Bristol-Myers Squibb Co v F H Faulding & Co Ltd [2000] FCA 316

FEDERAL COURT OF AUSTRALIA

BLACK CJ, LEHANE AND FINKELSTEIN JJ

BLACK CJ AND LEHANE J:

1 This appeal concerns two petty patents for methods of administering taxol. Taxol has been known, for about three decades, to have anti-carcinogenic properties. It inhibits the division of cancer cells. Other drugs used in the treatment of cancer have that effect also; taxol, however, does so by a mechanism that differs from the way in which other drugs inhibit cell division. Consequently, taxol has for many years been recognised as potentially efficacious where other drug treatments have failed.

2 There are, however, considerable difficulties with the use of taxol in the treatment of cancer. One difficulty is its scarcity. It is a naturally occurring compound extracted from the bark or the needles of the western, or Pacific, yew. Extraction is a slow process and taxol is not plentiful. Secondly, taxol is relatively insoluble in water and is administered (there was no evidence of any other possible mode of administration) in a mixture of Cremophor EL and dehydrated ethanol. Thirdly, taxol is highly toxic: among its side effects are toxicity of the blood (particularly, neutropenia) and of the nervous system (peripheral neuropathy). Additionally, the administration of taxol was found frequently to produce hypersensitivity reactions, often severe reactions: this may have been due either to the Cremophor or to the taxol itself.

3 The appellant was the proprietor of the two petty patents in suit, No. 641894 and No. 651307. They were sealed on 30 September 1993 and 14 July 1994 respectively. The term of the former expired on 29 January 1999; the term of the latter expired on 15 December 1999. The priority date of each was 3 August 1992. Both were granted under the *Patents Act 1990* (Cth) (the "1990 Act").

4 The claims of the earlier patent were:

> *"1. A method for administration of taxol to a patient suffering from cancer comprising infusing from 135 to 175 mg/m^2 of taxol over a duration not exceeding 6 hours.*
>
> *2. The method of claim 1, wherein said administration comprises infusion of 135 mg/m^2 of taxol.*
>
> *3. The method of claim 2, wherein the duration of said infusion is not greater than 3 hours."*

The claims of the later patent were:

> *"1. A method for treating cancer in a patient suffering therefrom including infusing from 135 to 175 mg/m^2 of taxol over a duration less than 6 hours wherein said method results in a reduction of hematological toxicity and neurotoxicity compared with infusing greater than 170 mg/m^2 of taxol over a duration of 24 hours.*
>
> *2. A method according to claim 1 wherein said method includes infusing 175 mg/m^2 of taxol.*
>
> *3. A method according to claim 1 or claim 2 wherein said method includes infusing said taxol over a duration not exceeding 3 hours."*

The complete specifications of the two patents were substantially identical. It will be necessary to consider some aspects of them later.

5 This is an appeal from a decision of a judge of the Court (Heerey J) in proceedings in which the appellant claimed that the respondent, in circumstances which we shall describe later in these reasons, infringed both patents. The respondent, by cross-claim, sought orders that the patents be revoked on the grounds that they disclosed no invention, that the method claimed was not a "manner of manufacture", that the alleged invention lacked novelty and an inventive step and that the claims were not fairly based on the complete specifications. His Honour, in reasons reported at (1998) 41 IPR 467, upheld the cross-claim, holding that each patent was invalid on each of the grounds pressed by the respondent. He held also that, if the patents had been valid, they would not have been infringed. The appellant attacks his Honour's conclusion on each issue; the respondent supports the judgment on all issues and, by notice of contention, seeks to rely on additional matters going to obviousness and fair basing.

6 It is convenient to deal with other factual matters in the course of considering the various grounds on which his Honour held the patents to be invalid and the question of infringement.

Manner of manufacture: "generally inconvenient"?

7 As the learned trial judge pointed out, the question whether a method of medical treatment of the human body is patentable was discussed extensively by each of the members of the Full Court in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 (*Rescare*). The examination of the question in that case included a review by Lockhart J of cases in Australia, New Zealand, the United Kingdom, Canada, the United States of America, Germany and Israel.

8 Having reviewed the authorities, Lockhart J concluded (at 18):

> *"I am not aware of any case in Australia where a process for the treatment of a human ailment or disease has arisen for consideration. In the* NRDC *case* [National Research Development Corporation v Commissioner of Patents (1959) 102 CLR 23(NRDC)] *the judges expressed in very tentative language their doubts about its patentability. The English cases, particularly* Schering, Eli Lilly *and* Upjohn *do not provide a satisfactory basis on which to halt the development of the law relating to patentability and processes for medical treatment. In* Schering *a distinction was drawn between a contraceptive process and medical treatment. In* Joos [Joos v Commissioner of Patents (1972) 126 CLR 611] *Barwick CJ distinguished the application of a substance to improve the strength of the hair and nails on the ground that it was not treatment to arrest or cure disease or a diseased condition or the correction of some malfunction or amelioration of some incapacity or disability. I agree with Davison CJ* [in Wellcome Foundation Ltd v Commissioner of Patents (1979) 2 NZLR 591] *that in both cases the courts established distinctions without a difference, in order to allow a patent. Both cases were ones where clinical substances were applied to the human body, in one case externally and in the other internally. In both cases the chemical produced a result in a changed condition of the body.*
>
> *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. *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. I agree with Davison CJ that the test enumerated in the* NRDC *case is whether the invention 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."

9 Lockhart J also observed that there is no statutory provision in Australia prohibiting the grant of a patent for a process of medical treatment, and that it was noteworthy that Parliament had the opportunity to exclude methods of treating the human body when it enacted the 1990 Act, but that the limit of the exclusion was s 18(2), namely:

"Human beings and the biological processes for their generation, are not patentable inventions".

10 Wilcox J (at 42) agreed with the reasons for judgment of Lockhart J and added comments of his own explaining why he considered that "in the unusual circumstances of this case" dicta of members of the High Court in *Maeder v Busch* (1938) 59 CLR 684 at 705-706 and 707, and *NRDC* at 270, should not be given the weight they would ordinarily command. He pointed out, too, that there had never been an actual decision by an Australian court to the effect of *Re C and W's Application* (1914) 31 RPC 235 and that Patent Office practice in this country had been to grant patents for methods of medical treatment. We should note here that, in his judgment at first instance, Gummow J also gave careful consideration to what had been said by members of the High Court before he rejected the submission that claims for a method of medical treatment of the human body were not patentable: see *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1992) 111 ALR 207 at 233-239.

11 On the appeal in *Rescare*, Sheppard J also gave full consideration to the question, but he came to a conclusion contrary to that of Lockhart J and Wilcox J. In the present case the trial judge agreed with, and adopted as a matter of principle, much of what Sheppard J said in *Rescare* at 40-41.

12 Accepting for present purposes that the conclusions of Lockhart J and Wilcox J in *Rescare* are not part of a ratio of the case, so that the primary judge was free to depart from them and that this Full Court is also free to decide the question on that basis, we are nevertheless of the opinion that we should act in accordance with the views of the majority.

13 In the only substantial consideration of this important question in Australia, prior to its consideration in the present case, four members of this Court gave very close attention to whether a method of medical treatment of the human body is patentable according to

Australian law, and three of them concluded that it is. That is the clear preponderance of opinion at appellate level. The consideration given to the question in this Court is quite recent and it has not been suggested to us that cases decided since 1994, here or elsewhere, throw further light on the controversy. The passing reference to the question in *Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Ltd* (1998) 194 CLR 171 at 190 does not, we think, do so.

14 We agree with the primary judge that the close historical, geographical, social and economic relationship of Australia and New Zealand make it a desirable policy objective in itself that, in important areas of commercial law, the law of the two countries be consistent and, as he pointed out, the New Zealand Court of Appeal in *Wellcome Foundation Ltd v Commissioner of Patents* [1983] NZLR 385 decided against patentability. In his judgment at first instance in *Rescare*, however, Gummow J drew attention to the fact that the considerations that moved the New Zealand Court of Appeal in that case are not all applicable to Australian circumstances (see at 238) and this is, of course, an important consideration. We note, too, that Gummow J added that, in any event, in his opinion the reasoning in the judgment of Davison CJ at first instance had the advantage of greater cogency and was closer to that of Barwick CJ in *Joos v Commissioner of Patents* (1972) 126 CLR 611.

15 It is in those circumstances that we consider that we should adopt and apply the view of the majority in *Rescare*: a view reached after a close and persuasive analysis of principle authority. In taking this course, we are fortified by two considerations. The first of these is what seems to us to be the insurmountable problem, from a public policy viewpoint, of drawing a logical distinction which would justify allowing patentability for a *product* for treating the human body, but deny patentability for a *method* of treatment: see per Davison CJ in *Wellcome Foundation Ltd v Commissioner of Patents* (above) at 620 and per Gummow J in *Rescare* 111 ALR 205 at 238. This seems particularly the case where, as here, the claim is for an invention for the administration of a product.

16 The second compelling consideration is the very limited extent to which the Parliament dealt with patents with respect to the human body when it enacted the 1990 Act, bearing in mind, too, that it did so at a time when the long-standing practice in Australia was

(as we are informed it still is) to grant patents for methods of medical treatment of the human body.

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

18 For those reasons, in our view the learned primary judge was in error in holding that the petty patents in suit were invalid on the ground of general inconvenience.

Invention; "manner of new manufacture"; inventive step

19 A "patentable invention" must be an "invention" as defined, and thus a "manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the *Statute of Monopolies*". The primary judge held, following *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1995) 183 CLR 655, that the opening words of s 18(1) impose a threshold requirement of inventiveness: a requirement independent of the specific provisions of s 18(1)(b) as to novelty and an inventive step, judged by comparison with the prior art base as it existed before the priority date. His Honour held that the claimed invention (we use that expression to refer to the invention claimed in each of the petty patents in suit) did not meet that threshold requirement. He held also that it did not involve an inventive step when compared with the prior art base. His Honour's conclusions were based upon two findings. One of them involved an application of the well known principle which denies patentability to a claimed invention which is "nothing but a claim for the use of a

known material in the manufacture of known articles for the purpose of which its known properties make that material suitable": *Commissioner of Patents v Microcell Ltd* (1959) 102 CLR 232 at 251. His Honour said at 477:

> *"At the priority date the material (taxol) had been known for many years. It is a naturally-occurring compound and thus in itself unpatentable. In the words of the specification, taxol had 'shown great promise as an anti-cancer drug' and 'been found to be an active agent against drug-refractory ovarian cancer' ... . The properties which made taxol effective against cancer, that is to say its biological mechanism, were well known. They had been discussed in the articles referred to in the specification which were 'incorporated by reference as if reproduced in full below' ... . Thus the specification is not merely a claim of a 'new use of an old substance' (*Re BA's Application *(1915) 32 RPC 348 at 349,* Mirabella*, 183 CLR at 661) but a claim for the* ***same*** *use of an old substance."*

The primary judge, at 477, expressed his other finding as follows:

> *"Further, the specifications disclose that the claimed inventions were the product of routine testing which merely verified a hypothesis arising from analysis of reports of earlier trials: see* WR Grace & Co v Asahi Kasei Kogyo Kabushiki Kaisha *(1993) 25 IPR 481 at 497-498.*
>
> *By using the term 'routine' I do not wish to be taken as in any way disparaging the skill and effort which obviously went into* [the study leading to the claimed inventions]. *But the petty patents in suit do not claim any method of scientific investigation or analysis. On their face they claim a particular dosage over a particular period of a substance known to be effective, in a known way, for the treatment of cancer, a dosage and a period arrived at by the 'ordinary methods of trial and error which involve no inventive step ...':* Van der Lely NV v Bamfords Ltd *[1963] RPC 61 at 71 per Lord Reid, cited with approval in* Nicaro Holdings Pty Ltd v Martin Engineering Co *(1990) 91 ALR 513 at 530 per Gummow J (with whom Jenkinson J agreed)."*

20 Nothing in the more recent decision of the High Court in *Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Ltd* (1998) 194 CLR 171 detracts from the binding effect, in this Court, of the decision in *Philips*. *Ramset* fell to be decided under the *Patents Act 1952* (Cth) (the "1952 Act"); the Court distinguished *Philips* on the basis that there were significant differences between the 1990 Act and its predecessor, so that *Philips* was not determinative of a question arising under s 100 of the 1952 Act. It is necessary, therefore, to ascertain precisely what was decided in *Philips*. The essence of the decision is, we think, to

be found in the following passage in the judgment of the majority, at 663, 664 (omitting citations of authority):

> *"The effect of those opening words of s 18(1) is that the primary or threshold requirement of a 'patentable invention' is that it be an 'invention'. Read in the context of s 18(1) as a whole and the definition of 'invention' in the Dictionary in Sch 1, that clearly means 'an alleged invention', that is to say, an 'alleged' 'manner of new manufacture the subject of letters patent and grant of privilege within s 6 of the Statute of Monopolies'. In the light of what has been said above about what is involved in an alleged manner of new manufacture, that threshold requirement of 'an alleged invention' will, notwithstanding an assertion of 'newness', remain unsatisfied if it is apparent on the face of the relevant specification that the subject matter of the claim is, by reason of absence of the necessary quality of inventiveness, not a manner of new manufacture for the purpose of the* Statute of Monopolies. *That does not mean that the threshold requirement of 'an alleged invention' corresponds with or renders otiose the more specific requirements of novelty and inventive step (when compared with the prior art base) contained in s 18(1)(b). It simply means that, if it is apparent on the face of the specification that the quality of the inventiveness necessary for there to be a proper subject of letters patent under the Statute of Monopolies is absent, one need go no further."*

The majority, at 663, rejected an argument:

> *"... that the fact that a claimed use is 'nothing but ... a new use of an old substance' and therefore 'outside the whole scope of what is known as an invention' under traditional principles of patent law will not of itself preclude it from being a proper subject of letters patent under the Act."*

21 Secondly, at 664, 665, the majority said:

> *"It is true that it can be argued that there is internal tension in an overall legislative scheme which imposes a threshold requirement of inventiveness reflecting the effect of the saving clause in s 6 of the* Statute of Monopolies *and then proceeds, if that threshold requirement be satisfied, to impose more specific requirements of novelty and inventive step. It seems to us, however, that there are several answers to that argument. One is that there is no construction of s 18(1) of the Act which is not susceptible of some legitimate criticism. Another is that traditional patents law under s 6 of the Statute of Monopolies long recognised cumulative requirements of an element of invention (as distinct, from, eg, mere discovery or analogous use) in the subject matter as described by the specification and novelty or newness as disclosed by comparison with a prior art base. The distinctive requirements of novelty and inventive step required by s 18 of the Act are emphasised by their elaboration in s 7. In that regard it may be noted that in the* 1952 Act *one of the grounds for revocation of a patent was that the invention 'was obvious and did not involve an inventive step, having regard to what was*

> *known or used in Australia' (s 100(1)(e)). More important, it seems to us to be highly unlikely that it was the legislative intent that there should be a significant alteration of the law as explained in* Microcell *by extending the ambit of a patentable invention so as to include what is 'nothing more' than 'the use of a known material in the manufacture of known articles for the purpose of which its known properties make that material suitable'. In that regard, we do not accept the argument on behalf of* Philips *that* Microcell *was decided on the question of newness and not on manner of manufacture."*

22 Thirdly, their Honours observed, at 667, that "… it would border upon the irrational if a process which was in fact but a new use of an old substance could be a 'patentable invention' under s 18 if, but only if, that fact were not disclosed by the specification". But, as the majority explicitly acknowledged, at 666, that observation was unnecessary to their decision. Fourthly, and finally, special leave to appeal had been granted on the basis that the sole issue on the appeal was the true construction of s 18(1)(a), including the opening words of s 18(1). Thus, the Court was not called upon to consider the correctness of the finding of the Full Court of this Court, that the claims of the patent in suit were indeed for nothing but a use of a known product for a purpose for which its known properties made it suitable.

23 It is important also to remember that the effect of the decision of the High Court in *Philips* was to affirm the decision of the Full Court (*NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1993) 44 FCR 239). There is no doubt that the majority of the Full Court (Lockhart J, with whom Northrop J agreed) drew what they perceived to be a clear distinction between obviousness or want of inventive step (s 18(1)(b)(ii)) and want of inventiveness sufficient to characterise the subject matter of a patent as a manner of new manufacture. So, at 263, Lockhart J said:

> *"Although grounds of objection in patent law sometimes overlap, objections of want of novelty and obviousness are nevertheless essentially distinct from each other. Likewise, the requirement that a patentable invention be a manner of new manufacture is inherently distinct from the requirements of novelty, lack of obviousness, involving an inventive step and utility as required by s 18 of the 1990 Act."*

And the point emerges clearly from the following observation of Lockhart J at 265:

> *"Many of the submissions made by counsel for the appellants on this point blurred the distinction between the requirement that the invention be a manner of new manufacture and obviousness. The respondent did not press its case at the trial (nor therefore on appeal) on obviousness, no doubt, at least in part, because the respondent could not establish that what is*

described in the evidence as the Vrenken Article was common general knowledge in Australia."

In other words, what cannot be established not to involve an inventive step, by reference to common general knowledge in Australia at the priority date, may nevertheless exhibit a want of the quality of inventiveness which is part of the concept of manner of new manufacture.

24 Four comments may be made. First, the proposition that "inventiveness" means in one context something quite distinct from the connotation, in the other, of "inventive step" (or lack of obviousness) is not easy to reconcile with the analysis of Gummow J, with whom Jenkinson J agreed, in *R D Werner & Co Inc v Bailey Aluminium Products Pty Ltd* (1989) 25 FCR 565 at 593, 599-601. Secondly, so far as the reasoning of Lockhart J depended (see at 263) upon regarding the 1990 Act as having made no relevant change in the law (a view with which it is easy to sympathise, given s 100(d) of the 1952 Act), the distinction between the two aspects of inventiveness having existed under the 1952 Act, that foundation appears to have been removed by *Ramset*. Thirdly, Lockhart J (upholding the primary judge) appeared to have looked solely at the specification in order to ascertain what was "known", for the purposes of the *Microcell* principle, though his Honour appears to have relied on other evidence as to aspects of the quality of inventiveness. Fourthly, and perhaps most importantly, little guidance is offered as to how one ascertains whether a claimed invention has the quality of inventiveness necessary to characterise it as a manner of new manufacture.

25 Just as it is not easy to see how one can describe something as new or novel except by reference to what has previously been made, done or published, we cannot see how inventiveness can be judged except by reference to a body of prior knowledge and from the standpoint of someone who has that knowledge. The question, then, is what knowledge, in whose possession, is relevant to the question whether the "inventiveness" component of "manner of new manufacture" is present?

26 It is important, we think, to recognise that the present separate requirements of novelty and an inventive step (s 18(1)(b)(i) and (ii)) themselves result from a process of development, both through the cases and in successive statutes, of the language of the *Statute of Monopolies*. The history is traced by Gummow J in *R D Werner* at 594-601 and need not be repeated. The ground of revocation, and now of opposition to grant, encapsulated in the terms "want of subject matter", "obviousness" and "lack of inventive step", is itself a

development and refinement of the language of the *Statute of Monopolies*. If one were still to apply the language used by Lord Esher MR in 1894 – "when you consider it, you come to the conclusion that it is so easy, so palpable, that everybody who thought for a moment would come to the same conclusion; or, in more homely language, hardly judicial, but rather business like, it comes to this, it is so easy that any fool could do it" (*Edison-Bell Phonograph Corp Ltd v Smith* (1894) 11 RPC 389 at 398) – the question would remain, what is the prior body of knowledge which makes it so easy? In *Philips*, Lockhart J said at 265:

> *"As mentioned earlier the expressions 'manner of new manufacture' and 'manner of manufacture' in this branch of law under the 1990 Act mean the same thing and involve the same concepts as they have been understood and developed since 1623 when the* Statute of Monopolies *was passed."*

But, with respect, that begs the question, which are the developments referred to? The modern notions of novelty and obviousness represent, as we have said, developments of the concepts in the Statute. Is there a *tertium quid?* If so, what precisely is it? It might, perhaps, be supposed that, by preserving the requirement of inventiveness incorporated in "manner of new manufacture", Parliament intended that there be two cumulative requirements, one reflecting the law as it had developed up to some statutory intervention – perhaps in 1952, perhaps in 1990 – the other reflected in the elaborate provisions of s 7(2) and s 7(3), read with the dictionary in Sch 1, of the 1990 Act. Where, however, the judicial and statutory development of the law are as interwoven as they have been in patent law, such a suggestion encounters great difficulty.

27 *Philips*, as we read it, does not provide a comprehensive answer to the question, by reference to what body of knowledge is that inventiveness judged? It holds, clearly, that the requirement of inventiveness is not satisfied in a case where the claims are for nothing more than the use of a known material in the manufacture of known articles for a purpose for which that material's known properties make it suitable. The majority judgment of the High Court in *Ramset* points out, at 192, two aspects of that proposition which are, we think, relevant to the present case. One is that the principle that "a claim for 'nothing but' a new use of an old substance lacked the quality of inventiveness" had emerged in the course of the development, during the nineteenth century, of "the doctrine with respect to obviousness and lack of inventive step"; the other is that, if an application for a patent claiming nothing but a new use of an old substance (to adopt the majority's shorthand) proceeded to grant, the grant

– under the 1952 Act – would have been liable to revocation under s 100(e) (obviousness) not s 100(d) (not an invention: that is, not a manner of new manufacture). In other words, the relevant ground of revocation being obviousness, the relevant body of knowledge was "what was known or used in Australia on or before the priority date of [the] claim": that is, common general knowledge, in the relevant field of endeavour, in Australia: *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd (*1980) 144 CLR 253 at 295.

28 *Microcell* was an appeal from a refusal by the Commissioner of Patents to accept an application and complete a specification. The Court held, at 246, that "[it] must be enough to warrant rejection that it should be clear on its face that the specification discloses no inventive step". Their Honours proceeded to hold that the specification in suit disclosed no such step. It is interesting to note, in passing, that their Honours used the phrase "inventive step", the terminology both of s 100(e) of the 1952 Act (which did not apply to the application before the Court: it was required to be considered under the *Patents Act 1903* (Cth)) and s 18(1)(b)(ii) of the 1990 Act. The claims were for the manufacture of self-propelled rocket projectors, using synthetic resinous plastic material reinforced with mineral fibres. The Court's conclusion was expressed at 251 as follows:

> *"We have in truth nothing but a claim for the use of a known material in the manufacture of known articles for the purpose of which its known properties make that material suitable. A claim for nothing more than that cannot be subject matter for a patent, and the position cannot be affected either by the fact that nobody thought of doing the thing before, or by the fact that, when somebody did think of doing it, it was found to be a good thing to do."*

The foundation of that conclusion, however, appears in the following paragraph, at 250:

> *"Here the specification does not on its face disclose more than a new use of a particular known product. To use Lord Buckmaster's words, no new product is obtained, and there is no new method of manufacture suggested or an old one improved. Tubular self-propelled-rocket projectors were at the relevant time well-known articles of manufacture. Synthetic resinous plastics reinforced with mineral fibres, and in particular polyester plastics reinforced with glass or asbestos fibres, were well-known materials. These things are to be gathered from the specification itself, which contains no suggestion of novelty in relation to the article to be manufactured or the material to be used. It further appears from matter published in Australia as early as 1946 that the reinforced plastic materials referred to in the specification had been used in the manufacture of a wide variety of articles. The properties of those materials were known generally, and in particular it was well known that they possessed that combination of great strength and lightness wherein,*

according to the specification itself, lies their virtue for the purpose in hand. The matter published in 1946 refers to their 'extraordinary strength in relation to weight' – they are 'stronger for their weight than steel' – and to their high tensile strength – another quality which the specification regards as a virtue for the purpose in hand. It was well known too that they possessed high impact strength and high resistance to heat. In these circumstances we do not think it can be said, merely because it does not seem previously to have occurred to anyone to make a rocket projector out of reinforced plastic, that any inventive idea is disclosed by the specification."

29 That passage makes it quite clear that the lack of inventive step appeared on the face of the specification. It makes it clear also that the conclusion that there was no inventive step was reinforced by a consideration of material earlier published in Australia, information in which was "well-known" and "known generally". Although the language used by the Court differs somewhat from the formulation adopted by Aickin J in the *Minnesota* case, the substance of the Court's finding was that what was apparent on the face of the specification was reinforced by proof that particular information had passed into common general knowledge, in the relevant field, in Australia.

30 The majority of the High Court in *Philips* explicitly say that their observations about a case where want of the threshold requirement of inventiveness is not apparent on the face of the specification are not necessary to their decision. And, in discussing the commencement point (what is "known") of the inquiry about inventiveness, their Honours refer only to the *Microcell* principle. In our view, in the light of the authorities to which we have referred, *Philips* stands for the proposition (as a matter of construction of the 1990 Act) that if, on the basis of what was known, as revealed on the face of the specification, the invention claimed was obvious or did not involve an inventive step – that is, would be obvious to the hypothetical non-inventive and unimaginative skilled worker in the field (*Minnesota* at 260 per Barwick CJ) – then the threshold requirement of inventiveness is not met. Some elaboration, however, is required in relation to what the specification reveals as "known". If a patent application, lodged in Australia, refers to information derived from a number of prior publications referred to in the specification or, generally, to matters which are known, in our view the Court – or the Commissioner – would ordinarily proceed upon the basis that the knowledge thus described is, in the language of s 7(2) of the 1990 Act, part of "the common general knowledge as it existed in the patent area". In other words, what is disclosed in such terms may be taken as an admission to that effect. In substance, we think, that is what happened, both in *Microcell* and in *Philips*. If, however, the body of prior knowledge

disclosed by the specification is insufficient to deprive what is claimed of the quality of inventiveness, then the only additional knowledge or information which will be taken into account is knowledge or information of a kind described in s 7(2) of the 1990 Act. That again, in our view, is consistent with the approach taken in *Microcell*. It is also, with respect, the only approach which does not, in practical terms, render s 18(1)(b)(ii) otiose. Of course, once that additional knowledge is taken into account, one is applying s 18(1)(b)(ii), not the opening words of s 18(1) – unless, perhaps, one might apply either, there being, in this respect, no difference between them.

31 The findings of the trial judge as to the failure of the claims to meet the threshold requirement of inventiveness relied, as to what was known and as to the studies leading to the claimed invention, only upon what is disclosed in the specifications. The specifications reveal, as his Honour pointed out, that both the efficacy of taxol as an anti-carcinogenic (particularly in relation to drug-refractory ovarian cancer) and the mechanism of its action were known. His Honour found, accordingly, that the claimed invention was not merely a claim for a new use for an old substance (his Honour's shorthand) but a claim for the same use of an old substance, thus failing the *Microcell* test. In our opinion, however, that formulation overlooks two things. One is that the claim is for a method, not a product; the other is the importance of the phrase "nothing but" in the *Microcell* principle: as to both points, see *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, especially at 262. Taxol may, if used in accordance with the claimed invention, be used for a purpose for which its known properties make it suitable; it does not follow that the method claimed does not involve an inventive step. Nor, if the method was proved to be efficacious by a routine process of trial and error (the authorities cited by his Honour have to do with how much, in order to destroy novelty, an anticipation must reveal), does it follow that the claimed invention is obvious or does not involve an inventive step: what matters is whether, to the skilled but unimaginative worker in the field, the claimed method was obvious in the sense that the worker, not necessarily seeing that the method was likely to be safe and efficacious, would have seen that it was one which justified investigation.

32 Because, for the reasons we have given, we respectfully disagree with the primary judge's approach to this part of the case, it is now necessary that we consider the

specifications for ourselves. The section entitled "background of the invention" begins as follows:

> *"Taxol is a naturally occurring compound which has shown great promise as an anti-cancer drug. For example, taxol has been found to be an active agent against drug-refractory ovarian cancer by McGuire et al. See 'Taxol: A Unique Anti-Neoplastic Agent With Significant Activity Against Advanced Ovarian Epithelial Neoplasms,'* Ann. Int. Med., *111, 273- 279 (1989). All patents, scientific articles, and other documents mentioned herein are incorporated by reference as if reproduced in full below.*
>
> *Unfortunately, taxol has extremely low solubility in water, which makes it difficult to provide a suitable dosage form. In fact, in Phase I clinical trials, severe allergic reactions were caused by the emulsifiers administered in conjunction with taxol to compensate for taxol's low water solubility; at least one patient's death was caused by an allergic reaction induced by the emulsifiers. Dose limiting toxicities include neutropenia, peripheral neuropathy, and hypersensitivity reactions."*

33 The article by McGuire and others, referred to in the first paragraph, describes also taxol's "unique" mechanism of action. The specifications proceed to discuss a good deal of literature concerning taxol, particularly a number of reports of Phase I and Phase II clinical trials (the purpose of a Phase I trial is to ascertain a safe dose limit; a Phase II trial tests for efficacy under particular treatment regimes, within the safe limit established by Phase I trials). What the specifications say is not altogether easy to follow, because their account of the teaching of the various articles quoted is, in many cases, somewhat abbreviated and the writings are not discussed in chronological order, so that it is difficult to see the way in which expert thinking about the administration of taxol evolved during the period covered by the writings, from 1986 to 1991. For example, the specifications report this:

> *"Since early trials using a bolus injection or short (1-3 hour) infusions induced anaphylactic reactions or other hypersensitivity responses, further studies were carried out in which taxol was administered only after premedication with steroids (such as dexamethasone), antihistamines (such as diphenhydramine), and H_2-antagonists (such as cimetidine or ranitidine), and the infusion time was extended to 24 hours in an attempt to eliminate the most serious allergic reactions. Various Phase I and Phase II study results have been published utilising 24-hour infusions of taxol with maximum total dosages of 250 mg/m^2, generally with the course being repeated every three weeks."*

34 Nevertheless, one of the most recent of the trials referred to, a Phase I trial reported in a July 1991 article by Brown and others, was one in which taxol was provided by a six-hour

infusion every twenty-one days without premedication. The authors reported that the incidence of hypersensitivity reaction was "schedule-dependent, 6 to 24-hour infusions of drug having a 0% to 8% incidence of hypersensitivity reactions". The specifications paraphrase the authors as reporting also "that hypersensitivity reactions persist with or without premedication despite prolongation of infusion times".

35 Among the matters which emerge from the writings quoted are that the toxicity of the drug limited the dose which could safely be administered, the maximum tolerated dose being about 275mg/m^2 ("m^2" refers to the surface area of the skin of the patient); the incidence of hypersensitivity reactions appeared to be substantially reduced by a combination of premedication and prolongation of the infusion period to six hours or longer; but none of the material reported the administration of the drug over a period of less than six hours with premedication; however it was unclear whether those reactions were caused by the taxol or the vehicle in which it was administered; and, because hypersensitivity reactions frequently occurred within a short period after the commencement of infusion, the proposition that lengthening infusion time minimised the likelihood of reaction was uncertain; and because of the relatively high number of the trials which had used a twenty-four hour infusion schedule, there was a lack of data as to the efficacy of infusion over a shorter period. The specifications continue:

> *"The conflicting recommendations in the prior art concerning whether premedication should be used to avoid hypersensitivity reactions when using prolonged infusion durations, and the lack of efficacy data for infusions done over a six hour period has led to the use of a 24-hour infusion of high doses (above 170 mg/m^2) of taxol in a Cremophor EL emulsion as an accepted cancer treatment protocol.*
>
> *Although it appears possible to minimise the side effects of administering taxol in an emulsion by use of a long infusion duration, the long infusion duration is inconvenient for patients, and is expensive due to the need to monitor the patients for the entire 6 to 24-hour infusion duration; further, the long infusion duration requires that patients spend at least one night in a hospital or treatment clinic."*

36 The matters, therefore, requiring to be addressed were the need to reduce the infusion period sufficiently so that both premedication and infusion could be completed during the course of a day, so that patients could be treated as outpatients; the consequent desirability of limiting infusions to a maximum of six hours while nevertheless providing sufficient taxol to

have the desired therapeutic effect, at the same time avoiding toxicity; the desirability of minimising premedication, to reduce both patient discomfort and the expense and duration of treatment; and the desirability of reducing doses, if possible, not only to reduce side effects but also to "extend the supply of taxol".

37 The objects of the invention are stated as follows:

> *"Therefore, it is a primary object of the present invention to provide a new method for administering taxol over a shorter period of time than the present 6 to 24-hour infusion protocols, while minimising toxic effects induced by the administration of taxol.*
>
> *It is another object of the present invention to provide a new method for administration of taxol which reduces the amount of taxol administered to a patient, without sacrificing the anti-neoplastic effects desired by administering taxol.*
>
> *It is yet a further object of the present invention to provide a new method for administration of taxol which utilizes both lower dosages of taxol and shorter infusion periods, without sacrificing the anti-neoplastic benefits of the administration of taxol."*

38 There follows a detailed description of the invention which, although it is lengthy, we think it is desirable to set out in full:

> *"Despite the conventional understanding that it is necessary to infuse patients over a 24-hour period with high dosages of taxol (greater than 170 mg/m^2) following premedication to minimize or eliminate hypersensitivity responses, while obtaining the desired anti-neoplastic effect, it has been surprisingly discovered that taxol can be safely administered to cancer patients via infusions lasting less than 6 hours at dosages of about 135 mg/m^2 to about 175 mg/m^2. In a preferred embodiment, taxol is administered via an infusion having a duration of about three hours, with a taxol dosage of about 135 mg/m^2 or about 175 mg/m^2. Of great significance is a surprising discovery that the short term infusion causes less myelosuppression, which leads to a lower incidence of infections and fever episodes (e.g., febrile neutropenia). Following the preferred infusion schedules of the present invention provides an objective response rate of greater than 10% for patients suffering from epithelial ovarian carcinoma, and preferably an objective response rate of 14% or greater for groups of at least 150 patients suffering from ovarian carcinoma.*
>
> *The surprising discovery that taxol could be safely administered via a short infusion (e.g., less than six hours and preferably over about 3 hours) means that it will now be possible to administer taxol on an out-patient basis, saving*

patients the time and expense of yet another hospitalization while improving patient quality of life.

It has also been surprisingly discovered that lower taxol dosages, such as about 135 mg/m^2 can be administered via infusions lasting about 3-hours to about 28-hours, and still be antineoplastically effective."

39 The specifications proceed to discuss the study from which the applications for the petty patents resulted. It was a randomised comparative study, conducted in a number of centres in Canada and Europe, of treatment with taxol of patients suffering from ovarian carcinoma who had previously been treated with platinum-based drugs. Each patient was assigned to one of four "arms". Those in Arm A were treated with infusions of 175mg/m^2 over twenty-four hours; those in Arm B with infusions of 175mg/m^2 over three hours; those in Arm C with infusions of 135mg/m^2 over twenty-four hours; and those in Arm D with infusions of 135mg/m^2 over three hours. All patients were premedicated to minimise acute hypersensitivity reactions.

40 What, then, was the outcome? As to response, complete or partial (reduction in tumour size), the specifications say:

"Thus, use of the present method for administration of taxol produces at least a 14% overall objective response rate for 157 patients. This is an astonishing result, since all of the patients were considered drug refractory. It is also remarkable that 3 out of 46 (7%) of these patients who had progressed on previous platinum containing chemotherapy responded to taxol. Overall, responses to taxol occurred in 13% of patients (14/114) who were considered resistant to platinum therapy ... . Further, 52% of patients (24/46) with disease truly refractory to platinum, and 53% of patients (16-36) with an early relapse after platinum, achieved a stabilization of their disease."

41 It may be noted in passing that the specifications do not distribute those results among the various treatment "arms". As for toxicity, the specifications record that serious neutropenia was five times more frequent among those patients infused over twenty-four hours than those treated with a three hour infusion; severe neutropenia was somewhat more prevalent in the high dose arms than in the low dose arms. Thus, we are told:

"... it is clear that both reducing the dosage and the infusion time will lower hematologic toxicity; however, reducing the infusion to 3 hours from 24 hours appears to have a greater impact on reducing toxicity than reducing the taxol dosage from about 175mg/m^2 to 135mg/m^2."

Peripheral neuropathy occurred more frequently in the high dose than in the lower dose arm, and somewhat more frequently in patients who received the 3 hour infusion than in those who were infused over 24 hours. Two patients suffered hypersensitivity reactions "which required acute therapeutic intervention". One was treated with 135mg/m^2 of taxol infused over twenty-four hours. It is not stated in which arm the other patient was treated. Less significant hypersensitivity reactions were experienced by some patients in all arms.

42 The results are summarised as follows:

> *"The success of the use of the new taxol infusion protocol of the present invention in the treatment of ovarian cancer makes it readily apparent that anti-neoplastically effective dosages of taxol can be infused over much shorter time periods than was previously believed possible, without inducing severe hypersensitivity reactions or inducing fatal anaphylactic shock. Thus, it is contemplated that the infusion protocol of the present invention may be utilized to treat solid tumors and leukemias, such as but not limited to lung cancer, breast cancers, and ovarian cancers. It is to be understood that treatment of different forms of cancer may require the adjustment of the taxol dosage to have optimal efficacy.*
>
> *The foregoing clearly establishes that taxol is both safe and effective in the treatment of cancer, such as ovarian cancer, when administered according to the protocol of the present invention. In particular, by use of a 3-hour infusion of about 135 mg/m^2 taxol, following premedication, a substantial reduction results in the frequency of myelotoxicity and neuropathy associated with the administration of taxol to patients suffering from cancer. Further, patients who exhibit severe hypersensitivity reactions can be rechallenged with taxol after treating the HSR symptoms by use of an infusion of about 24 hours or greater, preferably using a dosage of about 135 mg/m^2 to about 175 mg/m^2. Preferably, colony stimulation factors are administered to assist in ameliorating myelosuppression.*
>
> *The use of lower dosages of taxol to achieve antineoplastic results will allow for more patients to be treated with the present limited supply of taxol. Further, depending upon the toxicities noted in a patient during treatment with taxol according to the present protocol, the duration of infusion can be extended or shortened, or the taxol dosage can be reduced or increased, thus providing more flexibility in treating cancer with taxol. Further, patients capable of handling higher doses of taxol can be administered up to about 275 mg/m^2; should the patient encounter severe toxicity, such as a severe neuropathy, the protocol of the present invention allows for reducing the dosage.*
>
> *From the above teachings, it is readily apparent that many modifications and variations of the present invention are possible. It is to be therefore understood that the invention may be practiced* [sic] *than as otherwise specifically described."*

43 In order to determine whether the claimed invention had the necessary quality of inventiveness what must be asked, in our view, is whether in the light of the prior body of knowledge discussed in the specification, and given the desirability of treating patients as outpatients rather than admitting them overnight and, generally, of reducing cost and inconvenience, the skilled but non-inventive worker in the field would have seen that infusion over a period less than six hours (particularly, over three hours) with premedication, of approximately the doses actually selected for the trial, was worth trying. In answering that question, it must be borne in mind that "trying" was plainly a process which would involve considerable effort on the part of a large number of people, much expense and the subjection of patients, already very ill, to a form of treatment which, while it might in some cases produce some remission, was known to have the potential to cause very unpleasant, and sometimes life-threatening, side effects: the circumstances by no means resemble the example of the stainless steel sink referred to in *Microcell* at 248.

44 What can be gathered from the specification is that the previous teaching encouraged longer infusions (usually twenty-four hours, but certainly not less than six), doses at the upper end of, or above, the range claimed in the petty patents and premedication. Infusions of shorter duration had been tried, without premedication, and had been found unsatisfactory. Given that, frequently, hypersensitivity reactions occurred shortly after the commencement of an infusion, there was some doubt as to whether the infusion period was actually of much significance in relation to reactions of that kind. Nevertheless, it could not be said that there was anything in the teaching referred to which particularly encouraged a view that a three hour infusion of dosages within the range claimed would be safe and would work. The position was simply that the administration of taxol in that way had not (so far as the material referred to goes) been tried, with premedication, and there were several practical reasons why it was desirable to reduce infusion times if possible. Is the Court, armed with that knowledge, equipped with the hindsight against which authority warns (see *Minnesota* at 293) but otherwise on the basis of its own untutored understanding (particularly, without the benefit of expert evidence), to say that the claimed invention lacks inventiveness (would have been obvious to the skilled worker in the field)? In our view, we should be very slow to do so. If one puts aside the benefit of hindsight, how is the Court to know whether experts would have found what was tried obvious or, for reasons of which we know nothing, counter-intuitive? It is important to remember warnings (see, for instance, *CCOM Pty Ltd v*

Jiejing Pty Ltd (1994) 51 FCR 260 at 285) that "[the] Court should be careful to avoid assuming a technical expertise it does not have". We are not prepared to hold, on the material before us, that the quality of inventiveness was lacking.

45 Indeed, there is in our view an element of unreality, in a case such as the present, even in posing the question in that form. Although *Philips* suggests that there may be such cases (it does not decide the question, because obviousness was not pressed), it is not easy to envisage circumstances in which a claimed invention may lack the threshold requirement of inventiveness, but yet involve (for the purposes of s 18(1)(b)(ii)) an inventive step. This is not a case, like *Philips*, where there was no attack on the patents on the ground of obviousness. It was, instead, a case where expert evidence, including evidence as to common general knowledge, was available (and was given). Where the Court has evidence on the basis of which it can make a finding about common general knowledge, and the other information referred to in s 7(2) and s 7(3), and about what would or would not have been obvious to persons skilled in the relevant art, it must be only rarely that it will be appropriate to find (by resort to a "threshold test") lack of inventiveness on the face of a specification. In our opinion this is not a case where such a finding is justified.

46 We turn to the ground of obviousness. The trial judge's finding (at 484) on this issue was straightforward:

> *"There is a considerable, perhaps entire, overlap between the evidence on this issue and that on the issue of invention. Comparison with the prior art base referred to in the specifications discloses a lack of an inventive step, for the reasons already discussed."*

47 We accept that ordinarily, at least, it would follow that if there were no invention there would be no inventive step. Because, however, we respectfully disagree with his Honour's conclusions on the question of invention, inventive step, or obviousness, requires further consideration.

48 We have already referred several times, in passing, to s 7. It is desirable to set out sub-sections (2) and (3) in full:

> *"(2) For the purposes of this Act, an invention is to be taken to involve an inventive step when compared with the prior art base unless the invention would have been obvious to a person skilled in the relevant*

art in the light of the common general knowledge as it existed in the patent area before the priority date of the relevant claim, whether that knowledge is considered separately or together with either of the kinds of information mentioned in subsection (3), each of which must be considered separately.

(3) For the purposes of subsection (2), the kinds of information are:

(a) prior art information made publicly available in a single document or through doing a single act; and

(b) prior art information made publicly available in 2 or more related documents, or through doing 2 or more related acts, if the relationship between the documents or acts is such that a person skilled in the relevant art in the patent area would treat them as a single source of that information;

being information that the skilled person mentioned in subsection (2) could, before the priority date of the relevant claim, be reasonably expected to have ascertained, understood and regarded as relevant to work in the relevant art in the patent area."

49 The respondent sought to support his Honour's conclusion on obviousness by reference to an editorial by Rowinsky and Donehower published in the *Journal of the National Cancer Institute* in December 1991 (before the priority date). His Honour found that the editorial was an important review article, as it plainly is, written by respected authors. His Honour found that "[it] would have been read with interest by the hypothetical skilled addressee in early 1992 and regarded as reliable". The importance of the editorial was that it revealed the existence and nature of the trials which led to the claimed invention. Heerey J quoted, at 474, 475, the following passages from the editorial:

"Both addition of the pre-medication regimen and the scheduled change, however, were carried out at the same time. Therefore, the relative merits of each manoeuvre [in reducing hypersensitivity reactions] *are not entirely known. Further clinical trials should examine whether the 24-hour infusion which mandates hospitalisation, is necessary when the pre-medication regimen is given. This is one of the questions being evaluated in a European-Canadian study with a bifactorial design which is comparing 3- and 24-hour infusions at doses of 135 and 175mg/m^2 in patients with ovarian cancer. ...*

Nevertheless we are still in the dark at this juncture regarding the optimal therapeutic doses and the importance of a dose-response effect for taxol. The pivotal European-Canadian study mentioned above with a bifactorial design is currently attempting to address this issue in ovarian cancer by randomly assigning patients who have received previous platinum therapy to one of two

> *different taxol doses (135 and 175mg/m^2) and one of two different schedules (24- and 3- hour infusions). Still, the discrepancy between the two doses used in this trial may not be wide enough to detect a significant dose-response effect in a heavily pre-treated and overall drug refractory patient population."*

50 His Honour's finding about that editorial must be read with an earlier finding, at 471, to which senior counsel for the respondent referred us also:

> *"The field of cancer medicine is a global one. A number of eminent Australian specialists gave evidence in this case. It is apparent from their evidence that they travel regularly to attend overseas conferences and have access to overseas journals."*

51 It should be noted also that his Honour referred specifically to certain passages in the evidence, including oral evidence, in support of the proposition that the editorial would, at the relevant time, have been known to the hypothetical skilled addressee.

52 Senior counsel for the appellant submitted that the findings to which we have referred do not "go so far as to show that it is being held by his Honour to be part of the common general knowledge in the sense that it's known to persons working in the art and is treated by them as part of their basic common general knowledge". In our view, however, it is difficult to read his Honour's findings in any other way. If Australians working in the field customarily read major overseas literature (and it would be very surprising if they did not) and if, before the priority date, they read the editorial (as his Honour held that they would have) and believed it to be reliable (as, again, his Honour held that they would have) it is not easy to see what element is lacking without which it would not be right to describe the information in the editorial as being, from early 1992, part of the relevant common general knowledge. No such element was referred to in argument; we do not think there is one; and, consequently, we accept the submission made on behalf of the respondent.

53 Our difficulty, however, is that this is, as we have mentioned, a case in which there was a great deal of expert evidence. Some of that evidence was referred to in submissions, written and oral, but we have not considered all the evidence and do not think it would be appropriate for us to attempt to do so. Particularly in a case concerning a complex and specialised field of knowledge, we do not think it would be appropriate to make a finding that no inventive step was involved without an appreciation of the expert evidence – particularly

the totality of the evidence as to common general knowledge – as a whole. For that reason, if the trial judge's finding of invalidity could not be supported on other grounds, we would reluctantly conclude that the matter should be remitted to his Honour for further consideration of the ground of obviousness.

Novelty

54 It is a requirement of a patentable invention (s 18(1)(b)(i)) that, when compared with the prior art base as it existed before the priority date, it be novel. Section 7(1) describes the circumstances in which an invention is not to be taken to be novel:

> *"7 (1) For the purposes of this Act, an invention is to be taken to be novel when compared with the prior art base unless it is not novel in the light of any one of the following kinds of information, each of which must be considered separately:*
>
> *(a) prior art information (other than that mentioned in paragraph (c)) made publicly available in a single document or through doing a single act;*
>
> *(b) prior art information (other than that mentioned in paragraph (c)) made publicly available in 2 or more related documents, or through doing 2 or more related acts, if the relationship between the documents or acts is such that a person skilled in the relevant art in the patent area would treat them as a single source of that information;*
>
> *(c) prior art information contained in a single specification of the kind mentioned in subparagraph (b)(ii) of the definition of 'prior art base' in Schedule 1."*

55 It is not necessary to refer in detail to the definition of "prior art base" in the dictionary; it is sufficient to say that it includes information in a document publicly available anywhere in Australia.

56 The trial judge held that each of seven documents, all available in Australia before the priority date, deprived the claimed invention of novelty. The matter is best approached, we think, by taking the first five of those documents as the starting point. Each is a report of a Phase I trial of taxol. The first is an article written by Mark G Kris and other authors in the publication *Cancer Treatment Reports*, May 1986. It reported on trials at doses ranging from 15mg/m^2 to 230mg/m^2 and including 135mg/m^2 and 160mg/m^2. Taxol was infused over a

period of three hours. Toxicity and hypersensitivity reactions were observed; no therapeutic effects were noted. The authors concluded:

> *"Hypersensitivity reactions constitute a severe and unpredictable treatment-limiting toxicity for the present cremophor-containing formulation of taxol given on this schedule. Further studies are needed to see if pretreatment regimens, alternative schedules ..., or a reformulated preparation will permit the safe administration of this compound."*

57 The second of the reports, by Stephen M Longnecker and other authors, was published in *Cancer Treatment Reports*, January 1987. It described a liquid chromatographic assay method for the analysis of taxol concentrations in biological fluids. For the purposes of the trial, taxol was administered to groups of patients in doses ranging from 15mg/m^2 to 265mg/m^2, including 135mg/m^2 and 170mg/m^2. The duration of the infusions was six hours. The article did not report therapeutic effects and said little about safety. The third report was published in *Cancer Research* in May 1987. Its first named author was Peter H Wiernik. It reported a Phase I study, involving infusions over six hours, of doses ranging from 15mg/m^2 to 275mg/m^2, including 135mg/m^2 and 175mg/m^2. Although the purpose of the trial was, once again, to ascertain a safe dosage level, some clinical response was recorded in four of the patients, though none of the clinical responses, as tabulated in the paper, occurred at a dose within the range claimed in the petty patents. The authors reported observations which suggested "that a long duration of exposure may increase the efficacy of taxol as an antitumour agent" and consequently recommended a twenty-four hour infusion trial. Their recommended dose for a Phase II trial was 250mg/m^2.

58 The fourth article, by Ross C Donehower and others, was published in *Cancer Treatment Reports* in December 1987. Again the trial was directed primarily to safety, although partial clinical responses were noted in two cases. Infusions were administered initially over one hour, but because there was a high incidence of acute hypersensitivity reactions the duration was increased to six hours and patients were premedicated. Doses ranged from 15mg/m^2 to 265mg/m^2 and included 135mg/m^2 and 170mg/m^2. Toxicity appeared to occur more severely in patients who had already been heavily treated with other forms of therapy. The authors recommended doses of 170mg/m^2 and 212mg/m^2 for heavily and minimally treated patients respectively. Both the increase of the infusion period and aggressive premedication were reported to have substantially reduced the incidence of hypersensitivity reactions:

> *"The frequency and severity of acute reactions to taxol were similarly decreased, making further clinical development of this drug more realistic and worthwhile based on the antitumour activity seen. It does, however, seem prudent that initial Phase II studies of taxol with this or other schedules be conducted in institutions familiar with its use, and facilities should be readily available for the management of severe type I hypersensitivity reactions."*

59 Finally, there was an article by R B Lipton and others published in the journal *Neurology* in March 1989. The paper reported on two trials, one in which taxol was infused over twenty-four hours and the other involving six hour infusions. Doses ranged from 15mg/m^2 to 275mg/m^2. The trials were directed primarily to ascertaining the dosage at which neuropathy occurred. The results were summarised as follows:

> *"Neuropathic symptoms were not present in any patients treated with less than 200mg/m^2 of taxol. Fifty-five percent of patients treated with doses greater than or equal to 200mg/m^2 developed neuropathy, with more cases at the higher doses. Although the development of neuropathy is dose-dependent, the sample size is too small to conclude that the incidence of neuropathy increases proportionately with doses beyond 200mg/m^2."*

The authors' conclusion was cautious:

> *"Additional work is required to characterize the mechanism and spectrum of taxol neuropathy. This work will be of great significance if taxol realizes its promise as an antineoplastic agent. In addition, the relationship between taxol toxicity and neuronotrophic factors may yield fundamental insights about the role and regulation of microtubules in neuronal function."*

60 The trial judge, as we have mentioned, held that each of those papers disclosed the use of the claimed method. Some qualification of that finding is, in any event, required. In fact, only the first of the papers, Kris (1985), discloses the administration of taxol in a dosage and over a period falling within all the claims of each of the petty patents. None of the others discloses administration of taxol according to the method claimed in claim 3 of either petty patent (infusion of a duration not exceeding three hours). It may for present purposes be accepted that disclosure of an infusion period of six hours was substantial disclosure of the method claimed in the second petty patent, involving infusion "over a duration less than six hours", five hours and fifty-nine minutes being literally within the claim. Additionally, we accept, as his Honour held, that publication of a method of medical treatment may nonetheless be a disclosure when it takes the form of a report of clinical trials (although, since the trials in question were Phase I trials designed to test for safety rather than efficacy,

we are not sure about his Honour's statement, at 483, that "[it] is to be assumed that the medical practitioners involved are also treating their patients with a rational and ethical objective of alleviating their condition and would only continue treatment if there was a reasonable prospect of success"). The substantial question, however, is whether the mere disclosure, in the context which we have described at some length, that in the course of the trials doses had been administered literally according to the claims of the petty patents, deprived the claimed invention of novelty. As to that, the trial judge held, in substance, that it was necessary only to ask whether the method was disclosed with sufficient clarity and that in each case it was. It was not to the point that the information in any of the prior publications did not recommend to the skilled reader the utility of the method disclosed:

> *"The test is not whether such a reader would be persuaded by what is disclosed in the publication to work the invention. As already noted, there was much evidence from Bristol-Myers' witnesses to the effect that there was not enough data publicly available at the priority date to confirm that a three hour infusion period of taxol was safe. But disclosure of an invention is not a matter of scientific proof, nor warranty of effectiveness."*

61 In *Meyers Taylor Pty Ltd v Vicarr Industries Ltd* (1977) 137 CLR 228 at 235 Aickin J said:

> *"The basic test for anticipation or want of novelty is the same as that for infringement and generally one can properly ask oneself whether the alleged anticipation would, if the patent were valid, constitute an infringement."*

62 In the case of a paper anticipation the reverse infringement test cannot be applied literally. The hypothetical infringement arises not because of its publication but because someone hypothetically does, or makes, what it describes or suggests. And the words "basic" and "generally" are not to be overlooked. As Gummow J said (with the agreement with Jenkinson J) in *Nicaro Holdings Pty Ltd v Martin Engineering Co* (1990) 91 ALR 513 at 528:

> *"But Aickin J described this test only as 'generally' applicable. Where the alleged anticipation is a paper publication, particularly a prior patent specification, there may be ground for debate in a comparison with the specification in suit as to the presence of inessential integers and mechanical equivalents. ... There may also be dispute whether what has been disclosed sufficiently reveals an essential integer, in the light of the principles in Hill v Evans (1862) 4 De G F & J 288."*

A similar point was made by Lockhart J in *R D Werner* at 569.

63 It is necessary to turn to the judgment of Lord Westbury in *Hill v Evans* (1862) 4 De G F & J 288. Lord Westbury said at 300:

> *"The question then is, what must be the nature of the antecedent statement? I apprehend that the principle is correctly thus expressed: – the antecedent statement must be such that a person of ordinary knowledge of the subject would at once perceive, understand, and be able practically to apply the discovery without the necessity of making further experiments and gaining further information before the invention can be made useful. If something remains to be ascertained which is necessary for the useful application of the discovery, that affords sufficient room for another valid patent."*

And, at 301, 302:

> *"The invention must be shewn to have been before made known. Whatever, therefore, is essential to the invention must be read out of the prior publication. If specific details are necessary for the practical working and real utility of the alleged invention, they must be found substantially in the prior publication.*
>
> *Apparent generality, or a proposition not true to its full extent, will not prejudice a subsequent statement which is limited and accurate, and gives a specific rule of practical application.*
>
> *The reason is manifest, because much further information, and therefore much further discovery, are required before the real truth can be extricated and embodied in a form to serve the use of mankind. It is the difference between the ore and the refined and pure metal which is extracted from it.*
>
> *Again, it is not, in my opinion, true in these cases to say, that knowledge, and the means of obtaining knowledge, are the same. There is a great difference between them. To carry me to the place at which I wish to arrive is very different from merely putting me on the road that leads to it. There may be a latent truth in the words of a former writer, not known even to the writer himself; and it would be unreasonable to say that there is no merit in discovering and unfolding it to the world.*
>
> *Upon principle, therefore, I conclude that the prior knowledge of an invention to avoid a patent must be knowledge equal to that required to be given by a specification, namely, such knowledge as will enable the public to perceive the very discovery, and to carry the invention into practical use."*

64 Senior counsel for the appellant relied on those passages. He relied also on well known observations of Parker J in *Flour Oxidising Co Ltd v Carr & Co Ltd* (1908) 25 RPC 428. That case involved a claim for a process: conditioning flour by passing it "through an atmosphere containing a gaseous oxide of nitrogen or chlorine or bromine oxidising agent in

the gaseous or vapourised state" and an apparatus by which the process could be implemented. The claim was resisted on the basis that the patent was anticipated by two prior specifications, one for treating flour in a somewhat different atmosphere and for apparatus for that purpose, the other for treating substances such as flour by "subjecting the substances to be treated to the action of electricity whether in the form of rays from lamps, currents or sparks"; again, the patent illustrated apparatus said to be appropriate for performing that operation. Parker J found that the apparatus illustrated in each of the prior specifications might be used for the purpose of treating flour by the method claimed in the patent in suit. He held, however, that neither prior specification amounted to an anticipation. His Lordship said, at 457:

> *"But where the question is solely a question of prior publication, it is not, in my opinion, enough to prove that an apparatus described in an earlier Specification could have been used to produce this or that result. It must also be shown that the Specification contains clear and unmistakable directions so to use it."*

Parker J proceeded to hold that the directions in one of the earlier specifications taught directly against so using the apparatus and, as to the other (at 458):

> *"... though there is nothing in his Specification absolutely inconsistent with its being used as it has been in the Defendants' experiments, there are certainly no clear directions which would lead to such user."*

65 Similarly, in *Canadian General Electric Co Ltd v Fada Radio Ltd* (1930) 47 RPC 69 at 90, the Privy Council approved of the following statement by the trial judge:

> *"Where the question is solely one of prior publication, it is not enough to prove that an apparatus described in an earlier specification could have been used to produce this or that result. It must also be shown that the specifications contain clear and unmistakable directions so to use it."*

66 Senior counsel for the respondent relied on the decision of the Court of Appeal in *The General Tire & Rubber Co v The Firestone Tyre and Rubber Co Ltd* [1972] RPC 457, particularly two passages in the judgment at 485:

> *"If the earlier publication ... discloses the same device as the device which the patentee by his claim, so construed, asserts that he has invented, the patentee's claim has been anticipated, but not otherwise. In such circumstances the patentee is not the true and first inventor of the device and his claimed invention is not new ...*

> *... If the prior inventor's publication contains a clear description of, or clear instructions to do or make, something that would infringe the patentee's claim if carried out after the grant of the patentee's patent, the patentee's claim will have been shown to lack the necessary novelty, that is to say, it will have been anticipated."*

It is important to remember, however, that the Court also said this, at 486:

> *"If, on the other hand, the prior publication contains a direction which is capable of being carried out in a manner which would infringe the patentee's claim, but would be at least as likely to be carried out in a way which would not do so, the patentee's claim will not have been anticipated, although it may fail on the ground of obviousness. To anticipate the patentee's claim the prior publication must contain clear and unmistakable directions to do what the patentee claims to have invented ... . A signpost, however clear, upon the road to the patentee's invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee."*

67 What all those authorities contemplate, in our view, is that a prior publication, if it is to destroy novelty, must give a direction or make a recommendation or suggestion which will result, if the skilled reader follows it, in the claimed invention. A direction, recommendation or suggestion may often, of course, be implicit in what is described and commonly the only question may be whether the publication describes with sufficient clarity the claimed invention or, in the case of a combination, each integer of it. But in this case medical practitioners hardly needed to be told that it was possible to infuse a particular dose of taxol over three hours, or how to do it. Nor, equally obviously, is that the point of the claims. The claims of the earlier of the petty patents are for a method for administration of taxol to a patient suffering from cancer; the claims of the later one are for a method of treating cancer. In each case the method involves a particular regimen for the infusion of taxol. The context was that great difficulties had been encountered in using taxol, despite its known anti-carcinogenic properties, in the treatment of cancer, because of the drug's side effects. Each of the trials reported in the articles referred to was an investigation directed towards finding a solution of the difficulties: directed, particularly, to ascertaining safe dosage levels. But, though methods falling within the claims of the patents were used in each trial, none of the reports can be said to teach (a word which in this context encompasses direct, recommend and suggest) that which the petty patents claim.

68 Senior counsel for the respondent acknowledged that not every prior published description of a method falling within the claims would amount to an anticipation. He accepted that a mere speculation as to whether the method subsequently claimed would work would not, of itself, destroy novelty. With somewhat greater hesitation, he accepted that a mere proposal for a trial of the method claimed might not be an anticipation. But he submitted that, in any event, the circumstance that the methods of administration described in the articles had been put into effect in the Phase I trials necessarily meant that the reports anticipated the claims. He referred, in this context, to the decision of the House of Lords in *Bristol-Myers Company (Johnson's) Application* [1975] RPC 127. But there are several difficulties with that. Prior use, even if unwitting, of a chemical compound subsequently claimed is, as the authorities made clear, a different thing altogether: there is, of course, no question of what the use teaches. Secondly, the particular use (reported in the publications relied on here) cannot itself be relied upon as an anticipation (and it was not relied on), because it took place outside Australia; but, that being so, the fact that actual use is reported in a prior publication cannot, in principle, make any difference. The question is still, what does the prior publication teach? Each of the reports taught, no doubt, some useful things relating to the administration of taxol. But none of them taught the method of the claims.

69 For those reasons we respectfully disagree with the conclusion of the trial judge that each of the Phase I trial reports was an anticipation. In our view none of them was. That being so, it is necessary to turn to the other two prior publications relied on.

70 We have already referred to the earlier of those two publications, the December 1991 editorial by Rowinsky and Donehower in the *Journal of the National Cancer Institute*, entitled "Taxol: Twenty Years Later, the Story Unfolds". It will be recalled that that editorial recorded a decision by the National Cancer Institute that future trials should utilise twenty-four hour infusions, together with premedication, and mentioned that the trials, leading to the claimed invention, were in progress: it mentioned them as trials the results of which might indicate whether a twenty-four infusion was indeed necessary and throw some light on the optimum therapeutic dose of taxol, particularly in patients who had previously received other therapy. Applying the principles which we have discussed, that article is no more an anticipation than are the reports of the Phase I trials: it teaches the method no more than they do.

71 The last of the publications, however, is in our view a different matter. It is an abstract, the author of which was Dr W W ten Bokkel Huinink of the Netherlands Cancer Institute, Amsterdam. Dr ten Bokkel Huinink was involved in the joint European-Canadian trial which led to the claimed invention. He wrote:

> *"Toxicity of taxol so far consists of dose limiting neutropenia, general malaise, muscle cramps, alopecia and hypersensitivity reactions, maybe related to the carrier in so far used formulations: Cremophor. Due to these side effects and based on preclinical screening antitumor continues* [sic] *infusions of 24 hours have been used so far. Phase I and II studies revealed activity against cisplatin refractory ovarian cancer, breast cancer and lung cancer. Further studies to evaluate the feasibility of shorter infusion time, 3 hours versus 24 hours and a lower 135mg/m^2 versus a maximum tolerated dose of 175mg/m^2 are now in progress in relapsing ovarian cancer patients both in Canada and in Europe. Already more than 200 patients have been entered into this four-arm randomized, NCIC guided international study. Indeed, the 3 hours infusion time administration schedule proved to be feasible, if given concomitantly to profylactic* [sic] *measures as high dose dexamethasone, cimetidine and difenhydramine. This makes even outpatient treatment with this first available representative of this new class of antitumor agents possible. Major steps forward in medical oncology are rare. After doxorubicine in the seventies, and cisplatin and carboplatin in the eighties, taxol and its European pendant Taxotere ranks high to become the outstanding drugs of the nineties."*

72 It was submitted that it was necessary to decide the question of anticipation by reference to what the skilled reader would have drawn from the abstract; and we were taken to evidence that skilled readers would have treated the words "feasibility" and "feasible" in the abstract as referring to safety, not efficacy. Even if that is right, however, other aspects of the abstract must be taken into account. We are told that earlier studies had revealed taxol's "activity against" certain forms of cancer; that the point of the studies then underway was to evaluate the "feasibility of shorter infusion time" and a lower dose "versus a maximum tolerated dose of 175mg/m^2". We are told (apparently) that what the tests have already revealed "makes even outpatient treatment with this first available representative of this new class of antitumour agents possible". In other words, it is already known that taxol is effective against certain cancers; it is known that 175mg/m^2 is a maximum tolerated dose; the purpose of the trial is to test the feasibility of a three hour infusion of that dose and a smaller dose; and the three hour infusion has already proved feasible, so that outpatient treatment has been demonstrated to be possible. Prudent practitioners might well take the view that they would prefer to await the final outcome of the trials, both as to efficacy and as to safety,

before rushing to embrace the proposed method. But, in our view, there can be no serious doubt that the abstract teaches the shorter infusion period, with premedication, as a "treatment" of cancer. The necessary consequence, as it was conceded that the abstract was published in Australia before the priority date, is that the claimed invention lacked the novelty required by s 18(1)(b)(i). We note that that conclusion is consistent with the decision of the English Patents Court (to which we were not referred) concerning a similar European Patent (though on rather different evidence and under legislation which differs in significant respects from ours): *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253.

Section 40

73 So far as it relates to matters relied on by the respondent, s 40 provides:

> *"40 ...*
>
> *(2) A complete specification must:*
>
> *(a) describe the invention fully, including the best method known to the applicant of performing the invention; ...*
>
> *(3) The claim or claims must be clear and succinct and fairly based on the matter described in the specification."*

74 Heerey J found that the petty patents in suit contravened s 40. His Honour referred to a number of aspects of them. The first was the fact that the claim was for a method of administration to patients suffering from any form of cancer; but the trial involved patients suffering from one form of cancer only; in those circumstances, could the specifications be taken to disclose that the method might with equal confidence be applied to those suffering from any form of cancer? Secondly, the only short infusion duration tried was a three hour infusion, but the claims cover infusions (in one case) not exceeding six hours and (in the other) less than six hours. Thirdly, the method was claimed in the first petty patent to "comprise" and in the second to "include" infusing a specified dosage of taxol over a specified infusion period; the claims therefore included the administration of taxol in combination with other drugs, but no such combination was disclosed. His Honour, at 485, summed it up as follows:

*"Thus, having regard to the three features already mentioned, the petty patents effectively claim a monopoly for the use of taxol in **any** dosage in the range 135 to 175 mg/m^2 in combination with **any** other drug in the treatment of **any** cancer in **any** outpatient treatment."*

75 On appeal, the respondent supported his Honour's reasons and conclusion. Having filed an appropriate notice of contentions, it relied on the following additional matters:

"1.(a) The specification of each of the petty patents promises a new method of administration of taxol which utilises both lower dosages of taxol and shorter infusion periods without sacrificing the anti-neoplastic benefits of the administration of taxol.

(b) This involves a comparison between the anti-neoplastic effects of 135mg/m^2 over 3 hours and 175mg/m^2 over 24 hours.

(c) The specification provides no data to support that promise. In fact, the design and sample size of the reported trial were incapable of showing an absence of statistically significant sacrifice in anti-neoplastic benefit by use of the invention.

(d) The claimed benefit was, accordingly speculative.

(e) To the extent that any claim is for a method of treatment which purports to fulfil that promise of the specification:

(i) that method is not fully described in the body of the specification; further or alternatively,

(ii) that claim is not fairly based on the matter described in the specification.

(f) Further, the claims are not fairly based on the matter described in the specification because they include methods of treatment that do not achieve the promised benefit.

2. In the case of each of the petty patents the complete specification does not describe or fully describe a method of administration of taxol at dosages of either 135mg/m^2 or 175mg/m^2:

(a) over less than 3 hours;

(b) between 3 hours and 6 hours; or

(c) at 6 hours;

3.(a) The claims of petty patent 651307 include the requirements that the method 'results in a reduction of hematological toxicity and

neurotoxicity compared with infusing greater than 170mg/m^2 of taxol over a duration of 24 hours'.

(b) The body of the specification does not contain any description of such a reduction of neurotoxicity arising by reason of the use of the method claimed.

(c) In the premises, the claims of petty patent 651307:

(i) fail fully to describe the invention; further or alternatively

(ii) fail clearly to define the invention; further or alternatively

(iii) are not fairly based on the matter described in the specification."

76 Because we have concluded that the petty patents in any event fail for want of novelty, it is unnecessary for us to reach conclusions on the issues arising under s 40. In this case, though ordinarily we would prefer to reach a decision on each ground argued, we think it is preferable not to do so. Fair basing and sufficiency are by no means straightforward topics. That is demonstrated by the extended discussions by Full Courts of this Court in *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 51 FCR 260 at 275-285 and in *Leonardis v Sartas No. 1 Pty Ltd* (1996) 67 FCR 126 at 136-144. Each party filed written submissions which dealt in some detail with aspects of the s 40 issues; but they were dealt with only briefly in oral argument, which left some significant matters substantially unexplored.

77 The invention claimed is, after all, a very simple one. The fact (if it is the fact) that not every method of performing the invention will, for example, have a therapeutic effect on every kind of cancer would not mean that the specifications do not meet the requirement of "sufficiency" as ordinarily understood. Carr J, with whom the other members of the Full Court agreed, in *Patent Gesellschaft AG v Saudi Livestock Transport and Trading Company* (1997) 37 IPR 523 at 530, said:

> *"The specification contains a full description if it makes the nature of the invention plain to persons having reasonably competent knowledge of the subject and also makes it plain, to persons having reasonable skill, how to perform the invention."*

78 To an extent, at least, similar comments might be made in relation to fair basing. For example, in *Rehm Pty Ltd v Websters Security Systems (International) Pty Ltd* (1988) 81 ALR 79 at 94, 95, Gummow J said:

> *"It is important when dealing with 'fair basing' to bear in mind the different functions served by the body of a specification and the claims. As s 40 itself indicates, the task of the body of the specification is fully to describe the invention including the best method of performing it known to the applicant. The description primarily is addressed to 'all and sundry who may wish to construct the device after the patent has expired': ... . The function of the claims is to define the invention and mark out the ambit of the patentee's monopoly, and primarily is addressed to potential rivals: ... . The circumstance that something is a requirement for the best method of performing an invention does not make it necessarily a requirement for all claims; likewise, the circumstance that material is part of the description of the invention does not mean that it must be included as an integer of each claim. Rather, the question is whether there is a real and reasonably clear disclosure in the body of the specification of what is then claimed, so that the alleged invention as claimed is broadly, that is to say in a general sense, described in the body of the specification."*

79 Questions of fair basing may, no doubt, involve matters of degree (see, e.g., *Aktiebolaget Hässle v Alphapharm Pty Ltd* [1999] FCA 628 at par 200 and par 201): and there is a point at which matters of the kind relied on here by the respondent go to inutility (a ground of invalidity which the respondent does not raise) rather than lack of fair basing.

80 Beyond that, we shall confine ourselves to two particular aspects of this part of the case. One was not raised before us or, apparently, before the trial judge. That may perhaps be explicable by reference to some of the evidence to which we were not referred. It is that whereas the claims cover infusion of taxol in any vehicle and with or without premedication, the specification describes infusion in a Cremophor vehicle and with premedication; and it is made clear that premedication is thought appropriate to minimise hypersensitivity reactions caused, possibly, by the Cremophor. Presumably – all the evidence to which we were referred suggests it – the only means so far discovered of administering taxol is that which has been used in all the trials, despite the problems associated with it. But if a later inventor were to discover some other way of infusing taxol, which perhaps did not give rise to hypersensitivity reactions, administration in such a way ought not, we should think, be prevented by claims based on the specifications of the petty patents. So far as the commercial issues between the parties are concerned, perhaps it does not matter whether that

is so or not: but it may well be that claims which include administration in some other vehicle or without premedication are not, to that extent, fairly based on the specifications.

81 Secondly, while the word "comprising" used in the claims of the first petty patent may invite a narrower construction, in our view his Honour was right in construing the claims of the later petty patent ("… including infusing from 135mg/m^2 over a duration less than six hours") as extending to the administration of taxol, as claimed, in combination with other therapy. We are quite unable to see why the claims, to that extent, do not "[travel] beyond the matter disclosed in the specification": *Olin Corporation v Super Cartridge Co Pty Ltd* (1977) 180 CLR 236 at 240 per Barwick CJ.

Infringement

82 Because the facts relied on to establish infringement were those set out in an agreed statement of facts, it is convenient to start with the trial judge's summary, at 485, 486:

> *"Those facts concern Faulding's conduct in Australia in relation to a drug it marketed under the name Anzatax. The active ingredient of that drug is admitted to be taxol, which is also referred to as paclitaxel. To avoid confusion I shall continue to use the term "taxol", except for direct quotation from documents.*
>
> *Since 23 January 1995 Faulding sold and supplied taxol to doctors and hospitals in Australia, together with a product information guide. The guide, consisting of fourteen A4 pages, commences with information as to the properties of taxol. There is reference to the various forms of toxic reactions. Under the heading "Dosage and administration" details are given as to premedication and the following is stated (CB 4/1079):*
>
> > *'For the treatment of metastatic ovarian cancer or metastatic breast cancer, it is recommended that paclitaxel be used as a single agent at a dose of 175 mg/m^2. Paclitaxel should be administered as an intravenous infusion over 3 hours. The infusion should be repeated every 3 weeks as tolerated. Patients have tolerated treatment with up to nine cycles of paclitaxel therapy, but the optimal course of therapy remains to be established.'*
>
> *As at the date of the agreed statement of facts, taxol was approved under the Therapeutic Goods Act 1989 (Cth) in Australia only for use in the treatment of metastatic ovarian cancer and metastatic breast cancer, after failure of standard therapy.*

Also, in March 1993 Faulding publicly announced that it would supply taxol under the Special Access Scheme (SAS). Under the scheme, introduced in December 1992, it is possible for a patient with a prescription from his or her treating medical practitioner to gain access to a drug that has not yet received marketing approval from the Australian Therapeutic Goods Administration. If a practitioner forms a view that the patient is terminally ill, or seriously ill with a life threatening condition, the practitioner may, upon receiving the informed consent of the patient, advise the patient that the drug is not registered for marketing in Australia and complete an authority to supply form. This form identifies the drug, the patient, the dosage and duration of infusion. Faulding then supplies the hospital with taxol under SAS. There were 39 hospitals identified for the purposes of SAS. They are situated in every state and in the Australian Capital Territory.

The agreed statement of facts states (para 5) that Faulding:

> *'... undertook the supply of paclitaxel to hospitals under the SAS in conjunction with so-called 'protocols', although those were not clinical protocols.'*

The protocols are annexed to the agreed statement of facts. It is not quite clear who prepared them. They typically refer to a named 'principal physician' and a 'treatment centre' such as the Peter McCallum Cancer Institute in Melbourne. The 'drug sponsor' is a named company which is said to be a division of Faulding. In any event they include the statement:

> *'Taxol will be given as 135mg/m^2 or 175mg/m^2 as a continuous intravenous infusion for 3 hours every 3 weeks for a maximum nine courses.'*

It is also stated in the agreed statement of facts that Faulding 'arranged' two clinical trials in Australia in 1992 and two further clinical trials in 1994 in which taxol was administered. Faulding supplied taxol to various named centres 'so as to enable them to take part in the trials'. Clinical trial protocols were prepared. The protocols provided for a dose of 175 mg/m^2 and an infusion duration of 3 hours.

Bristol-Myers' final submissions included the assertion that the protocols for the two clinical trials in 1994 'were prepared by Faulding'. Paragraph 1 of the agreed statement of facts is cited as authority for that proposition but I doubt if the language of para 1 supports the assertion."

83 One qualification should be added. The appellant submitted that the trial judge was wrong in finding that it was not clear who prepared the protocols for the clinical trials, and senior counsel for the respondent did not suggest otherwise. The appellant's submission is, we think, clearly right. Paragraph 7 of the agreed statement of facts says:

> *"Clinical trial protocols TAX-8/94 and TAX-10/94 were prepared by FHF* [the respondent]. *Clinical trial protocols TAX-1/92 and TAX-2/92 were jointly prepared by FHF and the Peter MacCallum Cancer Institute."*

84 Use of taxol in accordance with the method recommended in the respondent's product information guide, and use in accordance with the protocols, would (assuming validity) infringe the petty patents. The question, in those circumstances, is whether the respondent infringed them.

85 The 1990 Act does not define infringement (cf *Copyright Act 1968* (Cth) s 36 and s 101). Section 13(1), however, provides that:

> *"Subject to this Act, a patent gives 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 word "exploit" is defined in the dictionary in Sch 1:

> *" 'exploit', in relation to an invention, includes:*
>
> *(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."*

Part 1 of Chapter 11 contains provisions which in some respects expand, and in others limit, the concept of infringement (that is, generally, the doing of an act, without the authority of the patentee, which the patentee has the exclusive right to do). Of those provisions, only s 117 is relevant for present purposes. It provides:

> *"117(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 a licensee of the patent.*
>
> *(2) A reference in subsection (1) to the use of a product by a person is a reference to:*

> *(a) if the product is capable of only one reasonable use, having regard to its nature or design – that use; or*
>
> *(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."*

86 The respondent supplied taxol in the ways stated in the agreed statement of facts. The question to be decided is whether the supply was an infringement. In submitting that an affirmative answer should be given to that question, the appellant relied both on par (b) and par (c) of s 117(2), though oral argument concentrated on par (c). There is a textual difficulty – which, given our conclusion about par (c), we do not need to resolve – with the suggested application of par (b). The use to which the appellant had reason to believe that the taxol which it supplied would be put was, in part, use in the treatment of patients with cancer and, in part, use in clinical trials involving patients suffering from cancer. It is not clear, we think, that the particular method by which it was expected to be used is properly to be described as the use to which it was to be put. If one were to ask, to what use is a therapeutic drug, prescribed for a patient, put, the answer might be: "It is to be taken to cure the patient's condition". It would not, perhaps, be: "It is to be taken three times daily, before meals."

87 Paragraph (c) raises a more complex question. The appellant's argument commenced with the uncontroversial proposition that use of taxol in accordance with the product information guide or the protocols would infringe the petty patents; the next step was that the guide and the protocols were instructions (in the sense of directions or recommendations) given by the respondent for the use of the taxol which it supplied, and we accept that proposition. Then, it was said, s 117(1) applied, having regard to the dictionary in subs (2), as follows:

> *"If the use of* [taxol] *by a* [medical practitioner]*, in accordance with any instructions for the use of taxol ... given to the* [medical practitioner] *by the* [respondent] *..., would infringe* [either of the petty patents]*, the supply of that* [taxol] *by* [the respondent] *to* [the medical practitioner] *is an infringement of the* [petty patent] *by the* [the respondent] *unless* [as was not the case] *the* [respondent] *is the patentee or a licensee of the* [petty patent]*."*

88 It may be said immediately that there is considerable force in that way of looking at it. It involves, after all, a literal application of the words of s 117. The respondent, however, contended for a different approach, the one adopted by Heerey J. According to that approach, the starting point is not s 117 but the definition of "exploit". Where an invention is a method or process, use of a product exploits the invention only if the product is one which results from use of the method or process. Section 117, the argument proceeds, is concerned only with a case where the use of a product by a person would infringe a patent (because the person, not the patentee or a licensee, exploited it); and, where the patent is for a method or process, that will not be so unless the product is one which results from the use of that method or process.

89 Authority favours the construction for which the respondent contends. Gummow J considered the point in *Rescare*. It was submitted, in that case, that the supply of certain devices (themselves allegedly infringing products), with instructions for use, was itself an infringement of a method claimed by the supplier. Gummow J said, at 154:

> *"The difficulty with that proposition is that a pre-condition to the operation of s 117 in relation to a method claim such as claim 9, is that there is a product the use of which by the respondent would infringe claim 9. In other words, that user would have to amount* [to] *an 'exploitation' within the monopoly conferred by s 13, which is to be read with para (b) of the definition of 'exploit'.*
>
> *As I have indicated, where the invention relevantly claims a method or process, exploitation occurs, other than by use of the method or process, only by the doing of an act mentioned in para (a) of the definition of 'exploit'. There must be an act done 'in respect of a product resulting from such use'. Here, the respondent urges, and I agree, there is no such product with the result that, in a case such as the present, s 117 has no operation."*

Gummow J compared the position with that which arises under the rather different provision of the 1977 United Kingdom legislation.

90 It was submitted by the appellants that Gummow J's reasoning was limited to the particular type of case with which he was dealing (one where the device supplied was an "allegedly infringing device" and where the apparatus supplied might be used to alleviate either of two conditions, one falling within the claims, the other not), was not of general application and could be distinguished. We do not accept that argument. Gummow J

expressed himself in general terms. The relevant claim (claim 9 of the patent of which his Honour was concerned) was not distinguishable, for present purposes, from the claims of the petty patent: claim 9 read:

> *"A method of treating snoring and/or obstructive sleep apnoea in a patient comprising: applying air through a nose piece at a pressure maintained slightly greater than atmospheric substantially continuously throughout the breathing cycle."*

Thus, as here, the method claimed involved using an article or product, not one resulting from the use of the method, in a particular way.

91 On appeal, the Full Court held that the patent was wholly invalid and, therefore, it was not necessary to consider questions of infringement. Sheppard J, accordingly, did not consider the construction of s 117. Lockhart J said, at 24:

> *"The last remaining point is whether the primary judge erred in holding that s 117 of the 1990 Act did not apply in relation to the alleged infringement of claims 9 and 11 in that he held that it was a precondition to the operation of that section in relation to a method claim that there be a product the use of which would infringe that method claim. In my opinion his Honour decided that question correctly."*

Wilcox J, in this respect, simply agreed with the reasons given by Lockhart J. In *Sartas No. 1 Pty Ltd v Koukourou & Partners Pty Ltd* (1994) 30 IPR 479 Gummow J reiterated, at 495, the view which he had expressed in *Rescare*.

92 In those circumstances the trial judge followed the view expressed by Gummow J and affirmed by the Full Court in *Rescare*. However, there can be no doubt that the observations of Lockhart J, with which Wilcox J agreed, were unnecessary to the decision in *Rescare* and they were made without elaboration and in passing: they are obiter in the true sense of the word. In the circumstances, and as the matter has been argued before us, we think it is open to us to examine the question of construction for ourselves and, because of the importance of the matter, desirable that we do so. The first thing to be said is that if the views expressed in *Rescare* are right, s 117 has a very limited operation: perhaps, no practical operation at all. If the invention is a product, then to hire, sell, or otherwise dispose of it is to "exploit" it and therefore exclusively the right of the patentee. It is not easy to imagine circumstances in which the supply of a product is not a sale, hire, or disposal of it. If so, the supplier who, by

operation of s 117, is an infringer is an infringer in any event, as one who "exploits". It is equally difficult to see what practical operation s 117 would have in relation to an invention which is a method or process, the use of which results in a product. If the product supplied is that which results from the use of the method or process, then the position is exactly the same as that where what is supplied is a patented product. If, on the other hand, the product supplied is one the use of which in the patented method or process results in some new product, then the case is no different from that where use of a patented method or process does not result in any product; an application of the construction preferred in *Rescare* would, as a matter of logic, require the conclusion that s 117 could not make the supply an infringement. Hence our opening comment: the *Rescare* construction leaves s 117 virtually, if not completely, otiose.

93 The second thing to be said is that it seems clear that s 117 was not meant by its framers to have the limited meaning given to it in *Rescare*. The report of the Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia*, 1984, dealt with contributory infringement in par 14.2. That paragraph begins as follows:

> *"A patentee may encounter serious difficulty in enforcing his patent where it is prone to infringement by an eventual consumer who is supplied by an unauthorised person with the means to infringe.*
>
> *For example, a process patent for using a selective herbicide which is a known chemical would be infringed by a farmer who bought a container and followed instructions for use which, when followed, unknown to the farmer, resulted in infringement of the patent. Even if the patentee were prepared to bear the high cost of detecting infringement by the farmer and then to bring infringement proceedings, the result would almost certainly be unsatisfactory. The farmer would ordinarily be unaware of the patent and an award of damages would therefore be most unlikely. The farmer would be left with a stock of herbicide he was forbidden to use, and the patentee would find himself with no damages and a dissatisfied potential customer. To complicate the matter, there may be hundreds or thousands of such ultimate consumers.*
>
> *It is unreasonable and wasteful of resources for a patentee to have to sue all of the direct infringers with so unsatisfactory a result in each case, when the supplier is, in a real sense, far more responsible for the commission of the infringing acts.*
>
> *We believe that it would be far more effective, realistic and just for the patentee to be able to take action against the supplier or middleman who facilitates the commission of the infringing act by the ultimate consumer. The most common example of indirect, secondary or contributory infringement is where goods, materials or parts are supplied to a consumer with the intention*

> *that they be used, consumed or assembled in a way which constitutes an infringement of a patent. The intention might be evident, for example, from the provision of brochures containing instructions on how to make a product or use a process which would infringe a patent, or by advertisements soliciting the commission of an act which would infringe."*

The explanatory statement which accompanied the Bill for the 1990 Act stated (par 170 and par 171) that the purpose of the then cl 117 was to give effect to the Committee's recommendation.

94 In her article "Contributory Infringement of a Process Patent under the *Patents Act 1990*: Does it Exist after *Rescare*?" (1995) 6 AIPJ 217, Ms Ann Monotti discusses s 117 and its construction in *Rescare* and *Sartas No. 1*, and comes, as we do, to the conclusion that that construction substantially deprives s 117 of effective operation. She concludes as follows, at 228:

> *"In conclusion, the section can extend and clarify the common law and there is no justification for interpreting s 117 in a way that prevents the implementation of the policy decision made to incorporate contributory infringement in Australian Patent Law."*

95 We agree with that conclusion. We may say, with all the advantages of hindsight, that the drafting of s 117 is less than felicitous: we have already pointed to a possible difficulty with subs (2)(b) and, more generally, it is perhaps a pity that the drafter chose to use the phrase "use of a product", which contains such a clear reference to the terminology of par (a) of the definition of "exploit". But s 117 provides its own dictionary, in subs (2). And our paraphrase of s 117(1), incorporating subs (2)(c), shows, in our view, that the construction urged by the appellant is not only a possible construction but a literal one. That literal construction being consistent with the apparent purpose of the provision, it is, in our view, plainly to be preferred.

96 It follows that, assuming validity of the petty patents and taking what is contained in the statement of agreed facts as findings of fact, infringement is established, both in relation to taxol supplied with the product information guide and to that supplied for the purposes of the clinical trials.

97 Because, in our view, s 117 applied to the supply of taxol by the appellant, it is unnecessary to consider in detail the other bases on which, it was said, the appellant infringed the petty patents. We make two comments only. First, contrary to the view expressed by the trial judge, we agree with the view on which Gummow J proceeded in *Rescare* that the word "authorise" in s 13(1) of the 1990 Act should be taken, by analogy, to have the meaning it has in the comparable context of the *Copyright Act*. The context of s 13(1) is analogous to that of s 36 and s 101 of the *Copyright Act*; and there is nothing novel in finding similar concepts behind aspects of patent and copyright law (*Ramset Fasteners (Aust) Pty Ltd v Advanced Building Systems Pty Ltd* [1999] FCA 898 at par 37 and par 38). Secondly, the concepts of procurement of and participation in infringement, discussed in cases such as *Walker v Alemite Corporation* (1933) 49 CLR 643, were considered in some detail by the Full Court in *Ramset*. It may well be that there is little distinction, in principle, between what happened here and what was found to have occurred there: see at par 41.

Conclusion

98 It follows from our conclusions on novelty that the appeal must be dismissed and we so order. Given the appellant's success on a number of issues, however, we propose to seek written submissions from the parties as to the appropriate order for costs. We direct each party to file and serve written submissions on that aspect of the matter not later than 31 March 2000.

FINKELSTEIN J:

99 The important question: "is it ethical to patent a pharmaceutical substance or a method of medical treatment?" admits of no satisfactory answer. In a speech made in the French Parliament in 1843 the chemist, Gay-Lussac said:

> *"I admit that the quacks are a plague to society. But they pursue their fraudulent operations whether they have patents or not, and in all imaginable forms. If we should in this* [Patents Act] *exclude all trades in which quackery exists, the statute would be quite useless. There exists then no reasons for distinguishing the pharmaceutical preparations from the other inventions which can be protected by patent."*

On the other hand, Dr E R Squibb, the founder of the pharmaceutical house that is now merged in the appellant, is reported to have said: "I do not myself think that anything should

be patented by either physician or pharmacist."

100 The debate concerning the ethics of medical patents continues. One aspect of this debate remains substantially unresolved so far as the courts are concerned: whether it is possible to obtain a patent for medical treatment or a surgical procedure. The answer to this question cannot depend upon the resolution of moral or ethical issues. Judges should not be called upon to resolve moral questions and, speaking generally, legal principles are not to be ascertained by reference to standards of ethics or morality. However, as in many areas with which all lawyers are familiar, public policy often has a role to play in determining the content of a particular legal principle and one question that does arise in this case is whether, for reasons of public policy, a new medical or surgical procedure or process for the treatment of human beings is subject matter for a patent.

101 In the exercise of its prerogative, the Crown had the power to regulate trade. In the 16th century that prerogative was exercised to give special privileges to traders in order to preserve industries already established and in order to encourage the growth of new industries. According to an article by R A Klitzke entitled "History of Patents Abroad" appearing in *The Encyclopedia of Patent Practice and Invention Management* (1964) edited by R Calvert, the patent granted in 1552 to Henry Smyth, a London merchant, established monopoly patents as a regular custom for inventions. That patent was intended to introduce foreign workmen "mete and experte" in the making of Normandy glass in return for a monopoly privilege for twenty years under which unauthorised persons were prohibited from manufacturing such glass. See also E W Hulme "The History of the Patent System Under the Prerogative and at Common Law" (1896) 12 LQR 141 continued at (1900) 16 LQR 44, where it is suggested that the first patent for an invention of a process granted to an Englishman was in 1440 to John of Shiedame to introduce a method of making salt. There appears to have been no patent for an invention granted in the intervening 112 years.

102 The essence of the industrial monopoly was that in return for a new industrial process monopoly for a specified period, the grantee was required to introduce his process within a fixed time, to employ and to teach English subjects in the new process and sometimes to manufacture a minimum quantity within a given time: Sir W Holdsworth, *A History of English Law,* 3rd ed (1945) vol 4, 345.

103 The grant of monopolies was the subject of considerable abuse by the Crown, especially by Elizabeth I. Many of her subjects in the civil and military service were rewarded with monopoly patents, not in respect of new, but in relation to existing processes of manufacture. This resulted in a hindrance to trade and manufacture, high prices and inferior goods: Holdsworth, above at 347. These abuses led to the Case of Monopolies; *Darcy v Allin* (1601) 11 Co Rep 84b; SC Noy 178; 72 ER 830 which held certain monopolies to be void. Darcy, a groom in the Queen's Privy Chamber, had been granted a monopoly for making and selling playing cards for twenty-one years. The Court held the patent to be bad as "it is a monopoly against the common law". The Court said (11 Co Rep at 86b):

> *"…there are three inseparable incidents to every monopoly against the commonwealth, … the price of the same commodity will be raised, for he who has the sole selling of any commodity, may and will make the price as he pleases … that after the monopoly granted, the commodity is not so good and merchantable as it was before: for the patentee having the sole trade, regards only his private benefit, and not the common wealth. It tends to the impoverishment of divers artificers and others, who before, by the labour of their hands in their art or trade, had maintained themselves and their families, who now will of necessity be constrained to live in idleness and beggary…"*

104 The monopoly granted to Darcy was of a general kind and not one limited to a new invention produced or imported by the monopolist. In Noy's report of the case (at 182) the following passage appears:

> *"Now therefore I will shew you how the Judges have heretofore allowed of monopoly patents, which is that where any man by his own charge and industry, or by his own wit or invention doth bring any new trade into the realm, or any engine tending to the furtherance of a trade that never was used before: and that for the good of the realm: that in such cases the King may grant to him a monopoly patent for some reasonable time, until the subjects may learn the same, in consideration of the good that he doth bring by his invention to the commonwealth: otherwise not."*

105 The abuse of monopolies also led to the *Statute of Monopolies* in 1623: 21 Jac 1 c 3. The statute (in s 1) declared that "all monopolies … heretofore made or granted or hereafter to be made or granted … of or for the sole buying, selling, making, working, or using of anything within this realm … are and shall be utterly void and of none effect." In prohibiting these monopolies the statute was merely declaratory of the common law. Having declared a general prohibition of monopolies, the statute (in ss 5 to 14) made exceptions for certain

grants. For present purposes it is only necessary to notice s 6 which provides that no declaration contained in the statute shall extend:

> *" ... to any letters patent and grants of privilege for the term of fourteen years or under, hereafter to be made, of the sole working or making of any manner of new manufactures within this realm to the true and first inventor and inventors ...which others at the time of making such letters patent and grant 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;"*

106 Sir Edward Coke observed in 3 *Institutes of the Laws of England* (1644) at 183-184 that for a patent to be valid under s 6 it must possess seven properties: (1) it must be for a term of twenty-one years or under; (2) it must be granted to the true and first inventor; (3) it must be in respect of new (that is novel) manufactures; (4) the privilege must not be contrary to law; (5) it must not be mischievous to the State by raising the price of commodities at home; (6) the privilege must not be to the hurt of trade; and (7) it must not be generally inconvenient.

107 In what circumstances it was intended that a patent would be invalid because it was mischievous to the State, to the hurt of trade or generally inconvenient, is far from clear. Commenting on the words "mischievous to the State by raising prices of commodities at home" Sir Edward Coke said (3 *Institutes* at 184) that "in every such new manufacture that deserves a privilege there must be urgens necessitas and evidens utilitas". Obviously the hindrance to trade, etc caused by the abuse of monopolies was in the mind of the Parliament. So also may have been the common law offence of engrossing, that is obtaining or purchasing large quantities of "dead victuals" with intent to sell them again at a higher price. As has been said, monopolies had a like effect on other branches of trade: see W Blackstone 4 *Commentaries on the Laws of England* (1769) at 158.

108 In *Morgan v Seaward* (1837) 2 M&W 544; 150 ER 874, a case where the Court of Exchequer held that one part of a claimed invention concerning improvements in steam engines and in machinery for propelling vessels was void for lack of novelty, it was said by Baron Parke (2 M&W at 562; 150 ER at 881) that:

> *"A grant of a monopoly for an invention which is altogether useless may well be considered as 'mischievous to the state, to the hurt of the trade, or generally inconvenient,' within the meaning of the statute of Jac 1 which*

> *requires, as a condition of the grant, that it should not be so, for no addition or improvement of such an invention could be made by any one during the continuance of the monopoly, without obliging the person making use of it to purchase the useless invention…"*

Perhaps it was this decision that led R Frost to assert that the proviso to s 6 only gives rise to an objection that the invention is not new or useful: R Frost, *Treatise on Letters Patent for Inventions* (1912) at 30.

109 It is doubtful, however, if the excepted grants were intended to be limited to those that were not new or lacked utility unless the notion of utility was given an expanded meaning. In *Hindmarch on Patent Privileges* (1846) it was said (at 142) that the proviso:

> *" … seems also to mean that the excepted grants must not be for the sole making of any thing which is to be used for any purpose which is illegal, or 'contrary to law,' such as implements for house-breaking, picking pockets, locks, etc. Such grants, however, it is clear would be void, not only on the ground of want of public utility, but also because they are contrary to the policy of the law; and indeed it would be absurd if, by one law, patents might be granted to reward persons for providing the means of violating any other law."*

And in *Letters Patent for Inventions,* 2nd ed (1897) L Edmunds wrote (at 105):

> *"An invention which is 'mischievous to the State, to the hurt of trade, or generally inconvenient,' cannot by the very terms of the Statute of Monopolies be the subject-matter of a valid patent. Thus it has been said, a patent taken out so extensively as to deprive mechanics of the materials used in their trades, or a claim to* methods that may thereafter be discovered *of arriving at the result patented, or any patent for illegal inventions, such as a housebreaker's implement, would be invalid."*

It would seem that it was intended by the proviso that if the grant of a patent in respect of a new invention would be illegal, mischievous to the State or, for one reason or another, contrary to the public interest then the invention is not the proper subject matter for a patent.

110 The relevance of an inquiry into the scope of operation of s 6 of the *Statute of Monopolies*, and in particular the effect of the proviso, is that in Australia a patentable invention is an invention that "is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies": see s 18(1)(a) of the *Patent Act 1990*. The result of that inquiry will determine whether a medical process is a patentable invention.

111 The ability to patent a process for the medical treatment of the human body has been considered in a number of jurisdictions and the results have not been uniform. Many of the cases are collected in the judgments of Gummow J, sitting as a single justice of the Federal Court, in *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 25 IPR 119 and Lockhart J, one of the judges on the appeal: *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1. Although it will involve some repetition, it is appropriate to refer to a number of these cases.

112 The first occasion upon which a medical procedure patent was considered in England was *In the Matter of C & W's Application for a Patent* (1914) 31 RPC 235. C & W applied for the grant of a patent in respect of a process for extracting lead from persons suffering from lead poisoning. The Patent Office refused to grant the patent and on appeal the matter was considered by the Solicitor-General, Sir Stanley Buckmaster. The Solicitor-General took the view that for an invention to be patentable it must "in some way [be] associated with commerce and trade": 31 RPC at 235. He decided that the extraction of lead from the body of human beings was not any form of manufacture or of trade. This is the first ground for the decision.

113 Further, during the course of his reasons, the Solicitor-General also said that a patentable invention, which was required to be for "any manner of new manufacture … within section 6 of the *Statute of Monopolies*" did not bind the invention to be a manner of manufacturing a product, but "it may be a … process that can be used in making something that is, or may be, of commercial value": 31 RPC at 235-236. He held that a medical treatment process could not satisfy that description. This is the second ground for the decision.

114 Later cases have shown that the first ground upon which the Solicitor-General based his decision is not a good reason for denying a patent for a medical process. This was made clear in *Schering A.G.'s Application* [1971] RPC 337. That case concerned an application for a patent for a contraceptive process. The Patent Office had refused the application based on its practice not to grant any patent for "processes for the treatment of human beings". An appeal was taken to the Patent Appeal Tribunal constituted by two eminent patent lawyers, Graham and Whitford JJ. Their Lordships said (at 341) that it was clear that for a process or method to be patentable it did not necessarily have to result in the making of an object of value or be a process adapted to that end. (In Australia this had already been authoritatively

decided by the High Court in *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 (*NRDC*).) Nevertheless they expressed the opinion that the decision in *C & W's Application* was correct. Their Lordships' expression of opinion was obiter, because they held that a contraceptive process could not be described as a treatment of disease and thus the claim fell outside the prohibition. The principal reason given by Graham and Whitford JJ for the conclusion that a process for medical treatment was not patentable subject matter was that Parliament had, by necessary implication, proceeded on the assumption that such inventions were not within the statute when enacting what became s 41 of the *Patents Act 1949* (UK). That section, which had originally been introduced to the *Patents Act 1907* (UK) as s 38A(2) and into the *Patents Act 1919* (UK) as s 11, read:

> *"(1) Without prejudice to the foregoing provisions of this Act, where a patent is in force in respect of – (a) a substance capable of being used as food or medicine or in the production of food or medicine; or (b) a process for producing such a substance as aforesaid; or (c) any invention capable of being used as or as part of a surgical or curative device, the Comptroller shall, on application made to him by any person interested, order the grant to the applicant of a licence under the patent on such terms as he thinks fit, unless it appears to him that there are good reasons for refusing the application.*
>
> *(2) In settling the terms of licences under this section the Comptroller shall endeavour to secure that foods, medicines and surgical and curative devices shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.*
>
> *(3) A licence granted under this section shall entitle the licensee to make, use, exercise and vend the invention as a food or medicine, or for the purposes of the production of food or medicine or as part of a surgical or curative device, but for no other purpose."*

115 As their Lordships pointed out, s 41 did not relate to or even mention processes for medical treatment. Accordingly, s 41 could not apply to them. In their Lordships' opinion, this demonstrated that Parliament had proceeded on the assumption that a patent could not be granted for a process for medical treatment, because otherwise s 41 would have been extended to apply to those patents as well.

116 It is of interest to note that in *The Wellcome Foundation Limited v Plantext Ltd* [1974] RPC 514, a decision of the Supreme Court of Israel, Witkon J, when considering whether a medical process was patentable subject matter under the Mandatory Patents and Designs

Ordinance, concluded that, because that ordinance did not include a provision similar to s 41 of the *Patents Act 1949* (UK), such a process *was* within the ordinance.

117 In *Eli Lilly & Company's Application* [1975] RPC 438 the Patents Appeal Tribunal, again constituted by Graham and Whitford JJ, held that a patent should not be granted in respect of a discovery that certain compounds had anti-inflammatory properties. On this occasion their Lordships based their objection to the patentability of a medical process on the proviso to s 6 of the *Statute of Monopolies*, that is, on the basis that such a manner of manufacture is "mischievous to the State" or "generally inconvenient".

118 In 1977 the Court of Appeal in *The Upjohn Company (Robert's) Application* [1977] RPC 94 confirmed that a medical process was not capable of being an invention under the statute. The Court of Appeal did not give detailed reasons for its acceptance of this proposition, but referred with apparent approval to *C & W's Application* and to *Schering*. No reference was made to *Eli Lilly.*

119 In both *Schering* and *Eli Lilly*, Graham and Whitford JJ commented that the reason for the exclusion of medical process from patent protection was based on ethical grounds: see *Schering* at 340 and *Eli Lilly* at 445. These comments should not be taken to mean that ethical considerations provided the legal basis for the exclusion of medical process patents. In *Schering* their Lordships followed the decision in *C & W's Application* where it was not suggested that the practice which the Solicitor-General had approved was based on ethical considerations. It seems to me that their Lordships' reference to "ethical" considerations should be understood as a reference to considerations of public policy.

120 Whether medical or surgical processes constitute patentable subject matter has long been the subject of controversy in the United States. The controversy begins with *Morton v New York Eye Infirmary* 17 F Cas 879 (1862). Morton had discovered that an old and well-known agent (ether) had the effect of rendering a patient motionless and insensible during an operation. He obtained a patent for this discovery and brought proceedings against the infirmary for infringement. The trial court declared the patent to be invalid. On appeal to the Second Circuit Court of Appeals, the decision was affirmed. The Circuit Court accepted (at 883) that the discovery "rank[ed] among the great discoveries of modern times; … its value was too great to be estimated in dollars and cents." Nevertheless the Court said (at 883) "the

application of a well-known agent, by well-known means, to a new or more perfect use … is not sufficient to support a patent". Another reason the Court gave for the invalidity of the patent was (at 884) that "[n]either the natural functions of an animal upon which or through which [the new force or principle] may be designed to operate, nor any of the usual purposes to which [the new force or principle] may be applied" can be the subject matter of a patent. This passage in the judgment led to the view that medical and surgical methods of treating the human body were not patentable processes: see *Chisum on Patents* (1999) at para 1.03.

121 Thus in 1883 the Commissioner of Patents refused to grant a patent to an inventor who had discovered a method of treating haemorrhoids by the use of certain instruments: see *Ex parte Brinkenhoff* 24 Commissioner's Manuscript Decision 349 (1883) reproduced in (1945) 27 *Journal of the Patent Office Society* 797. In rejecting the patent the Commissioner relied upon *Morton*. He said "the methods or modes of treatment of physicians of certain diseases are not patentable … they are discoveries which may in a majority of the cases under certain conditions accomplish certain results, but no particular method or mode of treatment under all circumstances, and in all cases will produce upon all persons the same result, and, hence to grant a patent for a particular method of treatment would have a tendency to deceive the public by leading it to believe that the method therein described and claimed would produce the desired result in all cases." (27 *Journal of the Patent Office Society* at 798).

122 The decision in *Brinkenhoff* attracted a good deal of criticism: see eg the article by Dr I Fellner, "Patentability of Therapeutic Methods" (1946) 28 *Journal of the Patent Office Society* 90. First it was posited that the legislature did not rule out the propriety of patent protection for medical treatments as had been the case in countries such as France, Switzerland and Germany. Second it was said that the reasoning in *Brinkenhoff* – "no particular method or mode of treatment under all circumstances, and in all cases will produce upon all persons the same result" – was untenable in the light of modern science and technology. Third it was argued that *Morton* should be confined to its own facts.

123 In 1954 the Board of Patent Appeals in *Ex parte Scherer* 103 USPQ 107 (1954) overruled *Brinkenhoff*. The claim was for a method of injecting medicaments by a pressure jet. The Patents Office had rejected the claim on the basis that a method for the treatment of the human body was not patentable. The Appeals Board held that it was. It said that there was nothing in the patent statute that excludes such methods and no general rule of exclusion

had been developed by judicial decisions. With regard to *Morton,* the Board said that "no proper inference that any and all medical or surgical methods are excluded from the field of patentable subject matter can be drawn from the [decision] and neither do the facts upon which the [decision] is based warrant such a broad generalisation" (103 USPQ at 110). When dealing with *Brinkenhoff* the Board noted that the only specific reason given in that case for denying patent protection to medical methods was the uncertainty of the results. In the Board's view that was not a valid reason for refusing all methods. It pointed out, in my view correctly, that such an objection was more properly to be considered under the question of utility which is, of course, a separate and distinct question to that of patentability.

124 In the three decades following the decision in *Scherer* few medical procedure patents were granted. One commentator has suggested that the reason for this was that such a patent would be difficult to enforce: see "Medical Patents Trigger Debate Among Doctors", *Wall Street Journal*, 11 August 1994. By 1994 the position had changed. According to B McCormick in "Restricting Patents: Bipartisan Bill would Bar Ownership Claims for Medical Methods" (1995) 38 *American Medical News* 3, the Patent and Trade Mark Office granted at least a dozen medical procedure patents per week. In 1996 J Longacre estimated there to be approximately 100 surgical method patents: (1996) 10 *Annals of Vascular Surgery*, 1.

125 Two things became inevitable with the significant growth in the number of medical and surgical procedure patents. First, proceedings would be instituted for the infringement of one of these patents. Second, the commencement of such a proceeding would excite debate among the legal and medical professions and the public.

126 A proceeding was commenced by Dr S Pallin, an ophthalmologist. In 1990 Dr Pallin had developed a method for making a surgical incision in the eye when removing a cataract in a manner that would allow the wound to seal without a suture. The result was that far less scar tissue developed. Dr Pallin submitted an article describing the procedure to a leading medical journal, but it was not published. He then applied for and was granted a patent for his invention. In 1994 Dr Pallin brought proceedings against Dr J Singer and the Dartmouth-Hitchcock Medical Centre alleging that his patent had been infringed. The defendants' unsuccessful application for summary judgment is reported in 36 USPQ (2d) 1050 (1995).

127 Following the institution of the proceeding the American Medical Association House of Delegates voted to "condemn the patenting of medical and surgical procedures and work with Congress to outlaw this practice": see W D Noonan, "Patenting Medical and Surgical Procedures" (1995) 77 *Journal of the Patent and Trade Mark Office Society* 651. A broad group of medical associations led by the American Society of Cataract and Refractive Surgery was formed to achieve that goal. Their efforts, and those of other public interest pressure groups, led to legislation in 1996 that prohibited civil proceedings for damages or an injunction against a medical practitioner who performs a "medical activity" which would otherwise constitute an infringement or inducement to infringe a patent issued after the legislation: see 35 USC 287(c) (1996); see also G Mossinghoff, "Remedies Under Patents on Medical and Surgical Procedures" (1996) 78 *Journal of the Patent and Trade Mark Office Society* 789, where the history of the legislation is traced. The legislation specifically exempts the commercial activities of bio-technological, diagnostic and pharmaceutical companies and does not limit their ability to enforce patents against competitors. It also exempts from protection certain types of medical procedures by reason of the narrow definition given to "medical activity". That expression is defined in s 287(c)(2)(A) to exclude "the practice of a patented use of a composition of matter". Accordingly, the use of a drug for treatment where the claim involves the administration of the drug at a particular time, or a specified dose, or with a specified concomitant medical therapy, is not a "medical activity": see the Report of the House and Senate Conference accompanying the Bill which is reproduced in Appendix B to the article by Professor Mossinghoff. Also see B G Alten, "Left To One's Devices: Congress Limits Patents on Medical Procedures" (1998) 8 *Fordham Intellectual Property, Media & Entertainment Law Journal* 837.

128 A principled approach to the question whether a medical or surgical process is patentable requires the resolution of two separate issues. First, is such a process "a manner of new manufacture" within s 6 of the *Statute of Monopolies*? Second, if such a process is "a manner of new manufacture", does it fall within the proviso so as to be excluded from patentability?

129 In stating the first question in this way, I do not mean to suggest that the answer depends upon an interpretation of the word "manufacture" or the words "new manufacture" in s 6. The true question is whether, in the developing concepts of patent law, a medical or surgical process is a proper subject of letters patent under the 1990 Act: see *NRDC* at 269.

However, I have adopted the form of the first question in order to distinguish between an inquiry into subject matter, strictly so called, and the operation of the proviso. I do not believe it is likely that in separating the two issues in the way that I have that, for that reason, I will arrive at an incorrect conclusion.

130 The answer to the first question admits of no doubt and must be in the affirmative. In the first place in *NRDC* the High Court confirmed what had already long been established: that the word "manufacture" comprehends a process that produces a useful result and that it is not necessary for that process to bring into existence or relate to a vendible product. In this connection reference might also be made to *Cementation Co Ltd's Application* (1945) 62 RPC 151 and *H B Rantzen's Application* (1946) 64 RPC 63. This then disposes of one ground of objection to patentability put forward by *C & W's Application*. In the second place, most medical or surgical processes do have commercial application. In *Joos v Commissioner of Patents* (1972) 126 CLR 611 at 618 Barwick CJ said in relation to this issue:

> *"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 both obvious and may be regarded as sufficiently proximate, in my opinion, as to be capable of satisfying the economic element of an invention, if other elements are present and no impediments exist to the grant. One has only to recall the economic impact of workers' compensation, invalid pensions and repatriation costs to recognise that proximity."*

Thus, the other objection to patentability raised by *C & W's Application* disappears.

131 I can now consider the second, and that which appears to me to be the critical, question on this aspect of the case, namely whether a medical or surgical process should be excluded from patentable subject matter because it falls within the proviso to s 6. Such a process is not of course contrary to law or mischievous to the State by raising the price of commodities. However, to grant a patent for such a process may be "generally inconvenient", that is to say, it may be contrary to public policy and be excluded for that reason. It is to this issue I now turn.

132 There now appears to be general consensus that medical and surgical products are appropriate subject matter for patents. The General Agreement on Tariffs and Trade, Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 27 provides, in part, that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, [are non-obvious] and are capable of an industrial application" subject to the proviso that member States may exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans or animals". This is so notwithstanding the fact that many patients (perhaps millions around the world) are denied access to new pharmaceuticals, because of the price charged by the monopolist or its licensee. No doubt it is the ever-increasing cost of developing new and more effective pharmaceuticals and surgical products that underlies the support for medical and surgical product patents. That is to say, the investment needed for the research and the development of these products justifies patent protection. The support may also be explained, in part at least, by the fact that it is usually a commercial organisation rather than a physician that is the inventor of pharmaceuticals and surgical products.

133 The opponents to the grant of a monopoly in respect of medical and surgical processes raise objections that can be put into two broad groups: (i) the adverse effects on the provision of medical care; and (ii) the adverse effects on medical progress and education. In addition there is the related "ethical" question whether a medical practitioner (medical and surgical processes are usually invented by a medical practitioner) should be entitled to patent her invention consistent with her obligation to provide medical services to humanity.

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

135 It is also said that the traditional commitment of medical practitioners to develop, share and disseminate new knowledge will be repressed. That is to say, the medical practitioner who is seeking to discover a new medical or surgical process will deliberately withhold new medical knowledge from her colleagues so as to protect her discovery and enhance her ability to obtain patent protection for financial reward. Another aspect of this

argument is the potential conflict of interest which could arise when a medical practitioner has an economic interest in a patent: a conflict that might result in the practitioner not acting in the best interests of her patient. A further aspect of this argument is the suggestion that the existence of a patent is a disincentive to further invention.

136 On the other side of the debate is the underlying objective of patents, namely the promotion of science and the advancement of the arts for the general welfare of the State. As a general principle there can be no doubt that patent protection is desirable to encourage new medicines and surgical methods. It is an inescapable fact that inducement is necessary to encourage the great expense that is now required to evaluate and investigate the utility of many new medical processes and surgical methods.

137 As regards accessibility of information, there are of course the compulsory licensing procedures that are to be found in s 133 and s 134 of the 1990 Act. It is true that they may be cumbersome and expensive to apply. However, in relation to accessibility it may be thought that those who have obtained patent protection will seek to exploit their monopoly rights by granting licenses when appropriate.

138 On the issue of disclosure it has been a feature of the patent system since its inception that full disclosure of the invention is required as the consideration for the grant. Indeed publication with a specification of the means of working a patent may in many respects result in a much wider dissemination of the information therein contained than would be the case if the same information is published in a medical journal or at a medical convention.

139 Thus, patent protection provides some measure of guarantee that the public and not just the inventor will benefit from the invention. Further, it may be expected that providing patent protection to medical or surgical procedures will expedite the development of improved medical or surgical processes and will avoid the duplication of research efforts and expenditure. It may also be that publication of a patent will act as an incentive for others to break new ground and thus improve medical technology.

140 How is a court able to resolve these competing contentions? None of them are supported by evidence. Some may not even be capable of proof. Even if evidence was called to make good the unsubstantiated assertions, on what basis is the court to decide how the

public interest will best be served? In *Diamond v Chakrabarty* 447 US 303 (1980) the Supreme Court of the United States was asked to rule on whether a live human-made micro-organism is patentable subject matter. The argument against patentability raised the spectre of a serious threat to the human race posed by genetic research. The Supreme Court said, in relation to the dangers of allowing the patent (at 318):

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

141 I do not believe that in a controversial issue such as is raised by the present argument, I would be abandoning my responsibility as a judge to follow this approach and to hold that if public policy demands that a medical or surgical process should be excluded from patentability, then that is a matter that should be resolved by the Parliament.

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

143 So far it will be apparent that I have approached the issue as if it were res integra. This is how the trial judge regarded the question and how it was presented to this Court on appeal. In particular, the parties proceeded on the assumption that the point at issue was not part of the ratio of *Anaesthetic Supplies* at first instance or on appeal. However, I believe this assumption may not be correct. It is necessary to examine this question a little further.

144 *Anaesthetic Supplies* concerned a patent for an invention for treating snoring. Claims 9 and 11 of the patent were:

> *"9. A method of treating snoring and/or obstructive sleep apnoea in a patient comprising: applying air through a nose piece at a pressure maintained slightly greater than atmospheric substantially continuously throughout the breathing cycle.*
>
> *11. A method of treating snoring and/or obstructive sleep apnoea substantially as described with reference to the drawings."*

Rescare Ltd brought proceedings for infringement and Anaesthetic Supplies for revocation. In relation to claims 9 and 11, Anaesthetic Supplies based its claim for revocation on two grounds. First it was said that the claims were not for an invention within the meaning of the *Statute of Monopolies*, because they were methods of medical treatment of the human body. The second ground was that if the claims were for a medical treatment they were not fairly based upon matters described in the provisional specification.

145 Anaesthetic Supplies failed on the first ground. After an extensive examination of the relevant case law Gummow J held that a medical process was patentable subject matter, but went on to find that the claims were not fairly based. Before judgment his Honour heard an application that claims 9 and 11 should be amended in a way which, it was said, would limit the claims to the invention described in the provisional specification. The amendments were allowed. In the result, the revocation claim was dismissed and an injunction was granted restraining Anaesthetic Supplies from infringing the patent.

146 Anaesthetic Supplies then appealed to the Full Court. On appeal Anaesthetic Supplies sought to overturn the finding by the trial judge that claims 9 and 11 were valid as being for an invention. It also argued that claims 9 and 11 (as amended) were not fairly based on the provisional specification. The Full Court by majority (Lockhart and Wilcox JJ, Sheppard J dissenting) held that a medical process claim was patentable subject matter. However, the Court unanimously held that claims 9 and 11 were not fairly based on the provisional specification. Accordingly the appeal was allowed, the orders of the trial judge were set aside and instead it was declared, inter alia, that claims 9 and 11 were invalid and that the letters patent be revoked.

147 In summary then, three judges of the Court, Gummow J at first instance and Lockhart and Wilcox JJ on appeal, decided in considered reasons for judgment that a medical process claim was patentable subject matter. However, two of them held the particular patent to be invalid for lack of fair basing. One judge, Sheppard J, decided that claims 9 and 11 were invalid, because they both lacked subject matter and were not fairly based.

148 Every student of law knows that our legal system is hierarchical, where the decision of one court constitutes a binding precedent for every court that is lower in the hierarchy. What constitutes a binding precedent is the ratio decidendi of a case. Usually the ratio decidendi is understood to be the principle upon which the case was decided: *Osborne to Rowlett* (1880) 13 Ch D 774 at 785. However, a case often raises more than one issue. When a judge determines several issues that are raised for his consideration it is not always easy to determine how much of what the judge has said forms part of the ratio of the case.

149 Take as an example a case where one party raises two issues for consideration and contends that he is entitled to succeed on either issue. It is clear enough that if the judge rules in his favour on both issues, the reasons for both form part of the ratio decidendi: *London Jewellers Ltd v Attenborough* [1934] 2 KB 206: see also *Cheater v Cater* [1918] 1 KB 247 where Pickford LJ said (at 252): "If a judge states two grounds for his judgment and bases his decision upon both, neither of those grounds is a dictum." This is so even though the second reason is, speaking strictly, unnecessary for the ultimate order made by the court in view of the finding on the first issue.

150 What is the position if the judge rules in favour of one party on one issue, thus entitling him to obtain judgment, but rules in favour of the other party on the second issue? The generally accepted view is that the decision on the second point is not part of the ratio decidendi. The reason is to be found in the acceptance of the broad proposition that a statement of principle that is not necessary to found the judgment or order of the court, that is a statement which if not made or if decided differently, would not alter the outcome, is obiter. This seems to stem from a statement by Vaughan CJ in *Bole v Horton* (1673) Vaugh 360 at 382: "An opinion given in court, if not necessary to the judgment given of record, but that it might have been as well given if no such, or a contrary, opinion had been broached, is no judicial opinion, nor more than a gratis dictum."

151 Two recent applications of this view can be found in *Penn-Texas Corporation v Murat Anstalt* (No 2) [1964] 2 QB 647 and *In re Norway's Application (No 2)* [1990] 1 AC 723.

152 In *Penn-Texas*, an application was made under the *Foreign Tribunals Evidence Act 1856* (UK) that an English company, by its proper officer, should attend to give evidence on oath and produce documents for use in proceedings in New York. The Court of Appeal decided (*Penn-Texas Corporation v Murat Anstalt (No 1)* [1964] 1 QB 40) that whilst under the statute there was no power to order a company to give evidence, there was power to order it to produce documents, but only if they were specifically identified. Tthe court held, however, that no order should be made because the documents sought to be produced had not been sufficiently identified. The American company then made a further application for specifically identified documents. An order was made for their production and an appeal was taken to the Court of Appeal (*Penn-Texas (No 2)*). Before that court the English company again sought to raise the question whether there was power to order the company to produce documents, notwithstanding that this issue had been decided against it in the earlier decision. The Court of Appeal held what had been decided in *Penn-Texas (No 1)* was not part of the ratio of the case, because the ruling was not necessary for the decision. The result of the case would have been the same if the ruling had gone the other way.

153 *In re Norway's Application (No 2)* raised much the same issue. A Norwegian court issued a letter of request to the High Court for the examination of two witnesses in England. The Court of Appeal held that there was power to make the order sought under s 1 of *Evidence (Proceedings in Other Jurisdictions) Act 1975* (UK), but that no such order should be made, because the request was "fishing" (*In re State of Norway's Application (No 1)* [1987] QB 433). A second letter of request was issued setting out the specific questions that the witnesses were to be asked if an order for their examination was made. The orders sought were made. On appeal, the witnesses sought to argue that on the proper construction of s 1 there was no jurisdiction to make the order contrary to the ruling in *In re Norway's Application (No 1)*. The Court of Appeal held that this ruling was not part of the ratio of the case (*In re Norway's Application (No 2)*). The reason given was that statements of the Court of Appeal in the earlier case were not necessary for the decision of the Court. That is, the result of the case would have been the same had the issue of jurisdiction been decided the other way: see at 738 per May LJ, at 750 per Balcombe LJ and at 770 per Woolf LJ.

154 *Penn-Texas (No 2)* and *In re State of Norway's Application (No 2)* may be contrary to earlier authority. *Fairman v Perpetual Investment Building Society* [1923] AC 74 concerned a claim in negligence. The defendants owned a block of flats that were tenanted. The plaintiff lived as a lodger with her sister in one of the flats. She was injured when walking down the steps from her flat; the steps were part of the common property under the control of the landlord. The plaintiff argued that she was an invitee of the landlord and thus was owed a higher standard of care than would have been owed to a licensee. The House of Lords held that an invitee of a tenant was only a licensee of the landlord when using the stairway. In fact, the plaintiff would have lost on the facts, whether she was an invitee or a licensee, because the defect in the step on which she had slipped was perfectly obvious: see [1923] AC at 92 per Lord Sumner. For this reason Scott LJ in *Haseldine v C A Daw & Son Ltd* [1941] 2 KB 343, said (at 352) that the principle enunciated by the House of Lords in *Fairman*, namely that an invitee of a tenant was only a licensee of the landlord was obiter dictum. However, when the issue again came before the House of Lords in *Jacobs v London County Council* [1950] AC 361 a different view was taken. Lord Simonds (with whom the other Law Lords concurred) said that the question, invitee or licensee, was the issue that was raised in *Fairman's* case and had been decided by the House. He said (at 371) that: "To treat their [Lordships'] deliberate conclusions as obiter would not be consonant with the principle which is in my view essential to our system of case law and precedent." Thus he concluded that the House of Lords was bound by *Fairman's* case.

155 If the broad principle stated by Vaughan CJ in *Bole v Horton* was to be applied, then of course the decision in *Fairman* on the question "invitee or licensee?" should have been treated as obiter, because it was not necessary for the decision of the House in the sense that if the ruling had gone the other way the result would have been the same. However, Lord Simonds was prepared to treat the fact that the issue had been squarely raised by the pleadings, fully argued by the parties and the subject of a reasoned decision by the House, as sufficient to hold that it formed part of the ratio.

156 Another basis for thinking that what was decided in *Penn-Texas (No 1)* and *In re State of Norway's Application (No 1)* formed part of the ratio of those cases is that, in deciding whether there was power to grant the relief sought the Court of Appeal in each case was dealing with a point that was a necessary prelude to its further resolution of the case, namely whether that power should be exercised. Professors Paton and Sawer in an article entitled

"Ratio Decidendi and Obiter Dictum" (1947) 63 *Law Quarterly Review* 461 convincingly argue that in such a case the ruling on the preliminary point should be treated as part of the ratio. Their view is consistent with that of Lord Simonds in *Jacobs* who referred to the article in his speech.

157 In an increasingly complex society the disputes that come before the courts are also increasing in their complexity. Many cases raise numerous and complicated issues. Nowadays it is generally accepted that a trial judge, and even an intermediate appellate court, should deal with all (or at least most) of the issues raised for consideration by the parties. If a judge fails to adopt this approach and on appeal it is held that the ruling is in error, it would inevitably lead to a new trial so that the unresolved issues can be determined. If a judge, mindful of his duty, has dealt with all of the issues that have been raised for his decision, a new trial can often be avoided. The beneficial effect of this approach, both to the parties to the litigation and to the administration of justice generally, cannot be overstated.

158 When a judge takes it upon himself, conformably with his duty, to decide all of the issues that are raised for decision, particularly those issues which he regards as a necessary step to resolve the case, then should those of his reasons which do not form the basis of the order ultimately made be treated as a mere obiter to be disregarded by later courts? In my view, they should not be so treated. In the first place, there is no reason in logic to draw a distinction between a case where a judge decides two points of law in favour of one party that support the order made in favour of that party (where both rulings of law are part of the ratio) and a case where a judge decides one of those points against the party in whose favour an order is made. It is true as Oliver Wendell Holmes pointed out in one of his famous lectures "The life of the law has not been logic: it has been experience." However, this does not mean that logic should be foresaken altogether. Common law principles should be developed in an orderly and logical fashion to provide the certainty that a society demands from its legal system.

159 Second, to limit the ratio of a case to rulings that support the order ultimately made is to defer too much to form. It would often leave to the hand of the pleader the decision of what is and what is not to be the ratio of a case. The ever-increasing use of the declaratory order, negative and positive, shows the ease with which almost every issue that is raised in a case could be made the subject of an order if the pleader is sufficiently careful or, some might

say, unnecessarily pedantic. Presumably, if the parties in *Penn-Texas (No 1)* and *In re State of Norway's Application (No 1)* had sought declaratory relief in relation to the power of the court to make the orders sought, or if they had raised as questions for the determination of the court the proper construction of the applicable statutes, that would have transformed into ratio what the two subsequent Courts of Appeal decided was dicta.

160 In the third place, a more satisfying approach would be to discard the broad view of Vaughan CJ that a ruling can only be treated as ratio if it supports the ultimate order of the court and in its place adopt the principle that the ratio of a case is any ruling on a point of law that is put in issue by the parties, usually through their pleadings, and which the judge decides that he should resolve: compare N MacCormack *Legal Reasoning and Legal Theory* (1987) at 215. If this is too broad a proposition then, at a minimum, I would hold that the ratio of a case should at least include every ruling on a point of law that is treated by the judge as a necessary step in reaching his ultimate conclusion in a case whether or not that ruling is in favour of or against the party who obtains an order or judgment: see R Cross and J W Harris *Precedent in English Law*, 4th ed (1991) at 72.

161 As a result, in my opinion, the learned trial judge was not free to determine for himself whether a medical process was patentable subject matter. He was required to follow and should have followed *Anaesthetic Supplies* in holding that it was.

162 With regard to the other issues raised by this appeal, I am in general agreement with the reasons for judgment of Black CJ and Lehane J in holding that the appeal should be dismissed.