as one of the earliest statements, and "[p]erhaps the widest", on patentability. Eyre LCJ included in the scope of "manufacture":

> "new processes in any art producing effects useful to the public."

1. A perhaps unintended narrowing of the scope of patentability was effected in 1942 by a list of sufficient conditions, set out in *GEC's Application*, for characterising a method or process as a "manner of manufacture". The conditions, formulated by Morton J sitting as the Patents Appeal Tribunal, provided that a method or process could be so characterised if it resulted in the production, improvement, restoration or preservation of a vendible product. That the conditions were sufficient, disjunctive and not exhaustive appeared from Morton J's comment that:

> "In saying this I am not attempting to cover every case which may arise by a hard and fast rule."

Human nature being what it is however, linkage of a method or process to a "vendible product" seems to have been treated in practice as something approaching a necessary condition. Perhaps for that reason Morton J's list elicited a rather cautious response from Evershed J in *Cementation Company Ltd's Application*.

1. Having stated a reservation about the approach taken in *GEC*, Evershed J expressed the view that Morton J had used the word "product" in a broad sense. Later, in *Rantzen's Application*, Evershed J suggested that the term "vendible product" originated with the need to exclude from the scope of the Patent Acts methods or processes, such as those for treating diseases of the human body, which, however useful, could not be contemplated as falling within their ambit. That somewhat enigmatic, if not circular, observation may have reflected an underlying ethical objection to the patentability of such methods or processes. In the event, constraints on the patentability of methods or processes generally, which flowed from the focus on "vendible product" in *GEC*, were effectively removed as a result of the response of the courts of the United Kingdom to this Court's decision in *NRDC*. Before turning to the relevant decisions of this Court and the Federal Court of Australia it is necessary to look to the ways in which, historically, the courts of the United Kingdom dealt with the application of the term "manner of manufacture" to such methods or processes.

2. The starting point is the late 18th century decision of *Boulton v Bull*. Medical treatment may seem a long way from improved steam engines. However, in *Boulton v Bull*, Buller J discussed the scope of the term "manner of manufacture" in its application to methods and processes by reference to an hypothetical example of a medicine for the treatment of fever found by an ingenious physician to be "a specific cure for a consumption, if given in particular quantities". Could the physician be given a patent for the new use? The answer was:

> "I think it must be conceded that such a patent would be void; and yet the use of the medicine would be new, and the effect of it as materially different from what is now known, as life is from death."

Buller J put it thus: "[t]he medicine is the manufacture, and the only object of a patent, and as the medicine is not new, any patent for it, or for the use of it, would be void." Cunynghame's *English Patent Practice* referred to that observation as an example of the general proposition that for an "art" to be capable of being patented "[i]t must be an art connected with trade, that is to say, an industrial art." The author went on:

> "The art of curing an illness cannot be said to be an art of manufacture, and it follows therefore that all old things may be used in new ways by private persons, provided always that in so using them they are not manufacturing anything."

Cunynghame also used the example to support the proposition that a new use of an old material could not be patented unless such use itself constituted a manufacture.

1. The earliest reported case in the United Kingdom dealing directly with the patentability of a process of medical treatment arose under the 1907 UK Act in *C & W's Application*. The Solicitor-General, Sir Stanley Buckmaster, on appeal from the Comptroller-General, held that "a manner of new manufacture" had to be "in some way associated with commerce and trade." A method for the extraction of lead from human bodies, which was the subject of the patent in that case, was not such a process. A process to enhance the marketability of animals might be viewed differently. The decision reflected a constrained commercial notion of "manner of manufacture", which prevailed at the time. It accorded with what had appeared in Cunynghame's textbook 20 years earlier.

2. In his reasons for decision in *C & W's Application*, the Solicitor-General also attributed to the Patent Office a broad view that the application should be refused because it related to medical treatment simpliciter. He said:

> "I notice that the Patent Office have based their refusal upon the ground that the alleged invention relates simply to medical treatment, and I think that the foundation for that refusal is sound."

There was no elaboration in the brief reasons for judgment of the foundation for that refusal. Whatever its foundation, the Solicitor-General made clear that it had nothing to do with "humanity" or the ethics of the medical profession. He said:

> "I have altogether excluded such considerations from my mind."

It has been suggested that despite that disclaimer, the Solicitor-General's judgment was "fuelled by his view that doctors should not, on moral grounds, seek commercial monopolies in respect of their professional skills." It cannot be said that a clear and stable principle underlying the exclusion posited in *C & W's Application* was spelt out in that case. However that may be, the practice of the Patent Office in the United Kingdom following *C & W's Application* was to refuse to allow applications for grants of patents where the alleged invention related simply to a medical treatment.

1. The definition of "invention" in the 1903 Act and the 1952 Act has been considered in a number of decisions of this Court. Obiter dicta and passing references to the patentability of medical treatments have been made in four of those decisions, but in none of them has the question of patentability been determined.

2. The first of the four decisions of this Court was *Maeder v Busch*, which concerned "a process for forming permanent waves in hair". The

patent was held to be invalid on the basis of prior user and want of novelty. However, it was also argued that the claimed invention was not patentable "because it deals with the living tissues of the body, and no particular method will, in all circumstances and conditions, produce upon all persons the same results". Latham CJ, citing *C & W's Application*, was "very doubtful" whether a method or process of conducting an operation upon a part of the human body could be regarded as a "manner of manufacture". The Chief Justice thought the question "so important and possibly so far-reaching, that it is wise to abstain from deciding it until the necessity for doing so arises." Dixon J appeared to accept that there must be a commercial dimension to the relevant "art" in order to enable a process to be patented. There was, however, difficulty in basing legal distinctions on the motive or purpose of the operator:

> "The process may be intended for use in ordinary trade or business such as that of hairdressing, manicure, pedicure. The purpose, on the other hand, may be the relief of suffering by surgical or manipulative means. But the object is not to produce or aid the production of any article of commerce. No substance or thing forming a possible subject of commerce or a contribution to the productive arts is to be brought into existence by means of or with the aid of the process."

In the reference to "article of commerce" may be seen an anticipation of Morton J's "vendible product" and a reflection of Heath J's observation in *Boulton v Bull* equating "manufacture" with a vendible machine or substance. However, foreshadowing what would be said in *NRDC*, Dixon J referred to the "widening conception of a manner of new manufacture [that] has been a characteristic of the growth of patent law." In the event, like Latham CJ, he preferred to leave undecided the question whether a process for treating hair could be patentable. Evatt J agreed with the trial judge's finding of invalidity for prior public and common user.

1. The views expressed by Latham CJ and Dixon J in *Maeder v Busch* were obiter and inconclusive, but consistent with the views of the courts of the United Kingdom and Patent Office practice in the United Kingdom. Beyond Dixon J's reference to the connection of patentability to commercial purposes, there was no discussion of the underlying general principle. There was, however, a recognition of the logical difficulty involved in trying to draw a legal distinction between methods of medical treatment and other processes for treatment of the human body such as cosmetic procedures.

2. In 1959, this Court held in *NRDC*, which concerned a method for using a herbicide on crops, that the application of the criterion "manner of manufacture" to a method or process was not constrained by requiring the method or process to be linked to a narrowly defined understanding of a

"vendible product". The Court accepted, as had Dixon J in *Maeder v Busch*, that a widening conception of the notion of "manufacture" had characterised the growth of patent law. The word "product" was not to be confined to a "thing" in the sense of a physical article:

> "It is, we think, only by understanding the word 'product' as covering every end produced, and treating the word 'vendible' as pointing only to the requirement of utility in practical affairs, that the language of *Morton* J's 'rule' may be accepted as wide enough to convey the broad idea which the long line of decisions on the subject has shown to be comprehended by the Statute."

The Court applied that approach to processes, observing that:

> "The point is that a process, to fall within the limits of patentability which the context of the *Statute of Monopolies* has supplied, must be 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." (citation omitted)

1. The question of medical treatment arose almost peripherally in *NRDC*. Reference was made to *R v Wheeler*, decided in 1819, in which Abbott CJ had said that the word "manufacture" required something of a corporeal and substantial nature that could be made by man from matters subjected to his art or skill or at least some new mode of employing practically his art and skill. The Court was not prepared to treat that statement as conclusive of the question. It said:

> "The need for qualification must be confessed, even if only in order to put aside, as they apparently must be put aside, processes for treating diseases of the human body: see *Re C & W's Application*; *Maeder v Busch*." (footnotes omitted)

Immediately after the passage about processes quoted in the preceding paragraph of these reasons, the Court speculated, in parentheses, that the exclusion of methods of surgery and other processes for treating the human body could well lie outside the conception of invention "because the whole subject is conceived as essentially non-economic". It did not otherwise identify a rationale for the exclusion.

1. So far as it held that the notion of "manner of manufacture" in its application to a method or process was not limited by a narrow requirement related to the production, improvement, restoration or preservation of a "vendible product", *NRDC* was approved and followed in the United Kingdom. Initially it was not seen as displacing the authority of *C & W's*

Application or the Patent Office practice of rejecting claims for methods of medical treatment. Arguments that such claims should be accepted after *NRDC* did not find favour with supervising examiners in *United States Rubber Co's Application* and *London Rubber Industries Ltd's Patent*, the latter decision being supported on appeal by Lloyd-Jacob J.

2. In *Schering AG's Application*, Whitford J, delivering the decision of the Patents Appeal Tribunal, consisting of Graham J and himself, accepted that it was "difficult to see any logical justification for the practice in relation to processes for medical treatment". However, he found a distinction relevant to the patentability of medicines and the non-patentability of medical treatments in s 41 of the 1949 UK Act, which provided for the compulsory licensing of medicines. There was no such provision in relation to methods of medical treatment. Whitford J foreshadowed the possibility of change following the implementation of the Report of the Banks Committee, and said:

> "On a consideration of the terms of the statute as it now stands, it does, however, seem that claims to processes for medical treatment must be considered as being excluded from the scope of the Act and the practice of the office. Whatever, therefore, the origin of the exclusion may be, in so far [as] it relates to processes for the medical treatment of human beings to cure or prevent disease, it must be considered sound."

That observation left unrevealed the continuing basis for the exclusion beyond its long existence.

1. Thirteen years after *NRDC*, in *Joos v Commissioner of Patents* Barwick CJ reversed a decision of the Deputy Commissioner of Patents that an application for the grant of letters patent for a process for the treatment of parts of the human body, namely human hair and nails, whilst attached to or growing upon the human body, should not proceed. The Chief Justice put to one side, as obiter, what had been said in *Maeder v Busch* concerning the patentability of processes for treating human beings. He expressed scepticism about the speculation in *NRDC* that medical treatment was excluded as essentially non-economic. He spoke of the national economic interest in "the repair and rehabilitation of members of the work force, including management". He accepted, for the purpose of the appeal before him, that a narrowly defined class of process for the medical treatment of a part of the human body, the arrest or cure of a disease or diseased condition, or the correction of some malfunction or the amelioration of some incapacity or disability was not a proper subject of letters patent. The Chief Justice was not concerned to discover and express a basis for the exclusion. If he had to do so he would "place the exception, if it is to be maintained, on public policy as being, in the language of the *Statute of Monopolies*,

'generally inconvenient', not limiting what may fall within those words to things of a like kind to those described by the preceding words." As to that, it may be noted that Apotex has expressly disclaimed any reliance upon the "generally inconvenient" proviso in s 6 of the Statute.

2. In *Eli Lilly & Co's Application*, decided in 1974, the same Patents Appeal Tribunal which had decided *Schering AG's Application* asserted an ethical support for the exclusion. Their Honours cited *NRDC* as an authority against a limited approach to the definition of "invention" by reference to the idea of making tangible goods. Nevertheless, *NRDC* was not seen as warranting a judge-made change to the exclusionary rule:

> "It has long been established that claims to methods of medical treatment should not be accepted ... The reasons for such an exclusion appear to us to be based in ethics rather than logic but if there is to be a change of policy, which would appear to us to be sensible, this ought in our view to be effected by legislation rather than by interpretation."

In similar vein, the Court of Appeal in *The Upjohn Company (Robert's) Application* held that:

> "If the law in this regard should be changed, it must be for the legislature."

1. In Australia, following *Joos*, Patent Office practice excluded claims falling within the narrow definition of medical treatment adopted by Barwick CJ. In 1992, however, an important change in Australian law was initiated by the judgment of Gummow J in *Rescare Ltd v Anaesthetic Supplies Pty Ltd* in reasoning upheld by the Full Court of the Federal Court on appeal. Those decisions were much influenced by the first instance decision, in 1979, of the former Chief Justice of New Zealand, Davison CJ, in *Wellcome Foundation Ltd v Commissioner of Patents* ("*Wellcome Foundation*"). Reference should be made to that decision.

2. Davison CJ held that the rationale for *C & W's Application*, namely that a method of treatment lacks connection with any form of manufacture or trade, could not stand in the light of *NRDC*. The Chief Justice could find no other grounds for refusal of a patent for medical treatment stated in the decided cases in the United Kingdom and Australia from 1914 to 1961. Any long-established practice based on *C & W's Application* was no longer applicable. He rejected the proposition in *Eli Lilly* that the ground for the exclusion was ethical. The basis of the exclusion had always been that medical treatment was neither "an art of manufacture" nor a "form of manufacture or of trade". He quoted and relied upon the observations of Witkon J in the Supreme Court of Israel in *The Wellcome Foundation Ltd v*

Plantex Ltd:

> "There is thus no ground, either in law or in logic, for holding that a method of therapeutic treatment is unpatentable and any consideration that at one time might possibly have justified such a holding, is nowadays devoid of any substance. It may certainly not be said that such an invention is not within the realm of economic endeavour in accordance with the test laid down in *NRDC's Application* or that it is within the realm of 'fine art' as distinct from 'useful art'." (citation omitted)

Kahn and Kister JJ agreed with Witkon J, subject to a qualification against the patentability of a new use for a known therapeutic substance, composition or device. The decision of the Supreme Court of Israel involved the application of the Mandatory Patents and Designs Ordinance. It was common ground that in the general administration of the Ordinance, the Court was guided by the English law and practice on patents.

1. Davison CJ's decision was reversed by the Court of Appeal. Cooke J held that the law had not developed "to the point of holding patentable a process for the treatment of human illness or a new use of a known therapeutic drug." While acknowledging what Barwick CJ had said in *Joos* about the national economic interest, Cooke J invoked countervailing ethical considerations referring to "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." McMullin J and Somers J took similar approaches. The Court of Appeal in *Wellcome Foundation* held that any alteration to favour the grant of patents for methods of treating illness would best be left to parliament. It was the kind of alteration that demanded "a far wider range of review than is available to courts following our traditional and valuable adversary system".

2. The *Rescare* decisions concerned a patent for a device for treating sleep apnoea. Gummow J, at first instance, deciding in favour of patentability of a method claim, accepted the reasoning of Davison CJ in *Wellcome Foundation*. He rejected arguments that the patenting of such methods would be "generally inconvenient" within s 6 of the Statute. He also accepted the proposition, reflecting what Dixon J had said in *Maeder v Busch*, that under the 1952 Act "there was no normative distinction to be drawn between those processes for treatment of the human body for disease, malfunction or incapacity, and for cosmetic purposes."

3. On appeal, a majority of the Full Court of the Federal Court agreed with Gummow J. Lockhart J accepted that *NRDC* expounded the exclusion of processes for medical treatment of the human body, but found the ground of the exclusion "not entirely clear". The United Kingdom cases did not

disclose a persuasive ground for the exclusion after the foundation for the decision in *C & W's Application* had been removed. Adopting the reasoning of Davison CJ, his Honour said:

> "In my opinion, there is no justification in law or in logic to say that simply because on the one hand substances produce a cosmetic result or a functional result as opposed to a curative result, one is patentable and the other is not. I see no reason in principle why a method of treatment of the human body is any less a manner of manufacture than a method for ridding crops of weeds as in *NRDC*."

His Honour would have included a new use for an old compound as within the scope of a patentable invention. He said:

> "If a process which does not produce a new substance but nevertheless results in 'a new and useful effect' so that the new result is 'an artificially created state of affairs' providing economic utility, it may be considered a 'manner of new manufacture' within s 6 of the *Statute of Monopolies*". (citations omitted)

Wilcox J agreed with Lockhart J, adding the observation that the Australian Parliament had not been persuaded by policy considerations against patentability to provide an express exclusion for methods of medical treatment of human beings. Sheppard J rested his dissent upon the proposition that the grant of a patent for medical treatment was "generally inconvenient" within the meaning of s 6 of the Statute. In so doing he explicitly invoked ethical considerations:

> "the Court should not contemplate the grant of letters patent which would give to one medical practitioner, or perhaps a group of medical practitioners, a monopoly over, for example, a surgical procedure which might be greatly beneficial to mankind. Its denial might mean the death or unnecessary suffering of countless people."

1. The fourth and most recent reference by this Court to the question of patentability of medical treatments was made in 1998 in *Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Ltd*. In considering the operation of s 100 of the 1952 Act, setting out the grounds of revocation of a standard patent, the majority, Brennan CJ, Gaudron, McHugh and Gummow JJ, referred to the content of s 100(1)(d) having regard to the other specific grounds for revocation and observed:

> "Section 6 of the *Statute of Monopolies* excluded any manner of new manufacture which was 'contrary to the Law' or 'generally inconvenient'. The classification of certain methods of treatment of

> the human body as an inappropriate subject for grants under the Act appears to rest on this footing." (footnote omitted)

That observation was footnoted by reference to *Joos*. It appears to have been no more than an acknowledgement, rather than an adoption, of a basis upon which the claimed exclusion was said to rest.

1. In *Bristol-Myers Squibb Co v FH Faulding & Co Ltd*, the Full Court of the Federal Court followed its earlier decision in *Rescare*. Black CJ and Lehane J in their joint judgment identified:

> "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".

A second compelling consideration was:

> "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 ... to grant patents for methods of medical treatment of the human body."

The question whether the exclusion from patentability of methods of medical treatment subsisted had been resolved in the negative by two decisions of the Full Court of the Federal Court. In the meantime, in New Zealand, the decision of Davison CJ, which had been influential in the reasoning adopted at first instance in *Rescare* and by the Full Court in *Rescare* and *Bristol-Myers*, was itself to receive a short-lived vindication from the Court of Appeal.

1. In 1999, the Court of Appeal of New Zealand, sitting a Bench of five Judges in *Pharmaceutical Management Agency Ltd v Commissioner of Patents* ("*Pharmac*"), overruled its earlier decision in *Wellcome Foundation* insofar as it would have excluded, from patentability, so-called "Swiss form" claims. As described in *Wellcome Foundation*, in such a claim the integer representing the inventive subject matter and novelty is the new use for which the medicament is made. In delivering the judgment of the unanimous Court in *Pharmac* however, Gault J made some broader observations antithetical to the reasoning of the Court of Appeal in *Wellcome Foundation*. His Honour agreed with Davison CJ's conclusion at first instance in *Wellcome Foundation* that there was little logic in maintaining the exclusion. In so doing, he referred to the decisions of Gummow J and the Full Court of the Federal Court in *Rescare*. Gault J said:

> "What emerges from this is that it no longer can be said that a method of treating humans cannot be an invention. To the extent that the judgments in *Wellcome* express that view we depart from them. The exclusion from patentability of methods of medical treatment rests on policy (moral) grounds. The purpose of the exclusion is to ensure that medical practitioners are not subject to restraint when treating patients. It does not extend to prevent patents for pharmaceutical inventions and surgical equipment for use in medical treatment."

Despite the generality of his Honour's observations about the patentability of methods of medical treatment, Gault J indicated later in his reasons for judgment that the Court of Appeal was only deciding the "narrow question", namely whether there could be invention and novelty in the discovery of unrecognised properties of known pharmaceutical compounds.

1. The Court of Appeal of New Zealand in *Pfizer Inc v Commissioner of Patents* characterised the decision in *Pharmac* as one concerned with the patentability of Swiss form claims and said:

> "In our view the medical treatment exclusion does have a statutory base, and to the extent that the obiter observation in *Pharmac* may cast doubt on that, we would respectfully differ."

The generality of the observation in *Pharmac* was at odds with what was decided in *Wellcome Foundation*. Nevertheless, following *Pfizer* the position in New Zealand appears to be that the exclusion of methods of medical treatment of human beings from patentability is maintained.

Approach to resolution of the question of patentability

1. It may be concluded from the preceding survey that the question whether a particular class of claimed invention meets the criterion of being "a manner of manufacture" requires for its resolution the application of the common law process discussed earlier in these reasons. The question whether medical treatments for human beings generally and new medical uses of non-pharmaceutical products in particular are capable of being "manners of manufacture", must be decided according to principles and constraints of the kind applicable to the development of the common law. An important constraint is that a propounded development of legal principle involving large questions of public policy and reconciliation of interests in tension is, for the most part, best left to the legislature. On the other hand, a qualification or exception to a general principle may have become anomalous to such an extent that its removal would enhance the logical and/or normative coherence of the law. The history of the exclusion of medical treatments from patentability does not disclose a stable, logical or

normative foundation and seems to depend upon rather nice distinctions for its maintenance. As recognised in *Eli Lilly*, there is a logical and normative tension between the patentability of pharmaceutical products and the exclusion from patentability of methods of medical treatment. Moreover, there is difficulty in drawing a boundary between medical and cosmetic procedures. The latter may include procedures having both medical and cosmetic benefits: for example, lap band surgery. The endeavour to achieve coherence in this area falls more readily within the institutional competence of the courts than an endeavour to strike some balance between competing public and private interests.

2. The field of intellectual property law generally is notoriously one in which there are public interests and private interests in fierce competition with each other. A public interest may lie in using the grant of monopoly to encourage technical innovation. A competing public interest may lie in ensuring unconstrained access by medical practitioners and their patients to new medical methods and processes. The interests of inventors and investors in inventions and the interests of members of the public whose lives could be improved or saved by use of innovative medical treatments may be in tension with each other and with aspects of the public interest. There is room for debate about whether the law does or should reflect "proprietarianism" as its "dominant normative influence" or whether it should be seen as "instrumental" in support of publicly beneficial goals. Professor Peter Drahos has written of the latter approach:

> "The practical import of the theory would be that the interpretation of intellectual property law would be driven in a systematic fashion by the purpose of that law rather than more diffuse moral notions about the need to protect pre-legal expectations based on the exercise of labour and the creation of value."

The identification of the public policy objectives of a statute is a matter within the institutional competency of the courts. Choosing between or balancing competing objectives may overlap with the legislative function.

1. As a general proposition, the reasoning of Gummow J at first instance in *Rescare* and of Lockhart J on appeal to the Full Court, and that of Davison CJ at first instance in *Wellcome Foundation*, lend powerful support to the proposition that the exclusion of medical treatment is an anomalous qualification on the principles governing patentability under the rubric "manner of new manufacture". A decision to dispense with the exclusion may be seen as a development of existing principle. To the extent that the Court enunciates such a development to enhance coherence in the law, it is not required to endeavour to resolve complex tensions between public and private interests which may be affected. Such tasks are largely matters for the legislature. They may require informed appraisal of

a range of considerations backed by empirical evidence and expert advice concerning the practical significance of striking the balance in any particular way. The question whether, in the interests of coherence, this Court should support or reject the propounded exclusion of methods of medical treatment should now be considered in light of the decisions below and the submissions put to this Court by the parties. First it is appropriate to refer briefly to the decisions at first instance and in the Full Court.

The decisions in the Federal Court

1. At first instance, Apotex did not challenge the correctness of the Full Court's decisions in *Rescare* and *Bristol-Myers*, but reserved the right to do so on appeal. In its written submissions to the Full Court, Apotex contended first that methods of medical treatment are not patentable, and second that methods of medical treatment for a "second or later medical use" are not patentable. In oral argument to the Full Court, Apotex did not press the first contention, that methods of medical treatment are not patentable. Apotex's second use contention fell away because of the view that the Full Court formed of the proper construction of the claim in the Patent. On the first contention, Keane CJ, having referred to the decision of the Full Court in *Rescare*, said that the question whether or not patentability should be expanded to cover methods of medical treatment was a matter for determination by the legislature, rather than the judiciary below the level of this Court. Bennett and Yates JJ took a similar approach to the *Rescare* and *Bristol-Myers* decisions. Like Keane CJ, and like Wilcox J in *Rescare*, they placed some weight upon legislative silence on the topic. Their Honours expressed no view on Apotex's contention relating to second or later use.

Patentability of medical treatments — A common law answer

1. Apotex submitted, correctly, that a method of treating a human being with a known substance was never held to be capable of being an invention under the 1949 UK Act and its predecessors. Its submission that that was the position which had been accepted before 1990 as the law in Australia attached a more definite characterisation to *Maeder v Busch* and *NRDC* than the reasons in those decisions could bear. It is, however, correct to say that the exclusionary proposition has not been examined directly in any decision of this Court. While the obiter observations in the decisions reviewed in these reasons invite respect and close attention, they do not determine the answer to the question before this Court in this appeal.

2. The respondents submitted that Apotex's argument required the recognition of a special exclusion from the concept of patentability in relation to methods of human treatment. They invoked legislative inaction on the question as negativing an implied exclusion. That aspect of their submission should not be accepted. The resolution of this important

question cannot rest upon the shifting sands of legislative silence. The argument has to engage with the case-by-case development of principle, which the legislature has left to the courts, as appears from the Explanatory Memorandum to the 1990 Act and the acceptance, reflected in that Memorandum, of the rationale for retaining "manner of manufacture" as a criterion of patentability.

3. The primary submission of the respondents on the question of the exclusion should be accepted. The exclusion from patentability of methods of medical treatment represents an anomaly for which no clear and consistent foundation has been enunciated. Whatever views may have held in the past, methods of medical treatment, particularly the use of pharmaceutical drugs, cannot today be conceived as "essentially non-economic". Although Barwick CJ's reference in *Joos* to the national economic interest in "the repair and rehabilitation of members of the work force" may be seen as reducing human beings to economic units, there is no gainsaying the economic significance of medical treatments independently of the flow-on benefits of a well-maintained work force. Recognition of the economic dimensions of this question is not inconsistent with the concurrent recognition of the large public policy questions which it raises. They may involve competing philosophies of proprietarianism and instrumentalism and the relative values to be accorded to different public goods: alleged incentives to innovation on the one hand, and the widest possible availability of new methods of medical treatment to relieve suffering on the other. To decide that the concept of "manner of new manufacture" does not logically exclude methods of medical treatment from patentability does not engage with those large questions, although it may have significant consequences for public policy. This is a case in which such considerations are best left to the legislature. In my opinion the application of the rubric "manner of new manufacture" in a logically and normatively coherent way is not served by excluding from its scope methods of medical treatment of human beings. Methods of medical treatment can fall within the scope of a manner of new manufacture within the meaning of s 6 of the Statute and therefore within s 18(1)(a) of the 1990 Act. Nor, on the reasoning which supports that conclusion, does "general inconvenience" (upon which, in any event, Apotex placed no reliance) appear to provide any basis for their exclusion.

Conclusion

1. On the remaining questions concerning the purposive character of the Patent and the application for special leave on the question of infringement, I agree with the reasons given by Crennan and Kiefel JJ. I agree with the orders proposed by their Honours.

HAYNE J.

The issue

1. The issue in the appeal to this Court is whether the method of prevention or treatment of human disease claimed in the patent in suit is a patentable invention. There is no decision of this Court which determines that a method of prevention or treatment of human disease is a proper subject for the grant of a patent. In this case, the Full Court of the Federal Court followed two earlier decisions of that Court holding that a method of prevention or treatment of human disease is a patentable invention.

2. These reasons will demonstrate that a method of prevention or treatment of human disease is not a patentable invention. Such a method, even if it is novel, involves an inventive step and is useful, is a method or process used to produce a product (a result, outcome or effect) which is personal to the individual concerned. Use of the method or process may allow the individual better to exploit his or her capacities economically (whether by selling his or her labour or otherwise). The individual's more effective use of his or her capacities may be of economic advantage to society or some section of it. But that advantage follows from what the individual can do and chooses to do. Others, including the person who owns the right to use the method or process, cannot trade in or otherwise exploit the improvement in health that results from using the method or process to prevent or treat disease in the individual concerned. That kind of result places the process beyond the (very wide) ambit of a "manner of manufacture" within the meaning of s 6 of the *Statute of Monopolies* 1623 (21 Jac I c 3). A method of preventing or treating human disease is a process which is not a proper subject for the grant of a patent.

The organisation of these reasons

1. These reasons will describe the facts of the matter shortly (under the headings: "Leflunomide" and "Apotex's product") and then record the essential features of the proceedings in the Federal Court and in this Court.

2. Consideration of the substantive issues in the appeal commences with the statutory framework (under the headings: "Patentable invention – a statutory question" and "Asking the right question about the statute"). One issue which was not raised, and must be put aside from consideration, is identified (under the heading: "'[G]enerally inconvenient'"), and two warnings are given (under the headings: "Analogical reasoning" and "The dangers of verbal formulae").

3. Consideration of the substantive issues proceeds thereafter (under the headings: "The *NRDC Case* and 'vendible product'" and "Methods of prevention or treatment of human disease"). Separate consideration is then given to six cases bearing on the patentability of methods of prevention or

treatment of human disease (*In the Matter of C & W's Application for a Patent*, *Maeder v Busch*, *National Research Development Corporation v Commissioner of Patents* ("the *NRDC Case*"), *London Rubber Industries Ltd's Patent*, *In re Schering AG's Application* and *Joos v Commissioner of Patents*). Having summarised the position reached in those cases (under the heading: "The state of authority after *Joos*"), these reasons then examine the Federal Court's earlier decisions in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* and *Bristol-Myers Squibb Co v F H Faulding & Co Ltd*.

4. In the light provided by all eight of the cases that have been mentioned, four questions which arise from the decisions are further identified (under the heading: "The questions presented by the cases"). Those questions are then examined (under the headings: "Legislative silence in the face of past practice?"; "Distinguishing between patentability of pharmaceutical substances and methods of treatment"; "Economic significance of process or product?"; and "The product of prevention or treatment of human disease").

5. Finally, brief consideration is given to an issue of threatened infringement which would arise if the patent in suit were valid.

Leflunomide

1. In December 1979, Hoechst AG was granted Australian Patent Number 529341 ("the 341 patent"). Claim one of the 341 patent claimed a compound called, in these proceedings, "leflunomide", which has since been used to treat active rheumatoid arthritis ("RA") and active psoriatic arthritis ("PsA"). Claim four of the 341 patent claimed a "[m]ethod for the treatment of inflammations, rheumatic complaints or multiple sclerosis by administering to the patient an effective amount" of leflunomide. The 341 patent expired in 2004.

2. In 1999, leflunomide was included on the Australian Register of Therapeutic Goods ("the ARTG") then maintained under s 17 of the *Therapeutic Goods Act* 1989 (Cth) ("the TGA"). Section 16(1)(e) of the TGA provided that, for the purposes of those provisions of the TGA which concerned the ARTG, "therapeutic goods are to be taken to be separate and distinct from other therapeutic goods if they have ... different indications". The term "indications" was defined, in relation to "therapeutic goods", as "the specific therapeutic uses of the goods".

3. Leflunomide was initially registered on the ARTG giving, as its indication, the treatment of active RA. That registration was later extended to include an indication for active PsA. Leflunomide was "not indicated for the treatment of psoriasis that is not associated with manifestations of arthritic disease".

4. On 29 March 1994, Hoechst AG applied for the patent in suit (Australian Patent Number 670491). It claimed "[a] method of preventing or treating a skin disorder, wherein the skin disorder is psoriasis, which comprises administering to a recipient an effective amount of a pharmaceutical composition containing as an active ingredient" leflunomide. The patent will expire in 2014.

Apotex's product

1. In 2008, the appellant ("Apotex") obtained registration on the ARTG of its generic version of leflunomide. The product information document for Apotex's product ("Apo-Leflunomide") indicated the use of the product for the treatment of active RA and active PsA and, like leflunomide, said that Apo-Leflunomide was "*not* indicated for the treatment of psoriasis that is *not* associated with manifestations of arthritic disease" (emphasis added).

The proceedings

1. The respondents brought proceedings in the Federal Court alleging, among other things, that Apotex would infringe the patent in suit by supplying Apo-Leflunomide in Australia for the treatment of PsA. Apotex disputed the validity of the patent in suit and denied that its supply of Apo-Leflunomide for the treatment of PsA would infringe that patent.

2. The primary judge, Jagot J, held that the patent in suit is valid and that, because use of the compound to treat PsA would inevitably treat or prevent psoriasis, Apotex's intended supply of Apo-Leflunomide for the treatment of PsA would infringe the patent in suit. The primary judge noted that Apotex reserved its right to challenge the correctness of what had been said in the two earlier Full Court decisions about whether a method of prevention or treatment of human disease was patentable.

3. Apotex's appeal to the Full Court of the Federal Court (Keane CJ, Bennett and Yates JJ) was dismissed. The plurality (Bennett and Yates JJ) observed that "the position represented by the dicta in this Court that support the patentability of methods of medical treatment" was a position which "represent[ed] orthodoxy in Australian patent law". How or why those dicta were to be regarded as concluding the issue was neither explored nor explained.

4. By special leave, Apotex appealed to this Court, alleging that the patent in suit is invalid. Apotex also sought special leave to appeal against the Full Court's dismissal of its appeal against the finding of threatened infringement. That application for special leave was referred for argument, as if on appeal, together with the appeal.

5. Resolution of the issue of patentability must begin by identifying the right question to ask, and that, in turn, must begin with the statute.

Patentable invention – a statutory question

1. The patent in suit was granted under the *Patents Act* 1990 (Cth) ("the 1990 Act"). At that time, s 18 of the 1990 Act provided that:

> "(1) Subject to subsection (2), 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; and
>
> (b) when compared with the prior art base as it existed before the priority date of that claim:
>
> (i) is novel; and
>
> (ii) involves an inventive step; and
>
> (c) is useful; and
>
> (d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.
>
> (2) Human beings, and the biological processes for their generation, are not patentable inventions."

1. Section 6 of the *Statute of Monopolies* relevantly provided:

> "That any Declaration before-mentioned shall not extend to any Letters Patents and Grants of Privilege for the Term of fourteen Years or under, hereafter to be made, of the sole Working or Making of any manner of new Manufactures within this Realm, to the true and first Inventor and Inventors of such Manufactures, which others at the Time of Making such Letters Patents and Grants shall not use, so as also they be not contrary to the Law, nor mischievous to the State, by raising Prices of Commodities at home, or Hurt of Trade, or generally inconvenient".

Asking the right question about the statute

1. Section 18(1)(a) of the 1990 Act provided that a patentable invention

is an invention that (among other things) is "a manner of manufacture within the meaning of section 6 of the Statute of Monopolies". In this respect, the 1990 Act, like its predecessors the *Patents Act* 1903 (Cth) and the *Patents Act* 1952 (Cth) ("the 1952 Act"), and corresponding Acts of the United Kingdom, defined "the word 'invention', not by direct explication and in the language of its own day, nor yet by carrying forward the usage of the period in which the *Statute of Monopolies* was passed, but by reference to the established ambit of s 6 of that Statute". That is, the statutory expression – "a manner of manufacture within the meaning of section 6 of the Statute of Monopolies" – is not to be understood, or applied, by taking its words and attempting to assign one or more synonyms to any or each of them to produce some other collection of words intended to mark out the metes and bounds of the field which the expression as a whole, or the particular phrase "manner of manufacture", is to be understood as describing. Rather, as was held in the *NRDC Case*:

> "The inquiry which the definition [of 'invention'] demands is an inquiry into the scope of the permissible subject matter of letters patent and grants of privilege protected by the section. *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*. ... It is therefore a mistake, and a mistake likely to lead to an incorrect conclusion, to treat the question whether a given process or product is within the definition as if that question could be restated in the form: 'Is this a manner (or kind) of manufacture?' It is a mistake which tends to limit one's thinking by reference to the idea of making tangible goods by hand or by machine, because 'manufacture' as a word of everyday speech generally conveys that idea." (emphasis added)

1. Accordingly, this Court held, in the *NRDC Case*, that in determining whether a given process or product is within the statutory definition of "invention", the right question to ask is: "Is this a proper subject of letters patent according to the principles which have been developed for the application of s 6 of the *Statute of Monopolies*?"

2. Before dealing further with the question whether the claim made in the patent in suit is a proper subject of letters patent, it is necessary to say something about the closing words of the operative part of s 6 of the *Statute of Monopolies*: "so as also they be not contrary to the Law, nor mischievous to the State, by raising Prices of Commodities at home, or Hurt of Trade, or *generally inconvenient*" (emphasis added).

<u>"[G]enerally inconvenient"</u>

1. The appellant did not submit that this Court should decide whether

the grant of a patent for a method of prevention or treatment of human disease would be "generally inconvenient", and thus within the exception to s 6 of the *Statute of Monopolies*. The respondents submitted that, in light of the way in which the proceedings below were conducted, no argument of that kind was open to the appellant in this Court. In these circumstances, it is neither necessary nor appropriate to consider whether, or how, the "generally inconvenient" exception to s 6 might apply to this case. It is not necessary, therefore, to examine what material a court could, or should, have available for consideration in deciding that question, or whether all of that material could, or should, be proved in the ordinary way.

2. At first sight, a question about "generally inconvenient" appears to invite attention, in a case of this kind, to the costs of, and the benefits flowing from, granting a patent for a method of prevention or treatment of human disease. In turn, those questions of costs and benefits appear to require consideration of how methods of prevention or treatment are discovered and tested, as well as consideration of questions about how health care can be, or is, provided. Examination of the provision of health care would, no doubt, direct attention to what roles government, researchers, clinicians, research institutes and profit-making enterprises each can, or should, play, both generally in the provision of health care and particularly in the development of new methods of prevention or treatment.

3. At least some of the questions which have been identified may not be readily answered without a very wide and deep examination of these issues, including economic and political issues of a kind not well suited to resolution by reference only to evidence adduced by the parties to adversarial proceedings. In addition, some of the questions may permit, even require, making value judgments which lie beyond the scope of legal notions of public policy.

4. None of these difficulties need be confronted in this case. No "generally inconvenient" argument having been advanced, the question need not be considered further.

Analogical reasoning

1. Recognising that the question is whether a method of prevention or treatment of human disease is "a proper subject of letters patent according to the principles which have been developed for the application of s 6 of the *Statute of Monopolies*" must be accompanied by recognition of an important consequence of framing the question in this way.

2. Analogical reasoning lies at the heart of the judicial developments that have occurred over the years in the application of s 6 of the *Statute of Monopolies* and, in particular, the phrase "manner of manufacture". It is

this form of reasoning which has underpinned the judicial expansion of the class of subjects identified as falling within the phrase "manner of manufacture" and thus as a proper subject for the grant of a patent. The phrase "manner of manufacture" has had to be considered in its application to inventions. By hypothesis, then, the phrase has had to be considered in its application to scientific and technological developments that not only were unknown at the time of the *Statute of Monopolies*, but also were unknown before the time when the phrase had to be applied. That being so, it is hardly surprising that "[i]n the varying applications of which the word 'manufacture' is capable analogy has always played a considerable part".

3. But there are limits to the proper use of analogical reasoning. In particular, care must be exercised lest argument by analogy become no more than a process of adding words used in reasons for judgment in one case to the words of some other judgment to yield the asserted new outcome. And the care that must be exercised is against pushing what was said in those reasons about the concepts embraced by the phrase "manner of manufacture" to "the limit of its logic", or using those reasons like dominoes, "wherein every explanatory statement in a previous opinion is made the basis for extension to a wholly different situation". Such caution is always necessary in arguing by analogy. But it is especially necessary in considering whether a particular subject is a proper one for the grant of a patent.

4. As Cardozo said, "[s]ome conceptions of the law owe their existing form almost exclusively to history". What is a proper subject for the grant of a patent is a prime example of a legal conception of that kind. Adopting and adapting Cardozo's words, it follows that the conception of what is a proper subject for the grant of a patent is not to be understood except as an historical growth. In the development of that conception, "history is likely to predominate over logic or pure reason".

<u>The dangers of verbal formulae</u>

1. In the *NRDC Case*, the Court said that:

> "The purpose of s 6, it must be remembered, was to allow the use of the prerogative to encourage national development in a field which already, in 1623, was seen to be excitingly unpredictable. *To attempt to place upon the idea the fetters of an exact verbal formula could never have been sound*. *It would be unsound to the point of folly to attempt to do so now*, 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." (emphasis added)

1. What the Court said in the *NRDC Case*, about the patentability of a process, must be understood in this light. Nothing said in the Court's reasons for decision in that case can be taken as an exact verbal formula which alone captures the breadth of the ideas to which effect must be given. And the same warning applies with equal force to the various expressions which are used in these reasons in the course of considering whether a method of prevention or treatment of human disease is a "manner of manufacture". Yet the cardinal features of the Court's decision in the *NRDC Case* are clear. For the purposes of this case, they are sufficiently indicated by considering the Court's discussion of the notion of a "vendible product", and "whether it is enough that a process produces a useful result or whether it is necessary that some physical thing is either brought into existence or so affected as the better to serve man's purposes".

The *NRDC Case* and "vendible product"

1. The Court's treatment of the notion of a "vendible product" in the *NRDC Case* is often summarised by reference to two propositions: that the word "product" should be understood "as covering every *end produced*" and the word "vendible" treated "as pointing only to the requirement of *utility in practical affairs*" (emphasis added). Consistent, however, with the general injunction against treating a particular verbal formula as definitive, neither of these propositions can serve as a complete or sufficient premise for deductive reasoning to a conclusion about what is a "manner of manufacture" within the meaning of s 6 of the *Statute of Monopolies* for the purposes of s 18(1)(a) of the 1990 Act. In particular, it would be wrong to take the individual words of either of these phrases and ask only whether the word in question could properly be applied to the process in issue. Two points may be made in amplification and support of that proposition.

2. First, several different words can be used to convey the ideas expressed by the understanding of "product" and "vendible" stated by the Court in the *NRDC Case*. "Product" can be described as a "result", an "outcome" or an "effect". It was described in the *NRDC Case* as "any physical phenomenon in which the effect, be it creation or merely alteration, may be observed". And "vendible" (treated as pointing only to the requirement of utility in practical affairs) was described as "some advantage which is material, in the sense that the process belongs to a useful art as distinct from a fine art", and as having "its value to the country ... in the field of economic endeavour". But both of these last two phrases must be understood in the context provided by the immediately preceding reference to "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*'" (emphasis added).

3. Second, and more fundamentally, it is of the first importance to recognise that the Court's treatment in the *NRDC Case* of the notion of a "vendible product" was directed to identifying whether the process in question was a proper subject for the grant of a patent. That issue was *not* treated as being determined by the conclusions that the process "was new, was not obvious, and was to be arrived at only by an exercise of scientific ingenuity, based upon knowledge and applied in experimental research". As the Court went on to say, after reaching those conclusions about the particular process in issue, the "central question" in the case remained: whether that process fell within "the category of inventions to which, by definition, the application of the [1952 Act] is confined". The Court's discussion of the notion of a "vendible product" was directed to this central question.

4. Utility lies at the heart of the answer the Court gave to the central question presented in the *NRDC Case*. But, as already noted, a particular kind of utility was identified ("utility in practical affairs"), and the "advantage" offered by a patentable process was described as lying in "its value to the country ... in the field of economic endeavour". The utility thus identified was to be found in the *consequences* of using the process (its product, result, outcome or effect). That is, the product, result, outcome or effect of the process (the description applied does not matter) had to be one having "utility in practical affairs".

5. The breadth of application of the notion of "utility in practical affairs" need not be examined immediately. For present purposes, the critical observation to make is that the *NRDC Case* held that the patentability of a process depended upon the *result*, *outcome* or *effect* of the process (its product) having a particular characteristic (described by the expression "utility in practical affairs"). But, as will later be explained, subsequent cases shifted attention from whether the result, outcome or effect of the process had the characteristic of "utility in practical affairs" to the quite distinct issue of whether the *process* was one capable of economic exploitation. Subsequent cases asked: would people be prepared to pay to use the process? That is, the inquiry about economic advantage or value shifted from the *product* (the result, outcome or effect) of the process to whether the *process* itself could be exploited commercially. That shift in reasoning was not expressly acknowledged. Rather, as again will later be explored further in these reasons, the reasoning employed in the subsequent cases was said to be consistent with, even supported by, this Court's decision in the *NRDC Case*. Yet this Court did *not* hold in the *NRDC Case* that a process was a proper subject for the grant of a patent simply because it was a process which people would be prepared to pay to use.

Methods of prevention or treatment of human disease

1. Whether a method of prevention or treatment of human disease is a proper subject for the grant of a patent must be examined with these considerations in mind. It is convenient to begin that examination by looking at what has been said in decided cases about the subject. In particular, reference must be made to three English cases – *C & W's Application*, *London Rubber* and *Schering* – which established, or at least accepted, the proposition that a method of prevention or treatment of human disease is not a proper subject for the grant of a patent. Reference must also be made to the two decisions of this Court which point towards acceptance of the same proposition (*Maeder v Busch* and the *NRDC Case*) and to a third, single Justice, decision of this Court (*Joos*) which points in the opposite direction. Finally, reference must be made to the two decisions of the Full Court of the Federal Court upon which the Full Court relied in this matter: *Rescare* and *Bristol-Myers*.

2. It is useful to deal with the cases in chronological order of decision. Consideration of the cases in that order will reveal that the decision in *Schering* marked the shift in reasoning that has already been noted. Before *Schering*, a necessary element in demonstrating that a process was a proper subject for the grant of a patent was that the process yielded a product (a result, outcome or effect) which could be exploited commercially. *Schering* conflated the process and its product in considering the question of commercial exploitation. It decided that a process for treatment of the human body, *not* directed to prevention or cure of disease, was patentable if the process achieved a result *for which people would be expected to be prepared to pay*. That is, *Schering* decided that it was enough to show that the *process* (as distinct from the product, result, outcome or effect of its use) was a process that could be exploited commercially. The correctness of that shift in reasoning is critical to whether a method of prevention or treatment of human disease is a proper subject for the grant of a patent.

C & W's Application

1. In 1914, the Solicitor-General, Sir Stanley Buckmaster, concluded, in *C & W's Application*, that a process for extracting metals, including lead, from the human body was not a proper subject for the grant of a patent. In the course of his reasons, the Solicitor-General noted that the Patent Office had "based their refusal [of the patent] upon the ground that the alleged invention relates simply to medical treatment". The Solicitor-General went on to say that he thought that the foundation for the refusal was "sound".

2. It is important, however, to notice that the Solicitor-General did not confine his reasoning to endorsing the soundness of this Patent Office practice. Rather, the foundation for the conclusion expressed in *C & W's Application* was that the process was not (or perhaps was not sufficiently) "associated with commerce and trade". More particularly, the process was

not one that could be "used in *making* something that is, or may be, of commercial value" (emphasis added).

3. The reference to "something that is, or may be, of commercial value" may very well have to be understood as proceeding from the premise that the product of a patentable process must be tangible. And, as has been noted earlier in these reasons, that is now seen to be too confined a view. But the conclusion reached in *C & W's Application* did not depend upon some distinction between tangible and intangible products of processes. Rather, the conclusion depended upon treating the achievement of some bodily improvement in the human being as taking an invented process for achieving that end beyond the bounds of a proper subject for the grant of a patent. Thus, the Solicitor-General said:

> "So far as human beings are concerned, it cannot be suggested that the extraction of lead from their bodies is a process employed in any form of manufacture or of trade, though the human being may be a better working organism when the lead is extracted."

And the various statements in the reasons reserving for later consideration whether a process of the kind in question, if applied to animals, might be patentable emphasised that the conclusion which the Solicitor-General reached depended upon giving determinative significance to the end which the patent claimed was achieved by application of the process. That end was an improvement in the health of the human body. The process for achieving that end, though novel and inventive, was not patentable because a human being is not an object of commerce and a process for improvement of the health of a human being does not yield a product (a result, outcome or effect) which is itself of commercial value.

1. *C & W's Application* founded Patent Office practice in the United Kingdom for many subsequent years and corresponding practice in Australia.

Maeder v Busch

1. In *Maeder v Busch*, this Court dismissed an appeal from orders made by the Supreme Court of South Australia consequent on that Court holding that patent claims for a process for producing permanent waves in human hair were invalid by reason of "prior public commercial user and want of novelty". In the course of argument in this Court, the Court raised the broader question of whether the process was a proper subject for the grant of a patent. Latham CJ and Dixon J expressly accepted that *C & W's Application* required the conclusion that a process for prevention or treatment of human disease was not a proper subject for the grant of a patent. The issue raised by the Court was whether that proposition entailed

that a process for improving the appearance of the human body, or ameliorating its condition, was patentable.

2. Because of the conclusions reached on other issues, this broader question was not decided. But the dicta of Dixon J, in particular, are instructive.

3. The central point made by Dixon J was that "[t]he application of a process or method of treatment to part of the human body for the purpose of improving its appearance or ameliorating its condition is distinguished from processes which may form the subject of patentable invention in aim and result". The *aim* of the process was described as "the alteration of some state or condition, feature or attribute belonging temporarily or permanently to a person"; the *result* "may be an improvement in his or her physical welfare or an increase in his or her pride of appearance". That is, the aim was to alter the state or condition of the human body; the result intended may be either therapeutic or cosmetic. But the aim and the result, together, were seen as taking a process of either kind (therapeutic *or* cosmetic) beyond the proper scope for the grant of a patent.

4. Dixon J acknowledged that "[t]he purpose of the patentee and those intended to employ the process may be entirely commercial" and that the process "may be intended for use in ordinary trade or business". Dixon J also acknowledged that its purpose may instead "be the relief of suffering by surgical or manipulative means". But Dixon J pointed out that in none of the cases described was the object "to produce or aid the production of any article of commerce". "No substance or thing forming a possible subject of commerce or a contribution to the productive arts is to be brought into existence by means of or with the aid of the process."

5. *Maeder v Busch* cannot be treated as deciding this issue; the case was decided on other grounds. The dicta of Dixon J must be read, no doubt, in the context provided by all that his Honour said. In particular, Dixon J noted that "a widening conception of a manner of new manufacture has been a characteristic of the growth of patent law", and expressly left undecided whether, as the plaintiff had submitted, a process for treating the hair may be held to be patentable on the basis that the hair was "an adjunct which plays no part in the vitality of the body".

The *NRDC Case*

1. Much has already been said in these reasons about the *NRDC Case*. Particular attention has already been directed to the notable advancements made in that case about the question which is to be asked in considering the application of s 6 of the *Statute of Monopolies* to new processes.

2. For immediate purposes, however, it is necessary to notice two statements made by the Court in the *NRDC Case* that have not already been mentioned. First, the Court said that certain statements made in *R v Wheeler* required qualification "even if only in order to put aside, as they apparently must be put aside, processes for treating diseases of the human body", and referred in that regard both to *C & W's Application* and to *Maeder v Busch*. Second, the Court said that "[t]he exclusion of methods of surgery and other processes for treating the human body may well lie outside the concept of invention because the whole subject is conceived as essentially non-economic", and in that regard referred to the reasons of Dixon J in *Maeder v Busch*.

3. No doubt, both of these statements in the *NRDC Case* are properly seen as parenthetical interjections in the Court's reasoning. But both are wholly consistent with the reasoning and conclusion in respect of the immediate issue for decision in that case. In particular, the reference to "the whole subject" of "methods of surgery and other processes for treating the human body" as "essentially non-economic" serves to explain why a process for eradicating weeds from arable land is patentable but a process for preventing or treating human disease is not. Eradicating weeds from arable land is a process "that offers some advantage which is material, in the sense that ... its value to the country is in the field of economic endeavour". As these reasons will show, a process for prevention or treatment of human disease may well be capable of commercial exploitation, but it produces no *outcome* which is capable of commercial exploitation.

London Rubber

1. London Rubber Industries Ltd sought a patent for a process of birth control by oral administration of known hormonal drugs. The Comptroller refused the application.

2. On appeal to the Patents Appeal Tribunal, Lloyd-Jacob J upheld the refusal, concluding that "the improvisation of a method of treating a human being cannot in reason be regarded as affording proper subject matter for letters patent". This conclusion, his Lordship considered, followed from "the practice established in the Patent Office for upwards of the past fifty years of refusing grant to forms of medical treatment of the human body", from the decision in *C & W's Application*, and from this Court's decisions in *Maeder v Busch* and the *NRDC Case*. The reference made in the *NRDC Case* to putting aside "processes for treating diseases of the human body", coupled with the reference in the *NRDC Case* to *Maeder v Busch*, was taken by Lloyd-Jacob J to show that a process for treating diseases of the human body is not patentable because "(a) the object is not to produce or aid in the production of any article of commerce; [and] (b) no substance or thing forming a possible subject of commerce or a contribution to the

productive arts is to be brought into existence by means of or with the aid of the process".

Schering

1. Schering AG sought a patent claiming a method of contraception comprising the administration of gestagen in doses sufficient to prevent conception but not such as to suppress ovulation. The superintending examiner refused the application and Schering AG appealed to the Patents Appeal Tribunal. The Tribunal (Graham and Whitford JJ) allowed the appeal.

2. The question for the Tribunal, as it had been for the Patent Office, was whether it was plain that there was no patentable subject matter. That is, as the Tribunal framed the question: was there "no reasonable doubt that a manner of manufacture [was] not being claimed"?

3. The immediate basis for the decision to allow the appeal was that, although "patents for medical treatment in the strict sense must be excluded ..., the claims the subject of the application do not appear to fall within this prohibition" because the method of treatment claimed was not a treatment to cure or prevent disease. Whitford J, giving the reasons of the Tribunal, said:

> "Unless any treatment of the human body, as opposed to medical treatment to cure or prevent disease, is to be considered as being outside the scope of patent protection, there seems to be no reason why such a claim [to avoid or suppress conception] should not be allowed. *The process is in the field of the useful as opposed to the fine arts*. *It is of commercial significance because it will produce a result which people are going to be prepared to pay for* and which is widely considered desirable in the present climate of public opinion. It ought to be protected if it is, as must be accepted for present purposes, of inventive merit and because it is a process which others no doubt would be only too anxious to adopt, if they could, without paying tribute to anyone." (emphasis added)

1. This reasoning constituted a sharp, albeit unacknowledged, departure from the reasoning of Lloyd-Jacob J in *London Rubber*. In *Schering*, the focus was upon whether people would be prepared to pay for the *process* to achieve the intended result. By contrast, in *London Rubber*, the question critical to patentability had been seen as whether the process yielded a *product* (a *result*, *outcome* or *effect*) which was capable of commercial exploitation.

2. To say that the result of the process in issue in *Schering* (prevention

of conception) was "a result which people are going to be prepared to pay for" was to answer a question which was directed only to whether the *process* was one which may be exploited commercially. But as the decision of Lloyd-Jacob J in *London Rubber* shows, questions of commercial exploitation were seen, until *Schering*, as directed to the nature of the *end produced* by the process in question, not simply whether people would be prepared to pay to use the process. Unlike the absence of weeds in an arable field (which can be exploited commercially by yielding a better harvest), the absence of human conception is an end produced which cannot be exploited commercially.

Joos

1. In *Joos*, Barwick CJ considered a patent claiming a process for improving the strength and elasticity of keratinous material, especially human hair and nails. The Deputy Commissioner of Patents had decided that the application should not proceed because it "claimed as an invention a process for the treatment of parts of the human body". Mr Joos appealed to this Court.

2. As in *Schering*, the question for this Court was whether what was claimed *could* be regarded as a proper subject for the grant of a patent. Could the Commissioner of Patents, "properly directing himself, ... reasonably hold that there was no reasonable doubt as to the invention being outside the [*Statute of Monopolies*], that is to say, that the application was plainly without possible justification"? Barwick CJ decided that the application was not without possible justification and allowed the appeal.

3. In his reasons, Barwick CJ began his consideration of the issues "at the point which is reached by the Court's decision" in the *NRDC Case*. For the purposes of argument, Barwick CJ accepted that "a process for the treatment of the human body *as a means of curing or preventing a disease, correcting a malfunction or removing or ameliorating an incapacity* is not a proper subject matter for the grant of a monopoly under the [1952] Act" (emphasis added). And although Barwick CJ said that it was not essential to the decision of the matter "to controvert that proposition or to discover and express its basis in law", his Honour did say that if he "had to do so ... [he] would place the exception, if it is to be maintained, on public policy as being, in the language of the *Statute of Monopolies*, 'generally inconvenient'".

4. It is important to notice that Barwick CJ considered that there is a "relevantly radical" distinction between "a process for treating the diseases of the body and a process for improving the cosmetic appearance of the body". The proposition which his Honour accepted for the purposes of argument was one narrowly confined to processes for the therapeutic, as

distinct from the cosmetic, treatment of the human body. And Barwick CJ concluded that a process for the *cosmetic* treatment of the human body could lawfully be the subject of a patent under the 1952 Act.

5. The Commissioner, as respondent to the appeal, had submitted that the "process fails to have economic significance because it is for treating parts of the human body". By contrast, the appellant had submitted that the test for the patentability of a process had two elements:

> "first that the process must have as its end result an artificial effect or an artificially created state of affairs which may be considered to be the 'product' of a process, and secondly that the *product* must have a significance which is *economic* or has an *industrial, commercial or trading character*". (emphasis added)

1. Barwick CJ disposed of this issue briefly, holding that the Commissioner's submission "involved ... a misconception of what is meant by the need for the invention to be in the commercial field". But the nature of the supposed misconception was not expressly identified in (indeed, it appears directly opposed to) the appellant's argument and is apparent only from consideration of what Barwick CJ had said earlier in his reasons about the *NRDC Case* and about *Schering*.

2. Barwick CJ had said that whilst the *NRDC Case* "made it plain that the claimed process, in order to be an invention, need not by its use result in the production or improvement of a vendible article, this Court did emphasize the need for the claimed process to have *a commercial application*" (emphasis added). Barwick CJ had also acknowledged that a process, to be patentable, "must be 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". But the necessary "economic value" of the process was said "not always [to] be directly supplied by the nature of the activity which would utilise the process". And Barwick CJ did not identify the decision in *Schering* as departing in any respect from what had been decided by this Court in the *NRDC Case*. Rather, *Schering* was treated as supporting the distinction which Barwick CJ drew between medical treatment of disease and other forms of treatment of the human body.

3. The statement that a process must have "a commercial application" is ambiguous. It does not distinguish between the commercial exploitation of the *process* and the commercial exploitation of the *product* (the *result*, *outcome* or *effect*) of that process.

4. Thus, when Barwick CJ referred to the "commercial activity of hairdressing" and to that sector accounting "for a great deal of employment", the references were evidently intended to describe a commercial application

for the process in the sense that it was a process for which people would be prepared to pay in connection with a commercial venture. Barwick CJ gave no express consideration to whether the *product* of that process could be exploited commercially by turning that product to economic advantage or account, instead treating "indirect" economic advantage as sufficient.

5. Although reference was made to the "obvious" "national economic interest in the *product* of good surgery" (emphasis added), that reference must be understood in the light provided by the emphasis given by Barwick CJ to the commercial application of the process. And it must also be understood in the light provided by the observation that there was no difficulty in "conceding, for the purpose of the decision [in *Joos*], that a process for the medical treatment of a part of the human body is not a proper subject of letters patent". Hence, like *Schering*, the decision in *Joos* depended upon discarding the requirement, identified in the *NRDC Case*, that a process produce a *product* (a *result*, *outcome* or *effect*) which could itself be turned to commercial advantage. And it discarded that requirement without explanation.

The state of authority after *Joos*

1. The subsequent decisions of the Federal Court in *Rescare* and *Bristol-Myers* must be understood in light of the then state of authority. This Court had not decided whether a method of prevention or treatment of human disease was a proper subject for the grant of a patent. In *Maeder v Busch*, and in the *NRDC Case*, the Court had assumed that it was not. In *Joos*, Barwick CJ, sitting as a single Justice, had assumed for the purposes of argument that it was not, but had decided the case in a way which depended upon a distinction between therapeutic and cosmetic treatment which, despite his Honour's expressed view to the contrary, was convincingly shown, in *Rescare*, to be difficult to maintain. And, most importantly, in *Joos*, Barwick CJ had made the same critical shift in reasoning which had been made in *Schering*.

2. If attention is focused, as it was in *Schering* and in *Joos*, on whether the *process* (as distinct from its *product*) can be exploited commercially, no logically defensible justification for deciding that a method of prevention or treatment of human disease is not a proper subject for the grant of a patent is readily discerned. It is, then, unsurprising that the Federal Court decided *Rescare* and *Bristol-Myers* as it did.

Rescare

1. In *Rescare*, both at first instance, and on appeal to the Full Court of the Federal Court, extensive consideration was given to the patentability of a process for the treatment of obstructive sleep apnoea. Although the case

was decided on other issues, both at trial and on appeal, the general tenor of the decisions of Gummow J (at trial) and the majority of the Full Court (Lockhart and Wilcox JJ, Sheppard J dissenting) was that a process for the treatment of human disease is a proper subject for the grant of a patent. In each of the judgments, both at trial and on appeal, there was a close analysis of the decided cases, both in Australia and elsewhere. It is sufficient to refer to the discussion of those matters in those judgments without traversing that ground again in these reasons.

2. At trial, Gummow J took three critical steps. First, he treated the *NRDC Case* as establishing "that it is not essential for the grant of a monopoly for a process that the use of the process should produce or improve a vendible article". Rather, in words evidently adopted from the reasons of Barwick CJ in *Joos*, Gummow J said that "[i]t is enough that the process has a commercial application". Second, Gummow J held that, under the 1952 Act, "there was no normative distinction to be drawn between those processes for treatment of the human body for disease, malfunction or incapacity, and for cosmetic purposes". Third, Gummow J expressed agreement with the suggestion, made by Barwick CJ in *Joos*, that any continued exclusion of methods of prevention or treatment of human disease from patentability should be based on the "generally inconvenient" exception to s 6 of the *Statute of Monopolies* and public policy. Accordingly, Gummow J concluded that the attack which had been mounted on certain of the claims (as not being proper subjects for the grant of a patent) failed.

3. On appeal, Lockhart J said that there was "no justification in law or in logic to say that simply because ... substances produce a cosmetic result or a functional result as opposed to a curative result, one is patentable and the other is not". Accordingly, Lockhart J concluded that there was "no reason in principle why a method of treatment of the human body is any less a manner of manufacture than a method for ridding crops of weeds" as in the *NRDC Case*. Yet, despite reaching this opinion, Lockhart J said that it was not necessary to deal with the arguments advanced on the ground of "generally inconvenient". How that could be was not explained.

4. The other member of the majority in the Full Court, Wilcox J, considered that the *NRDC Case* had held that "it is enough to support a patent that the subject process produce a useful result", and this, in his Honour's view, "swept away" the rationale of *C & W's Application*.

5. Central, then, to the decision in *Rescare*, both at trial and on appeal, was the conclusion that a process was a proper subject for the grant of a patent so long only as the process produced a "useful" result in the sense that the result was one for which it may be expected that people will be prepared to pay. That is, the statements made in *Rescare* about the

patentability of processes for the prevention or treatment of human disease depend upon the shift in reasoning that was made first in *Schering* and then in *Joos*.

Bristol-Myers

1. In *Bristol-Myers*, the Full Court of the Federal Court (Black CJ, Lehane and Finkelstein JJ) held that a method of medical treatment of the human body was a proper subject for the grant of a patent.

2. The plurality (Black CJ and Lehane J) followed the decision in *Rescare* and said that they were fortified in their decision to do so by two considerations. The first was identified as being "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" (original emphasis). The second was described as "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".

3. The third member of the Court, Finkelstein J, considering the matter afresh, decided that "medical treatment and surgical process are patentable under the legislation and, if public policy requires a different result, it is for the Parliament to amend the 1990 Act".

The questions presented by the cases

1. Several questions arise from the cases that have been discussed. They can be identified as follows.

2. First, what is to be made of: (a) the absence of any provision dealing directly with the patentability of methods of medical treatment; (b) the provision of s 18(2) of the 1990 Act that "[h]uman beings, and the biological processes for their generation, are not patentable inventions", and the provision by s 119A of infringement exemptions for certain acts in respect of a "pharmaceutical patent"; and (c) the practice of granting patents for methods of treatment of the human body?

3. Second, can a distinction properly be made between allowing patentability for a *product* for treatment of the human body, but denying patentability for a *method* of treatment?

4. Third, is a process a proper subject for the grant of a patent under the 1990 Act only if it results in a product (a result, outcome or effect) which

can be exploited commercially?

5. Fourth, if a process is a proper subject for the grant of a patent only if it results in a product (a result, outcome or effect) which can be exploited commercially, does a method of prevention or treatment of human disease meet that requirement?

6. Although the third and fourth questions are the more fundamental of the questions identified, it is convenient to deal with the questions in the order in which they are stated, and to dispose of the first two questions relatively briefly.

Legislative silence in the face of past practice?

1. No provision of the 1990 Act provides directly for whether a method of medical treatment is a proper subject for the grant of a patent. At the time of enactment of the 1990 Act, there was no decision of this Court that methods of medical treatment were not patentable. *Maeder v Busch* and the *NRDC Case* pointed against patentability, but the decision of Barwick CJ in *Joos* provided ample basis for argument about the question. It is, then, unsurprising that, both before and after the enactment of the 1990 Act, patents for methods of medical treatment had been granted. It has not been clear beyond argument that claims of that kind cannot be regarded as a proper subject for the grant of a patent. The practice of granting patents for such claims that has emerged must be understood as indicating no more than that a claim for a method of prevention or treatment of human disease is not unarguably bad.

2. If the 1990 Act had said expressly whether a method of prevention or treatment of human disease is a proper subject for the grant of a patent, the question would have been put beyond doubt. But no provision of that kind was made. As Gummow J noted in *Rescare*, the recommendation which the Industrial Property Advisory Committee made to government, evidently accepted and given effect in the 1990 Act, was that the "threshold test of patentability", by reference to the expression "manner of new manufacture" and s 6 of the *Statute of Monopolies*, be retained in the patent legislation without specific legislative inclusions or exclusions. The question of patentability of methods of prevention or treatment of human disease therefore remained unresolved by express statutory provision directed specifically to its resolution. The question must now be answered by this Court.

3. Nothing can usefully be made of the *absence* from the 1990 Act of provisions dealing expressly with the patentability of a method of prevention or treatment of human disease. There is nothing in the 1990 Act itself, or in extrinsic materials which might be relevant to its construction,

which provides any foundation for inferring from the *absence* of express provisions about the matter that one construction or application of the 1990 Act should be preferred over another. The absence of express provision about the subject means no more than that the questions of construction and application of the general provisions of the 1990 Act remain. What, if anything, is to be made of s 18(2) or s 119A?

4. Neither party suggested that s 18(2) of the 1990 Act speaks directly to the issues in this appeal and it does not. It may be put aside from consideration.

5. Section 119A(1) was inserted into the 1990 Act in 2006. It provides that the rights of a patentee of a "pharmaceutical patent" are not infringed by a person exploiting an invention claimed in the patent if the exploitation is solely for purposes connected with obtaining inclusion in the ARTG of certain goods intended for therapeutic use, or for purposes connected with obtaining similar regulatory approval under a foreign law. A "pharmaceutical patent" is defined as (among other things) a patent claiming "a *method*, use or product relating to a pharmaceutical substance" (emphasis added).

6. Contrary to the respondents' submissions, s 119A provides no assistance in the resolution of the issue of patentability. The definition of "pharmaceutical patent" in s 119A(3), and the provisions of s 119A generally, recognise that there are patents which claim a method of treatment of human disease. That is, s 119A recognises the practice that had emerged, before s 119A was inserted into the 1990 Act, of granting patents for methods of medical treatment. But, by providing that certain steps taken to obtain inclusion of a product on the ARTG do not infringe the rights of the patentee, s 119A neither directly nor indirectly assists in resolving the issue of patentability that is presented by the application of s 18(1) of the 1990 Act. In particular, statutory recognition that patents for methods of prevention or treatment of human disease have been granted says nothing about whether those grants are valid. It is not necessary, in these circumstances, to explore the difficulties involved in using the amendment made to the 1990 Act after the grant of the patent in suit to construe the provision of that Act under which the patent in suit was granted.

7. The second of the matters relied on by Black CJ and Lehane J in *Bristol-Myers* as fortifying their conclusion that methods of medical treatment are patentable should be put aside.

<u>Distinguishing between patentability of pharmaceutical substances and methods of treatment</u>

1. There is no doubt that a pharmaceutical substance useful for preventing or treating disease in humans is a proper subject for the grant of a patent under the 1990 Act.

2. Opinions differ about whether, and to what extent, granting a monopoly over exploitation of newly discovered substances which prevent or treat human disease, and thus alleviate human suffering, is sound public policy. Those differences of opinion are reflected in the different forms of legislative provision for such matters that have been made by various nations. And those differences of opinion reflect differing judgments made about the costs and benefits of providing for a monopoly and the moral or ethical issues which may be thought to be presented.

3. If patentability of a method of prevention or treatment of human disease depended upon a public policy judgment which was informed by moral or ethical considerations, it seems probable that the moral or ethical issues presented would be the same as those which relate to the patentability of pharmaceutical substances. On the face of things, it would be difficult to justify answering those particular issues differently in respect of a method of treatment from the answers given in respect of a pharmaceutical substance. But the costs and benefits of providing a monopoly in respect of a pharmaceutical substance may very well differ from the costs and benefits of providing a monopoly over a method of prevention or treatment of human disease.

4. The costs of discovering new pharmaceutical substances are typically very high and very many new pharmaceutical substances are discovered by large commercial enterprises engaged in extensive and expensive research programs. In addition, the costs of testing those pharmaceutical substances and bringing them to market are very high. It is not self-evident, however, that new methods of prevention or treatment of human disease are typically discovered in circumstances sufficiently similar to those which obtain in respect of the discovery of new pharmaceutical substances to attribute the same balance of costs and benefits to the grant of a monopoly over methods of treatment as may be struck in respect of the grant of a monopoly over new pharmaceutical substances. As noted earlier in these reasons, in connection with the question of "generally inconvenient", those are matters for demonstration, not assumption, and no demonstration of that proposition was attempted in this case.

5. A logical tension, of the kind suggested by Black CJ and Lehane J in *Bristol-Myers*, between holding that pharmaceutical substances are patentable, and holding that methods of prevention or treatment of human disease are not, arises only if the considerations relevant to the two different cases are identical. As has been noted, it may be that identical moral or ethical issues are presented. But it is not to be assumed that the same costs

and benefits apply in both cases. And unless the costs and benefits are the same, there is no necessary contrariety in holding that pharmaceutical substances are patentable but methods of prevention or treatment of human disease are not. It is not demonstrated that there is any logical tension if different outcomes are reached in the two cases.

6. It may be noted that reference is made in these reasons to methods of prevention or treatment of human disease without attempting to distinguish between medical and surgical treatment. It is not necessary to decide whether some stable and clear distinction could be made between methods of treatment that are "medical" and other methods that are "surgical". It is as well to say, however, that there would seem to be no little difficulty in identifying criteria that could be used to draw such a boundary.

7. It is also not necessary to decide whether some stable and clear distinction could be made between methods of treatment involving a hitherto unknown therapeutic use of a pharmaceutical substance and methods of treatment used by doctors or others in the course of treating patients. It would seem, however, very hard to draw any line between those methods according only to who developed them. It cannot be assumed that new methods of medical treatment are discovered only by large commercial enterprises or that only an enterprise of that kind could or would seek to profit from the discovery of a new and useful method of prevention or treatment of human disease. The distinction posited assumes, but does not demonstrate, that only some kinds of methods of treatment can be practically applied in commerce.

8. There remain for consideration the two questions which lie at the heart of whether a method of prevention or treatment of human disease is a proper subject for the grant of a patent. Must a process, to be patentable, yield a product (a result, outcome or effect) which can be exploited commercially? If it must, does a method of prevention or treatment of human disease yield a product of that kind?

Economic significance of process or product?

1. The *NRDC Case* emphasised the economic significance and utility of the product of the process considered in that case. As noted earlier in these reasons, there are to be found in the reasons of Barwick CJ in *Joos*, and those of Gummow J at first instance in *Rescare*, statements to the effect that the *NRDC Case* established that the claimed process must have "a commercial application" if it is to be patentable. As also noted earlier, that proposition is ambiguous. It may refer to "commercial application" in the sense of either commercial exploitation of the process, or commercial exploitation of the product (the result, outcome or effect) of the process. The further logical possibility that the expression should be understood as

encompassing either form of commercial exploitation may be acknowledged but should be put aside from consideration. It may be put aside because, if the product of the process can be exploited commercially, it follows inevitably that the process itself can be. For present purposes, attention must be confined to the first of the two possible meanings identified. It is that meaning which was adopted and applied in *Schering* and in *Joos*. It is that meaning which underpins the decisions in *Rescare* and *Bristol-Myers*.

2. A person who has the exclusive right to use any process which is novel, involves an inventive step and is useful can command a price for exploiting the process by using it. The price that can be charged will depend, no doubt, upon the utility of the process to its user. If the process yields a product which can be exploited commercially, the price for use of the process will be affected by the market price for the resulting product. But even if there is no marketable product of the process, the extent to which users consider the process to be useful (for any reason, commercial or not) will determine its price. And the process is thus capable of commercial exploitation *because* it is novel, involves an inventive step and is useful.

3. As *Joos* demonstrates, a process for alteration of the state of the human body (in that case, a process for altering the condition of human hair and nails) can be exploited commercially even though the process yields no more than a temporary change thought to be aesthetically desirable. Likewise, a person who has the exclusive right to use a method of prevention or treatment of human disease which is novel, involves an inventive step and is useful can command a price for use of that method. The price which that person can charge depends upon the utility of the method (limited, no doubt, by the capacity and preparedness of the payer to pay for its use). The method can be exploited commercially; it has "a commercial application".

4. Two considerations point firmly against accepting that a process is a proper subject for the grant of a patent so long as it is a process which will "produce a result [for] which people are going to be prepared to pay".

5. First, s 18(1) of the 1990 Act required that a patentable invention, so far as claimed in any claim, have five characteristics. It must be a manner of manufacture within the meaning of s 6 of the *Statute of Monopolies*. That is, it must be a proper subject for the grant of a patent. When compared with the prior art base as it existed before the priority date of that claim, it must be novel and it must involve an inventive step. It must be useful. It must not have been secretly used in the patent area before the priority date of that claim. To hold that a process is patentable if the process is one for which people are likely to be prepared to pay would

result in treating the first of these requirements as superfluous. The requirement that the process be a "manner of manufacture" would inevitably be satisfied by demonstration of the second and fourth requirements of novelty and utility. Because the process is novel and useful, it is a process for which people will be prepared to pay.

6. Second, and no less importantly, the whole history of the development of the law in this Court, until the decision in *Joos*, was that, for a process to be patentable, the product (the result, outcome or effect) of that process, as distinct from the process itself, must have a particular characteristic. And in that respect, the decisions of this Court mirrored the development of the law of patents that had occurred in England and Wales. At first described as a requirement for a vendible product, that characteristic was enlarged in its application by the various descriptions given to it in the *NRDC Case*: "some advantage which is material"; "value to the country ... in the field of economic endeavour"; "utility in practical affairs"; "the significance of the product is economic"; and possessing "its own economic utility". But none of these amplifying expressions can be read as discarding the requirement that the "new and useful effect" observed, the "end produced", the "artificial effect" or "artificially created state of affairs, discernible by observ[ation]" produced, or "separate result" produced by the process, be of a character that makes the process a proper subject for the grant of a patent.

7. This requirement that, for a process to be patentable, the product (the result, outcome or effect) of that process, as distinct from the process itself, must have a particular characteristic is one that should not now be discarded as irrelevant. Discarding it may possibly be justified as a logical extension of what has been said in earlier cases about the commercial purposes of the patent system. But, as already noted, an extension of that kind depends upon speaking of "a commercial application" in the abstract, without condescending to particular identification of whether it is the process or its product that is being applied in the realm of commerce. And even if taking that step can be justified in logic, it is one which, if taken, would sever what is a proper subject for the grant of a patent from its historical roots. *Any* process, whatever its application and whatever may be the result of its use, would be a proper subject for the grant of a patent if it were novel and useful. No case decided before the *NRDC Case* took that step. The *NRDC Case* did not take that step. This Court should not now do so.

8. What, then, is the nature of the product (the result, outcome or effect) of applying a method of prevention or treatment of human disease?

<u>The product of prevention or treatment of human disease</u>

1. There can be no doubt that a healthy population is in the national

interest and is economically advantageous to the nation as a whole. As Barwick CJ said in *Joos*:

> "The *national economic interest in the product of good surgery* – and therefore in the advancement of its techniques – if in no other respect than the repair and rehabilitation of members of the work force, including management in that grouping, *is ... obvious*". (emphasis added)

But it is important to recognise that these are propositions about the overall economic advantages of good health in the community. They are statements which appeal, at least implicitly, to comparisons over time or place between rich and poor societies and seek to assert and rely upon what, according to more recent economic history studies, can be described as the "synergistic improvement of health and living standards". They are propositions which speak only of the overall or aggregate effect of improvements in the health of the population and neither assign any particular cause for any improvement in health, nor assess what are the costs or the benefits associated with whatever may have been the cause or causes for improvement.

1. The question at issue in this case is more particular. It is whether using a method of prevention or treatment of human disease produces a result, an outcome or an effect which can be described in terms of the kind used in the *NRDC Case*. Can it be said that a method of preventing or treating a disease of the human mind or body, or "correcting a malfunction or removing or ameliorating an incapacity" of the human body, produces a result which could be described as: having "some advantage which is material"; something of "value to the country ... in the field of economic endeavour"; having some "utility in practical affairs"; having "significance ... [which] is economic"; and possessing "its own economic utility"?

2. What a method of prevention or treatment of human disease produces in the individual to whom it is applied cannot be described in those terms. The method of treatment, if successful, prevents, reduces or eliminates some disease, discomfort or incapacity of the individual. The effect on the individual can be regarded as artificially created by the method of treatment. (No doubt, the individual must respond to the treatment and the treatment may very well depend upon responses which could be seen as naturally occurring in response to the treatment. For present purposes, however, no attention need be paid to those observations.)

3. The effect on the individual is undoubtedly useful to him or her. The effect may permit the individual better to exploit his or her capacities economically (whether by selling his or her labour or otherwise). In that

way, the effect may be useful to society generally or to some section of it. It may enable the individual concerned to make a better and more valuable contribution to national production; it may reduce the costs to society which the individual may have caused in his or her previous state. In those ways, use of the process may have economic consequences for the individual and, according to that individual's choices, for the wider society.

4. The effect of using the process is personal to the individual. It is not an effect which the person who owns the right to use the process, or *any* person other than the individual who has been treated, can turn to economic account in any way, whether directly or indirectly. If the individual who has been treated can turn the effect to economic account, he or she can do so only indirectly: by taking advantage of better health to make a more valuable contribution to national production. The individual is not a subject of commerce. The product of the process in the individual (having better health than might otherwise have been the case) cannot be sold. Absence of the product (of good or better health) may be a cost to the individual and a cost to society. Relief from that cost by achieving good or better health is a benefit to the individual, but what that individual does with that product is a matter wholly and solely for that individual. It is not a benefit that the person who owns the right to use the process, or *any* person other than the individual who has been treated, can turn to commercial account.

5. The product (the result, outcome or effect) produced by use of the process places the process beyond the (very wide) ambit of a "manner of manufacture" within the meaning of s 6 of the *Statute of Monopolies*. The product is not of a kind which makes the process a proper subject for the grant of a patent.

6. A method of prevention or treatment of human disease is not a proper subject for the grant of a patent.

Arguments not considered

1. Apotex advanced two arguments which are not considered in these reasons. First, it drew attention to the ways in which several other jurisdictions have dealt with the patentability of a method of prevention or treatment of human disease. But neither the statutory regimes enacted in those jurisdictions, nor judicial decisions interpreting those provisions, provide any substantial assistance in resolution of this appeal.

2. Second, Apotex submitted that the patent in suit claimed what is a second or subsequent medical use for a compound and that the claim made, being limited by the purpose for which the compound was used, was not patentable. For the reasons that have been given, this issue is not reached and need not be considered.

Threatened infringement

1. Having regard to the conclusion reached about patentability, the issue of threatened infringement which Apotex sought to raise is not reached, and, accordingly, the application by Apotex for special leave to appeal against so much of the orders of the Full Court as dealt with the question of infringement should be dismissed. It is as well, however, to say something shortly about the issue.

2. It will be recalled that it was held, at first instance, that Apotex would have infringed the patent in suit by supplying Apo-Leflunomide for the treatment of PsA because use of the compound to treat PsA would inevitably treat or prevent psoriasis. It will also be recalled that Apotex supplied (and supplies) Apo-Leflunomide with a product information document stating that Apo-Leflunomide is "not indicated for the treatment of psoriasis that is not associated with manifestations of arthritic disease". And it will be further recalled that, under the TGA, Apo-Leflunomide, as a therapeutic good registered on the ARTG and indicated for active RA and active PsA, but *not* psoriasis not associated with manifestations of arthritic disease, is a therapeutic good which is separate and distinct from any therapeutic good having different indications (including, in particular, one that is indicated for the treatment or prevention of psoriasis).

3. Against this background of regulation, Apotex, as supplier of Apo-Leflunomide, would have reason to believe that those to whom it supplied the product would put it to the uses described in the indications with which the product was registered on the ARTG. That is, Apotex would have reason to believe that Apo-Leflunomide would be put to the use of preventing or treating either active RA or active PsA.

4. Apotex was not shown to have any reason to believe that Apo-Leflunomide would be put to any other use. More particularly, Apotex was not shown to have any reason to believe that Apo-Leflunomide would be put to the use of preventing or treating psoriasis not associated with manifestations of arthritic disease. The product was registered on the ARTG with an express exclusion of that indication for its use.

5. A person suffering active RA or active PsA may have psoriasis. Administration of an effective amount of Apo-Leflunomide to treat the active RA or active PsA would be likely to relieve the patient's psoriasis. But the Full Court was right to conclude that the claim in suit, on its proper construction, was confined to the deliberate administration of the compound to prevent or treat psoriasis. Apotex had reason to believe that Apo-Leflunomide would be put to the use of preventing or treating either active RA or active PsA, not psoriasis.

Conclusion and orders

1. The appeal to this Court should be allowed with costs. The application for special leave to appeal against so much of the orders of the Full Court of the Federal Court of Australia as dealt with the question of threatened infringement should be dismissed with costs. The orders of the Full Court of the Federal Court of Australia made on 18 July 2012 should be set aside. In their place, there should be orders that the appeal to that Court is allowed in part; orders 2, 3, 4, 6 and 8 of the orders of Jagot J made on 18 November 2011 and order 1 of the orders of Jagot J made on 24 February 2012 are set aside and in their place there be orders that Australian Patent Number 670491 is revoked. In accordance with the appellant's submission, the costs of the appeal to the Full Court and of the trial should be in the discretion of the Full Court.

2. CRENNAN AND KIEFEL JJ. The appellant ("Apotex") appeals from a decision of the Full Court of the Federal Court of Australia in favour of the respondents. The appeal mainly concerns the validity of Australian Patent No 670,491 ("the Patent"), held by the second respondent, for an invention entitled "Pharmaceutical for the treatment of skin disorders". The single claim of the Patent, claim 1, is for "[a] method of preventing or treating a skin disorder, wherein the skin disorder is psoriasis, which comprises administering to a recipient an effective amount of [leflunomide]".

3. The main issue for determination on this appeal is whether the subject matter of claim 1 is a "manner of manufacture" and hence a patentable invention within the meaning of s 18(1) of the *Patents Act* 1990 (Cth) ("the 1990 Act"). A discrete, narrower issue in respect of validity, also framed by reference to s 18(1), is whether claim 1, for a hitherto unknown therapeutic use of a pharmaceutical substance (having prior therapeutic uses), is a "manner of manufacture". By cross-claim, Apotex sought revocation of the Patent and, at the same time, denied infringement of claim 1 as alleged by the respondents. If the primary judge's order dismissing Apotex's cross-claim remains undisturbed, as it was left by the Full Court of the Federal Court, a third issue, the infringement issue, remains to be determined. That issue is whether the proposed supply by Apotex of leflunomide to treat psoriatic arthritis ("PsA") would infringe the Patent under s 117(1) of the 1990 Act, given that claim 1 is limited to the use of leflunomide for the prevention and treatment of psoriasis.

4. The application for special leave to appeal in respect of infringement was referred to this Court to be argued as on an appeal.

5. In these reasons it will be concluded that Apotex's application for revocation of the Patent must be refused on the basis that claim 1 discloses a patentable invention. Further, it will be explained that claim 1 is a claim

limited by purpose. A method claim, for the administration of a pharmaceutical substance (with prior therapeutic uses) for a hitherto unknown therapeutic use, can be a patentable invention. Thus Apotex's narrower attack on the validity of the Patent fails. These reasons will also explain why Apotex's proposed supply of leflunomide to treat PsA is not an infringement of claim 1.

Background facts

1. On 14 December 1979, Hoechst AG, a subsidiary of the second respondent, applied for and was granted a patent in Australia for the compound leflunomide, Australian Patent No 529,341 ("Patent 341"), which expired in 2004. For present purposes it can be noted that claim 1 of Patent 341 claimed the compound leflunomide and claim 4 claimed a "[m]ethod for the treatment of inflammations, rheumatic complaints or multiple sclerosis by administering to the patient an effective amount of [leflunomide]".

2. On 29 March 1994, Hoechst AG applied for and was granted the Patent. The Patent has a priority date of 31 March 1993 and expires on 29 March 2014. Claim 1 has been set out above.

3. Sanofi-Aventis Deutschland GmbH, the second respondent, is the registered owner of the Patent under the 1990 Act; Sanofi-Aventis Australia Pty Ltd ("Sanofi-Aventis"), the first respondent, supplies leflunomide in Australia under the trade names "Arava" and "Arabloc"; together with Aventisub II Incorporated, the third respondent, Sanofi-Aventis owns copyright in product information documentation relating to Arava (collectively, "Sanofi").

4. In 1999, leflunomide was included on the Australian Register of Therapeutic Goods ("the ARTG") for the treatment of rheumatoid arthritis ("RA") and PsA. In July 2008, Apotex obtained registration of its generic version of leflunomide, Apo-Leflunomide, on the ARTG. Apotex intends to supply and offer for supply Apo-Leflunomide in Australia for the treatment of RA and PsA.

5. A number of related facts, about which there was no dispute in this Court, can be summarised. Psoriasis is a skin condition which occurs in about two per cent of the Australian population. Its occurrence is a diagnostic criterion of PsA. Almost every person with PsA has or will develop psoriasis. Patients who suffer from psoriasis will usually be referred to a dermatologist for treatment. Leflunomide is not used in Australia to treat psoriasis alone. Dermatologists do not prescribe leflunomide for that purpose; however, leflunomide is used by rheumatologists to treat RA and PsA. The evidence established that when

this compound is prescribed to treat a patient with PsA, it is usually expected to also prevent or treat the patient's psoriasis, if that person has a concurrent case of psoriasis.

The litigation

1. In 2008, Sanofi commenced proceedings in the Federal Court of Australia, claiming that Apotex's proposed supply in Australia of Apo-Leflunomide to treat PsA would infringe the Patent. Sanofi further claimed that Apotex's failure to warn potential customers that the use of Apo-Leflunomide would infringe the Patent constituted misleading and deceptive conduct under s 52 of the *Trade Practices Act* 1974 (Cth). Further, Sanofi alleged breach of copyright by Apotex under the *Copyright Act* 1968 (Cth). Sanofi's claims under the *Trade Practices Act* and the *Copyright Act* were dismissed by the Full Court and were not pursued on appeal to this Court.

2. In addition to denying infringement of claim 1, relied on by Sanofi, Apotex, by cross-claim, sought revocation of the Patent on a number of grounds, including the ground that claim 1 did not disclose a patentable invention. Before the primary judge, Apotex reserved its right to challenge the correctness of two decisions of the Full Court of the Federal Court, namely *Anaesthetic Supplies Pty Ltd v Rescare Ltd* and *Bristol-Myers Squibb Co v F H Faulding & Co Ltd*, as to whether a method of medical treatment of the human body is a patentable invention.

3. On 18 November 2011, the primary judge (Jagot J) made orders in the Federal Court dismissing Apotex's cross-claim and restraining Apotex from infringing claim 1 of the Patent, in particular from supplying or offering to supply its leflunomide products "for the treatment of psoriatic arthritis". The Full Court dismissed Apotex's appeal in respect of its cross-claim and, notwithstanding construing claim 1 differently from the primary judge, the Full Court also dismissed Apotex's appeal concerning infringement.

The statutory framework

Background

1. Briefly, the first Australian patent legislation, the *Patents Act* 1903 (Cth) ("the 1903 Act"), imported into Australia principles established and enacted in legislation then current in the United Kingdom, where the law of patents had been wholly statutory since the *Statute of Monopolies* 1623.

2. Relevantly, "Invention" was defined in the 1903 Act to mean "any manner of new manufacture the subject of letters patent and grant of

privilege within section six of the Statute of Monopolies". That definition was continued in the *Patents Act* 1952 (Cth) ("the 1952 Act") and in the 1990 Act. Given that history, it is useful to observe, as Lord Diplock did, that the law of patents originated before the dawn of the modern sciences of physics and chemistry.

3. Until 1977, legislation in the United Kingdom continued to define "invention" by reference to s 6 of the *Statute of Monopolies* with the addition of "and any new method or process of testing applicable to the improvement or control of manufacture". However, on the introduction of the *Patents Act* 1977 (UK), requirements for patentability were codified for the purposes of harmonisation, following the Convention on the Grant of European Patents (1973) ("the EPC"), about which more will be said later. It can be noted that s 130(7) of the *Patents Act* 1977 (UK) declares that various provisions "are so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of the [EPC and] the Community Patent Convention".

4. Returning to Australian patent legislation, revocation (originally by the prerogative writ of *scire facias* − in essence a writ to show cause) could be ordered upon a petition to the relevant court on the basis of any ground which would have been available at common law. Lack of subject matter was a ground available pursuant to that writ. Again, reflecting developments in the United Kingdom, the 1952 Act introduced a consolidated list of grounds for the revocation of a patent, including the precursor to the ground under the 1990 Act relied upon by Apotex.

5. After the decision of Barwick CJ sitting in the original jurisdiction of the High Court in *Joos v Commissioner of Patents*, which will be discussed later, the Australian Patent Office's *Patent Examiner's Manual* ("the Patent Manual") was changed to include an instruction to examiners of applications for patents that "no objection is to be taken to methods or processes for the treatment, medical or otherwise, of the human body or part of it, only on the basis that the human body is involved."

6. The Industrial Property Advisory Committee ("the IPAC") reviewed the 1952 Act and reported to the Minister for Science and Technology on 29 August 1984. The IPAC noted that specific legislative exclusions from patentability "would be likely to prove a very slow, blunt and inefficient instrument for influencing the economic direction of particular industries or fields of technological development in Australia." The IPAC referred to the codified approach to patentability in the *Patents Act* 1977 (UK) and then said:

> "We consider that the existing concept [manner of new manufacture] operates quite satisfactorily. It has the advantage of being

> underpinned by an extensive body of decided case law which facilitates its application in particular circumstances. At the same time it has, in the past, exhibited a capacity to respond to new developments. To replace it with a codification would be likely to produce far more problems, with attendant costs, than it would solve."

1. As will be explained later in these reasons, that codified approach included a provision (now repealed) which expressly excluded from patentability methods of treatment of the human body. The IPAC's recommendation was accepted when the 1990 Act was enacted.

2. The Agreement on Trade-Related Aspects of Intellectual Property Rights (1995) ("the TRIPs Agreement"), to which Australia is an original signatory, necessitated amendments to the 1990 Act so as to comply with Australian obligations under that Agreement. Importantly, Art 27(1) provides that subject to Art 27(3), "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." Article 27(3)(a) relevantly gives all contracting States the option to "exclude from patentability ... diagnostic, therapeutic and surgical methods for the treatment of humans". The abovementioned amendments to the 1990 Act did not enact Art 27(1) or Art 27(3)(a) of the TRIPs Agreement into Australian domestic law. However, the requirements for patentability under the 1990 Act are consistent with Australia's international obligations under Art 27(1).

Relevant provisions of the 1990 Act

1. In its cross-claim, Apotex relied on ss 138(3)(b) and 18(1)(a) of the 1990 Act. Section 138(3)(b) provides, as a ground of revocation, "that the invention is not a patentable invention". "Invention" is defined in Sched 1 to the 1990 Act to mean:

> "any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies, and includes an alleged invention."

1. Section 18(1)(a) of the 1990 Act provides that "an invention is a patentable invention ... if the invention, so far as claimed in any claim ... is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies". Paragraphs (b), (c) and (d) of s 18(1) contain other requirements including that an invention be novel, involve an inventive step, and be useful. It can be noted that s 18(2), which first appeared in the 1990 Act, provides that "[h]uman beings, and the biological processes for their generation, are not patentable inventions."

2. In *SmithKline Beecham PLC's (Paroxetine Methanesulfonate) Patent*, Lord Walker of Gestingthorpe explained that the constitutional importance of the *Statute of Monopolies*, which generally declared void all monopolies, lay in its effect in curbing the prerogative of the Crown. The proviso in s 6 excepts grants of letters patent for a term of 14 years or less, in respect of the "making of any manner of new manufactures within this Realm". The proviso is subject to a further proviso in s 6 excluding grants which are "contrary to the law ... mischievous to the State, by raising prices of commodities at home, or hurt of trade, or generally inconvenient".

3. In *Grain Pool of Western Australia v The Commonwealth*, this Court, citing *National Research Development Corporation v Commissioner of Patents*, explained the effect on patent law of the passage of the *Statute of Monopolies*:

> "Thereafter, the scope of permissible patentable subject matter involved an inquiry 'into the breadth of the concept which the law [had] developed by its consideration of the text and purpose of [that statute]'".

So much was accepted by Apotex.

1. Further, it was generally accepted that the basic purpose of patent legislation is to encourage invention (and any underlying research leading to an invention) by granting an inventor/patentee the protection of a limited monopoly, in exchange for benefit to the public of a full disclosure of the invention including the practical use to which it can be put.

2. Under the Royal Grant, once part of the words of grant of letters patent deriving from the *Statute of Monopolies*, the patentee received "full power [and] sole privilege ... [to] make, use, exercise and vend the ... invention". It was for the patentee alone to "have and enjoy the sole use and exercise and the full benefit of the ... invention".

3. Section 13(1) of the 1990 Act provides to the patentee "the exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention." The definition of "exploit" in Sched 1 distinguishes between the circumstance where an invention is a product and where it is a method or process:

> "(a) where the invention is a product—make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or
>
> (b) where the invention is a method or process—use the method

or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use."

1. A distinction between product and method is also made in s 119A, which creates an exception to infringement for acts undertaken solely for the purpose of applying for the inclusion of therapeutic goods on the ARTG. Section 119A(3) defines a "pharmaceutical patent" as including both a "pharmaceutical substance" and a "method, use or product relating to a pharmaceutical substance". A "pharmaceutical substance", defined in Sched 1 to the 1990 Act, means a substance for therapeutic use which involves "interaction ... with a human physiological system" or "action on an infectious agent, or on a toxin or other poison, in a human body". The expression "therapeutic use" as defined in Sched 1 includes "use for the purpose of … preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons".

2. Section 70 confines extensions of term of standard patents relating to pharmaceutical substances to patents which claim (a) pharmaceutical substances *per se*; or (b) pharmaceutical substances that are "produced by a process that involves the use of recombinant DNA technology".

3. Section 133, which provides for compulsory licensing, applies to both products and methods or processes which can be patented and envisages licensing a licensee "to work the patented invention." "Work" is defined in Sched 1 in relation to an invention which is "a method or process".

4. Sanofi's claim regarding infringement rests on s 117 of the 1990 Act, which governs infringement by supply. Section 117 will be examined later in these reasons.

Primary judge

Patentable invention?

1. The primary judge rejected Apotex's narrow attack on the validity of the Patent.

Infringement

1. The primary judge also rejected the construction of claim 1 of the Patent urged by Apotex. Regarding the infringement issue, Jagot J held that Apotex's intended supply of Apo-Leflunomide would infringe the Patent under s 117(1) of the 1990 Act. Her Honour's conclusions on infringement depended on the construction of claim 1, on which the parties disagreed. Her Honour explained:

> "The essence of the dispute between the parties insofar as it related to the construction of the patent is ultimately whether the claim for a 'method of preventing or treating a skin disorder, wherein the skin disorder is psoriasis' by administration of a compound should be construed as involving the purpose, object or aim of the administration … or the effect in fact of the administration."

1. Apotex preferred the former construction. Sanofi favoured the latter construction, which resulted in a finding of infringement dependent upon whether the administration of leflunomide would in fact have the effect of preventing or treating psoriasis.

2. Accepting Sanofi's construction of claim 1, the primary judge found that the supply of Apo-Leflunomide for the treatment of PsA would infringe the Patent, as that use of the compound would inevitably lead to the treatment of psoriasis. Her Honour considered that "if leflunomide is administered to a patient with PsA, that administration would be expected also to prevent or treat the patient's psoriasis, to some extent at least." It followed that Apotex's intended supply of its generic leflunomide product to treat PsA would infringe the Patent under s 117 of the 1990 Act. Her Honour also found that Apotex's approved product information document instructed rheumatologists to use Apo-Leflunomide for the treatment of psoriasis, which brought its intended supply of the pharmaceutical substance within s 117(2)(c).

Full Court of the Federal Court

1. The Full Court (Keane CJ, Bennett and Yates JJ) unanimously dismissed the appeal.

Patentable invention?

1. Keane CJ observed that, having regard to the passage of time since the decision of the Full Court of the Federal Court in *Bristol-Myers Squibb*, the federal Parliament had been afforded ample opportunity to amend the 1990 Act to exclude methods of medical treatment of the human body as proper subject matter for the protection of patent legislation, and had not done so.

2. Bennett and Yates JJ, in a joint judgment, refused to depart from the position expressed in *obiter dicta* in *Rescare* and *Bristol-Myers Squibb*, that methods of medical treatment of the human body can be patented. That position was described by their Honours as "representing orthodoxy in Australian patent law." Bennett and Yates JJ also considered that it was "significant" that the federal Parliament had not been persuaded to amend the 1990 Act to give effect to policy considerations, to the extent that such

considerations might tend against the patentability of methods of medical treatment of humans.

Infringement

1. Turning to the infringement issue, Keane CJ considered that the primary judge had erred in construing claim 1 of the Patent as the administration of leflunomide in an effective amount, so that a patient's psoriasis was prevented or treated. His Honour considered that this construction failed to recognise that claim 1 was for a method of treatment of a specific human ailment, which "necessarily presuppose[d] a deliberate exercise of diagnosis and prescription by a medical practitioner … and the consequent prescription of the application of leflunomide." Keane CJ held that the claim in the Patent was limited to the use of leflunomide as an agent for the prevention or treatment of psoriasis. It followed that the Patent, on its true construction, would not be directly infringed by the application of leflunomide to prevent or treat PsA.

2. Keane CJ went on to consider whether, despite his conclusions on the true construction of claim 1, Apotex would still be liable for infringement under s 117(1) of the 1990 Act. Based on the primary judge's findings of fact regarding Apotex's product information document, which engaged s 117(2)(b) and (c), his Honour found that the intended supply by Apotex of Apo-Leflunomide to treat PsA would infringe the Patent.

3. Bennett and Yates JJ were satisfied that it was open to the primary judge to find that Apotex's product information document contained an instruction to use Apo-Leflunomide to treat psoriasis, which engaged s 117(2)(c) of the 1990 Act. Their Honours also considered that there was no error in the primary judge's conclusions that Apotex had reason to believe that Apo-Leflunomide would be used to treat psoriasis, engaging s 117(2)(b). It followed that, as s 117(1) was engaged against Apotex, the appeal on the question of infringement could not succeed.

Submissions

1. Before this Court, Apotex submitted that methods of medical treatment of the human body were not a "manner of manufacture" and, therefore, were not patentable inventions in accordance with the principles developed for the application of s 6 of the *Statute of Monopolies*. Apotex eschewed the "generally inconvenient" rationale, considered by Barwick CJ in *Joos*, as the preferable basis for excepting from patentability methods of medical treatment of the human body. This involved accepting that the requirements of novelty, inventive step and utility, and correlative grounds for revocation, subsume and embody what was once covered by the "generally inconvenient" ground for a refusal of grant.

2. Instead, relying on *obiter dicta* of this Court in the celebrated *NRDC Case*, Apotex argued that methods of medical treatment of humans are "essentially non-economic". Apotex contended that when the 1990 Act came into force, the established law in Australia and the United Kingdom was that a method (or process) of medical treatment of the human body is not a manner of manufacture and hence not a patentable invention. Apotex went on to submit that the abovementioned *obiter dicta* in the *NRDC Case* was insufficiently apprehended in *Joos*, *Rescare* and *Bristol-Myers Squibb*. In the latter two cases, albeit also in *obiter dicta*, it was said that a method of medical treatment of the human body can be a "manner of manufacture" and hence a patentable invention. Apotex submitted that *Rescare*, followed in *Bristol-Myers Squibb*, was in that respect wrongly decided.

3. Further, Apotex contended that the majority in *Rescare* failed to recognise that methods of medical treatment of the human body should not be regarded as "industrialised". That submission seemed to evoke public policy considerations in addition to the idea that methods of medical treatment of the human body are not capable of being industrially applied. An elusive distinction which Apotex ventured between a medicine (long considered a manner of manufacture, therefore an invention) and a method of treatment involving the administration of a pharmaceutical substance was that the latter improves the condition of a human being, which is not an article of commerce. For this reason, Apotex submitted that a method of medical treatment of the human body cannot be a patentable invention. In the alternative, Apotex contended that the administration of leflunomide (a known compound with prior therapeutic uses) for a hitherto unknown purpose is not a manner of manufacture within s 18(1)(a) of the 1990 Act.

4. On the infringement issue, Apotex submitted that the question before this Court was whether Apotex had "reason to believe" that medical practitioners would use Apo-Leflunomide for the claimed purpose, being the prevention and treatment of psoriasis. It was contended that special leave should be granted to determine what constitutes the necessary "reason to believe" under s 117(2)(b) of the 1990 Act.

5. Sanofi submitted that the language and context of the 1990 Act made clear that the expression "manner of manufacture" in s 18(1)(a) included methods of medical treatment of the human body. Sanofi also relied on the circumstance that no decision of this Court has held that methods of treatment of the human body are not patentable. Further, Sanofi refuted the proposition that methods of medical treatment are excluded from patentability on the ground that they are "non-economic". Sanofi contended that no point of principle was raised by the question of infringement under s 117(1) of the 1990 Act and that the Full Court's decision on this point was correct.

Patentable invention?

1. The question posed by Apotex's claim for revocation of the Patent is whether, assuming all other requirements for patentability are met, a method of medical treatment of the human body can be a patentable invention. That question has not been decided by this Court. There being no express exclusion of such methods in the 1990 Act, the question of the construction of s 18(1)(a) is to be decided by reference to the principles developed for the application of s 6 of the *Statute of Monopolies*.

2. Whether a method of medical treatment of the human body is a proper subject matter for a grant of monopoly under a patent system has been considered by tribunals and courts in a number of major jurisdictions, some with patent legislation which similarly defines invention by reference to the expression "manner of manufacture" in s 6 of the *Statute of Monopolies* (as in the United Kingdom, until 1977, and New Zealand), and some with patent legislation which defines invention otherwise (as in the United States of America and Canada).

3. To speak of "methods of medical treatment of the human body" is to employ an expression of sufficient generality to encompass both drug therapies capable of industrial application and the know-how involved in a medical practitioner's diagnosis and methods of treatment (including surgery) of patients. Distinguishing the two types of activity has proved problematic in many jurisdictions.

4. Irrespective of the differences in national patent legislation, a clear, perhaps insoluble, conflict has emerged between two relevant competing considerations. The first consideration is the undesirability of having a patent system intruding on the freedom of a medical practitioner to treat a patient, without being restrained by the need to consider whether a patent licence is necessary. The conflicting consideration is the desirability of having a logical patent system which encourages research and invention in relation to drug therapies, not only by granting monopolies for novel medicines (and for that matter novel medical implements), but also by not excluding from patentability hitherto unknown therapeutic uses of known compounds, where novelty requirements can most directly be satisfied by a claim to a method or process, which is in effect a claim limited to the hitherto unknown therapeutic use. Professor Cornish and his co-authors have remarked:

> "In the second half of the twentieth century, patent law in every industrial state had to develop in ways which mediated this conflict."

Relevant authorities

1. In Australian law, the starting point is the recognition in the *NRDC Case* that any attempt to define the word "manufacture" or the expression "manner of manufacture", as they occur in s 6 of the *Statute of Monopolies*, is bound to fail. Apotex agreed that "manner of manufacture" refers to a broad concept indicating "the scope of the permissible subject matter of letters patent", which has continually widened since 1795, when *Boulton v Bull* was decided. The continual widening of the concept reflects the growth of patent law as patent law, in turn, reflects scientific and technical developments. In *Boulton v Bull*, Eyre LCJ included in the concept of manufacture "new processes in any art producing effects useful to the public." The concept was widened when it was finally settled in 1842 in *Crane v Price* that a process may be an art for patent law purposes. The word "method" was also accepted as a synonym for "process". What remained unsettled before the *NRDC Case* was whether it was sufficient for a process to produce a useful result or whether it was necessary for a physical thing either to be brought into existence by the process, or to be so affected "as the better to serve man's purposes."

2. In contending that the 1990 Act must be construed as excepting or excluding methods of medical treatment of the human body from patentability, Apotex relied on *obiter dicta* in *Maeder v Busch* and the *NRDC Case*, and on various decisions in the United Kingdom pre-dating the *Patents Act* 1977 (UK). The first three decisions discussed below form the backdrop to the reasoning and conclusions of this Court in the *NRDC Case*.

1914 – Re C & W's Application

1. In *Re C & W's Application*, Sir Stanley Buckmaster (as he then was), sitting as second law officer on an appeal from the refusal of a grant, decided that a process for extracting metals from living bodies, particularly from persons suffering from lead poisoning, was not a manner of manufacture and was therefore not an invention suitable for patent protection under the *Patents and Designs Act* 1907 (UK). That conclusion was underpinned by two considerations: first, the process under consideration was not used in the making of an object of commercial value, nor was it adapted to that end; and second, the process was not employed "in any form of manufacture or of trade", even though the process might be useful in improving the condition of humans.

1938 – Maeder v Busch

1. This Court's decision in *Maeder v Busch* concerned an application for grant in respect of a process for permanently waving human hair, which was found to be invalid for reasons of prior use. However, Sir Stanley Buckmaster's rationale was taken up, in *obiter dicta*, by Dixon J. His

Honour said of a process or method of treatment of the human body, including a process or method for the relief of suffering by surgical or manipulative means:

> "[T]he object [of the process or method] is not to produce or aid the production of any article of commerce. No substance or thing forming a possible subject of commerce or a contribution to the productive arts is to be brought into existence by means of or with the aid of the process."

1942 – GEC's Application

1. It seems that after 1914 in the United Kingdom, it was accepted as axiomatic that there could be no patents for methods of medical treatment of the human body. A broad rule, relying on Sir Stanley Buckmaster's approach, was formulated by Morton J in *GEC's Application*, seeking to draw a helpful (although not exhaustive) line between a method or process which is a manner of manufacture and one which is not. A method or process was said by Morton J to be a manner of manufacture if it (a) resulted in the production of some vendible product; or (b) improved or restored a vendible product; or (c) preserved a vendible product from deterioration. Whilst Morton J's rules were influential in both the United Kingdom and Australia, it was suggested in a series of subsequent cases in the United Kingdom that when the expression "vendible" is used in the context of a process, it is a reference to a capacity for commercial or industrial application.

1959 − The NDRC Case

1. The *NRDC Case* concerned an appeal from a decision of the Deputy Commissioner of Patents, directing that certain claims be deleted from the specification of an application on the ground that the method claimed was not a manner of manufacture because it did not result in any vendible product. In coming to his decision, the Deputy Commissioner had relied on *Re C & W's Application* and *GEC's Application*.

2. In determining that a novel use of known substances (for the eradication of weeds from crops) was a patentable invention, this Court (Dixon CJ, Kitto and Windeyer JJ) decided that it was not essential that a process produce or improve a vendible article. Their Honours explained, by reference to the doctrine of analogous uses set out in *BA's Application*:

> "If ... the new use that is proposed consists in taking advantage of a hitherto unknown or unsuspected property of the [known] material ... there may be invention in the suggestion that the substance may be used to serve the new purpose; and then, provided that a practical

> method of so using it is disclosed and that the process comes within the concept of patent law ultimately traceable to the use in the *Statute of Monopolies* of the words 'manner of manufacture,' all the elements of a patentable invention are present ... It is not necessary that in addition the proposed method should itself be novel or involve any inventive step".

1. Their Honours went on to decide that a hitherto unknown use of a (known) material can qualify as a manner of manufacture if the process "offers some advantage which is material", in the sense that the process belongs to a useful art (as distinct from a fine art), and has "value to the country … in the field of economic endeavour."

2. Parenthetically, citing *Re C & W's Application* and *Maeder v Busch*, their Honours noted "[t]he need ... to put aside, as they apparently must be put aside, processes for treating diseases of the human body". The rationale assumed for the exclusion from patent protection of "methods of surgery and other processes for treating the human body", now relied on by Apotex, was that "the whole subject is conceived as essentially non-economic".

1971 – In re Schering AG's Application

1. In *In re Schering AG's Application*, the Patents Appeal Tribunal (Graham and Whitford JJ) allowed an application for a contraceptive to proceed to grant on the ground that a contraceptive was strictly distinguishable from a method of medical treatment of the human body. The Tribunal accepted that although the *Patents Act* 1949 (UK) did not, in terms, exclude from patentability methods of medical treatment of humans, so much inferentially appears to have been in the contemplation of Parliament at least since enacting s 41 of the *Patents Act* 1949. Reference was also made to the 50 year old practice of the Patent Office of refusing such applications (first referred to in *Re C & W's Application*). Since novel therapeutic products and curative devices could secure patent protection, the Tribunal noted that, despite the strong support to be found in s 41 for excluding processes for medical treatment from patentability, the exclusion appeared to be based on ethics rather than logic. That reasoning was affirmed subsequently in *Eli Lilly & Co's Application.*

1972 – Joos

1. In *Joos*, decided under the 1952 Act, Barwick CJ sat on an appeal from a refusal of grant in respect of a method or process for the treatment of hair and nails. His Honour referred to *In re Schering AG's Application* with approval and went on to distinguish medical prophylactic or therapeutic methods or processes from cosmetic methods or processes, both of which applied to the human body. Although his Honour said it was not necessary

for him to identify the basis for excepting the former class of method or process claims, if an exclusion from patentability were to be maintained it should be on "public policy [grounds] as being, in the language of the *Statute of Monopolies*, 'generally inconvenient'". In expressing that opinion, the Chief Justice rejected "[p]art at least of the premises on which the observations [by Dixon J in *Maeder v Busch*] were made ... that surgery or other processes for treating the human body were of their nature essentially non-economic." The possibility that such treatments might have economic utility, or commercial or industrial application, seemed obvious to his Honour, given the economic impact of worker's compensation, invalid pensions and repatriation costs. As explained above, Patent Office practice was altered after *Joos* so as to permit applications for patents which claimed methods or processes of medical treatment of the human body.

1980 – Wellcome Foundation v Commissioner of Patents

1. Following developments in the United Kingdom, in *Wellcome Foundation Ltd v Commissioner of Patents* this Court determined that novel packaging, containing directions for using a known substance or compound for a hitherto unknown use or purpose, may be a "manner of manufacture". In so doing, the Court elucidated the expansion of the concept of "manner of manufacture" decided in the *NRDC Case*, distilled thus:

> "This principle [in the *NRDC Case*] extends to a process which does not produce a new substance but results in 'a new and useful effect'. If the new result is *'an artificially created state of affairs' providing economic utility*, it may be considered a 'manner of new manufacture' within s 6 of the Statute of Monopolies". (emphasis added)

1. Such was the relevant case law concerning methods of medical treatment of the human body before the passage of the 1990 Act.

Rescare and Bristol-Myers Squibb

1. At first instance in *Rescare Ltd v Anaesthetic Supplies Pty Ltd*, the patent in suit contained method claims as well as product claims. The primary judge (Gummow J) rejected a claim for revocation of the method claims for treatment of the human body on the basis that they did not claim an "invention" (within the definition of "invention" in the 1952 Act). His Honour accepted the suggestion made by Barwick CJ in *Joos*, that the only basis upon which the exclusion from patentability of methods of medical treatment of humans could be continued (if it should be) was "general inconvenience". This was essentially because there was no logical distinction to be made between a patent for a method or process for treatment of the human body and a product for the same.

2. To ensure that the method claims were fairly based, his Honour was prepared to allow amendments to those claims, to claim a treatment of obstructive sleep apnoea in humans. Like Barwick CJ in *Joos*, his Honour did not accept the generality of the *obiter dicta* in *Maeder v Busch*, repeated in the *NRDC Case*, that methods of medical treatment of the human body are "essentially non-economic". The method claims with which his Honour was dealing did not involve surgery and there does not appear to have been any suggestion that the claims, as amended, would lack commercial application.

3. On appeal, a majority of the Full Court of the Federal Court (Lockhart and Wilcox JJ, Sheppard J dissenting) upheld the primary judge's reasoning and decision in respect of methods of medical treatment of the human body, although their Honours found that the method claims in issue were not fairly based on the provisional specification.

4. In the majority, Lockhart J found that once the notion of the necessity for a vendible product (as in *Re C & W's Application*) is eliminated (as it was in the *NRDC Case*), there is no distinction in principle between a product for treating humans and a method for treating humans. His Honour considered that the distinctions between a contraceptive and other methods of treatment of the human body (*In re Schering AG's Application*), and between processes which produce a cosmetic result and processes which produce a curative result (*Joos*), were distinctions without a difference which could not sustain a principle distinguishing what is an invention and patentable from what is not. His Honour said:

> "I see no reason in principle why a method of treatment of the human body is any less a manner of manufacture than a method for ridding crops of weeds as in *NRDC*. 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 changing needs and times ...
>
> If a process which does not produce a new substance but nevertheless results in 'a new and useful effect' so that the new result is *'an artificially created state of affairs' providing economic utility*, it may be considered a 'manner of new manufacture' within s 6 of the *Statute of Monopolies*". (emphasis added)

1. That reasoning is correct. In agreeing with Lockhart J, Wilcox J noted Parliament's deliberate decision not to exclude methods of treatment of humans from patentability in the 1990 Act. His Honour considered that courts should hesitate to introduce the exclusion, especially given the developments in the application of the concept of "manner of new manufacture", which widened rather than narrowed the concept.

2. Before turning to consider briefly the position elsewhere, it can be noted that in *Bristol-Myers Squibb*, decided under the 1990 Act, a Full Court of the Federal Court, following *Rescare*, overturned a finding that the patents in suit claiming a method of administering an anti-cancer drug were invalid on the grounds of "general inconvenience". Black CJ and Lehane J acknowledged "the difficulty ... of drawing any logical distinction between a method of treatment and a patentable pharmaceutical product that produces the same beneficial results." Agreeing with the joint reasons, Finkelstein J referred to the TRIPs Agreement and took the view that if public policy required medical treatment and surgical processes to be excluded from patent protection, it was for Parliament to amend the 1990 Act.

The position elsewhere

1. Decisions from overseas, including those of the European Patent Office, are of course not binding on this Court. The Court has noted the existence of significant divergences between the case law concerning the 1952 Act and the 1990 Act, and patent legislation in the United Kingdom in 1949 and 1977, in relation to the patentability requirements of obviousness and inventive step. However, the theory and purpose of patent legislation everywhere have much in common, and the 1990 Act includes provisions designed to "harmonise [Australian patent law] with the laws of Australia's major trading partners" and to ensure compliance with Australia's international obligations under the TRIPs Agreement. The question of whether methods of medical treatment of humans can (or should) be patented does not turn on any express or implied exclusion in the 1990 Act, or on any normative distinctions to be drawn from its provisions. Further, an understanding of the position in Europe and the United Kingdom informs Apotex's second attack on the validity of the Patent. The TRIPs Agreement, to which there are 159 contracting States including Australia, has influenced the developments described below in Europe, the United Kingdom and New Zealand.

Europe

1. As a prelude to discussing an express exception to patentability of methods of medical treatment of the human body in the EPC, the general position in relation to hitherto unknown therapeutic uses is set out in Terrell's textbook:

> "Historically, the first inventor of a new product suitable for use in medical treatment was entitled to a claim to the product *per se*. This remains the case. Difficulties arise where the product is already known and the invention resides in the discovery of a novel medical use (first medical use), or where, although known for medical use,

the invention resides in the discovery of a novel second medical use."

1. In conformity with Art 27(1) of the TRIPs Agreement, Art 52(1) of the EPC provides that "patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application." Article 53, headed "Exceptions to patentability", provides for heterogeneous exceptions to that general approach to patentability.

2. Relevantly, an exception for methods of treatment of the human body is set out in Art 53(c):

> "European patents shall not be granted in respect of ...
>
> (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods."

1. Article 54(4) ameliorates the effect of that exception: a substance or compound is deemed novel in respect of a new therapeutic use. That such use of a (known) substance or compound is not denied novelty is squarely within the general principle established in the *NRDC Case*, that the discovery of a new use of a known substance which has both an artificial effect and economic utility can be a "manner of manufacture", and therefore a patentable invention.

2. Claims for a second (or subsequent) hitherto unknown therapeutic use of a known compound were not expressly permitted under the original (1973) EPC but came to be allowed in a decision of the Enlarged Board of Appeal of the European Patent Office ("EPO") in *Eisai/Second medical indication* approving "Swiss type" claims. A "Swiss type" claim is generally in the form of a claim to "the use of [known] compound X in the manufacture of a medicament for a specified (and new) therapeutic use", the Swiss Federal Intellectual Property Office having first instituted a practice of allowing such claims in 1984.

3. The essential purpose of a "Swiss type" claim was described by Jacob J in *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc*:

> "By taking the [Swiss] form ... the claim is trying to steer clear of two obstacles to patentability, namely the requirement of novelty and the ban on methods of treatment of the human body by therapy."

1. Of the sophistry involved, Jacob J said:

> "[I]f one accepts that a patent monopoly is a fair price to pay for the extra research incentive, then there is no reason to suppose that that would not apply also to methods of treatment. It is noteworthy that in the US any such exception has gone, and yet no-one, so far as I know, suggests that its removal has caused any trouble."

Inevitably, the monopoly granted in respect of such claims is limited given that the substance has prior therapeutic uses.

1. Following *Eisai*, in *Mobil/Friction reducing additive* an Enlarged Board of Appeal upheld a claim to the use of a specified lubricant for the reduction of friction in engines, even though it had previously been used as a rust inhibitor. In *Merrell Dow Pharmaceuticals Inc v HN Norton & Co Ltd*, Lord Hoffmann noted the difficulties which this type of claim might cause in respect of infringement but refrained from holding that a claim in that form was invalid.

2. Article 54(5) of the (2000) EPC now deems novel second (and subsequent) therapeutic uses in respect of (known) substances or compounds.

3. In describing the relevant amendments to the EPC in 2000 (including the redrafted Art 54(5)), an Enlarged Board of Appeal in *Abbott Respiratory/Dosage regime* stated that excluding methods of treatment of the human body from patentability (as in Art 52(4) of the original (1973) EPC) on the basis of the "fiction" that such methods were incapable of industrial application became untenable, when the real reason for the exception was "socio-ethical and public health considerations." The Board said that the limited purpose of the exception from patentability in Art 53(c) (and its predecessor, Art 52(4)) is to free from restraints a medical practitioner's diagnosis and treatment of patients, which the Board described as "non-commercial and non-industrial medical … activities". The Board also considered relevant extrinsic material and stated that amendments permitting the patenting of second (and subsequent) uses of known substances and compounds rendered the EPC "TRIPs-compliant" in respect of Art 27(1). Such claims must, of course, still satisfy the requirements of novelty and inventive step, and be capable of industrial application. For the sake of completeness, it can also be noted that key expressions in the exception in Art 53(c), "surgery", "therapy" and "diagnostic methods" (followed in the cognate s 4A(1) of the *Patents Act* 1977 (UK)), have all been subject to decisions or considerations turning on fine, and some have said troubling, distinctions.

4. The current position in Europe is set out in the EPO Guidelines for

Examination 2012. As a result of the amendments to the EPC in 2000, claims for second (or subsequent) hitherto unknown uses of known substances or compounds may be drafted more simply and directly than "Swiss type" claims (now not permitted) as "substance X for use in the treatment of disease Y".

United Kingdom

1. Since the passage of the *Patents Act* 1977 (UK), law and practice in the United Kingdom have followed that in Europe.

2. The former definition of an invention as a "manner of new manufacture" in the *Patents and Designs Act* 1907 (UK) has been replaced by statutory requirements for patentability set out in ss 1(1) to 1(4) of the *Patents Act* 1977 (UK). A patent may only be granted if four conditions are satisfied. Two of the four conditions relevant for present purposes are that an invention must be capable of industrial application and must not be otherwise excluded under the Act, including under s 4A. It can be noted that before amendments were made to the EPC in 2000, as described above, s 4(2) of the *Patents Act* 1977 (UK) (now repealed) employed the "fiction" criticised in *Abbott's Case* by providing that a method of treatment of the human body by surgery or therapy or a method of diagnosis "shall not be taken to be capable of industrial application."

3. Section 4(1) of the *Patents Act* 1977 (UK) provides that an invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.

4. Section 4A(1) of the *Patents Act* 1977 (UK) excludes from patentability:

> "(a) a method of treatment of the human or animal body by surgery or therapy, or
>
> (b) a method of diagnosis practised on the human or animal body."

1. Relevantly, s 4A(2) excludes from the exception "a substance or composition for use in any [excluded] method"; s 4A(3) deems novel a known substance or composition in respect of a first hitherto unknown therapeutic use; and s 4A(4) essentially deems novel a known substance or composition in respect of a second (or subsequent) hitherto unknown therapeutic use, in each case by the legislative technique of "deeming" novel the known substance or composition.

2. The decision in *Eisai* was followed by the English Court of Appeal

in *Actavis UK Ltd v Merck & Co Inc.* The Court of Appeal confirmed that "[n]ovelty of purpose for use can confer novelty even if the substance is old and unpatentable as such." The Court of Appeal also said that the difficulties concerning infringement with such "purpose" claims, referred to by Lord Hoffmann in the *Merrell Dow Case*, were ameliorated in the pharmaceutical industry by the strict regulation of the manufacture and sale of pharmaceutical products.

New Zealand

1. Section 2(1) of the *Patents Act* 1953 (NZ) defines "invention" in terms of s 6 of the *Statute of Monopolies*. Methods of treatment of the human body are not expressly excluded from patentability. Such methods were, however, held by the Court of Appeal of New Zealand not to be patentable in *Wellcome Foundation Ltd v Commissioner of Patents* and *Pfizer Inc v Commissioner of Patents*. The exclusion from patentability reflected a longstanding practice in the New Zealand Patent Office of refusing grants for such methods.

2. Notwithstanding the exclusion, in *Pharmaceutical Management Agency Ltd v Commissioner of Patents* the Court of Appeal of New Zealand approved a Practice Note of the Commissioner of Patents to the effect that "Swiss type" claims would henceforward be permitted. In doing so, the Court of Appeal followed the reasoning in *Eisai.* In reviewing developments in Europe, and in the United Kingdom both before and after the *Patents Act* 1977 (UK), the Court of Appeal said:

> "[I]t seems that the exclusion from patentability of methods of medical treatment of humans is now supported only on ethical grounds. Yet patents are granted for pharmaceutical and surgical products.
>
> As Davison CJ concluded in the *Wellcome* case[], there is little logic in maintaining the exclusion ...
>
> [I]t no longer can be said that a method of treating humans cannot be an invention. To the extent that [appellate] judgments in *Wellcome*[] express that view we depart from them. The exclusion from patentability of methods of medical treatment rests on policy (moral) grounds. The purpose of the exclusion is to ensure that medical practitioners are not subject to restraint when treating patients. It does not extend to prevent patents for pharmaceutical inventions and surgical equipment for use in medical treatment."

1. The Court of Appeal concluded that once it is accepted that a hitherto unknown use of a (known) compound could be an invention (as has

been held in Europe and the United Kingdom), the *Patents Act* 1953 (NZ) should, if possible, be construed to have that effect, thereby discharging the obligations which New Zealand had undertaken by its accession to the TRIPs Agreement, particularly under Art 27(1). The Court of Appeal pointed out that a more logical approach, leading to the same result, would be to permit claims to extend to a method of treatment, by using the compound or composition, but to require from the patentee a disclaimer of any right to sue the medical practitioner.

United States of America

1. Article 1, §8, cl 8 of the Constitution of the United States empowers Congress to legislate:

> "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries".

1. Section 101 of the *Patents Act* 1952 defines patentable subject matter:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

1. The position in the United States has changed over time. Early decisions which held that methods of medical treatment (including surgery) of the human body were not patentable were distinguished or overruled in 1954 in *Ex parte Scherer*.

2. In *Scherer*, the Board of Appeals of the Patent Office stated:

> "[I]t cannot be categorically stated that all ... methods [of treatment of the human body for some medical or surgical purpose] are unpatentable subject matter merely because they involve some treatment of the human body."

1. In *Diamond v Chakrabarty*, it was decided that live, human-made microorganisms were patentable subject matter within the statutory requirements of the *Patents Act* 1952. This was because the bacterium was new and had "markedly different characteristics from any found in nature". In the course of delivering the opinion of the Court, Burger CJ stated that although §101 may have been intended to "include anything under the sun that is made by man", three implied exceptions, the laws of nature, physical phenomena and abstract ideas, constrained what was patentable.

2. A method or process of medical treatment of the human body, dependent on the laws of nature, will not be "patent-eligible" if a claim does no more than simply recite or describe, rather than apply, a law of nature. Absent claims, including method claims, applying a law of nature, even a medically significant discovery or breakthrough may fall within the laws of nature exception to patentability. For example, composition claims to a naturally occurring deoxyribonucleic acid (DNA) segment, focussing on the genetic information encoded in two genes associated with certain cancers, have been held to claim subject matter falling within the exception, even though such important and useful genes had never before been located, or isolated from surrounding genetic material.

3. It appears that significant numbers of patents have been granted in the United States in respect of methods of medical treatment of the human body (including surgery). Sanofi was able to point to an example where a method of treatment claim was in similar form to claim 1 of the Patent.

4. However, after an eye surgeon sued other surgeons for patent infringement in respect of a new technique for cataract surgery, the *Patents Act* 1952 was amended by the inclusion of §287(c), the effect of which is to permit the patenting of surgical methods to continue but to bar actions for patent infringement against medical practitioners (and "related health care entit[ies]") for "the performance of a medical or surgical procedure on a body".

Canada

1. Section 2 of the *Patent Act* defines an "invention" as "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter". It contains no express exclusion from patentability of methods of medical treatment of the human body.

2. The Supreme Court of Canada has held that such methods are not patentable. However, a novel use of a known compound is considered patentable subject matter. Applying that approach, in *Apotex Inc v Wellcome Foundation Ltd* the Supreme Court upheld a claim to the use of a known drug, AZT, in the following form:

> "A pharmaceutical formulation comprising an amount of (AZT) effective for the treatment or prophylaxis of an AIDS infection, in association with a pharmaceutically accepted carrier."

1. Canada's *Manual of Patent Office Practice* states that such "use" claims are permitted, as long as they do not include a medical or surgical step. For example, a claim to the "[u]se of compound Y as an

antiarrhythmic agent" is considered acceptable. However, a claim encompasses non-patentable subject matter when it "covers an area for which a physician's skill or judgment is expected to be exercised".

2. Sanofi submitted that in these overseas jurisdictions the subject matter of claim 1 would be patentable, either directly as a method of treatment or through one of the drafting devices referred to above.

Can methods of medical treatment of the human body be patentable inventions?

1. Claim 1, for a method of preventing or treating psoriasis, claims a hitherto unknown therapeutic use of a pharmaceutical substance which was first disclosed, together with prior therapeutic uses, in Patent 341 (now expired).

2. Apotex's submissions, derived from *obiter dicta* in the *NRDC Case*, that the subject matter of claim 1 is "essentially non-economic" must be rejected.

3. First, in the context of patent law, the expression "essentially non-economic" takes its meaning from the long-understood requirement that the subject matter of a patent (whether a product, or a method or process) must have some useful application, that is, must be capable of being practically applied in commerce or industry. A requirement that an invention have "economic utility" raises the same considerations as the requirement in the *Patents Act* 1977 (UK) and the EPC that an invention must be susceptible or capable of industrial application. So much is apparent from the definition of "exploit" in the 1990 Act, referring to products and to methods or processes, and the case law developed and applied for a very long time in respect of the requirement of utility, now found in ss 18(1)(c) and 18(1A)(c).

4. Secondly, the 1990 Act contains no specific exclusion from patentability of methods of medical treatment of the human body, nor can any be implied. Section 133, which provides for compulsory licensing, is in general terms and covers both patented articles and patented methods or processes. Section 70, providing for extensions of term in respect of pharmaceutical substances that are defined in terms of effects on the human body, infers that patents which claim a method of treatment of the human body can be granted, but not extended. Section 119A, the operation of which has been explained above, defines a "pharmaceutical patent" to include method patents for using or administering a pharmaceutical substance.

5. Parliament accepted the IPAC's recommendation that the 1990 Act

should not include a codification of requirements for patentability. Section 119A, described above, was introduced in 2006. It can be noted that Parliament has amended the 1990 Act 24 times since its enactment, including 20 times since the TRIPs Agreement entered into force on 1 January 1995. Relevantly, amendments to the 1990 Act following the TRIPs Agreement did not enact Art 27(3) into Australian domestic law. That Article gives contracting States the option to exclude methods of medical treatment of the human body from patent protection. However, to construe s 18(1)(a) of the 1990 Act as excluding methods of medical treatment of the human body would be to introduce a lack of harmony between Australia and its major trading partners, where none exists at present.

6. Thirdly, as noted by the primary judge in *Rescare Ltd v Anaesthetic Supplies Pty Ltd*, there is no normative distinction to be drawn from the provisions of the 1990 Act between methods of treatment of the human body which are cosmetic and those which are medical.

7. Fourthly, and critically, the subject matter of a claim for a new product suitable for therapeutic use, claimed alone (a product claim) or coupled with method claims (combined product/method claims), and the subject matter of a claim for a hitherto unknown method of treatment using a (known) product having prior therapeutic uses (a method claim), cannot be distinguished in terms of economics or ethics. In each case the subject matter in respect of which a monopoly is sought effects an artificially created improvement in human health, having economic utility. It could not be said that a product claim which includes a therapeutic use has an economic utility which a method or process claim for a therapeutic use does not have. It could not be contended that a patient free of psoriasis is of less value as a subject matter of inventive endeavour than a crop free of weeds. Patent monopolies are as much an appropriate reward for research into hitherto unknown therapeutic uses of (known) compounds, which uses benefit mankind, as they are for research directed to novel substances or compounds for therapeutic use in humans. It is not possible to erect a distinction between such research based on public policy considerations.

8. Fifthly, leaving aside, for the moment, the relevant *obiter dicta* in the *NRDC Case*, a method claim in respect of a hitherto unknown therapeutic use of a (known) substance or compound satisfies the general principle laid down in the *NRDC Case*. Such a method belongs to a useful art, effects an artificially created improvement in something, and can have economic utility. The economic utility of novel products and novel methods and processes in the pharmaceutical industry is underscored by s 119A of the 1990 Act and by their strict regulation in the *Therapeutic Goods Act* 1989 (Cth) ("the TGA").

9. Sixthly, while not determinative of the construction issue, the practice of the Australian Patent Office, following *Joos* (which practice was in evidence in *Rescare*, and about which there was no negative evidence led in this case), is consonant with Art 27(1) of the TRIPs Agreement.

10. Seventhly, the *obiter dicta* in the *NRDC Case*, upon which Apotex relied, conveys some hesitation about "putting aside" methods of treatment of the human body. That hesitation arose in circumstances where this Court was not called upon to decide whether the position under the 1952 Act, in relation to methods of medical treatment of humans, differed from the position in the United Kingdom under the *Patents Act* 1949 (UK) and case law in the United Kingdom following *Re C & W's Application*. In other respects, the decision in the *NRDC Case* diverged from the case law in the United Kingdom, not only in respect of a "vendible product" requirement for a patentable process, but also in respect of the eligibility of agricultural products for patenting. The *obiter dicta* plainly refers to medical treatments, which are readily distinguishable from therapeutic uses of pharmaceutical substances as defined in the 1990 Act.

Conclusion on patentability

1. Assuming that all other requirements for patentability are met, a method (or process) for medical treatment of the human body which is capable of satisfying the *NRDC Case* test, namely that it is a contribution to a useful art having economic utility, can be a manner of manufacture and hence a patentable invention within the meaning of s 18(1)(a) of the 1990 Act.

2. There is, however, a distinction which can be acknowledged between a method of medical treatment which involves a hitherto unknown therapeutic use of a pharmaceutical (having prior therapeutic uses) and the activities or procedures of doctors (and other medical staff) when physically treating patients. Although it is unnecessary to decide the point, or to seek to characterise such activities or procedures exhaustively, speaking generally they are, in the language of the *NRDC Case*, "essentially non-economic" and, in the language of the EPC and the *Patents Act* 1977 (UK), they are not "susceptible" or "capable" of industrial application. To the extent that such activities or procedures involve "a method or a process", they are unlikely to be able to satisfy the *NRDC Case* test for the patentability of processes because they are not capable of being practically applied in commerce or industry, a necessary prerequisite of a "manner of manufacture".

3. Apotex's claim for revocation of the Patent, on the ground that claim 1 does not disclose a patentable invention, cannot succeed and should stand dismissed.

Construction of claim 1

1. Claim 1 is recognisably a claim limited to the specific purpose of preventing and treating psoriasis. Given the prior art, any novelty and inventive step reposes in, and is confined to, that hitherto unknown therapeutic use of leflunomide. The compound (with prior therapeutic uses) was disclosed in Patent 341. The monopoly granted in respect of claim 1 is limited to the purpose (hitherto undiscovered) for which the (known) compound can be used.

2. Drawing on jurisprudence in Europe and the United Kingdom, Apotex contended that in Australia, a hitherto unknown therapeutic use of a substance (having prior therapeutic uses) is not a manner of manufacture. This appeared to be a reinvigorated attack on novelty, or a suggestion of obviousness, in the guise of a s 18(1)(a) objection, stimulated by the construction of claim 1 favoured by the primary judge. Reliance was placed on the circumstance that there is no equivalent in the 1990 Act to sub-ss (3) and (4) of s 4A of the *Patents Act* 1977 (UK), which "deem" novel known substances and compounds in respect of their first and subsequent (hitherto unknown) therapeutic uses. Those deeming provisions are the legislative response in the United Kingdom to the express exclusion from patentability of pharmaceutical method patents, from which the 1990 Act is free.

3. Novelty of purpose can confer novelty even if a substance is known, a principle determined in the *NRDC Case*, which can be seen in the relevant passages extracted above. Provided a hitherto unknown therapeutic use of a pharmaceutical substance or compound can satisfy the requirements of novelty and inventive step and is not obvious, such a use can be an invention within the meaning of s 18(1)(a) of the 1990 Act, irrespective of whether it is a first or subsequent novel use.

4. It is true, as noted above and as contended by Apotex, that a claim in a patent specification limited to a hitherto unknown use of a substance (with prior therapeutic uses) may pose difficulties in the context of infringement, as observed by Lord Hoffmann in the *Merrell Dow Case*. Nevertheless, for the reasons given, Apotex's second attack on the validity of claim 1 of the Patent must also be rejected.

Infringement

1. Infringement proceedings may be brought to enforce the exclusive rights granted to a patentee under s 13 of the 1990 Act to "exploit" an invention, as that term is defined in Sched 1, for the term of the patent. Infringement is determined by reference to those exclusive rights.

2. Claim 1, for a hitherto unknown therapeutic use of a pharmaceutical substance (having prior therapeutic uses), is limited to the purpose of treating or curing psoriasis and cannot be directly infringed by the exploitation of leflunomide for the treatment of PsA.

3. However, Sanofi's claim of infringement rests on s 117 of the 1990 Act, headed "Infringement by supply of products", which sets out the conditions under which a supply of a product will constitute an infringement of an indirect or contributory kind. Section 117 relevantly provides:

> "(1) If the use of a product by a person would infringe a patent, the supply of that product by one person to another is an infringement of the patent by the supplier unless the supplier is the patentee or licensee of the patent.
>
> (2) A reference in subsection (1) to the use of a product by a person is a reference to:
>
> (a) ...
>
> (b) if the product is not a staple commercial product—any use of the product, if the supplier had reason to believe that the person would put it to that use; or
>
> (c) in any case—the use of the product in accordance with any instructions for the use of the product, or any inducement to use the product, given to the person by the supplier or contained in an advertisement published by or with the authority of the supplier."

1. The TGA must also be considered in the context of the claim of infringement under s 117. The TGA provides for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia, whether produced in Australia or elsewhere, or exported from Australia. "Therapeutic goods" are goods likely to be taken to be for "therapeutic use", which is, in turn, defined to include use in or in connection with "preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons". Therapeutic goods which are entered on the ARTG are taken to be "separate and distinct" from other therapeutic goods if they have "a different name", "different indications", or "different directions for use", amongst other things.

2. Section 23(2)(ba) of the TGA provides that an application for registration or listing of therapeutic goods on the ARTG, in the case of a

restricted medicine (which leflunomide is), must be accompanied by product information in the form approved under s 7D. Appendix 8 of the Therapeutic Goods Administration's *Australian Regulatory Guidelines for Prescription Medicines* (2004) (which the parties agreed were applicable) stated that a product information document:

> "is to present a scientific, objective account of the medicine's usefulness and limitations as shown by the data supporting the application. It is to be devoid of promotional material."

1. In relation to its supply of Apo-Leflunomide, Apotex's approved product information document contains the following statements:

> "INDICATIONS
>
> Apo-Leflunomide is indicated for the treatment of:
>
> - Active Rheumatoid Arthritis.
>
> - Active Psoriatic Arthritis. Apo-Leflunomide is not indicated for the treatment of psoriasis that is not associated with manifestations of arthritic disease."

1. As mentioned, the primary judge held that despite those instructions, Apotex's approved product information document instructed rheumatologists to use leflunomide to treat psoriasis, thus engaging s 117(2)(c) of the 1990 Act.

2. Turning to s 117, the legislative history of that section was outlined by this Court in *Northern Territory v Collins*. The difficulties of enforcing a patentee's rights against indirect or contributory infringers under the common law rules, described by Dixon J in *Walker v Alemite Corporation*, were also considered by the IPAC report, to which reference has already been made. Recommendation 33 of the report, subsequently accepted, stated that "in general the supply of goods *whose only use would infringe a patent*, or which are accompanied by *a positive inducement* for the ultimate consumer to perform actions which would innocently or knowingly infringe a patent should itself be an infringement of the patent" (emphasis added). Whether a supply of a product is an infringement under s 117 depends on the nature of the product and the use or uses to which it is put.

3. A decision of the Supreme Court of the United States, *Dawson Chemical Co v Rohm & Haas Co*, is illustrative of the scope of s 117(2)(b) and (c) of the 1990 Act and was used by the IPAC to illustrate the need for relieving a patentee from indirect or contributory infringement. The patentee in *Dawson* (the respondent on appeal to the Supreme Court) owned

a patented method claim for the use of an unpatented product to inhibit the growth of certain weeds. The appellants supplied the unpatented product to persons (which was not a direct infringement of the method patent) with instructions to apply the product in accordance with the patented method. Unanimously, the United States Court of Appeals for the Fifth Circuit found that the appellants' conduct constituted contributory infringement of the patent. That finding was not disputed on appeal to the Supreme Court.

4. Having regard to the definition of "exploit" in relation to a "method" in the 1990 Act, which must be read with s 117, a person who supplies Apo-Leflunomide, but does not use the patented method to do any act set out in the definition of "exploit" referable to method patents, does not directly infringe the method patent. It is difficult to understand how the supply of an unpatented product, the use of which by a supplier would not infringe a method patent, can give rise to indirect infringement of a method patent by a recipient of the unpatented product from the supplier. The difficulty reflects the prior art and Sanofi's limited novelty in the hitherto unknown therapeutic use of the pharmaceutical substance, which is the claimed subject matter of the Patent.

5. Further and separately, as an item registered on the ARTG, Apo-Leflunomide is a therapeutic good registered for its indicated uses, which specifically exclude use of the patented method identified in claim 1. In light of the provisions of the TGA, to which reference has been made, the expression "indication" in the product information document is an emphatic instruction to recipients of Apo-Leflunomide from Apotex to restrict use of the product to uses other than use in accordance with the patented method in claim 1. Apotex's approved product information document does not instruct recipients to use the unpatented pharmaceutical substance, which it proposes to supply, in accordance with the patented method, and therefore the product information document does not engage s 117(2)(c) of the 1990 Act.

6. For the purposes of the application of s 117(2)(b), it was not shown, nor could it be inferred, that Apotex had reason to believe that the unpatented pharmaceutical substance, which it proposes to supply, would be used by recipients in accordance with the patented method, contrary to the indications in Apotex's approved product information document.

Conclusion on infringement

1. For the reasons given, Apotex's proposed supply of Apo-Leflunomide does not engage s 117(2)(b) and (c). Thus, Sanofi's claim of infringement, resting on s 117 of the 1990 Act, fails.

Orders

1. We would make the following orders.

Matter No S1 of 2013

Appeal dismissed with costs.

Matter No S219 of 2012

1. Special leave to appeal on ground 3 of the Draft Notice of Appeal filed on 10 September 2012 granted.

2. Appeal allowed with costs.

3. Set aside the orders of the Full Court of the Federal Court of Australia made on 18 July 2012 and, in their place, order that:

   (a) the appeal be allowed in part;

   (b) orders 2, 3 and 6 of the Federal Court made on 18 November 2011 be set aside;

   (c) order 1 of the Federal Court made on 24 February 2012 be set aside; and

   (d) so much of the Amended Application dated 22 September 2009 as made in paragraphs 14 to 22 be dismissed.

4. Remit the matter to the Full Court on the questions of the costs of the appeal to that Court and the costs of the trial (which latter question may, at the discretion of the Full Court, be remitted to the primary judge).

1. GAGELER J. *National Research Development Corporation v Commissioner of Patents* ("*NRDC*") held that a process must have "two essential qualities" to be recognised as a manner of manufacture within the meaning of s 6 of the *Statute of Monopolies* 1623 (21 Jac I c 3). First, the process must result in an "artificially created state of affairs". Secondly, that resultant state of affairs must have "its own economic utility".

2. *NRDC* suggested, without deciding, that "processes for treating the human body may well lie outside the concept" of a manner of manufacture "because the whole subject is conceived as essentially non-economic". Underlying that suggestion was a reluctance to characterise as having economic utility a state of affairs, created by treatment of the human body, which might in different gradations be described as an "improvement in ... physical welfare" or as "relief of suffering".

3. *NRDC* nevertheless emphasised: that the purpose of s 6 of the *Statute of Monopolies* was to "encourage national development"; that "a widening conception" of manner of manufacture "has been a characteristic of the growth of patent law"; and that any attempt to fetter the exact meaning of manner of manufacture was "unsound to the point of folly".

4. The evolution of the conception continued. The suggestion that *all* processes for treating the human body might lie outside the concept of a manner of manufacture did not survive *Joos v Commissioner of Patents*. The holding in *Joos* was that a process which produced a cosmetic result lay within the concept of a manner of manufacture. Whether processes for treating the human body which produced therapeutic or prophylactic results lay inside or outside the concept of a manner of manufacture remained undecided. Neither party to this appeal suggested that *Joos* was wrongly decided at the time or that its precise holding should now be revisited.

5. When s 18(1)(a) of the *Patents Act* 1990 (Cth) ("the Act") incorporated the concept of a manner of manufacture within the meaning of s 6 of the *Statute of Monopolies* into the definition of a "patentable invention" for the purposes of the Act, the holding in *Joos* represented the minimum extent to which the conception of a manner of manufacture within the meaning of s 6 of the *Statute of Monopolies* had relevantly developed.

6. Whether *all* processes for treating the human body ought now to be recognised as within the concept of a manner of manufacture within the meaning of s 6 of the *Statute of Monopolies* as incorporated by s 18(1)(a) of the Act, other than those specifically excluded by s 18(2)-(4) of the Act, need not be determined.

7. The principal issue in the appeal can be resolved by asking and answering a narrower question. That narrower question is whether a process of using a pharmaceutical product to produce a therapeutic or prophylactic result ought now to be recognised as within that concept as so incorporated.

8. The seven reasons given by Crennan and Kiefel JJ for concluding that methods of medical treatment of the human body can be patentable inventions persuade me to answer that narrower question "yes". The fourth reason is to me the strongest. Black CJ and Lehane J gave it in *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* in the form of a rhetorical question: "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?" Where the new form of treatment is use of another pharmaceutical product, I can think of no satisfactory answer. In particular, I know of no reason for thinking in principle (and am aware of no data

which suggest) that such net national economic benefit as might potentially result from the availability of a patent would be greater in the case of a patent for a pharmaceutical product than in the case of a patent for a process by which another pharmaceutical product is used to produce the same therapeutic or prophylactic result.

9. To the seven reasons given by Crennan and Kiefel JJ, I would add an eighth. Irrespective of the weight now to be accorded to the earlier administrative practice to which Crennan and Kiefel JJ point, an affirmative answer to the question whether a process of using a pharmaceutical product to produce a therapeutic or prophylactic result ought to be recognised as within the conception of a manner of manufacture within the meaning of s 6 of the *Statute of Monopolies* as incorporated by s 18(1)(a) of the Act was given unequivocally and unanimously by the Full Court of the Federal Court in 2000 in *Bristol-Myers Squibb*. As Bennett and Yates JJ emphasised in their joint reasons for judgment in the decision under appeal, the position reached in *Bristol-Myers Squibb* has since been regarded as "representing orthodoxy in Australian patent law". That judicially sanctioned orthodoxy was assumed in the framing of the definition of "pharmaceutical patent" in s 119A of the Act, introduced into the Act in 2006. Now to substitute a negative answer would depart from that orthodoxy; disappoint commercial expectations legitimately formed and acted upon for at least 13 years; undermine the legislative assumption made seven years ago; and render the current legislative definition in part redundant.

10. I also agree with Crennan and Kiefel JJ in relation to the separate issue of construction in the appeal and in relation to the issue of infringement raised by the application for special leave to appeal. I therefore join in making the orders their Honours propose.