

HIGH COURT OF AUSTRALIA

GLEESON CJ, GAUDRON, McHUGH, GUMMOW, KIRBY, HAYNE
AND CALLINAN JJ

GLEESON CJ, GAUDRON, GUMMOW AND HAYNE JJ:

1 The appellants appeal from a decision of the Full Court of the Federal Court¹. They are members of the Astra pharmaceutical group which is based in Sweden. The first appellant is the patentee of Australian Standard Patent No 601,974 for an invention entitled "New Pharmaceutical Preparation for Oral Use" ("the Patent"). At the time of the grant, the *Patents Act* 1952 (Cth) ("the 1952 Act") was in force. The term of the Patent is for 20 years from 23 April 1987. The claimed priority date, apparently pursuant to s 141 of the 1952 Act, is 30 April 1986. This was the date of the basic application in the United Kingdom and the Australian application was made on 23 April 1987, that is to say, within the 12 months of the basic application as required by s 141. The second appellant is an Australian subsidiary of the Astra group and is the exclusive licensee of the Patent. It is convenient to refer to the appellants without distinction as "Astra".

The Patent

2 The Patent claims an oral pharmaceutical preparation in the form of a tablet, capsule or pellet containing omeprazole as the active ingredient. Omeprazole is a compound first synthesised in 1979. When absorbed in the upper part of the small intestine it inhibits gastric fluid secretions, and is useful in the treatment of gastric and duodenal ulcers. Astra held Standard Patent No 529,654 under the 1952 Act for this compound ("the compound patent"). This patent has expired and was not in suit in the present litigation.

3 The discovery of omeprazole and the grant of the compound patent was not itself sufficient to bring about the commercial exploitation of the compound by oral dosage. This was because the compound was not easily formulated into a satisfactory pharmaceutical composition. There was a problem in the administration of the drug which was answered with the formulation claimed in the Patent. The problem had several aspects. In broad terms, omeprazole rapidly degrades in an acid or neutral solution and, further, its stability also is affected by moisture and organic solvents. For omeprazole to work as a drug, it must be protected from acidic gastric juice on its way through the stomach and must be released rapidly when it reaches the top of the small intestine.

1 *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2000) 51 IPR 375; [2000] AIPC ¶91-636.

4 The Patent has 17 claims. Claims 1-12 are product claims, each for a pharmaceutical preparation comprising a particular combination of constituents. Claims 1-11 are for a tablet or pellet and claim 12 is for capsules. Claims 2-12 are dependent upon claim 1. Claims 13 and 14 are process claims and claim 15 is for a preparation obtained by the process claimed in claims 13 and 14. Claim 16 is for the use of a preparation according to any one of claims 1-12 and 15 for the manufacture of a medicament for the treatment of gastrointestinal diseases. Claim 17 is a method claim, the method being the administration in a therapeutically effective amount to a host in need of treatment for gastrointestinal disease. However, the focus in the litigation has been upon the broadest of the product claims, claim 1, and it is to the validity of that claim that attention will be given in these reasons.

5 The tablet or pellet claimed in claim 1 is a combination of three integers or elements. The first is the "core material" containing omeprazole as the active ingredient with an alkaline reacting compound; an alkali is a substance which neutralises or effervesces with acids. The second is one or more inertly reacting subcoating layer(s) on the core material, and the third an outer layer which is an enteric coating. An enteric coated tablet or pellet is one which assists through the stomach unaltered the contents then released in the intestine. The inert reacting subcoating layer(s), the second integer, comprise(s) excipients, that is to say, inactive substances that serve as a vehicle or medium for the core material. The excipients are soluble or rapidly disintegrating in water or are polymeric, water soluble, film-forming compounds optionally containing pH-buffering alkaline compounds.

6 The tablet or pellet thus claimed is a combination in the proper sense of that term, combining three elements which interact with each other to produce the new product; it is the interaction which is the essential requirement of invention and such a combination may be constituted by integers each of which is old or some of which are new². Thus, for example, in the present case, it is not to the point that of the three integers it may be said that omeprazole was known as an acid labile compound and that it was known that enteric coatings were resistant to acids. The question for decision concerns the ingenuity of the combination, not of the employment of any one or more integers taken individually. Astra complains that this analysis by dissection is what the Patent has wrongly been subjected to by the Full Court.

7 In many parts of the world, including Australia, Astra has sold a preparation manufactured in accordance with the Patent under the trade name "Losec". Losec has been a very effective and successful product. For example, for the period 1 July 1997 to 30 June 1998, the amount paid under the Commonwealth

2 *Commonwealth Industrial Gases Ltd v MWA Holdings Pty Ltd* (1970) 180 CLR 160 at 163; *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253 at 266; *Firebelt Pty Ltd v Brambles Australia Ltd* (2002) 76 ALJR 816 at 819-820 [21]; 188 ALR 280 at 285.

Pharmaceutical Benefits Scheme for Losec was considerably greater than the amount paid for any other branded drug.

The litigation

8 The respondent ("Alphapharm") markets "generic" drug formulations. In 1998, as the term of the compound patent neared its end, Alphapharm commenced steps to import and sell in Australia a pharmaceutical preparation containing omeprazole for therapeutic use in the treatment of gastrointestinal diseases. It applied to the Therapeutic Goods Administration to import and market in Australia such a pharmaceutical preparation. However, even after the compound patent expired and even if Alphapharm otherwise secured the necessary approvals by the Australian regulatory authorities, Alphapharm would not be at liberty to proceed with its proposals without overcoming the obstacle still presented by the Patent.

9 In August 1998, Astra instituted a proceeding in the Federal Court to restrain apprehended infringement of each of the claims of the Patent and for other relief. In its Defence, Alphapharm admitted it proposed to import and market its product in Australia after the compound patent expired and it had received the necessary regulatory approvals. However, it denied that there would be any infringement of any claim in the Patent and by its cross-claim sought revocation of the Patent.

10 The primary judge (Lehane J) held³ that, assuming validity, the acts threatened by Alphapharm would constitute infringement of several of the claims of the Patent. However, his Honour held that Alphapharm succeeded on its cross-claim. He made an order for revocation, with the result that the claim for infringement failed. The ground upon which his Honour determined that there should be revocation was obviousness. Alphapharm had attacked validity on various additional grounds, including lack of novelty. However, Lehane J held that none of the prior publications relied upon by Alphapharm rendered any of the claims not novel in Australia on the priority date⁴.

11 On or about 30 May 1997, that is to say, before suit, an amended specification of the Patent had been filed and the amendments sought had been allowed. Alphapharm made various complaints based upon the allowance of the amendments but these were rejected by the primary judge and, for present purposes, nothing turns upon them. Nor, despite the submissions by Alphapharm in this Court respecting alleged admissions by Astra against interest arising from the amendment process, does that process assist in dealing with the issues respecting obviousness with which this appeal is concerned.

3 (1999) 44 IPR 593; [1999] AIPC ¶91-474.

4 (1999) 44 IPR 593 at 634; [1999] AIPC ¶91-474 at 39,448.

12 An appeal by Astra to the Full Court (Wilcox, Merkel and Emmett JJ)⁵ was dismissed. The Full Court upheld the finding of Lehane J as to obviousness, but its reasoning in some significant respects differed from that of his Honour. The Full Court did not consider the additional matters raised by Alphapharm in its Notice of Contention. The issue on the appeal to this Court by Astra is whether the Full Court erred in not rejecting the finding by the primary judge with respect to obviousness. Were Astra to succeed in this Court, that would leave unresolved the balance of the issues before the Full Court. It should be added that the order for revocation made by the primary judge is, by order of the Federal Court, stayed until final determination of the appeal to this Court.

The Australian legislation

13 Section 100(1) of the 1952 Act relevantly stated:

"A standard patent may be revoked, either wholly or in so far as it relates to any claim of the complete specification, and a petty patent may be revoked, on one or more of the following grounds, but on no other ground:

...

- (e) that the invention, so far as claimed in any claim of the complete specification or in the claim of the petty patent specification, as the case may be, was obvious and did not involve an inventive step having regard to what was known or used in Australia on or before the priority date of that claim".

14 It should be observed immediately that the 1952 Act directed attention to what was known or used in Australia at the priority date and that for the patent in suit this is 30 April 1986. That lapse of time is sufficient, without more, to foreclose any consideration for present purposes of what information might have been available by electronic research methods since developed on an international scale.

15 The 1952 Act was repealed by s 230 of the *Patents Act* 1990 (Cth) ("the 1990 Act"). The 1990 Act commenced on 30 April 1991. The 1990 Act deals with obviousness in terms which differ from those found in the 1952 Act, a matter adverted to in *Firebelt Pty Ltd v Brambles Australia Ltd*⁶. However, Lehane J referred to authorities construing the transitional provisions in Ch 23 (ss 231-240) of the 1990 Act and concluded that, whilst the Patent might now be revoked only

5 (2000) 51 IPR 375; [2000] AIPC ¶91-636.

6 (2002) 76 ALJR 816 at 821-823 [31]-[36]; 188 ALR 280 at 287-289.

under the 1990 Act, for Alphapharm to succeed it would have to bring its case on obviousness within the terms of that ground as expressed in s 100 of the 1952 Act⁷. That was accepted as common ground by the parties in the Full Court⁸ and the appeal to this Court has been conducted on the same basis.

16 The distinctions between the 1952 Act and the 1990 Act in the treatment of obviousness are important for this litigation. The 1990 Act provides some relaxation of the rule established in this Court (to which further reference will be necessary) which forbade the use of prior disclosures which, whilst publicly available, were not proved to be part of common general knowledge at the priority date⁹. The further amendments by the *Patents Amendment Act 2001* (Cth) appear to continue this trend. However, the scheme of the 1990 Act was to preserve the rights of patentees under the 1952 Act by not imperilling validity through use of any broader grounds provided by the 1990 Act.

17 Nevertheless, the Amended Particulars of Invalidity filed by Alphapharm were framed in terms drawn from the text of the 1990 Act. Paragraph 8 of the Particulars used terms such as "prior art base" and "related documents" which a person skilled in the art "would treat ... as a single source of ... information". Reliance also was placed upon listed prior art documents taken alone as well as in combination and upon each of the integers of the claimed combination as forming part of the common general knowledge. Both the primary judge and the Full Court emphasised that it was the 1952 Act which was applicable. Nevertheless, as will appear, their treatment of the issues does suggest the intrusion of considerations adverse to *Astra* which may have had a firmer footing in the 1990 Act.

18 The warning by Judge Learned Hand in *Lyon v Bausch & Lomb Optical Co*¹⁰ respecting "unexpressed and unacknowledged [judicial] misgiving" about the facility with which patents appear to have been granted is in point here. His Honour added¹¹:

"Courts again and again shift their position; and, although they are apt to do so under cover of nice distinctions, they impose the risk of anticipating the changes upon those who may have acted upon the faith of the original."

7 (1999) 44 IPR 593 at 601; [1999] AIPC ¶¶91-474 at 39,421.

8 (2000) 51 IPR 375 at 377; [2000] AIPC ¶¶91-636 at 38,164.

9 *Firebelt Pty Ltd v Brambles Australia Ltd* (2002) 76 ALJR 816 at 822-823 [35]-[37]; 188 ALR 280 at 288-290.

10 224 F 2d 530 at 536-537 (1955).

11 224 F 2d 530 at 537 (1955).

Obviousness or lack of inventive step

19 The use of terms such as "obviousness", and lack or absence of "ingenuity", "subject-matter" and "inventive step", to distinguish a ground of revocation from that involved with "lack of novelty", "prior publication", "anticipation" and "prior use", has a fairly lengthy and evolving history in the decisions on patent law before the embodiment of the distinction in modern legislation¹². Paragraph (e) of s 100(1) of the 1952 Act, like par (f) of s 32(1) of the *Patents Act* 1949 (UK) ("the 1949 UK Act"), uses the expression "was [or 'is'] obvious and did [or 'does'] not involve an [or 'any'] inventive step having regard to what was known or used ... before the priority date of that claim".

20 On the other hand, in the United States, when a requirement for inventive quality was first embodied in statutory form by §103 of the 1952 *Patents Act* ("the 1952 US Act")¹³, this was done under a heading "Non-obvious Subject Matter" and with a text which did not refer to absence of "inventive step". Section 103 asks whether "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains". However, with respect to the juxtaposition of the phrases "was obvious" and "did not involve an inventive step", in the United Kingdom and Australia it has been accepted, as it was put in *Beecham Group Ltd's (Amoxycillin) Application*¹⁴, "[o]bviousness and inventiveness are antitheses. What is obvious cannot be inventive, and what is inventive cannot be obvious." In the present case, the Full Court made a statement to the same effect¹⁵ and this is accepted by both parties in this Court.

Hindsight and combinations

21 The defendant to an infringement action who cross-claims for revocation on the ground of obviousness bears the onus of establishing that case. This obliges the defendant to lead evidence looking back to the priority date, sometimes, as here, many years before trial. In those circumstances, the warnings in the authorities against the misuse of hindsight are not to be repeated as but prefatory averments and statements of trite law. The danger of such misuse will be particularly acute where what is claimed is a new and inventive combination for

12 *R D Werner & Co Inc v Bailey Aluminium Products Pty Ltd* (1989) 25 FCR 565 at 569-584, 591-601; *Lyon v Bausch & Lomb Optical Co* 224 F 2d 530 at 535-536 (1955).

13 35 USC.

14 [1980] RPC 261 at 290; cf *Genentech Inc's Patent* [1989] RPC 147 at 274.

15 (2000) 51 IPR 375 at 382; [2000] AIPC ¶¶91-636 at 38,168.

the interaction of integers, some or all of which are known. It is worth repeating what was said by Lord Diplock in *Technograph Printed Circuits Ltd v Mills & Rockley (Electronics) Ltd*¹⁶:

"Once an invention has been made it is generally possible to postulate a combination of steps by which the inventor might have arrived at the invention that he claims in his specification if he started from something that was already known. But it is only because the invention has been made and has proved successful that it is possible to postulate from what starting point and by what particular combination of steps the inventor could have arrived at his invention. It may be that taken in isolation none of the steps which it is now possible to postulate, if taken in isolation, appears to call for any inventive ingenuity. It is improbable that this reconstruction *a posteriori* represents the mental process by which the inventor in fact arrived at his invention, but, even if it were, inventive ingenuity lay in perceiving that the final result which it was the object of the inventor to achieve was attainable from the particular starting point and in his selection of the particular combination of steps which would lead to that result."

The present invention

22 The case presented by Astra in opposition to the attack on validity was that the formulation claimed in the Patent had been arrived at by the exercise of scientific ingenuity, based upon knowledge and experimental research¹⁷.

23 After omeprazole was first synthesised in 1979, Astra set up what was called "the Omeprazole Project Group". Its first task was to obtain a sufficiently stable dosage form for toxicological and initial human pharmacological studies. A solution of omeprazole was not practicable and the group prepared a suspension of omeprazole in alkaline aqueous phase and this was used in human tests. In late 1979, the team considered an oil formulation, but omeprazole proved unstable in oil. Early in 1980 the researchers moved to enteric coated pellets.

24 A complex of difficulties was encountered by the team. These arose, inter alia, because omeprazole had low solubility in water and was highly unstable, being sensitive to acid conditions, water, solvents, high temperature and light. Other problems included poor bioavailability and shelf life. In some cases, measures which might have overcome one of these problems exacerbated others. In December 1981 a "brainstorming" meeting was held at which a range of possibilities was proposed. It was one of these which eventually led to the invention, although this was not realised at the time. The evidence of Dr Pilbrant

16 [1972] RPC 346 at 362. See also *Olin Corporation v Super Cartridge Co Pty Ltd* (1977) 180 CLR 236 at 262-263.

17 cf *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 at 268.

(one of the inventors named in the Patent) respecting the position reached in December 1981 was:

"The range of ideas suggested reflected the fact that we could see no clear way forward, and there was no way that we could predict that any of the possibilities which had been suggested would solve the problems we had with omeprazole."

Further experiments resulted, by March 1982, in a subcoated pellet, tests of which for degradation, acid resistance and dissolution proved "promising". Early in 1983 a formulation, substantially the same as that which was ultimately marketed, was arrived at and could be subjected to long term stability studies. Dr Pilbrant's evidence was that it was not until the results of long term stability studies were available in 1985 that Astra could be sure that the invention solved the problems.

25 The evidence of another Astra witness, Dr Cederberg, was concerned with the conduct of trials in humans to see if various formulations proposed in the laboratory actually worked in the body. The Astra formulation team could be sure that the formulation worked only when supplied with these results. Trials were conducted over a period of almost four years.

The judgment at trial

26 Before Lehane J, Alphapharm called five expert witnesses, Drs Rowe, Story, Marshall, Thiel and Ashley. The experts called by Astra included Professors Rees and Rhodes, and from its research team Drs Pilbrant and Cederberg, to whose evidence reference has been made.

27 The primary judge noted the evidence of Dr Thiel that an Australian undergraduate at the priority date would have appreciated that an interaction could occur between the acidic enteric coat and the acid labile omeprazole. In a significant passage, his Honour then observed¹⁸:

"If that is so, it may not be unfair to comment that a large scientific team at Astra spent prodigally both time and resources in stumbling towards, and finally upon, what should have been an Australian undergraduate's first thought. But, more importantly, why should it have been thought that the core and the enteric coat were incompatible? No one gave evidence that he had previously, or since, encountered such a problem; there was no evidence of any product manufactured or marketed, before the priority date, in the making of which such a problem had had to be dealt with; there was evidence that other drugs which were both acid labile and alkaline (particularly erythromycin) had been successfully, and directly, enteric coated; each of the Alphapharm witnesses who gave evidence of the approach he would have followed in formulating omeprazole would have

18 (1999) 44 IPR 593 at 625-626; [1999] AIPC ¶91-474 at 39,441.

first tried a directly enteric coated formulation and (as senior counsel for Astra pointed out) Dr Marshall had no hesitation in applying an enteric coat directly to a core containing a significant quantity of a highly alkaline excipient; and, as the witnesses called by Astra said, there was a perfectly sound scientific explanation: in summary, that interaction should not occur in the absence of any significant quantity of free water."

28 To this it may be added, as Lehane J explained, that Dr Marshall had not arrived at the precise formulation claimed in the Patent even after the preparation of six reports on varying instructions from Alphapharm which developed his initial brief to formulate an appropriate dosage form of omeprazole for use by adults¹⁹. Dr Marshall's evidence was important because, unlike other Alphapharm experts, he was not shown the Patent²⁰.

29 Against that background, at first blush it is surprising that the primary judge held that Alphapharm had made out its case for revocation. It is necessary to trace the steps by which this result was reached.

30 Lehane J noted that there was no significant dispute as to who was to be regarded as the hypothetical non-inventive worker in the field; this was a person (or, it would seem to have been accepted, a team of persons) experienced in the practical work of formulating drugs for therapeutic use. Such persons would be highly qualified pharmaceutical chemists with, usually, a demonstrated capacity for original research. The hypothesis which the case law required fixed upon members of that class who were not "particularly imaginative or inventive"²¹. There are conceptual difficulties in applying what is said in some of the older authorities respecting "workmen" and the like to modern conditions in the pharmaceutical and other industries. But the employment of highly skilled research teams, as a matter of course, was noted over 70 years ago, well before the 1952 Act²². In this respect, there is no challenge to the way Lehane J approached the case.

31 The primary judge rejected Alphapharm's submission that the common general knowledge of the skilled formulator in Australia included material which the formulator might find by conducting computer searches and the like, being means available to and used by formulators. His Honour correctly did so because the corollary of the submission was that information should be treated as part of

19 (1999) 44 IPR 593 at 614-617, 629-630; [1999] AIPC ¶91-474 at 39,431-39,435, 39,444-39,445.

20 (1999) 44 IPR 593 at 614; [1999] AIPC ¶91-474 at 39,431.

21 (1999) 44 IPR 593 at 604; [1999] AIPC ¶91-474 at 39,424.

22 *In re Farbenindustrie AG's Patents* (1930) 47 RPC 289 at 321-322.

the common general knowledge in Australia, even in the absence of evidence of its general acceptance and assimilation by what he called "the formulating community". This was a proposition which Lehane J recognised²³ was foreclosed by the authority of this Court, in particular by *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd*²⁴.

32 However, the primary judge erred in his further identification of the legal concept of obviousness against which the facts were measured. The Full Court also fell into error in this respect. Before turning to consider the nature and extent of these false steps, it is convenient to isolate several preliminary matters concerning the statutory formulation for "obviousness" in par (e) of s 100(1) of the 1952 Act as it has been interpreted in this Court, and to compare the position in several other countries, in particular the United Kingdom and the United States.

The law respecting obviousness

33 The starting point is the statement by Hoffmann LJ in *Société Technique de Pulverisation Step v Emson Europe Ltd*²⁵:

"The words 'obvious' and 'inventive step' involve questions of fact and degree which must be answered in accordance with the general policy of the Patents Act to reward and encourage inventors without inhibiting improvements of existing technology by others."

34 In *The General Tire & Rubber Company v The Firestone Tyre and Rubber Company Ltd*²⁶, the English Court of Appeal, with reference to the ground in par (f) of s 32(1) of the 1949 UK Act, said²⁷:

"'Obvious' is, after all, a much-used word and it does not seem to [us] that there is any need to go beyond the primary dictionary meaning of 'very plain'."

These words do not aid Alphapharm; to the contrary, Alphapharm relies upon the Full Court judgment which employed such terms as "worthwhile to try", a phrase not readily understood as synonymous with "obvious".

23 (1999) 44 IPR 593 at 606; [1999] AIPC ¶91-474 at 39,425.

24 (1980) 144 CLR 253.

25 [1993] RPC 513 at 519.

26 [1972] RPC 457.

27 [1972] RPC 457 at 497.

35 More recently, Aldous J said that obvious is an "ordinary English word" which in patent law does not have "any technical meaning"²⁸.

36 However, those statements in the English cases should be treated with caution. The term "obvious" first appeared in the United States, United Kingdom and Australian legislation after detailed judicial exegesis over many years. Further, "obvious" does not stand by itself in the statute to specify a ground of revocation; the reader is required to "have regard" to what was "known or used" on or before a particular date, and to a particular geographical area. The notions of meaning and construction are interdependent and the meaning of "obvious" in par (e) of s 100(1) must be affected by the other words and syntax of the whole of s 100(1)(e)²⁹. Finally, the statute does not identify the characteristics of the persons with the knowledge or use in question, thus making further judicial exegesis inevitable for the operation of the provision.

37 It is at this stage that further and for this appeal acute difficulties commence. They may be introduced by observations by Diplock LJ in a passage frequently cited in the English authorities. In *Johns-Manville Corporation's Patent*, Diplock LJ remarked³⁰:

"I have endeavoured to refrain from coining a definition of 'obviousness' which counsel may be tempted to cite in subsequent cases relating to different types of claims. Patent law can too easily be bedevilled by linguistics, and the citation of a plethora of cases about other inventions of different kinds. The correctness of a decision upon an issue of obviousness does not depend upon whether or not the decider has paraphrased the words of the Act in some particular verbal formula. *I doubt whether there is any verbal formula which is appropriate to all classes of claims.*" (emphasis added)

38 This last point is borne out by a consideration of the judgment of Aickin J in *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd*³¹. In the course of that judgment, his Honour emphasised³² (i) inventions may be the result not only of long experiments and profound research but also of chance, sudden lucky thought or mere accidental discovery; (ii) not all inventions are to be classified as successful solutions to a problem which had presented a "long-felt want"; (iii) to

28 *Chiron Corporation v Murex Diagnostics Ltd* [1996] RPC 535 at 557.

29 *Collector of Customs v Agfa-Gevaert Ltd* (1996) 186 CLR 389 at 396-397.

30 [1967] RPC 479 at 493-494.

31 (1981) 148 CLR 262.

32 (1981) 148 CLR 262 at 272, 279, 287.

the contrary, inventions which are an advance of contemporary expectations and thus reveal an "unfelt want" may well involve an inventive step; and (iv) in cases falling within (iii), experiments and research would throw no light on the quality of what was claimed as an inventive step.

39 Proposition (i) certainly also represented the law under the 1949 UK Act. In *Dow Corning Corporation's Application*, Graham J said³³:

"An inventor may well arrive at his invention by a flash of genius which causes him no difficulty or concentrated thought at all, but the invention may still be a most brilliant one which would never have occurred to the notional skilled man in the art at all or only after prolonged investigation and the concentrated exercise of his, perhaps lesser, inventive faculty. In such a case, though it is in a sense obvious to the inventor, nevertheless the invention is undoubtedly worthy of patent protection."

40 However, propositions (ii), (iii) and (iv) may not represent the effect of the current English case law³⁴. Certainly they deny the general application of the proposition expressed by Lord Hoffmann in *Biogen Inc v Medeva plc*³⁵. This was³⁶:

"A proper statement of the inventive concept needs to include some express or implied reference to the problem which it required invention to overcome."

Biogen was the first case in which the House of Lords considered obviousness under the *Patents Act 1977* (UK) ("the 1977 UK Act"). What was said may reflect the "problem and solution" approach which is apparently mandated by the European Patent Convention which requires European patent applications to disclose the claimed invention "in such terms that the technical problem (even if not expressly stated as such) and its solution can be understood"³⁷. It will be necessary to return to the significance of the 1977 UK Act. However, earlier, in

33 [1969] RPC 544 at 560.

34 Blanco White, *Patents for Inventions*, 5th ed (1983), §4-222.

35 [1997] RPC 1.

36 [1997] RPC 1 at 45.

37 Paterson, *The European Patent System*, 2nd ed (2001), §12-04; Cole, "Inventive Step: Meaning of the EPO Problem and Solution Approach, and Implications for the United Kingdom – Part I", (1998) *European Intellectual Property Review* 214 at 215-216.

*Amoxycillin*³⁸, decided under the 1949 UK Act, Buckley LJ had spoken of the solution of "some recognised problem" and the meeting of "some recognised need".

41 In any event, the consistory clause in the Patent states that the invention claimed therein is designed to obtain a pharmaceutical dosage form of omeprazole which answers the problems referred to earlier in the body of the specification and indicated earlier in these reasons. The claim is for a combination, the interaction between the integers of which is the essential requirement for the presence of an inventive step. It is the selection of the integers out of "perhaps many possibilities" which must be shown by Alphapharm to be obvious, bearing in mind that the selection of the integers in which the invention lies can be expected to be a process necessarily involving rejection of other possible integers. This expression of the issue follows what was said by Aickin J in *Minnesota Mining*³⁹.

Divergence between Australian and United Kingdom law

42 In the argument in this Court, as in the Federal Court, reliance was placed upon various decisions in the United Kingdom. Reference has already been made to some divergence between the case law concerning the 1952 Act and the United Kingdom legislation in 1949 and 1977. There are further areas of divergence, the failure in an appreciation of which was of determinative significance for the decisions both of Lehane J and the Full Court.

43 The first concerns "mosaics" (a term of disparagement apparently first used by James LJ in 1880⁴⁰), and related issues. The holding for which *Minnesota Mining* is celebrated is the rejection, as inapplicable to the terms of the 1952 Act, of the reasoning in certain English decisions. This might have permitted the basing of an argument of obviousness upon prior publicly available publications, without evidence that they had become part of the common general knowledge at the priority date⁴¹. Common knowledge, Windeyer J had pointed out in *Sunbeam Corporation v Morphy-Richards (Aust) Pty Ltd*⁴², is the correlative of subject-matter or inventiveness, and available knowledge the correlative of lack of novelty.

38 [1980] RPC 261 at 290.

39 (1980) 144 CLR 253 at 293.

40 *Von Heyden v Neustadt* (1880) 50 LJ Ch (NS) 126 at 128.

41 The law in the United States also was based upon knowledge "available" to any person having ordinary skill in the art: Lipscomb's *Walker on Patents*, 3rd ed (1985), vol 2, §6.29.

42 (1961) 180 CLR 98 at 114.

44 The respondent in *Minnesota Mining* had relied upon a number of prior patent specifications available in Australia for public inspection to base an argument of obviousness. But the respondent led no evidence that they were part of the common general knowledge on or before the priority date. There was no evidence that those working in the field of adhesives or surgical tapes followed a practice of studying and making themselves familiar with all patent specifications as they became available for inspection in the Patents Office library. Therefore, the issue of obviousness was to be determined without reference to the prior publications⁴³. *A fortiori* obviousness was not determined by asking whether a diligent searcher might have selected the elements of the claimed invention by taking pieces from those prior publications and putting them together⁴⁴.

45 In accordance with this reasoning, the respondent's case in *Minnesota Mining* would have been no better off if the contents of the Patents Office library had been "online" and so even more readily available to search. The issue was not whether it was "obvious" to search there, but whether what a search would have disclosed had entered the body of common general knowledge. On the other hand, Aickin J did have regard to evidence relating to the use of surgical tapes in hospitals and in medical practice as indicative both of what products were the common general knowledge and of the problem awaiting solution⁴⁵.

46 The divergence in the case law marked by *Minnesota Mining* has since been widened by changes in statute law. It is unnecessary to consider further the changes in Australia brought about by the 1990 Act. They were discussed to some extent in *Firebelt*⁴⁶. In the United Kingdom, the 1977 UK Act caused, as Professor Cornish has put it⁴⁷, the "largest culture shock" received by the British patent system in its history.

47 Section 3 of the 1977 UK Act says that "[a]n invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2)". Section 2(2) provides:

"The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either,

43 (1980) 144 CLR 253 at 294-295.

44 (1980) 144 CLR 253 at 293.

45 (1980) 144 CLR 253 at 295-297.

46 (2002) 76 ALJR 816 at 821-823 [31]-[36]; 188 ALR 280 at 287-289.

47 *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 4th ed (1999), §3-01.

or anything else) which *has* at any time before the priority date of that invention *been made available to the public* (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way." (emphasis added)

Section 130(7) declares that various provisions, including ss 2 and 3, "are so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of the European Patent Convention [and] the Community Patent Convention".

48 The result has been to mandate what was foreseen as the "Europeanisation" of British law⁴⁸. This may bring a requirement, in broad terms, of a sufficiency or level of invention to support a patent grant⁴⁹, something more than the "scintilla" spoken of in this Court⁵⁰ and earlier British authorities⁵¹. The distinction may be reflected in the posing by Hoffmann LJ of the issue whether the patent in suit "discloses something sufficiently inventive to deserve the grant of a monopoly"⁵². This raises the barrier for patentees and its attempted importation for the 1952 Act may be implicit in the reasoning which led to adverse outcomes for Astra in this litigation.

49 The result in Britain of the shift in grundnorm is exemplified in the observation by Laddie J⁵³ that the skilled worker (identified in s 3 of the 1977 UK Act):

"is assumed to have read and understood all the *available* prior art".
(emphasis added)

The treatment of the point by Aickin J in *Minnesota Mining*, as indicated above, expressly rejected any assumption as to what in such a way may be expected of and attributed to the hypothetical addressee. That distinction is important in

48 Blanco White, *Patents for Inventions*, 5th ed (1983), §4-209, fn 52.

49 Cornish, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 4th ed (1999), §5-32.

50 For example, *Woolworths Ltd v W B Davis and Son Ltd Inc* (1942) 16 ALJ 57 at 59; *HPM Industries Pty Ltd v Gerard Industries Ltd* (1957) 98 CLR 424 at 436; *Meyers Taylor Pty Ltd v Vicarr Industries Ltd* (1977) 137 CLR 228 at 249.

51 For example, by the House of Lords in *Cleveland Graphite Bronze Co v Glacier Metal Co Ltd* (1950) 67 RPC 149 at 156.

52 *Société Technique de Pulverisation Step v Emson Europe Ltd* [1993] RPC 513 at 519.

53 *Cairnstores Ltd v Aktiebolaget Hässle* [2002] EWHC 309 (Ch) at [94].

considering the path taken by Lehane J in his judgment. It is convenient, before doing so, to refer to the notion of "routine" which also played a significant part in that reasoning.

"Matter of routine"

50 In *Wellcome Foundation*, Aickin J referred to the taking of a series of routine steps and the making of a series of routine experiments and continued⁵⁴:

"The test is whether the hypothetical addressee faced with the same problem *would have taken as a matter of routine whatever steps* might have led from the prior art to the invention, whether they be the steps of the inventor or not." (emphasis added)

Lehane J, in critical passages in his reasoning⁵⁵, referred to and applied what he understood to follow from this passage. Was that understanding correct? Alphapharm submits that his Honour was correct, and Astra the opposite. Both sides accept that *Wellcome Foundation* is binding; they differ as to its meaning.

51 What Aickin J had in mind as "routine" appears from an earlier passage in his judgment in which he was discussing the question whether evidence of the steps taken by the patentee was relevant and therefore admissible in a revocation action. His Honour said⁵⁶:

"Evidence of what he did by way of experiment may be another matter. It might show that the experiments devised for the purpose were part of an inventive step. Alternatively it might show that the experiments were of *a routine character* which the uninventive worker in the field *would try as a matter of course*. The latter could be relevant though not decisive in every case. It may be that the perception of the true nature of the problem was the inventive step which, once taken, revealed that straightforward experiments will provide the solution. It will always be necessary to distinguish between experiments leading to an invention and subsequent experiments for checking and testing the product or process the subject of the invention. The latter would not be material to obviousness but might be material to the question of utility." (emphasis added)

52 There are distinct strands of thought in this passage which may now be considered in terms applicable to the issues in this litigation. First, the working trials of which Dr Cederberg gave evidence may be (it is not necessary to determine the point) an example of the "subsequent experiments for checking and

54 (1981) 148 CLR 262 at 286.

55 (1999) 44 IPR 593 at 626, 629; [1999] AIPC ¶¶91-474 at 39,442, 39,444.

56 (1981) 148 CLR 262 at 280-281.

testing", to which Aickin J referred at the end of the above passage. Secondly, the invention claimed in the Patent lay not in perceiving "the true nature of the problem" to which "straightforward experiments" then would provide the solution; the invention was in the interaction between the integers of the compound, to answer the known problem. Thirdly, in a case such as the present, the relevant question was that posed in the first part of the passage. Were the experiments "part of" that inventive step claimed in the Patent or were they "of a routine character" to be tried "as a matter of course"? If the latter be attributable to the hypothetical addressee of the Patent, such a finding would support a holding of obviousness.

53 That way of approaching the matter has an affinity with the reformulation of the "Cripps question" by Graham J in *Olin Mathieson Chemical Corporation v Biorex Laboratories Ltd*⁵⁷. This Court had been referred to *Olin* in the argument in *Wellcome Foundation*⁵⁸. Graham J had posed the question⁵⁹:

"Would the notional research group at the relevant date, in all the circumstances, which include a knowledge of all the relevant prior art and of the facts of the nature and success of chlorpromazine, *directly be led as a matter of course to try* the –CF₃ substitution in the '2' position in place of the –C1 atom in chlorpromazine or in any other body which, apart from the –CF₃ substitution, has the other characteristics of the formula of claim 1, *in the expectation that it might well* produce a useful alternative to or better drug than chlorpromazine or a body useful for any other purpose?" (emphasis added)

That approach should be accepted.

The reasoning of the primary judge

54 Lehane J did not treat "routine" in that way. He erred by giving it an operation more favourable to Alphapharm's case. What his Honour did was in line with the position which now apparently obtains in England, that "all of the courses of action which present themselves without the exercise of invention are

57 [1970] RPC 157.

58 (1981) 148 CLR 262 at 267. See also *Washex Machinery Corporation v Roy Burton & Co Pty Ltd* (1974) 49 ALJR 12 at 16.

59 [1970] RPC 157 at 187-188. The approach taken in *Olin* appears now to be disfavoured by the English Court of Appeal: *Pharmacia Corp v Merck & Co Inc* [2002] RPC 775 at 819-820 but it still has support in the English profession: Cole, "Inventive Step: Meaning of the EPO Problem and Solution Approach, and Implications for the United Kingdom – Part II", (1998) *European Intellectual Property Review* 267 at 270.

obvious"⁶⁰. His Honour did not assess what was said by the expert witnesses concerning the procedures they would have followed by making findings whether they would have been led directly as a matter of course to pursue one avenue in the expectation that it might well produce the claimed compound.

55 His Honour also attributed to the hypothetical addressee the assistance to be gleaned from publications which had not been found to be part of the common general knowledge in Australia at the priority date. He correctly rejected the Alphapharm submission that the common general knowledge of the skilled formulator in Australia included material the formulator might find by conducting research, even if the information thus disclosed had not been generally assimilated and accepted by formulators⁶¹. But Lehane J then took a wrong turning in his reasoning process. His Honour said⁶²:

"It may not necessarily follow, however, that documents which would have been found on search, but do not form part of the common general knowledge, are simply irrelevant. Common general knowledge is, after all, the stock of knowledge on the basis of which one asks whether what is claimed to be an invention was obvious and did not involve an inventive step. It may be that to make use of the result of a *routine literature search* is no different in concept from making use of *a series of routine experiments* where common general knowledge would have suggested either to the hypothetical formulator attempting to formulate omeprazole." (emphasis added)

Later in his judgment, his Honour accepted Dr Story's evidence that he would have regard to the literature revealed by this process "not ... only for the purpose of finding precise directions" but "for more general ideas"⁶³ as a step in the statement of his conclusion that the Patent was bad for obviousness. That was an error. Further, the equating in this passage of "a routine literature search" with "a series of routine experiments" as something suggested by common general knowledge to the hypothetical formulator conflated two further errors. This came about as follows.

60 *Pharmacia Corp v Merck & Co Inc* [2002] RPC 775 at 818.

61 (1999) 44 IPR 593 at 606; [1999] AIPC ¶91-474 at 39,425.

62 (1999) 44 IPR 593 at 606; [1999] AIPC ¶91-474 at 39,425.

63 (1999) 44 IPR 593 at 629; [1999] AIPC ¶91-474 at 39,444.

Lehane J held that the claimed combination had not been obvious "considered at the *commencement* of a hypothetical attempt"⁶⁴ (original emphasis). However, he continued⁶⁵:

"The question is whether the hypothetical, not particularly imaginative skilled formulator, equipped with common general knowledge and embarking on the task at that time, *would be likely* to have arrived at the combination by taking routine steps which such a formulator would take for the purpose of formulating a drug." (emphasis added)

After referring to *Wellcome Foundation*, his Honour identified the "proper role" of expert witnesses as to what was "a matter of routine", saying⁶⁶:

"Thus, for instance, I accept the general descriptions given by Dr Story and Dr Rowe of the way in which they would go about the formulation of a new drug. Nor do I see any reason to doubt the evidence of Dr Story, Dr Rowe and Dr Thiel about the importance of the role played by manufacturers' literature or the evidence of Dr Story and Dr Rowe about the significance, to formulators in Australia, of patent searches."

This led to the finding⁶⁷:

"I have no difficulty with the proposition that a formulator asked, in April 1986, to formulate omeprazole would have done a literature search at least in order to discover what learning there was about omeprazole itself and its characteristics. Clearly enough such a search would have uncovered the compound patent, the omeprazole salts patent and Pilbrant and Cederberg. Pilbrant and Cederberg both indicated a number of the characteristics of omeprazole and pointed the formulator in a particular direction: an enteric coated dosage form seemed most likely to be the best possibility. That being so, there can be no surprise that the witnesses would have first tried directly enteric coating an omeprazole core, or that the particular 'controlled release' dosage form that Dr Marshall would have tried was an enteric coated one. I accept that that is what the hypothetical formulator would have done."

One flaw in this reasoning is that it treats what was "known or used" within the meaning of par (e) in s 100(1) of the 1952 Act as if it was directed to information which, whilst accessible, had not been assimilated into common

64 (1999) 44 IPR 593 at 626; [1999] AIPC ¶91-474 at 39,442.

65 (1999) 44 IPR 593 at 626; [1999] AIPC ¶91-474 at 39,442.

66 (1999) 44 IPR 593 at 626-627; [1999] AIPC ¶91-474 at 39,442.

67 (1999) 44 IPR 593 at 627; [1999] AIPC ¶91-474 at 39,443.

general knowledge. The reference to "the omeprazole salts patent and Pilbrant and Cederberg" was to an article published in 1985 by Drs Pilbrant and Cederberg, and to an Astra patent claiming principally a series of compounds which are alkaline salts of omeprazole. There was no finding that what was disclosed by those documents had entered the common general knowledge of those in Australia experienced in the practical work of formulating drugs for therapeutic use. Rather, reliance was placed upon the notion, illegitimate after *Minnesota Mining*, of a "routine literature search".

58 There follows the further conclusion⁶⁸ (later endorsed by the Full Court⁶⁹):

"I accept also that the process which would then have followed would have been a complex, detailed and laborious one, involving a good deal of trial and error, dead ends and the retracing of steps; and it is easy to fall into the twin traps of hindsight and over simplification. But there is no reason to doubt that the hypothetical formulator would, having tried the first simple formulation, have done substantially what Astra did: submitted it to appropriate tests, including tests for stability on manufacture and on storage and for acid resistance."

The tracing of a course of action which was complex and detailed, as well as laborious, with a good deal of trial and error, with dead ends and the retracing of steps is not the taking of routine steps to which the hypothetical formulator was taken as a matter of course. In *In re Farbenindustrie AG's Patents*⁷⁰, Maugham J had said that while "mere verification is not invention", what he likened to the citadel of invention:

"may be captured either by a brilliant *coup-de-main* or by a slow and laborious approach by sap and mine according to the rules of the art; the reward is the same".

Further, the routine, which Lehane J accepted, took as its starting point that which was attributed from the reading of information which he had not found to be part of the common general knowledge.

59 The result is that the reasoning by which the trial judge concluded that the Patent was to be revoked was flawed by errors of law.

The Full Court

68 (1999) 44 IPR 593 at 627; [1999] AIPC ¶91-474 at 39,443.

69 (2000) 51 IPR 375 at 406; [2000] AIPC ¶91-636 at 38,189.

70 (1930) 47 RPC 289 at 322.

60 There is a particular temptation to rely on hindsight by imprecisely identifying the issue which arises in determining an allegation of obviousness. To this, with apparent encouragement from English authorities upon which Alphapharm relies, the Full Court succumbed as support for its rejection of Astra's appeal. To this we now turn.

61 The Full Court was alive to the difficulty with that part of Lehane J's reasoning which fixed upon the "availability" of the omeprazole salts patent and the Pilbrant and Cederberg article as translating their contents into the body of common general knowledge. Their Honours correctly held, contrary to what had been decided by the trial judge, that it was impermissible to have regard to documents that would have been read merely for "general ideas"⁷¹. However, the Full Court passed around that difficulty by accepting Dr Rowe's evidence that the information in the manufacturer's literature, respecting "the basic characteristics of omeprazole", "could, and would" be readily obtained by a formulator carrying out "a series of routine tests"⁷². That would instruct the formulator that omeprazole was an acid labile compound, which would need to be stabilised, so that "[t]he first integer selects itself"⁷³. In this Court, Astra disputes the statement then made by the Full Court that Astra did not dispute that proposition. It is necessary here to take that point further.

62 This is because, in proceeding as it did, the Full Court considered each integer separately. It went on to say that it had been obvious to use an enteric coating and then said that⁷⁴:

"[t]he only integer whose presence raises a doubt about obviousness is the subcoat. Was it obvious, within the sense of the relevant legal authorities, for the hypothetical formulator to try out the idea of a subcoat? And, if so, was it *obvious* for the hypothetical formulator *to try out* a subcoat falling within the description contained in the patent? These are the questions critical to the claim of lack of inventive step. They overlap and may be addressed together." (emphasis added)

63 The Full Court stated as a proposition of law that, to make out a case of obviousness⁷⁵:

71 (2000) 51 IPR 375 at 392; [2000] AIPC ¶91-636 at 38,176.

72 (2000) 51 IPR 375 at 392, 409-410; [2000] AIPC ¶91-636 at 38,176, 38,191.

73 (2000) 51 IPR 375 at 392-393; [2000] AIPC ¶91-636 at 38,176.

74 (2000) 51 IPR 375 at 393; [2000] AIPC ¶91-636 at 38,177.

75 (2000) 51 IPR 375 at 382-383; [2000] AIPC ¶91-636 at 38,168.

"[i]t is enough that it be apparent to [a non-inventive skilled worker] that it would be *worthwhile to try each of the integers* that was ultimately successfully used." (emphasis added)

Their Honours then said that this was the point made in what they identified as a classic statement by Buckley LJ in *Amoxycillin*⁷⁶. That was to the effect that, for "a particular step or process" to be obvious, it will suffice if it be shown that to a person skilled in the art but lacking an inventive capacity it would appear that "to try" the step or process would be "worthwhile" in solving the recognised problem or meeting the recognised need.

64 Astra points to several errors of law in this approach which deprive the Full Court decision of any support it might otherwise give to the decision at trial. The errors are interrelated.

65 First, the focus upon each integer rather than the interaction between them in combination went against the teaching in authorities such as *Minnesota Mining*, to which reference has been made. Secondly, the reference to "worthwhile to try" led the Full Court into the following reasoning⁷⁷:

"[W]e reject the submission made by counsel for Astra that the finding made by Lehane J^[78] logically concluded the issue of obviousness in their clients' favour. It will be recalled that his Honour said that '*considered at the commencement of a hypothetical attempt ... the combination claimed in the patent was not obvious*'. That finding would dispose of the issue only if the concept of obviousness was restricted, in the case of a combination patent, to a situation where the hypothetical formulator could foresee, at the commencement of his or her task and without the necessity for testing or any process of trial and error, which particular integers (out of all those 'worth a try') would be most appropriate. However, that is not the law, as was made clear by Buckley LJ in the extract from [*Amoxycillin* quoted above⁷⁹]. Once it is accepted that it is sufficient that it be obvious to the hypothetical formulator that a particular possibility is worth trying (perhaps among many possibilities), it must follow that it is incorrect to say that an invention lacks obviousness simply because the hypothetical formulator would, or might, have been unable to say in advance which (if any) of the possibilities worth trying would prove most satisfactory." (emphasis added)

76 [1980] RPC 261 at 290.

77 (2000) 51 IPR 375 at 393; [2000] AIPC ¶91-636 at 38,177.

78 (1999) 44 IPR 593 at 626-627; [1999] AIPC ¶91-474 at 39,442.

79 (2000) 51 IPR 375 at 383; [2000] AIPC ¶91-636 at 38,168-38,169.

The Full Court added⁸⁰:

"This reasoning applies even where (as here) a problem unexpectedly appears during the course of routine steps undertaken for the purpose of creating a new product. Although the existence of the problem may not have been apparent at the outset, its solution (when it does appear) may be obvious, as distinct from inventive, depending on whether or not it would immediately be apparent to a skilled worker in the field to try the solution that in fact proved effective."

"Obvious" or "worthwhile" to try

66 It is by no means apparent that what was said by Buckley LJ in *Amoxycillin* was adapted to the purpose to which the Full Court put it. His Lordship was concerned with a claim to a single chemical substance (a penicillin) adapted for oral administration⁸¹, not, as was the Full Court, with the dissection of a combination into its integers. The step or process to which Buckley LJ referred was a step from the prior art to the substance claimed. This appears from the balance of the passage from his judgment set out by the Full Court⁸².

67 Further, in the event, Buckley LJ upheld the validity of the claim. His conclusion has resonances for this litigation, but to the detriment of Alphapharm's case not, as the Full Court saw it, for its advancement. The vital passage is as follows⁸³:

"I am fully prepared to assume on the evidence before the court that [prior patent] 978,178 should be regarded as having made clear to one skilled in the field of penicillins that the epimers of the para-hydroxy and the meta-hydroxy compounds were likely to prove fruitful avenues of research, possibly the most promising avenues known to exist. I accept that the lines which that research would follow would be what [the opponent's] witnesses described as 'routine', ie well-known. I accept that anyone experienced in penicillin research who pursued research along those avenues would probably have found what Beecham found. But with great deference to the learned judge, I do not agree that this is enough to constitute the claim to Amoxycillin as a penicillin for administration to humans obvious for the purposes of section 14(1)(e) of the [1949 UK Act]. To reach the discovery of the particular characteristics of Amoxycillin and its

80 (2000) 51 IPR 375 at 393; [2000] AIPC ¶91-636 at 38,177.

81 [1980] RPC 261 at 287.

82 (2000) 51 IPR 375 at 383; [2000] AIPC ¶91-636 at 38,168-38,169.

83 [1980] RPC 261 at 296.

suitability for treating humans the research worker would have had to embark upon a voyage of discovery. It is possible now to see that his voyage would have been short and perhaps uneventfully straightforward, but where each of his two, or possibly more, vessels would make landfall and what those places would be like would not have been obvious to him at the outset. The voyage might have been clearly worth trying but not as a means of reaching a specific hoped-for destination."

68 Buckley LJ did refer, among other authorities, to what had been said by Diplock LJ in *Johns-Manville*⁸⁴. Diplock LJ, after, as indicated above, decrying the use of particular verbal formulae, had rejected a postulate of prior certainty of success before actually performing particular tests; it was enough for a case of obviousness that the person versed in the art would assess the likelihood of success "as sufficient to warrant actual trial". Later, in *Technograph Printed Circuits Ltd v Mills & Rockley (Electronics) Ltd*⁸⁵, Lord Reid said that the hypothetical technician there under consideration must be supposed "to try everything which would appear to him as giving *any prospect* of valuable results" (emphasis added).

69 On the other hand, in *American Cyanamid Co v Ethicon Ltd*⁸⁶, Graham J held, with reference to *Johns-Manville*, that it was not obvious to try a substance (the invention claimed) which had been a candidate for inclusion in a research programme, given the extent of that programme. Reference has been made to what actually was decided in *Amoxycillin*. In *Johns-Manville*, the holding had been that the use of a known, but recently developed, flocculating agent to separate water from asbestos cement in the process of manufacture of asbestos cement pipes and boards was obvious. There was no question of dissection of a combination claim.

70 Later English decisions⁸⁷ applying the 1977 UK Act to chemical and biotechnological patents treat what was said by Diplock LJ in *Johns-Manville* as synonymous with "worth a try" and "well worth trying out". On that basis, a number of patents have been held invalid for obviousness. These cases include *Genentech Inc's Patent*⁸⁸ upon which Alphapharm relied. The outcome may

84 [1967] RPC 479 at 494.

85 [1972] RPC 346 at 356.

86 [1979] RPC 215.

87 See, for example, *Boehringer Mannheim GmbH v Genzyme Ltd* [1993] FSR 716 at 725; *Chiron Corporation v Murex Diagnostics Ltd* [1996] RPC 535 at 557; *Brugger v Medic-Aid Ltd* [1996] RPC 635 at 661. See further *Pharmacia Corp v Merck & Co Inc* [2002] RPC 775 at 818-819; *Lilly Icos Ltd v Pfizer Ltd* [2002] EWCA Civ 1 at [57].

88 [1989] RPC 147.

reflect the approach in European law that "the assessment of inventive step depends upon the extent to which a skilled person would have been technically motivated towards the claimed invention"⁸⁹. But cases such as *Genentech* mark a divergence from the treatment of obviousness in the decisions of this Court. The Full Court of the Federal Court recognised this in *ICI Chemicals & Polymers Ltd v The Lubrizol Corporation Inc*⁹⁰.

71 However, in the present case, a differently constituted Full Court, after setting out the passage from *Amoxicillin* to which reference has been made above, noted that⁹¹:

"Alphapharm does not suggest that the combination of integers disclosed in the patent would have been apparent to the skilled worker in the field prior to that worker attempting to formulate omeprazole",

but stated that the critical question in relation to the appeal was whether Alphapharm was correct in its further assertion that⁹²:

"each of the integers was at least worthwhile trying; therefore *the combination* itself was 'obvious', in the sense in which that word is used in this area of the law" (emphasis added).

72 In so expressing the critical question and then proceeding to answer it favourably to Alphapharm, the Full Court fell into various errors of law. Several points are to be made. First, the statute does not ask whether a particular avenue of research was obvious to try so that the result claimed therefore is obvious; the adoption of a criterion of validity expressed in terms of "worth a try" or "obvious to try" and the like begs the question presented by the statute. In a sense, any invention that would in fact have been obvious under the statute would also have been worth trying. Paragraph (e) of s 100(1) of the 1952 Act, applied to the present case, asks whether the combination claimed in claim 1 was obvious. The paragraph does not fix upon the direction to be taken in making efforts or attempts to reach that particular solution to the problem identified in the Patent. Nor does it direct an inquiry respecting each integer of the claimed combination. The paragraph asks whether "the invention ... as claimed", here the combination, was obvious, not each of its integers.

89 Paterson, *The European Patent System*, 2nd ed (2001), §12-43.

90 (2000) 106 FCR 214 at 240; their Honours referred in particular to *Genentech Inc's Patent* [1989] RPC 147 at 278, and see further Torremans, *Intellectual Property Law*, 3rd ed (2001) at 68-78.

91 (2000) 51 IPR 375 at 383; [2000] AIPC ¶91-636 at 38,169.

92 (2000) 51 IPR 375 at 383; [2000] AIPC ¶91-636 at 38,169.

73 In the United States, any criterion which adopts a notion of "obvious to try" has been rejected in a long series of decisions upon §103 of the 1952 US Act⁹³. The judgment in a number of these was given by Judge Rich, first as a member of the United States Court of Customs and Patent Appeals and latterly as a member of the United States Court of Appeals, Federal Circuit. In 1966, in *Application of Tomlinson*⁹⁴, his Honour wrote:

"Slight reflection suggests, we think, that there is usually an element of 'obviousness to try' in any research endeavor, that it is not undertaken with complete blindness but rather with some semblance of a chance of success, and that patentability determinations based on that as the test would not only be contrary to statute but result in a marked deterioration of the entire patent system as an incentive to invest in those efforts and attempts which go by the name of 'research.'"

74 Later, in *In re O'Farrell*⁹⁵, a case concerned with an invention using genetic engineering, Judge Rich observed:

"[F]or many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. There is always at least a possibility of unexpected results, that would then provide an objective basis for showing that the invention, although apparently obvious, was in law nonobvious."

75 Earlier, in *In re Farbenindustrie AG's Patents*⁹⁶, Maugham J had dealt with an application to revoke three "selection patents" relating to the manufacture of dyestuffs. The grounds advanced included lack of subject-matter, as it was then identified. His Lordship said⁹⁷:

"In a sense it is still true to say that there is no prevision in chemistry. Any one of the millions of dyestuffs in question might be found to possess some unexpected and distinctive properties, either of colour or fastness, or to have some other incidental advantage. There is no short cut to knowledge of this kind. A laborious and systematic investigation of a long series of combinations becomes necessary; and it is the fact that of recent years

93 Cooper, *Biotechnology and the Law*, (2001 rev), vol 1, §4.03[1][a][v].

94 363 F 2d 928 at 931 (1966).

95 853 F 2d 894 at 903 (1988).

96 (1930) 47 RPC 289.

97 (1930) 47 RPC 289 at 321-322.

certain industrial organisations with enormous financial resources have established laboratories where numbers of chemists of high scientific attainments devote their lives to a systematic examination on scientific principles of a vast number of chemical substances."

76

In *In re O'Farrell*⁹⁸, Judge Rich also said:

"The admonition that 'obvious to try' is not the standard under §103 has been directed mainly at two kinds of error. In some cases, what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. ... In others, what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it."

The reasoning in these and other United States authorities⁹⁹ should be accepted in preference to the path apparently taken in the English decisions, particularly after the 1977 UK Act, upon which Alphapharm relied. The United States decisions reflect an approach to the subject closer to that adopted in *Minnesota Mining and Wellcome Foundation*.

Conclusions

77

Astra complains that the Full Court denied it procedural fairness. The Full Court took the view that Lehane J may have had in mind a possible rather than a probable result of the hypothetical formulator's activity; if so, then, in the Full Court's view, Lehane J had erred¹⁰⁰. The Full Court then set out on a detailed review of the expert evidence. Astra complains that it was denied the opportunity of addressing the Full Court on the findings of fact which it made and that the Full Court wrongly assumed there to have been no dispute at trial respecting the evidence of Alphapharm's experts. It does appear that express rulings were never made at trial upon a number of objections. This failure by trial judges was

⁹⁸ 853 F 2d 894 at 903 (1988).

⁹⁹ Including *Application of Antonie* 559 F 2d 618 (1977), *Application of Goodwin* 576 F 2d 375 (1978), *In re Geiger* 815 F 2d 686 (1987), *In re Fine* 837 F 2d 1071 (1988), *Merck & Co Inc v Biocraft Laboratories Inc* 874 F 2d 804 (1989), *In re Vaeck* 947 F 2d 488 (1991) and *In re Nunberg* 33 United States Patent Quarterly 2d 1953 (1994).

¹⁰⁰ (2000) 51 IPR 375 at 389; [2000] AIPC ¶¶91-636 at 38,174.

described as unfortunate in *Firebelt*¹⁰¹ and this case provides another example. Parties should know, before addresses are taken, the final state of the evidence, whether the trial be by judge and jury or judge alone.

78 It is unnecessary, for this appeal, further to pursue Astra's submissions on this aspect of the litigation. After its review of the evidence, the Full Court concluded¹⁰² that Astra's "development" of the formulation "was essentially an exercise *in trying out* various known *possibilities* until the correct solution emerged" (emphasis added). That view of the matter wrongly takes as the starting point the assumed result. It succumbs immediately to the seduction of hindsight. Also, the notion of trying out possibilities invites the repetition of criticisms made earlier in these reasons.

79 The result is that the Full Court erred in the grounds upon which it supported the outcome at trial. The point is made from time to time that obviousness is a "jury question" and that the answer given to it by trial judges, juries long having since departed this scene in Australia, should be treated on appeal like any other factual resolution. All that is true, as it is, for example, of trials of negligence actions; but in all these fields the criteria of principle against which the evidence is measured are supplied by the law, whether by the common law, or by statute, in this case the 1952 Act and the decisions construing its provisions. In this litigation, both at trial and in the Full Court, Alphapharm was held to have made out its case by processes which were determined by errors of law.

80 Alphapharm and Astra referred to litigation in a number of countries respecting the validity of the patent protection for the formulation of omeprazole. This shows that upon variously expressed laws and differing factual findings a range of outcomes has been reached.

81 There are obvious advantages in a substantial measure of uniformity between the patent laws of countries with which Australia maintains international arrangements under its patents legislation. But these reasons reveal that the law respecting obviousness in various jurisdictions currently diverges and that the extent of this divergence changes from time to time. There is no universal view of a matter which at bottom reflects a range of attitudes to the balance of interests at stake in patent law. Nor is it to the point that had the obviousness of the claims of the Patent fallen for decision solely under the 1990 Act, whether in its initial or amended form, the law may have favoured Alphapharm's case more than did the 1952 Act.

Orders

101 (2002) 76 ALJR 816 at 824 [42]; 188 ALR 280 at 291.

102 (2000) 51 IPR 375 at 406; [2000] AIPC ¶91-636 at 38,189.

82 The appeal should be allowed with costs. The orders made by the Full Court on 9 October 2000 should be set aside. The matter is remitted to the Full Court for the determination of any remaining grounds on Alphapharm's Notice of Contention. The operation of order 2 made by Lehane J on 18 June 1999 (which dealt with revocation) should be further stayed until further order of the Federal Court. The costs of the whole of the proceedings in the Federal Court are to be in the discretion of the Full Court.

McHUGH J:

83 The issue in this appeal is whether "the invention, so far as claimed in any claim of the complete specification ... was obvious and did not involve an inventive step having regard to what was known or used in Australia on or before the priority date of that claim"¹⁰³. This issue raised a question of fact that had to be determined by applying a statutory expression. A summary of some of the extensive evidence adduced in the case is contained in the joint judgment of Gleeson CJ, Gaudron, Gummow and Hayne JJ.

84 I would dismiss the appeal on the ground that there are concurrent findings of fact by Lehane J and the Full Court of the Federal Court that should not be disturbed by this Court. They were findings that were open to them on the evidence, they involved the application of a flexible, indeterminate expression and they were not flawed by any legal error.

85 The meaning of ordinary English words in a statute is a question of fact. "Obvious" is an ordinary English word whose primary meaning is "very plain"¹⁰⁴. The question for Lehane J, therefore, sitting as a juror, was whether the inventive step claimed was "very plain". That involved making a judgment concerning a large volume of evidence. Different minds could reasonably have come to different conclusions about the effect of the evidence. If I had been the trial judge, I suspect that I would have applied the approach to the issue of "obviousness" that Gleeson CJ, Gaudron, Gummow and Hayne JJ follow in their joint judgment and if I had done so, I would probably have reached the same result as their Honours do. But, as a matter of law, I would not have been bound to use the approach that their Honours outline. Despite the many judicial statements to which their Honours refer, the issue in this case involved a factual conclusion¹⁰⁵ whose resolution could legitimately give rise to a number of differing approaches and

103 Section 100(1)(e), *Patents Act* 1952 (Cth).

104 *The General Tire & Rubber Company v The Firestone Tyre & Rubber Company Ltd* [1972] RPC 457 at 497.

105 *Société Technique de Pulverisation Step v Emson Europe Ltd* [1993] RPC 513 at 519 per Hoffmann LJ; *Chiron Corporation v Murex Diagnostics Ltd* [1996] RPC 535 at 557 per Aldous J.

answers¹⁰⁶. In *Johns-Manville Corporation's Patent*¹⁰⁷, Diplock LJ refrained from providing a definition of "obviousness" so that it could not be cited in later cases concerning different types of claims. Diplock LJ said that patent law "can too easily be bedevilled by linguistics" and that "obviousness" does not depend upon the use of a particular verbal formula or reliance upon cases about other inventions of different kinds.

86 A judge trying the obviousness issue is not bound, as a matter of law, to determine that issue by reference to persons who are not "particularly imaginative or inventive"¹⁰⁸. Nor is the judge, in a case like the present, bound to ask "whether the hypothetical addressee faced with the same problem would have taken as a matter of routine whatever steps might have led from the prior art to the invention, whether they be the steps of the inventor or not"¹⁰⁹. Nor is the judge bound to ask whether a notional research group would be directly led, as a matter of course, to try the approach of the "inventor" in the expectation that it might well produce a useful result or alternative¹¹⁰. These statements, and similar ones, have been made by judges, highly experienced and eminent in patent law, and applied by many other judges. A judge faced with a situation similar to those dealt with in a judgment containing one of these statements would be well advised to follow it, reflecting as it does the collective wisdom of the judiciary on this type of situation. And to do so helps to achieve consistency in fact finding, a matter of great importance if the law is to maintain the confidence of litigants. Equal justice under the law requires that like cases should be decided alike. Nevertheless, all such judicial statements merely reflect reasoning processes concerning factual issues. They do not lay down any legal principles and they have no precedent value. They are not binding upon judges hearing future cases.

87 In many fields of law governed by statute, such as income taxation, workers' compensation, environmental planning and patents, judges and practitioners, who specialise in those fields, have a tendency to treat judicial statements, determinative of particular cases, as principles of law. Few of them are. Most of the time, they simply reflect how experienced judges have resolved particular

106 *Johns-Manville Corporation's Patent* [1967] RPC 479 at 493-494 per Diplock LJ, Willmer LJ agreeing.

107 [1967] RPC 479 at 493-494.

108 *Aktiebolaget Hässle v Alphapharm Pty Ltd* (1999) 44 IPR 593 at 604.

109 *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262 at 286 per Aickin J.

110 cf *Olin Mathieson Chemical Corporation v Biorex Laboratories Ltd* [1970] RPC 157 at 187-188 per Graham J.

factual situations. As Dixon CJ once said¹¹¹, in rejecting an argument that a departure from observations made in an earlier case warranted the grant of special leave to appeal, "it is not everything that appears in the Law Reports that is law". Some may see this statement as a cynical reference to the Law Reports containing erroneous statements of legal principle. But given its context, I think that the great Chief Justice was emphasising that many statements in the Law Reports are concerned with reasoning about factual situations. So in *Conkey & Sons Ltd v Miller*¹¹², after referring to a passage in the judgment of Fullagar J in *The Commonwealth v Butler*¹¹³ with which Dixon CJ and Kitto J had agreed, Barwick CJ said:

"[*Butler*] does not decide any principle of law. The statute requires the death to result from work-caused injury: whether it does or does not is a matter of fact. Doubtless, in applying the concepts of causation, a statement by an eminent judge such as I have quoted is entitled to respect by those who have themselves to decide a question of fact upon the evidence of the case before them. But its persuasion rises no higher: and certainly does not bind in point of precedent."

88 When a trial judge has made, and an intermediate court of appeal has affirmed, a finding or findings of fact, this Court will almost invariably refuse to grant special leave to appeal against that finding or those findings. Unless the lower courts have misapplied the law in making the factual findings, the case is not "special" enough to warrant the grant of special leave to appeal.

89 I was a party to the grant of special leave to appeal in this case. At the time, I thought that, despite the concurrent findings of fact, the case arguably raised questions of principle. But after further examining the matter, I think that the case is really concerned with factual findings and reasoning.

90 Once special leave to appeal is granted, the Court, of course, must examine the evidence and facts for itself. But that does not mean that, in determining the appeal, the Court should or must always do so without regard to concurrent findings of fact made in the lower courts. Where the case involves the application of a flexible and indeterminate standard such as "reasonable", "fair" or "unconscionable" – or "obvious" – this Court should be slow to depart from the concurrent findings. Often – perhaps usually – there is no single, right answer to the question of fact posed by such indeterminate standards. Moreover, the trial judge has had the advantage of seeing and hearing witnesses give evidence, usually over many days. This is a significant factor even in a case where the credibility of

111 *White v The Queen* (1962) 107 CLR 174 at 175.

112 (1977) 51 ALJR 583 at 585; 16 ALR 479 at 485.

113 (1958) 102 CLR 465 at 471-472.

witnesses is not an issue. Even in a case of that kind, the trial judge's findings may well have been influenced, consciously or unconsciously, by the judge's perceptions of the witnesses and the evidence, as it has unfolded in detail over many days. That the judgment fails to record this fact is of little importance. As Lord Hoffmann pointed out in *Biogen Inc v Medeva PLC*¹¹⁴, the judgment of the trial judge is "inherently an incomplete statement of the impression which was made upon him by the primary evidence".

91 I am not persuaded that the learned trial judge and the judges of the Full Court misunderstood the law or the issue that they had to decide. Nor am I persuaded, after taking into account the advantages of the trial judge, that he erred in his conclusion concerning the issue for decision.

92 I would dismiss the appeal with costs.

KIRBY J:

93 In *Biogen Inc v Medeva plc*¹¹⁵ Lord Hoffmann observed that: "The question of whether an invention was obvious has been called 'a kind of jury question' ... and should be treated with appropriate respect by an appellate court."

Obviousness: a factual decision

94 Obviousness was the issue in these proceedings. The primary judge (Lehane J), and on appeal the Full Court of the Federal Court of Australia, unanimously concluded that issue in favour of the respondent, Alphapharm Pty Ltd ("Alphapharm"). Now Aktiebolaget Hässle, a Swedish corporation, and Astra Pharmaceuticals Pty Ltd (together "Astra"¹¹⁶), by special leave, challenge the factual conclusions reached at each level in the Federal Court.

95 The conclusions on obviousness in the proceedings below represented the outcome of a judicial evaluation of a mass of evidence. In the assessment of that evidence, and in the conclusion to be derived from it, the primary judge and the Full Court were better placed to perform the function of fact-finding than this Court is. Unless some error is shown in the application of the relevant law, it would be a rare step for this Court to condescend to re-evaluate such a factual conclusion,

114 [1997] RPC 1 at 45.

115 [1997] RPC 1 ("*Biogen*") at 45 citing *Allmanna Svenska Elektriska A/B v The Burntisland Shipbuilding Co Ltd* (1951) 69 RPC 63 at 70 per Jenkins LJ.

116 The same terms are used to describe the parties to the proceedings as are used in the joint reasons and in the Federal Court: see *Aktiebolaget Hässle v Alphapharm Pty Ltd* (1999) 44 IPR 593 ("*Aktiebolaget*") at 595 [1]; *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2000) 51 IPR 375 at 376 [1].

reached by concurrent decisions at two levels of the judicial hierarchy¹¹⁷. Cases like the present have been described as "difficult cases involving questions of degree"¹¹⁸. For that reason this Court normally leaves such decisions to others. Typically, they are cases that involve issues relating to the "particular application of legal principles, rather than the content of those principles"¹¹⁹.

96 A majority of this Court has concluded that the judges of the Federal Court erred in their respective approaches to the applicable law. I disagree. I remind myself at the outset that, under the Constitution, the function of this Court is to correct judgments and orders of the courts from which appeals come. It is not, as such, to correct every phrase or sentence in the exposition of reasons that explain how the judges of those courts arrived at the contested conclusion.

97 Because obviousness is ultimately a factual conclusion (of a kind once normally decided by a jury¹²⁰) it will not always be possible for judges, explaining their opinions, to express all of the considerations that lead them to the evaluative and partly intuitive conclusion required in the particular case. Any exposition of judicial reasons explaining such factual findings is "inherently an incomplete statement of the impression which was made upon [the judge] by the primary evidence"¹²¹. Judges having replaced juries in such matters in Australia, and having entangled themselves in a web of horrible verbal formulae, must do their best to explain their conclusions where, in the past, juries simply announced their verdicts.

117 *The Commonwealth v Introvigne* (1982) 150 CLR 258 at 260-261, 274; *Louth v Diprose* (1992) 175 CLR 621 at 633-635; *CDJ v VAJ* (1998) 197 CLR 172 at 230-231 [186.1]; *Graham Barclay Oysters Pty Ltd v Ryan* [2002] HCA 54 at [50]-[55] per Gleeson CJ.

118 *ICI Chemicals & Polymers Ltd v The Lubrizol Corporation Inc* (2000) 106 FCR 214 ("Lubrizol") at 240 [79] with reference to *Beecham Group Ltd's (Amoxycillin) Application* [1980] RPC 261 ("Beecham Group") at 290-291.

119 *R D Werner & Co Inc v Bailey Aluminium Products Pty Ltd* (1989) 25 FCR 565 ("Werner") at 602 per Gummow J.

120 *General Tire & Rubber Co v Firestone Tyre and Rubber Co Ltd* [1972] RPC 457 ("General Tire") at 498.

121 *Biogen* [1997] RPC 1 at 45 per Lord Hoffmann.

98 In this appeal we need to follow the judges of the Federal Court into the forest of verbal elaboration that now burdens this field of law¹²². We do so because that is what is customary. It is the way the matter was argued in the courts below, as well as in the appeal before this Court. No party has suggested a simpler and less convoluted approach.

99 However, before I enter upon the decisional verbiage, I remind myself of what essentially I am doing. This Court is reviewing for error the application of an extremely short passage of a statute enacted by the Australian Parliament, invoked by reference to the detailed facts proved in evidence at the trial. The passage ultimately calls forth a factual conclusion. In the end, that comes down to the application to the facts of simple words of the English language. Before this Court disturbs such a factual conclusion, it should remember that, in terms of the statute, the issue was not as complicated as legal ingenuity and judicial verbosity (often urged on by large commercial interests) have sometimes made it seem in the past. As was said in another context, courts must be wary of the professional danger that "attends the formulation of principles and doctrines and all reasoning a priori in matters which in the end are governed by the meaning of the language in which the Legislature has expressed its will"¹²³.

A similar conclusion in England

100 The proceedings now before this Court are the local aspect of a world-wide attempt by Astra to resist applications by manufacturers of "generic" pharmaceuticals to obtain the revocation of patents granted in the 1980s for a pharmaceutical product that in Australia (as in England) is sold under the proprietary name "Losec". Astra has already enjoyed the benefit of twenty years of patent protection for the pharmaceutical compound omeprazole ("the compound patent"), the active ingredient in Losec. In the financial year 1997-1998, more than 1.5 million packs of Losec were sold in Australia under the Commonwealth Pharmaceutical Benefits Scheme. In that year, the cost to the Federal Government was more than \$141 million¹²⁴. Ultimately, such cost is borne by Australian taxpayers.

101 The stakes for the parties are therefore high. The entry of generic drugs as cheaper substitutes for branded ones at the expiration of patent protection is a

¹²² *Johns-Manville Corporation's Patent* [1967] RPC 479 ("*Johns-Manville*") at 493-494 per Diplock LJ. See the reasons of Gleeson CJ, Gaudron, Gummow and Hayne JJ ("the joint reasons") at [37].

¹²³ *Country Roads Board v Neale Ads Pty Ltd* (1930) 43 CLR 126 at 135.

¹²⁴ *Aktiebolaget* (1999) 44 IPR 593 at 595 [3].

feature of the market for pharmaceuticals in many countries¹²⁵. The strategies that large pharmaceutical manufacturers have employed to avoid such generic competition, which include the use of intellectual property law, have been detailed elsewhere¹²⁶. They have attracted the attention and response of the Federal Trade Commission in the United States¹²⁷. Such battles have had their counterparts in many other countries. They present serious issues for the developing world¹²⁸. In its interpretation of the legislation, and in identifying the proper approach to the ultimately factual determination of obviousness called for by that statute, this Court should avoid creating fail-safe opportunities for unwarranted extensions of monopoly protection that are not clearly sustained by law.

102 The patents in suit relate to the formulation of an oral preparation that delivers the compound omeprazole to human patients. The compound is useful in the treatment of gastro-intestinal diseases because it inhibits the secretion of gastric juices. The compound patent granted to Astra expired in April 1999. The subject patents involve tablets or pellets devised to deliver omeprazole in such a way that the compound will pass through the stomach and into the intestines of the patient. The claim, the subject of the patents in suit, involves the form of oral administration of omeprazole in such a way as to be resistant to stomach acid but "bioavailable in the intestines"¹²⁹.

103 Concurrently with the proceedings in Australia that have now reached this Court, actions were commenced in the Patents Court of the High Court in England for revocation of the formulation patents granted to Astra's interests in the United Kingdom. After the decisions of the primary judge and the Full Court of the Federal Court in Australia, the judge of the Patents Court (Laddie J) gave his

125 See Nogués, "Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries", (1990) 24 *Journal of World Trade* 81 at 94-98.

126 Nogués, "Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries", (1990) 24 *Journal of World Trade* 81 at 98-102.

127 United States, Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration*, (2002).

128 Nielsen and Nicol, "Pharmaceutical Patents and Developing Countries: the Conundrum of Access and Incentive", (2002) 13 *Australian Intellectual Property Journal* 21 at 23; Kongolo, "Public Interest *versus* the Pharmaceutical Industry's Monopoly in South Africa", (2001) 4 *The Journal of World Intellectual Property* 609; cf Bale, "Patent Protection and Pharmaceutical Innovation", (1997) 29 *New York University Journal of International Law and Politics* 95. See also Drahos and Braithwaite, *Information Feudalism*, (2002) at 8-10.

129 *Cairnstores Ltd v Aktiebolaget Hässle* [2002] EWHC 309 (Ch) at [4].

judgment and published his reasons in March 2002¹³⁰. His decision was concerned, substantially, with factual questions relating to the obviousness said to affect the United Kingdom equivalent of the patents in suit, similar to those before the primary judge. In his reasons, Laddie J concluded that claim 1 of the European Patent (UK) granted to Astra's interests in 1986 was invalid for obviousness¹³¹.

104 It was common ground that the action for revocation of the patents in suit in these proceedings was to be decided by reference to the applicable ground of revocation stated in s 100(1)(e) of the *Patents Act* 1952 (Cth) ("the Act"). It was not to be judged in terms of later Australian legislation¹³². As the joint reasons in this Court point out, under the influence of European law, the patent law of the United Kingdom has lately introduced concepts in some ways different from those expressed in the Act, as interpreted by this Court. However, this divergence should not be overstated.

105 In *Mölnlycke AB v Procter & Gamble Ltd (No 5)*¹³³, in examining the operation of s 1 of the *Patents Act* 1977 (UK) ("the 1977 UK Act"), the Vice-Chancellor stressed a number of points: first, that the question of obviousness is a factual determination on which prior decisions¹³⁴ and semantic arguments¹³⁵ are of only limited assistance; secondly, that expert evidence is the primary evidence on which such determinations are based; and finally that the proper approach to determinations of obviousness under the 1977 UK Act is no different from the one followed with respect to earlier provisions¹³⁶.

130 *Cairnstores Ltd v Aktiebolaget Hässle* [2002] EWHC 309 (Ch). An appeal by Astra against Laddie J's judgment, not against his conclusion of obviousness, but on the ground of apprehended bias was dismissed by the English Court of Appeal: *Cairnstores Ltd v Aktiebolaget Hässle* unreported, Court of Appeal (Civil Division), 22 October 2002 at [27]-[28], [44]-[46].

131 *Cairnstores Ltd v Aktiebolaget Hässle* [2002] EWHC 309 (Ch) at [119].

132 Namely the *Patents Act* 1990 (Cth) which came into force in April 1991, after the patents in suit were granted.

133 [1994] RPC 49 at 112-115; cf *Genentech Inc v Wellcome Foundation Ltd* (1988) 15 IPR 423 ("*Genentech*") at 543-544.

134 Referring to *Savage v D B Harris and Sons* (1896) 13 RPC 364.

135 Referring to *Hallen Co v Brabantia (UK) Ltd* [1991] RPC 195.

136 In particular, referring to the approach of Oliver LJ in *Windsurfing International Inc v Tabur Marine (Great Britain) Ltd* [1985] RPC 59 at 73.

106 True it is, that on the definition of "[t]he state of the art" in s 2(2) read together with s 3 of the 1977 UK Act, skilled formulators in that country are deemed to have read more widely than their Australian counterparts under the Act as interpreted by the decision of this Court in *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd*¹³⁷. However, as the decision of the Full Court demonstrates, nothing turns in these proceedings on the inclusion or exclusion of particular documents affecting the common general knowledge¹³⁸.

107 Furthermore, an examination of the reasons of Laddie J in the English proceedings¹³⁹ shows that his Lordship substantially focussed his attention on a simple, straight-forward factual question. It was the one also posed by the terms of the Act for the Australian judges in these proceedings. In Laddie J's reasons, there was no ponderous examination of the mountain of decisional law typically urged on the Australian judges, and on this Court, in an endeavour to convert a factual conclusion into a legal one. In the English Patents Court, at least, judges seem at last to be heeding the plea of Diplock LJ not to approach cases of this kind with their minds frozen by opaque verbal expressions that aim to paraphrase the words of the Act and risk distracting the attention of the decision-maker from the evidence and the factual conclusions that must ultimately be arrived at¹⁴⁰.

108 Similar evidence was presented before Laddie J as had earlier been tendered in the Australian proceedings before the primary judge. In the English decision there is a thorough examination of that evidence. In the result, Laddie J reached a conclusion that is not only identical in its outcome with that reached by all judges of the Federal Court. It is similar in its reasoning. His Lordship said¹⁴¹:

"It follows that the notional skilled worker embarking on the task of making a formulation of omeprazole for oral administration would have found out almost immediately that an incompatibility problem existed as between the omeprazole and the enteric coating. He would have thought that an obvious route to try to overcome this would be to put a separating

137 (1980) 144 CLR 253 ("*Minnesota Mining*").

138 *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2000) 51 IPR 375 at 392 [77].

139 *Cairnstores Ltd v Aktiebolaget Hässle* [2002] EWHC 309 (Ch).

140 *Johns-Manville* [1967] RPC 479 at 494.

141 *Cairnstores Ltd v Aktiebolaget Hässle* [2002] EWHC 309 (Ch) at [92]. I do not agree that the reference by Laddie J in his reasons at [94] to the assumption that the "skilled worker is assumed to have read and understood all the available prior art", referred to in the joint reasons at [49], expresses a different approach. His Lordship made his meaning clear, in the context, in what immediately follows: "It is not in dispute that he will be taken to have read each of the pieces of prior art pleaded by the claimants and referred to below."

layer between the two. It would have been immediately apparent to him that such a separating layer would need to dissolve or disintegrate in the intestine to avoid bioavailability problems. There is nothing which would have deterred him from trying such a separating layer. In these circumstances Claim 1, and therefore all the remaining claims, fail for obviousness."

109 There is nothing in Laddie J's statement of the legal problem, in his mode of analysis or in his conclusion that depends upon new developments of English patents law, under the mysterious influence of the European Patent Office (possibly considered baleful by some Australian lawyers). The above conclusion is framed in terms of a simple finding of fact. In my view, it expresses an approach compatible with s 100(1)(e) of the Act, applicable to this case.

110 This Court was told that other cases between Astra's interests and makers of generic pharmaceutical products in other countries have resulted in differing outcomes. Let it be so. But Laddie J's reasons, reaching the same ultimate conclusion as the primary judge and the Full Court of the Federal Court upon similar factual evidence (and with no critical difference of legal considerations), provide an additional warning against disturbing the factual determinations reached by the primary judge and confirmed by the Full Court. That conclusion should stand.

The facts, the trial and common ground

111 The background facts of the dispute between Astra and Alphapharm are set out in other reasons¹⁴². So are the applicable provisions of the Act¹⁴³. So is the way in which, notwithstanding the enactment of the *Patents Act* 1990 (Cth) ("the 1990 Act"), the question of revocation argued in the appeal is to be decided in accordance with the law stated by the Act of 1952¹⁴⁴.

112 Also set out in other reasons is a description of the relevant background, including the course of the litigation¹⁴⁵ together with extracts from the reasons of the primary judge and from the conclusions of the Full Court. I will not repeat any of this material.

142 The joint reasons at [2]-[7].

143 The joint reasons at [13].

144 The joint reasons at [15]-[16]; cf *Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Ltd* (1998) 194 CLR 171 at 179-180 [6], 194 [42].

145 The joint reasons at [8]-[12].

113 On a number of crucial issues there was common ground between the parties. Thus, it was not contested that Alphapharm bore the onus in its cross-claim for revocation to establish obviousness; and that the issue of obviousness had to be determined, in terms of the Act, by reference to "what was known or used in Australia on or before the priority date". In this case that date was 30 April 1986. Nor was there any contest that this Court would apply the approach to the concept of obviousness in the Act, based on the decisions in cases such as *Minnesota Mining and Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd*¹⁴⁶.

114 The lastmentioned agreement does not, however, carry with it the degree of concurrence that Astra suggested. As McHugh J points out in his reasons¹⁴⁷, the question of obviousness turns upon the particular facts under consideration. The way in which the approach formulated in cases such as *Minnesota Mining and Wellcome Foundation* will be applied in a different factual setting must be illuminated by the evidence about the claimed invention, and particularly the relevant field of knowledge and research which may be significantly different from, or more complicated than, those considered in other decisions¹⁴⁸. The Act remains the same. Its language is relevantly unaltered. The words remain comparatively simple. A factual determination is still required. But it is a factual determination that must now be derived from different scientific evidence, in the context of a particular problem that presented itself for solution, and in a particular field of knowledge that is also not static.

115 What will, or will not, be "obvious" (and therefore what will, or will not, involve an "inventive step") necessarily depends upon the field of knowledge in question. It moves in pace with the practices and complexity of such a field. That was certainly the argument that Alphapharm urged, successfully, in the Federal Court but which Astra resisted. For reasons that I will explain, I consider Alphapharm's argument correct in this respect. It sustains the approach and conclusions of the primary judge and the Full Court. Those decisions are compatible with the reasoning of this Court in *Minnesota Mining and Wellcome Foundation*, when such reasons are read in the light of the evidence, offered in a case such as the present, considering the nature of the particular field and the state of the prior knowledge involved.

116 Because the parties agreed at trial that the conclusion about obviousness was to be decided by reference to the answer to the question: "whether the invention would have been obvious to a non-inventive worker *in the field*,

146 (1981) 148 CLR 262 ("*Wellcome Foundation*").

147 Reasons of McHugh J at [86].

148 cf Sherman, "Biological Inventions and the Problem of Passive Infringement", (2002) 13 *Australian Intellectual Property Journal* 146.

equipped with the common general knowledge in *that particular field* as at the priority date, without regard to documents in existence but not part of such common general knowledge"¹⁴⁹, it was necessary for the primary judge (and on appeal the Full Court) to answer that somewhat opaque, but common, interrogatory. To provide his answer, the primary judge accepted the evidence of the Australian formulators tendered by Alphapharm¹⁵⁰. He noted that Astra had not called anyone with the Australian experience of such formulators to contradict their evidence concerning the factual matters that were within their knowledge and experience at the applicable time¹⁵¹. These conclusions present a very substantial evidentiary obstacle for Astra to overcome.

117 The twenty year term of the compound patent expired at the same time as the primary judge delivered his decision in this case¹⁵². The patents in suit did not claim the compound omeprazole. The primary judge found that the addition of an alkaline compound to the core and the use of the enteric coat (described as the first and third integers of claim 1), were both "obvious" at the outset of the formulation stage¹⁵³. The potential for a reaction between a (basic) core and an (acidic) enteric coat and the use of an intermediate (water-soluble) film to isolate one from the other would also have been readily apparent to those working in the art.

118 The primary judge also accepted that, on or before the priority date, a formulator in Australia asked to formulate omeprazole in a form suitable for oral dosage, would have started with a literature search at least to discover the learning that was readily available about omeprazole and its characteristics¹⁵⁴. Having discovered such characteristics from the then readily available literature and "having tried the first simple formulation", the formulator would have done "substantially what Astra did". He or she would have "submitted it to appropriate tests, including tests for stability on manufacture and on storage and for acid resistance"¹⁵⁵. Having encountered a problem of incompatibility between the core and the enteric coat, the primary judge concluded that the formulator, as a matter

149 *Wellcome Foundation* (1981) 148 CLR 262 at 270 per Aickin J (emphasis added) who was, in turn, applying *Minnesota Mining* (1980) 144 CLR 253 at 293-295.

150 *Aktiebolaget* (1999) 44 IPR 593 at 608 [50].

151 *Aktiebolaget* (1999) 44 IPR 593 at 627 [110].

152 *Aktiebolaget* (1999) 44 IPR 593 at 595 [2], [4].

153 *Aktiebolaget* (1999) 44 IPR 593 at 627-628 [112]-[113], 629-630 [119].

154 *Aktiebolaget* (1999) 44 IPR 593 at 627 [112].

155 *Aktiebolaget* (1999) 44 IPR 593 at 627 [112].

of routine steps, taken in the course of the formulation process, would readily have reached the combination claimed in the patents in suit¹⁵⁶.

119 In reaching these conclusions, the primary judge made it clear that he was not considering the irrelevant question of whether the individual *integers* of the combination were obvious. Instead, he was addressing the relevant question, namely whether the *combination* was obvious¹⁵⁷. In this Court, the primary judge was criticised for applying the test of obviousness to the separate integers of the formulation. Had he done this it would indeed have been a mistake¹⁵⁸. With inventions it will often be the case that particular steps in the right general direction, viewed in isolation and separately (and especially with the benefit of hindsight¹⁵⁹), will be obvious although the combination of such steps (from all the others that would theoretically be possible) will constitute the "inventive step" and negate the claim of obviousness. The primary judge was clearly alert to the danger of such fallacious reasoning. His reasons explicitly demonstrate that his mind was concentrated on whether the identified formulator would "have arrived *at the combination*"¹⁶⁰.

120 Just because a claim is for a combination of a number of integers which interact in some way, that does not mean that it is automatically non-obvious and thus patentable under the Act¹⁶¹. The way in which the primary judge went about resolving the question whether the combination was obvious, in light of evidence about the research *process*, was entirely legitimate. As a first step, his Honour accepted the experts' evidence that the starting point of the formulation would be an enteric coated alkaline dosage of omeprazole. From there, what Astra did was to follow the predictable course that a skilled though unimaginative formulator would have followed as a matter of course or as a matter of routine.

121 The primary judge was fortified in his conclusion by the evidence of Dr Marshall, called by Alphapharm¹⁶². Dr Marshall undertook a task of simulated or hypothetical formulation, without having seen the patent and based on

156 *Aktiebolaget* (1999) 44 IPR 593 at 612-613 [66], 616-617 [81], 629 [117].

157 *Aktiebolaget* (1999) 44 IPR 593 at 629 [118].

158 *Minnesota Mining* (1980) 144 CLR 253 at 293.

159 A danger which the primary judge also explicitly recognised: *Aktiebolaget* (1999) 44 IPR 593 at 630 [120].

160 *Aktiebolaget* (1999) 44 IPR 593 at 626 [110] (emphasis added); see also at 629 [118].

161 cf *Minnesota Mining* (1980) 144 CLR 253 at 293.

162 *Aktiebolaget* (1999) 44 IPR 593 at 629 [119].

instructions "to formulate an appropriate dosage form of omeprazole for use by adults"¹⁶³. Astra made much of the fact that, in his reports, Dr Marshall did not arrive at the precise combination of the patent. His failure to do so was trumpeted by Astra as proof that its "invention" was not "obvious". This submission has found favour in this Court¹⁶⁴.

122 In my respectful opinion this is erroneous reasoning. The primary judge correctly recognised the evidence of Dr Marshall for what it was. As he pointed out, it "was not an actual formulation of a substance which he had but a theoretical or hypothetical one, and that presented difficulties and (as he commented) frustrations"¹⁶⁵.

123 The primary judge went on¹⁶⁶:

"[D]espite the limitations of the exercise, several aspects of his report are striking. He, like all the other witnesses, thought that an enteric coated dosage form was appropriate. He moved quickly to that position following his initial general comments about the formulation process and about sustained and controlled release; I do not doubt that it was his own independent idea to opt for an enteric coat, not merely the product of a suggestion to him by someone else. His formulation of the core included, apparently as a matter of course calling for no particular comment, a strongly alkaline substance ... When presented with scenarios, which had to take the place of actual tests but were, I think, a reasonable reflection of the Astra experience, one of the things which he thought might be occurring was an interaction between core and coat and one of the steps which he suggested was the incorporation of a subcoat, initially of (water insoluble) ethylcellulose. ... [W]hen asked to consider what he would do if tests showed poor bioavailability, he suggested changes to the subcoat."

124 In pursuing the course he did, Dr Marshall simply followed "the routine processes of the craft"¹⁶⁷. In the artificial circumstances in which he was asked to proceed, he largely tracked the steps that Astra had taken, without knowing those steps. They were logical and, according to the primary judge, would, in a practical setting, have led to the alternative subcoating materials, including the one referred to in the patents in suit. This process of reasoning led the primary judge to his ultimate conclusion that, having regard to common general knowledge at the

¹⁶³ *Aktiebolaget* (1999) 44 IPR 593 at 614 [71].

¹⁶⁴ cf the joint reasons at [28]-[29]; reasons of Callinan J at [186].

¹⁶⁵ *Aktiebolaget* (1999) 44 IPR 593 at 629 [119].

¹⁶⁶ *Aktiebolaget* (1999) 44 IPR 593 at 629-630 [119].

¹⁶⁷ *Aktiebolaget* (1999) 44 IPR 593 at 629 [118].

priority date, the combination claimed did not involve an "inventive step". It was "obvious" in the sense in which that word is used in the Act.

The appeal to the Full Federal Court

125 Nor, in my view, are the criticisms of the reasons of the Full Court made good. It is important to read the Full Court's reasons in the light of the primary judge's reasons and the issues raised in Astra's appeal to the Full Court.

126 Although before this Court Astra suggested that it had been deprived of natural justice before the Full Court, it did not appeal against the primary judge's treatment of the objections to evidence mentioned in other reasons¹⁶⁸. It will often be convenient, at trial, to proceed as the primary judge did in this case. There was no substantive injustice in the course that the primary judge took. It involved a common approach, often sensible and practical. Before offering criticism, this Court should also recall that the primary judge, at the request of both parties, was hearing the suit as a matter of urgency because the compound patent was then about to expire. In my view, and particularly heeding Lord Hoffmann's warning in *Biogen*¹⁶⁹, this provides an additional reason for caution in an ultimate appellate court before disturbing the findings of the primary judge.

127 Much of the force of Astra's appeal to the Full Court was addressed, as would be normal in such a proceeding, to the factual findings and conclusions reached at trial. Before the Full Court, extensive oral and written submissions on behalf of Astra addressed the facts. In the circumstances, discharging its appellate function properly in an appeal by way of rehearing, the Full Court was bound to address the parties' arguments¹⁷⁰. Astra submitted that the primary judge's ultimate finding required a conclusion contrary to that which the judge had reached. The "error of principle" involved, in this regard, was the statement by the primary judge that the combination in the patent claim "might"¹⁷¹ (rather than "would"¹⁷²) have been arrived at by the hypothetical formulator. Because Alphapharm bore the onus of proof to sustain its cross-claim for revocation of the patents in suit, this focus on the primary judge's words (although they are borrowed virtually word for word

168 cf the joint reasons at [77]; reasons of Callinan J at [200]-[201].

169 [1997] RPC 1 at 45. See these reasons at [97].

170 *Warren v Coombes* (1979) 142 CLR 531 at 551-553; *State Rail Authority (NSW) v Earthline Constructions Pty Ltd (In Liq)* (1999) 73 ALJR 306 at 321 [64], 325-327 [81]-[86]; 160 ALR 588 at 607, 613-615.

171 *Aktiebolaget* (1999) 44 IPR 593 at 629 [118].

172 *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2000) 51 IPR 375 at 389 [62].

from *Wellcome Foundation*¹⁷³) became a central foundation for Astra's attack in the Full Court on his reasons.

128 In my opinion, it would have been open to the Full Court to have dismissed this suggestion of error by reference to the way in which the primary judge, in the same paragraph, went on to conclude¹⁷⁴:

"The evidence of the formulators suggests, and Astra's experience confirms, that that view was likely to have been maintained with considerable firmness."

129 The "view" there referred to was that an enteric coated alkaline dosage would be the appropriate starting point for the formulation. As I have pointed out, according to his Honour's evaluation of the evidence, selecting that as the appropriate starting point would have led to the subsequent steps and the ultimate result actually reached¹⁷⁵.

130 However, doubtless aware of the interests at stake and the possibility of an application to this Court for special leave following its decision, the Full Court assumed that the reference to a possibility ("might") in the primary judge's reasons could be viewed as ambiguous. The Full Court therefore proceeded, in an orthodox appellate way, to review the evidence for itself. In reviewing the expert evidence, the Full Court, like the primary judge, pointed to the fact that an enteric coated dosage was considered the appropriate starting point in the formulation by all the experts called¹⁷⁶. Having done this, the Full Court unanimously concluded that solving the interaction between the core and coat by the introduction of a subcoat to separate them did not show that the combination involved an "inventive step". On such evidence, the combination was, having regard to the common general knowledge available in Australia on or before the priority date, "obvious". The most that could be said was, in effect, that Astra was "first in the field, or richer or more determined"¹⁷⁷.

131 The Full Court also considered that it should review the factual findings on the basis that it might be concluded that the primary judge had fallen into error by

173 (1981) 148 CLR 262 at 286 per Aickin J.

174 *Aktiebolaget* (1999) 44 IPR 593 at 629 [118] (emphasis added).

175 *Aktiebolaget* (1999) 44 IPR 593 at 629 [118].

176 *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2000) 51 IPR 375 at 396 [96], 397 [103], 398 [111], 403 [124], 407 [141].

177 *Genentech* (1988) 15 IPR 423 at 544; cf *Terrell on the Law of Patents*, (2000) at 177 [7.29].

making reference to documents found after a routine literature search. The Full Court did not express a final view on this issue, as their Honours held that, even without reference to the documents and the manufacturers' literature, the primary judge's conclusion on obviousness would stand. Again, there was no error in his Honour's reasoning. Any skilled formulator in the field of pharmaceutical formulation, presented with a problem however simple, would, as a first step, have sought access to such literature commonly available in Australia¹⁷⁸. In my view, allowing a reference to be made to the results of a routine literature search is not inconsistent with the words of the Act, nor for that matter with the approach of this Court in *Minnesota Mining*. I shall return to this issue.

132 If the view is taken, as I would favour, that the approach of the primary judge was fundamentally correct and that no error in his reasoning necessitated (or justified) a reconsideration of the evidence by the Full Court, the primary judge's decision would stand. This Court should affirm the Full Court's judgment unless some new error is discerned that invalidates the conclusion that was reached at trial. In my opinion, the Full Court's entry upon the review of the evidence in the case was unnecessarily cautious. There was no error in the approach of the primary judge. The criticisms of his reasoning are unconvincing. This Court should confirm the primary judge's conclusion and judgment.

Analysis: the proper approach

133 *Factual findings and lawyers' fictions*: There is great force in McHugh J's note of caution in this case, with which I agree, about attempting to turn a process of reasoning as to findings of fact into binding propositions of law¹⁷⁹. Nevertheless, some of the concepts applied to test the obviousness of a claimed invention (such as the hypothetical skilled formulator and the notion of the prior knowledge or art base) are embedded in patent law and practice and are consistently applied in the case law¹⁸⁰. Such constructs, although artificial, are said to provide consistency, as well as a structured and principled approach to the fact-finding required, which is consonant with the terms, objectives and policy of the Act. However, they do not relieve the primary decision-maker of the responsibility to examine the relevant evidence. Even less, do they pre-determine the answer to the inquiry.

134 In light of the foregoing observations, and because these issues were fully argued by the parties (and are addressed in other reasons), I will add some observations of my own as to the proper approach to making findings on obviousness. In particular, I will express my reasons for the conclusion that the

¹⁷⁸ *Aktiebolaget* (1999) 44 IPR 593 at 612 [64], 613 [69], 614 [73].

¹⁷⁹ Reasons of McHugh J at [85]-[87].

¹⁸⁰ Further, the hypothetical "person skilled in the relevant art" finds statutory expression in the provisions of the 1990 Act: see s 7(2).

approach of the primary judge in evaluating the evidence was legitimate, error-free and in fact preferable. In my view, his Honour's approach is not only consistent with the words of the Act, but also with subsequent judicial attempts to flesh out and explain the statutory language.

135 *Statutory construction and purposive interpretation*: First, it is necessary to recall a basic point already alluded to. The duty of this Court is ultimately to the Act. It is the Act that states the applicable law. When a statute becomes encumbered in such a way as to obscure its operation and obfuscate the meaning of the simple words used (such as here, "obvious" and "inventive step"), it is time to return to basics. As was said long ago, in another area, courts must arrest the practice, common amongst lawyers, that introduces "lamentable and disgraceful technicalities"¹⁸¹.

136 The Act is not set apart from the development of general principles for the interpretation of Australian statutes. True, it has ancient predecessors and a long history. It is concerned with large and valuable property interests. It is reasonable that parties should seek predictability in the operation of statutory language, drawn from judicial approaches to that language in the past. But in the end the duty of courts is owed not to judicial synonyms or lawyers' metaphors used to explain the language of the statutes. The duty is to the statutory language itself.

137 From time to time, specialist lawyers need to be brought back to such basic principles. Otherwise, they may take possession of provisions enacted by the Parliament and read them with spectacles focussed only on the glosses of decisional history. There is no justification for treating the Act differently from other federal statutes. I remain of the opinion that I stated in the context of another Act that has likewise become entangled in unnecessary decisional verbiage¹⁸²:

"It is hubris on the part of specialised lawyers to consider that 'their Act' is special and distinct from general movements in statutory construction which have been such a marked feature of our legal system in recent decades. The Act in question here is not different in this respect. It should be construed, like any other federal statute, to give effect to the ascertained purpose of the Parliament."

138 In deciding this case, the primary judge was, as this Court is, giving meaning to the words "was obvious and did not involve an inventive step having regard to what was known or used in Australia". Such statutory language should be read in the interpretive manner now generally followed in Australia. The words

¹⁸¹ *R v Ruyton (Inhabitants)* (1861) 1 B & S 534 at 545 [121 ER 813 at 817].

¹⁸² *Federal Commissioner of Taxation v Ryan* (2000) 201 CLR 109 at 146 [84]. See also *Steele v Deputy Federal Commissioner of Taxation* (1999) 197 CLR 459 at 477 [52].

should be read in context¹⁸³. They are not to be read literally, in isolation, but in the entire sentence and provision in which they appear¹⁸⁴. In this instance, the reference to "what was known or used in Australia" in s 100(1)(e) affords some meaning to the terms "obvious" and "inventive step". To decide "what was known or used", a reference point is necessary. Hence the invention of the hypothetical skilled worker in the field. The larger context also matters. The Act in the same section (s 100(1)(g)) makes it clear that novelty alone is not sufficient to sustain a valid patent. This requirement adds further meaning to the concepts of obviousness and inventive step. What does not find expression in the Act as part of the concept of an "inventive step" is mere effort, labour or the expenditure of resources.

139 Secondly, the statutory language is to be read so far as possible to achieve the purpose of the legislation discerned from the words, the context and any other available and permissible sources¹⁸⁵. The mischief which the original *Statute of Monopolies* 1623 (Eng)¹⁸⁶ sought to address included the excessive grant of monopolies by the Crown, and the negative effects this had for the public at large¹⁸⁷.

140 In this Court, Astra submitted that "the undoubted policy underlying the patent system is to encourage and reward research and development". I agree that this is one important purpose of the Act. But it is not the only one. Another, equally important, object is to avoid the grant of monopoly protection where there is no merit of inventiveness, that is, where there is no contribution to the general

183 *Newton v Federal Commissioner of Taxation* (1958) 98 CLR 1 at 7-8 per Lord Denning; [1958] AC 450 at 465.

184 *Collector of Customs v Agfa-Gevaert Ltd* (1996) 186 CLR 389 at 397 with reference to *R v Brown* [1996] AC 543 at 561 per Lord Hoffmann; *Minister for Immigration and Multicultural Affairs v Khawar* (2002) 76 ALJR 667 at 685-686 [109]; 187 ALR 574 at 600; *SGH Ltd v Commissioner of Taxation* (2002) 76 ALJR 780 at 797 [88]; 188 ALR 241 at 265.

185 *Project Blue Sky Inc v Australian Broadcasting Authority* (1998) 194 CLR 355 at 381 [69]. See also *Bropho v Western Australia* (1990) 171 CLR 1 at 20 with reference to *Kingston v Keprose Pty Ltd* (1987) 11 NSWLR 404 at 421-424 per McHugh JA.

186 21 Jac I c 3.

187 On the controversies surrounding the excessive use of patents in the Elizabethan era see Loughlan, "Patents: Breaking into the Loop", (1998) 20 *Sydney Law Review* 553 at 557-559.

knowledge that was not only new (and possibly overcame a problem¹⁸⁸), but also would not have been evident or readily discoverable to anyone possessing the relevant skill and knowledge in the field.

141 The role of the tests of novelty and obviousness in patent law has been described, correctly in my view, in this way¹⁸⁹:

"One possibility whereby an unnecessary dead-weight loss could arise is if patent protection is granted for a non-innovative product or process. In this case society might incur a monopolistic welfare cost without obtaining a new product or process in return. This point alerts us to the fact that the tests of novelty and non-obviousness in the patent law fulfil the useful economic function of preventing undeserved monopoly profits. This potential misuse of monopoly rights must be prevented by strict application of the screening criteria in the patent law."

142 An attempt to resolve the clash of competing policies in particular cases may involve asking "whether there is sufficient invention to justify a monopoly being granted"¹⁹⁰; or whether "the invention is undoubtedly worthy of patent protection"¹⁹¹; or whether the patent "discloses something sufficiently inventive to deserve the grant of a monopoly"¹⁹². Such formulations have not always found favour¹⁹³. While they restate, and act as a reminder of, the ultimate object of the inquiry, they do not provide sufficient guidance particularly for primary level decision-making.

143 Another, and I think more satisfactory formulation of the objects of the patentability test of non-obviousness in the *Patents Act* 1952 (US), was proposed

188 *Werner* (1989) 25 FCR 565 at 574.

189 Australia, Bureau of Industry Economics, *The Economics of Patents*, (1994) at 45.

190 *Britain v Hirsch* (1888) 5 RPC 226 at 232 per Cotton LJ.

191 *Dow Corning Corporation's Application* [1969] RPC 544 at 560 set out in the joint reasons at [39]; cf reasons of Callinan J at [192]. See also *Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Ltd* (1998) 194 CLR 171 at 193-194 [42.2] and Ricketson, *The Law of Intellectual Property*, (1984) at 952-953 [49.51]-[49.52].

192 *Société Technique de Pulverisation Step v Emson Europe Ltd* [1993] RPC 513 at 519.

193 *Mölnlycke AB v Procter & Gamble Ltd (No 5)* [1994] RPC 49 at 112.

by Clark J, writing for the United States Supreme Court in *Graham v John Deere Co*¹⁹⁴. In that case, Clark J said¹⁹⁵:

"[T]he underlying policy of the patent system [is] that 'the things which are worth to the public the embarrassment of an exclusive patent' ... must outweigh the restrictive effect of the limited patent monopoly. The inherent problem was to develop some means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent."

144 *Routine steps, worthwhile to try*: Attempts by judges and lawyers to give meaning to the concept of obviousness, including under the Act presently the subject of consideration, have produced a mountain of verbal formulations to explain the reasons for making a particular factual determination. Some such formulations have included: that the invention was "very plain"¹⁹⁶ or "lying in the way"¹⁹⁷; that the steps taken from the prior art to the invention were "a matter of routine"¹⁹⁸; that the hypothetical formulator would "directly be led as a matter of course" to the particular solution¹⁹⁹, yet that "it is not necessary to establish that [the] success [of a step or process] is clearly predictable"²⁰⁰; or that the steps taken were obvious or worthwhile to try²⁰¹.

145 The parties to the present appeal urged one or another of those formulations as buttressing their case and representing the proper approach to the inquiry mandated by the statute. An illustration of the distraction that can occur when placing excessive emphasis on such formulations may be found in the consideration given in the case to the use by the primary judge of the word

194 383 US 1 (1966).

195 383 US 1 at 10-11 (1966) citing Thomas Jefferson.

196 *General Tire* [1972] RPC 457 at 497.

197 *Elconnex Pty Ltd v Gerard Industries Pty Ltd* (1991) 32 FCR 491 at 507 per Burchett J.

198 *Wellcome Foundation* (1981) 148 CLR 262 at 286.

199 *Olin Mathieson Chemical Corp v Biorex Laboratories Ltd* [1970] RPC 157 at 187-188.

200 *Beecham Group* [1980] RPC 261 at 290.

201 *Olin Corporation v Super Cartridge Co Pty Ltd* (1977) 180 CLR 236 at 262 with reference to *Technograph Printed Circuits Ltd v Mills & Rockley (Electronics) Ltd* [1972] RPC 346 at 355; *W R Grace & Co v Asahi Kasei Kogyo Kabushiki Kaisha* (1993) 25 IPR 481 at 493-495; cf *Johns-Manville* [1967] RPC 479 at 494; *Washex Machinery Corp v Roy Burton & Co* (1974) 49 ALJR 12 at 16.

"routine". In this respect, once again, the judge was merely borrowing a word used by Aickin J in this Court in *Wellcome Foundation*²⁰². The word is not mentioned in the Act itself. In some judicial expositions it has been elevated almost to a statutory status. This is so although it is little more than a synonym to convey an attribute of obviousness existing in some cases. To some extent, the Full Court also may have fallen into the same trap, by placing excessive emphasis on the primary judge's use of "might" instead of "would".

146 The various formulations outlined above may have presented useful lines of inquiry in the particular factual circumstances, research settings and fields of knowledge in individual cases. But as Diplock LJ warned, there is no verbal formula that precisely captures the correct reasoning in making a finding on obviousness provided by a statute²⁰³. None of the verbal formulations from past judicial decisions represents a universally appropriate paraphrase of the words of the statute. None is a binding statement of law that will pre-determine the answer in every case. As Windeyer J²⁰⁴ observed in another setting where a factual determination by a judge was called for, the answer to such questions can "[i]n no case ... be found in words, however eloquent, uttered by judges, however eminent, about the facts of some other case".

147 There is nothing in the language of s 100(1)(e) of the Act that confines the "obvious" to universally simple and self-evident concepts. On the contrary, the context (in a field of endeavour such as the development of modern pharmaceutical drugs) may envisage that a team of highly trained and qualified scientists, with relevant knowledge about the field, would be engaged in the research. If to such a team (as distinct from to a judge or an ordinary citizen) the invention claimed in the patent in suit is "obvious", that would provide a relevant ground for revocation. Thus, the measure of obviousness depends on the art or field relevant to the invention. It also depends on the skills and expertise essential to the particular field and the nature of the research process involved.

148 *The hypothetical skilled formulator and the relevant field:* It is appropriate to remember why courts in the past have invented the hypothetical formulator instead of simply expressing their own opinions on subjects of this kind. The reason for interposing this fictitious person is clear. Judges themselves (or juries in the days when juries decided such questions) could not be expert in all the fields of science and technology involved. They were, therefore, invariably reliant upon expert evidence in the particular field to prove what was "obvious" at the relevant date and what was not; what involved an "inventive step" and what did not. It would defeat the purpose of the Act if the applicable test were to be expressed in

202 (1981) 148 CLR 262 at 286.

203 *Johns-Manville* [1967] RPC 479 at 493-494.

204 *Sungravure Pty Ltd v Meani* (1964) 110 CLR 24 at 37.

terms of what was obvious, as such, to a jury, to a judge or even to a reasonable person.

149 It follows that the posited formulator must necessarily have some knowledge of the relevant art, if only to be in a position to evaluate the presence, or absence, of obviousness. What is imagined cannot be a layman completely unskilled in the art. It must be someone sufficiently skilled and competent to answer the questions posed by the Act. A dullard or ignoramus the hypothetical formulator cannot be. And yet courts have also said that what is required is someone skilled but "non-inventive"²⁰⁵ or someone "unimaginative"²⁰⁶ or someone "lacking in inventive capacity"²⁰⁷.

150 The foregoing exposition illustrates why this field of law has become encumbered with verbal expressions, sometimes remote from the statute. Unfortunately, such expressions are then picked up and applied to the case in hand in place of the statute itself. The special difficulties inherent in constructing the fictitious worker in a field such as pharmaceutical formulation were recognised by the primary judge²⁰⁸. The process has introduced so many layers of obscurity that there is now a real danger of entering upon "a degree of unreality ... going well beyond reasonable hypothesis"²⁰⁹ so that even a conscientious decision-maker will lose the way and forget that the statute is ultimately the only true statement of the governing law.

151 It is true that the words of the Act provide but limited guidance as to the approach in deciding inventiveness. Some judicial elaboration is therefore probably necessary. The Act makes reference to the concept of obviousness in relation to "what was known or used". Ascertaining what was "known or used" cannot be done in a vacuum. Thus, in giving meaning to the statutory words, the focus is on the knowledge and practices of the skilled formulators in the field or discipline and at the priority date. This provides an anchor for the decision-maker. It is a matter of evidence. It presents a question of fact.

152 In *Genentech*, Mustill LJ observed that in construing the 1977 UK Act, deciding the meaning of "inventive step" and "obvious" and the characteristics

205 *Wellcome Foundation* (1981) 148 CLR 262 at 271.

206 *Aktiebolaget* (1999) 44 IPR 593 at 604 [36]; *Minnesota Mining* (1980) 144 CLR 253 at 260; *Washex Machinery Corp v Roy Burton & Co Pty Ltd* (1974) 49 ALJR 12 at 16 per Stephen J.

207 *Beecham Group* [1980] RPC 261 at 290.

208 *Aktiebolaget* (1999) 44 IPR 593 at 604 [36].

209 *Lubrizol* (2000) 106 FCR 214 at 236 [67].

attributed to the hypothetical skilled worker will "take one much of the way, if not necessarily all the way, to a conclusion on the issue as a whole"²¹⁰. This statement emphasises the factual nature of the inquiry. It also illustrates why it is illusory to speak about a divergence in the law, since the answer is to be provided by reference to the standards of the field relevant to the particular invention. It is implicit in his Lordship's statement that the particular field of knowledge, which is the proper reference point, needs to be identified and characterised.

153 The identification of the relevant field will, in its turn, determine the characteristics of the notional worker skilled in the art who must provide the answer to the question whether the invention was obvious. Such characteristics will include the qualifications of the notional worker, the setting in which and resources with which he or she operates²¹¹ and the practices and techniques that he or she will regard as commonplace and known. This proposition was accepted, to some extent, by Astra. Thus, it did not submit that s 100(1)(e) of the Act would be applied by reference to what was "obvious" to an *individual* researcher working on his or her own. Astra accepted that hypothetical formulators would, at least in the art involved in this case, commonly perform research in *teams*²¹². This being the case, it was common ground that obviousness was to be judged, in such circumstances, by reference to the pooled knowledge of a hypothetical team²¹³.

154 In the area of pharmaceutical development, the hypothesised formulator will ordinarily have postgraduate qualifications in science²¹⁴, just as in other fields it has been acknowledged that skilled formulators will be "trained engineers and scientists, who are well versed in the periodical literature of their subjects"²¹⁵. The notion that such a formulator sits alone, speculating with nothing more than

210 (1988) 15 IPR 423 at 540.

211 *Genentech* (1988) 15 IPR 423 at 545.

212 cf *General Tire* [1972] RPC 457 at 485; *Leonardis v Sartas No 1 Pty Ltd* (1996) 67 FCR 126 at 146.

213 *Lubrizol* (2000) 106 FCR 214 at 234-235 [61] where the Full Court of the Federal Court cited with approval the primary judge's conclusion that the notional skilled worker may not be limited to a single person: *ICI Chemicals & Polymers Ltd v Lubrizol Corporation Inc* (1999) 45 IPR 577 at 597 [100] where the primary judge was in turn relying on the observations of Sachs LJ (made in the context of anticipation) in *General Tire* [1972] RPC 457 at 485.

214 *Aktiebolaget* (1999) 44 IPR 593 at 604 [36]. Although the necessary qualifications will differ depending on the nature of the field and the nature of the invention: *Genentech* (1988) 15 IPR 423 at 548.

215 *Sunbeam Corporation v Morphy-Richards (Aust) Pty Ltd* (1961) 180 CLR 98 at 112.

knowledge remembered from university lectures that are retained at the front of the mind, is absurd. It has rightly been rejected by the courts²¹⁶.

155 *Effort and resources or inventive step*: In *Biogen* Lord Hoffmann suggested that "[a] proper statement of the inventive concept needs to include some express or implied reference to the problem which it required invention to overcome"²¹⁷. This was because the evaluation of whether or not a particular product involved an inventive step would depend upon the formulation of the inventive concept. Thus, the way in which the objective of the researcher in undertaking the particular research is stated may influence whether or not the outcome is judged to be obvious. In some circumstances merely stating or identifying the problem may indicate the non-obvious element or the inventive step, and primary decision-makers should be alert to such a possibility.

156 In *Beecham Group*, Buckley LJ made reference to a situation where the "uninventive but skilled man having a particular problem or need in mind" is "attempting to solve [that] problem ... which has not been resolved or satisfied by the prior art but which appears to his uninventive mind to be possibly capable of solution or satisfaction by taking the step or doing the thing under consideration"²¹⁸. In such circumstances, his Lordship felt that, if the particular step has the consequences hoped for, it is likely to be found to be obvious and not inventive. On the other hand, his Lordship indicated that the result may be different where "the skilled man has no particular problem or need in mind but merely regards some part of the known art as giving a good lead for further research, which may result in the discovery of some useful further knowledge"²¹⁹.

157 Buckley LJ's judgment in *Beecham Group* was cited both by the appellants and the respondent in support of their submissions before this Court. Alphapharm latched onto the statement that it is sufficient to show it would be apparent to the hypothetical formulator that "to try the step or process would be worthwhile"²²⁰. Astra on the other hand pointed to the result in that case – namely, the invention was held not to be obvious. I reiterate, that Buckley LJ's analysis has no precedential value beyond the facts of that case. However, his Lordship's mode of reasoning is instructive. In *Beecham Group* the patent was found to fall into the latter of the categories outlined – it was the choice of the particular path as a good

216 *ICI Chemicals & Polymers Ltd v Lubrizol Corporation Inc* (1999) 45 IPR 577 at 599 [112] cited with approval by the Full Court of the Federal Court in *Lubrizol* (2000) 106 FCR 214 at 232 [57]. See also *General Tire* [1972] RPC 457 at 497.

217 *Biogen* [1997] RPC 1 at 45.

218 *Beecham Group* [1980] RPC 261 at 291 per Buckley LJ.

219 *Beecham Group* [1980] RPC 261 at 291 per Buckley LJ.

220 *Beecham Group* [1980] RPC 261 at 290 per Buckley LJ.

lead for further research without a specific destination in mind that constituted the inventive step.

158 The foregoing reasoning affords an explanation for the approach of the courts in the case at hand. It was a legitimate approach. It involved no legal error. The identification of the problems that Astra's team had to solve did not constitute an inventive step. The solution that was apparent was the one ultimately arrived at. Both the destination and the selection of the research path to follow were obvious. Simply because more than one problem was faced in the process, does not require a conclusion that the combination involved an inventive step.

159 It may well be, as the primary judge conceded, that at the time, a similar problem had not been encountered, at least in Australia, in the formulation of enteric coated drugs²²¹. This may be because no other compound presented similar properties, and no other entity would be doing work on omeprazole since Astra owned the compound patent. In that sense, while the final outcome may have been novel, that does not mean it was not obvious. That a reaction may occur between an alkaline core and an acidic coat would have been apparent to "any ordinary man with a working knowledge of chemistry"²²². To proceed by adding a subcoat would have involved merely "employing an obvious technique to get round an awkward corner"²²³. This was precisely the way in which Dr Marshall proceeded in his hypothetical formulation. The hypothetical researcher would thus have overcome the problems encountered through "pertinacity, sound technique or trial and error, with no more"²²⁴.

160 It is true that Astra had a strong commercial incentive to pursue the research in order to be able to market the compound. However, that fact is not relevant to the issue of obviousness²²⁵. It may also be true that the research path was not short; although this point should not be overstated. Astra proceeded to the ultimate solution fairly quickly. Much of the time that elapsed before the finalisation of the formulation is explained by the need for verification and long-term stability tests and experiments which are not only necessary, but essential to deliver on the market a drug for human subjects. However, such testing does not in any way add to the stock of knowledge. It did not turn an obvious concept into an inventive one.

221 *Aktiebolaget* (1999) 44 IPR 593 at 625-626 [107].

222 *In the Matter of Alsop's Patent* (1907) 24 RPC 733 at 759.

223 *Beecham Group* [1980] RPC 261 at 291 per Buckley LJ.

224 *Genentech* (1988) 15 IPR 423 at 542-543.

225 *Hallen Co v Brabantia (UK) Ltd* [1989] RPC 307 at 327.

161 It is not diligence and determination or the input of time, labour, skill and effort or the expenditure of resources that meet the criteria in the Act²²⁶. Something more is needed. And this, it seems to me, presents the substantive difference between the approach that I favour, and that of other members of this Court. As Mustill LJ puts it²²⁷:

"If the criteria for patentability are pitched too low there is a risk that mere hard work or superiority of resources, or simple good luck, will entitle a researcher to a monopoly, the commercial and social justification for which is by no means clear, given the risk of stultifying the development of the industry by open competition."

162 The process of developing a formulation of omeprazole that would be bioavailable in the intestines, in the end, may have involved a "triumph of method"²²⁸. It was a useful and commercially important achievement. It may also have involved a substantial investment in resources before it was finally brought to the market. However, judged by the standards of the relevant art at the priority date, it did not involve an inventive step in the sense that that criterion is required by the Act.

163 *Common stock of knowledge and routine literature searches*: Much has been made in this Court of the primary judge's discussion of the appropriate role to be assigned to documents which a formulator would have obtained as a result of a routine literature search. However, as the reasons of the Full Court demonstrate, in this particular case the conclusion of obviousness did not turn on this issue. The documents to which the primary judge made reference included the Pilbrant and Cederberg article, as well as the compound and salts patents²²⁹. They were only useful to the extent that they contained information about the properties of omeprazole, which the Full Court correctly concluded the skilled formulator would have been able to obtain through standard experiments and tests²³⁰. The existence of the other two documents (Shin-Etsu H-17 and the Röhm-Pharma notes) prior to the priority date was thought to corroborate the expert evidence as

226 *Crane v Price* (1842) 4 Man & G 580 at 605 [134 ER 239 at 248-249] per Tindal CJ; *Wellcome Foundation* (1981) 148 CLR 262 at 271 per Aickin J.

227 *Genentech* (1988) 15 IPR 423 at 526. Note that in *Wellcome Foundation* (1981) 148 CLR 262 at 279 Aickin J expressed an opinion that "chance or luck ... may produce an invention". That statement was obiter, and the controversy is not relevant to the present appeal.

228 *Genentech* (1988) 15 IPR 423 at 545.

229 *Aktiebolaget* (1999) 44 IPR 593 at 627 [112].

230 *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2000) 51 IPR 375 at 391-392 [76].

to what was commonly known and used in the industry at the relevant time²³¹. However, the Full Court found that "[o]ur ultimate conclusion ... does not depend on the contents of manufacturers' literature"²³². I address this issue only because it raises an important question of principle.

164 The Full Court, and the majority of this Court, have found fault in the approach of the primary judge who held that the skilled though unimaginative formulator could be assumed to have had access to documents that would be found on a routine literature search²³³. This approach is said to be illegitimate after *Minnesota Mining*. I disagree.

165 The identification of what forms part of the common general knowledge is in itself a somewhat artificial exercise. It only arises because of the statutory command that whether or not a patent claim is obvious is to be determined by reference to "what was known or used in Australia" at or before the priority date. While *Minnesota Mining* held that the mere existence of particular documents, without more, did not mean that they formed part of the common general knowledge, Aickin J in that case also emphasised the fact-specific nature of the inquiry and the importance of evidence of common practices in the relevant art²³⁴.

166 Once it is accepted that the common practices of researchers in the relevant field are relevant and that "the whole of the content of 'common general knowledge'" need not be "within the conscious awareness of the hypothetical non-inventive skilled worker"²³⁵ it becomes clear that whether or not particular documents or publications are part of "what was known or used" is also a matter of degree.

167 Reference to the results of a routine literature search may be important in certain fields of knowledge (which include the formulation of pharmaceutical drugs) for at least two reasons. First, to deny such an inquiry, would be to take a completely artificial approach to the process of research and formulation in such fields. The experts giving evidence before the primary judge would all have started the process of formulation by a search of the literature. Secondly, if the inclusion of documents in the common stock of knowledge is a matter of degree, then the fact that a skilled (though unimaginative) worker would have located certain documents only after a routine literature search, or that such documents are readily

231 *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2000) 51 IPR 375 at 392 [78].

232 *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2000) 51 IPR 375 at 392 [77].

233 *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2000) 51 IPR 375 at 392 [77].

234 *Minnesota Mining* (1980) 144 CLR 253 at 294.

235 *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2000) 51 IPR 375 at 391 [73].

available or accessible, should be evidence that they are more likely to be part of the relevant general knowledge. This may explain why the primary judge was confining his comments to publications found as a result of a routine search, as opposed to what would be found by a diligent searcher of more obscure sources²³⁶.

168 What does or does not form part of the common knowledge should also depend upon the practices of workers in the field in question. It was correct for the primary judge to take into account the approach that skilled but un inventive workers in the field would have had to solving the presented problem. Even if a solution were immediately apparent, workers in the field of pharmaceutical chemistry would normally, as a first step, consult the basic literature readily available. Even if particular documents are known to exist and form part of the common stock of knowledge, a "routine" search, whether library or (more recently) electronic, would be necessary to locate them²³⁷.

The remaining issues raised by the respondent

169 The evidence accepted by the primary judge was that Australian formulators in this particular art, at the relevant time, knew of, and routinely used, available technology to search for the characteristics of a pharmaceutical compound to be formulated in order to understand the nature of the problems to be overcome in any formulation. In reaching this conclusion, the primary judge relied on the expert evidence, which his Honour accepted, as to the usual practices in the area of pharmaceutical formulation²³⁸:

"What is important, however, is the steps which the hypothetical formulator would have taken and where those steps would have led. I have no difficulty with the proposition that a formulator asked, in April 1986, to formulate omeprazole would have done a literature search at least in order to discover what learning there was about omeprazole itself and its characteristics. Clearly enough such a search would have uncovered the compound patent, the omeprazole salts patent and Pilbrant and Cederberg."

170 In his Honour's view, while documents found as a result of such a search were not necessarily part of the common general knowledge, they were not irrelevant²³⁹. The Full Court expressed doubts about the primary judge's reasoning

236 cf *Minnesota Mining* (1980) 144 CLR 253 at 294.

237 *Aktiebolaget* (1999) 44 IPR 593 at 629 [117].

238 *Aktiebolaget* (1999) 44 IPR 593 at 627 [112].

239 *Aktiebolaget* (1999) 44 IPR 593 at 606 [43].

on whether reference could be made to the results of a literature search²⁴⁰. On this basis, Alphapharm, by a notice of contention, argued that the Full Court erred in not applying the primary judge's reasoning²⁴¹. Further, it argued that if there was evidence that computer searches were "used" by the relevant workers, there was no need to limit the results of such searches if the evidence supported the carrying out of a more extensive search.

171 As long ago as 1930 it was said in the English High Court (certainly not then under the influence of European patents law) that to be deemed inventive, "the result achieved must not be obvious even to persons skilled in the art and well acquainted with the published information in regard to the problem with which the invention is concerned"²⁴².

172 In construing s 100(1)(e) of the Act in *HPM Industries Pty Ltd v Gerard Industries Ltd*²⁴³, Williams J said in this Court:

"It is clear ... that in deciding what was obvious, it is necessary to consider what would have been obvious to the hypothetical skilled craftsman in the state of knowledge in the particular art existing at the priority date of the patent and that *this knowledge consists of everything disclosed by the literature on the subject* (including prior specifications), and revealed by the articles then in use and of the common general knowledge."

173 In *Minnesota Mining*, the above statement by Williams J was disapproved²⁴⁴. A distinction was drawn between information disclosed in publications which were not shown to be part of the common general knowledge in the relevant field and knowledge generally known and accepted by "the bulk of those who are engaged in the particular art", that can be described as "part of their common stock of knowledge relating to the art"²⁴⁵. This distinction was drawn because the Act talks of "what was known or used in Australia" rather than what was available to a researcher operating from Australia. However, the availability of a much greater range of scientific literature and the advent of technology making such literature more easily accessible may make important information more readily "known ... in Australia" to formulators in this art.

240 *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2000) 51 IPR 375 at 392 [77]-[78].

241 *Aktiebolaget* (1999) 44 IPR 593 at 624-625 [104]-[105].

242 *In the Matter of I G Farbenindustrie AG's Patents* (1930) 47 RPC 289 at 322 (emphasis added).

243 (1957) 98 CLR 424 ("*HPM Industries*") at 438 (emphasis added).

244 *Minnesota Mining* (1980) 144 CLR 253 at 292.

245 *British Acoustic Films Ltd v Nettlefold Productions* (1935) 53 RPC 221 at 250.

174 According to the findings of the primary judge, it was no longer necessary, at the relevant date, to go offshore or to search obscure literature available but only far away. By reason of information resources within Australia and advances in technology, which were "used" by formulators at the relevant time, such knowledge was more readily accessible. It could easily be retrieved. If, therefore, on or before the priority date, a person with ordinary skill in the given art would know of certain documents or sources of knowledge, or could readily access them after a literature search if that were essential to the task in hand; and if there was also evidence that such techniques were "used" in the field, there is no reason to deny access to the results of a search in the determination of obviousness.

175 There is nothing in the language of s 100(1)(e) of the Act that locks the decision-maker into a particular technology or confines the hypothetical formulator to the knowledge and information about the art enjoyed according to sources then physically present in Australia. Once one returns to the language of the Act, it adapts quite easily to the contemporary practices in the relevant field, including in some circumstances searches of the literature if they are found to be commonly used in that field. As I have pointed out, Aickin J in *Minnesota Mining* also made reference to the significance of evidence as to the common practices of skilled workers in the relevant field in deciding what does or does not form part of the prior knowledge²⁴⁶.

176 Once it is appreciated that we are talking here about a "skilled" worker in a sophisticated and technical art; that the worker may, and usually will, operate within a team; and that he or she may take routine experimental steps and conduct tests so as to check hypotheses, the notion that reference cannot be made to industry literature and other readily available data, found on a routine search of the literature, takes on a surrealist air. It is not a conclusion that is necessary, either by the terms of the Act or the decisions of this Court.

177 It may be that Williams J's view in *HPM Industries* was consistent with the terms of s 100(1)(e) of the Act and is in fact preferable. It may also be that it is more consistent with international developments in patent law²⁴⁷. That view has now arguably found a statutory expression in Australia in the 1990 Act²⁴⁸. It may be that Williams J's interpretation is also consistent with a proper analysis of what falls into the "common general knowledge" particularly in those fields of endeavour, which would include most areas of scientific research, where it is normal for researchers to approach tasks by a search of the literature as a very first step. The primary judge may have been too cautious in limiting the results of the

246 *Minnesota Mining* (1980) 144 CLR 253 at 294, 295-297. See also *Sunbeam Corporation v Morphy-Richards (Aust) Pty Ltd* (1961) 180 CLR 98 at 112.

247 eg *Patents Act* 1977 (UK), s 2(2).

248 See *Patents Act* 1990 (Cth), s 7.

literature search. There is no reason why something that was commonly used, or based on an act commonly done in practice, should be treated differently from that which is known, or is in a document or in basic texts in a standard scientific library. However, although this is my opinion, it is not necessary to explore it further in this appeal. The primary judge and the Full Court reached their conclusions without reference to this consideration.

178 In light of this analysis, it is unnecessary to consider Alphapharm's further contention concerning the inferences alleged to be available as a result of Astra's late action in obtaining the amendment of the patents in suit²⁴⁹. It is also inherent in what I have said that I would reject Astra's complaints of procedural unfairness in the Federal Court.

Conclusion: the primary judge was right

179 When the issues in this appeal are approached from the foregoing standpoint, no error is disclosed in the reasoning of the primary judge. Astra's criticisms of his Honour's conclusion are unjustified. The Full Court was correct to dismiss the appeal from his judgment.

180 By the standards of the applicable art, judged at the priority date, the evidence accepted by the primary judge sustained his conclusion that Astra's invention was "obvious" and did not involve an "inventive step". No appealable error being shown, there was no basis for the Full Court to intervene. There is even less basis for this Court, acting effectively as a jury, to substitute a different conclusion of its own. Parting from this appeal, I recall to mind the observation of Dr Burke Inlow, in 1950, that "[o]ne of the great fictions in modern legal theory is that the determination of a patentable invention is a question of law"²⁵⁰. In construing the statute, this Court should not enlarge that fiction.

Order

181 The appeal should be dismissed with costs.

CALLINAN J:

182 The facts, relevant provisions of the *Patents Act* 1952 (Cth) ("the Act") and the substance of the reasons for judgment of the primary judge and the Full Court of the Federal Court are set out in the other judgments of the members of this Court.

183 The only question with which this Court is concerned is, whether a pill for the treatment of stomach ulcers, containing as its active agent a previously patented

²⁴⁹ cf *Aktiebolaget* (1999) 44 IPR 593 at 639-640 [163]-[174].

²⁵⁰ Inlow, *The Patent Grant*, (1950) at 133 cited in Loughlan, "Patents: Breaking into the Loop", (1998) 20 *Sydney Law Review* 553 at 556.

chemical compound, omeprazole, and coated with two layers of material in order to survive part of the digestive system without degradation so as to be released into that part of the system where it may be beneficial, was a properly patentable invention. That question arose for determination because the respondent, in answer to an application by the appellants to restrain the infringement of the patent which they had been granted in respect of the pill, sought its revocation, relevantly on the ground for which s 100(1) of the Act made provision²⁵¹:

"A standard patent may be revoked, either wholly or in so far as it relates to any claim of the complete specification, and a petty patent may be revoked, on one or more of the following grounds, but on no other ground:

...

- (e) that the invention, so far as claimed in any claim of the complete specification or in the claim of the petty patent specification, as the case may be, was obvious and did not involve an inventive step having regard to what was known or used in Australia on or before the priority date of that claim".

184 Without reference to the long history of the Act and the glosses that have been placed upon it, a reader might read the clause, giving all of its words meaning and effect, to mean that a patent should be revoked if, but only if, the invention, that is, its manner of manufacture was not new as appeared in and from the complete specification, it was obvious, *and* it involved no inventive step. And, as to the last, regard to what was known or used in Australia on or before the priority date of the claim would be necessary.

185 On the basis of such a meaning, on the evidence, and the trial judge's findings, the respondent's application for revocation would be bound to fail. There was no doubt that the manner of manufacture, the coating of this active agent with the layers of the particular materials used in the respective quantities, thicknesses and places, was new. Let it however be assumed that the invention was "obvious", that is, in the sense that an enteric coated omeprazole pill was such a desirable product that as a concept it was familiar, and therefore obvious to those interested in the subject. Two matters, one clearly, and the other either implicitly found or such that it should have been found by the trial judge, nevertheless necessarily established that an inventive step was involved, having regard to whatever was known or used in Australia at the relevant time, a matter itself of some controversy. The first is that the development of a process of manufacturing an enteric coated pill (after a manufacturer understood that an enteric coated dosage might be

251 The *Patents Act* 1990 (Cth), s 230 repealed the *Patents Act* 1952, however by virtue of the transitional provisions of the 1990 Act, ss 233 and 234, the 1952 Act continues to apply to patents granted under the 1952 Act.

effective) which would have followed would have been "a complex, detailed and laborious one, involving a good deal of trial and error, dead ends and the retracing of steps". That such a process might be undertaken as a matter of scientific and industrial routine may readily be accepted. But what actually and precisely had to be done, and was done, by way of unravelling the complexities, identifying and correcting errors, and, in particular, in deciding which steps to retrace, and in which direction to step thereafter, must have involved one or more inventive steps.

186 It is not entirely clear whether the trial judge did in terms accept the uncontradicted evidence of Dr Marshall an expert called by the respondent. I summarise it. He was the only one of the respondent's experts who was not given a copy of the appellants' patent. He was, in effect, asked to devise his own manner of manufacture of an effective form of oral dosage of omeprazole for adults. In all he made six reports. After the first, he searched a database containing abstracts of various articles. At that stage he had the benefit also of a report by Pilbrant and Cederberg²⁵² which was provided to him by the respondent. The respondent then instructed Dr Marshall to do further work on the basis of some assumptions that the former asked him to make. Neither his research, any of the further five reports that he made, nor various other communications from the respondent, resulted in an acceptable form of manufacture. In short, Dr Marshall's failure to achieve a satisfactory result, armed as he was with the materials and suggestions that I have mentioned, argues strongly against the absence of any "inventive step". There is no reason why the trial judge should not have accepted Dr Marshall's evidence and given effect to it. Accordingly, I will take his fairly detailed reference to it as acceptance and not a mere narration of it.

187 However, the ordinary and natural meaning of the words of s 100(1)(e) may not be read, uninstructed by long standing authority. The terms "obvious" and "inventive step" are the antitheses of each other. Buckley LJ in *Beecham Group*²⁵³ said that "[w]hat is obvious cannot be inventive"²⁵⁴ notwithstanding that the word "obvious" when used in the Act qualifies "invention" that is, manner of manufacture, whereas "inventive" qualifies a step or steps involved in that manner of manufacture.

188 The primary judge posed the question for himself in this way²⁵⁵:

²⁵² Pilbrant and Cederberg, "Development of an oral formulation of omeprazole", (1985) 20 (supp 108) *Scandinavian Journal of Gastroenterology* 113.

²⁵³ *Beecham Group Ltd's (Amoxycillin) Application* [1980] RPC 261.

²⁵⁴ *Beecham Group Ltd's (Amoxycillin) Application* [1980] RPC 261 at 290.

²⁵⁵ (1999) 44 IPR 593 at 626-627 [110].

"Certainly, considered at the *commencement* of a hypothetical attempt, immediately before the priority date, to formulate omeprazole, the combination claimed in the patent was not obvious. The question is whether the hypothetical, not particularly imaginative skilled formulator, equipped with common general knowledge and embarking on the task at that time, would be likely to have arrived at the combination by taking routine steps which such a formulator would take for the purpose of formulating a drug. The test is whether the hypothetical addressee, faced with the same problem, would have taken as a matter of routine whatever steps might have led from the prior art to the invention, whether they be the steps of the inventor or not²⁵⁶: In my view, each of the expert witnesses sought conscientiously to fulfil the proper role of such a witness. Thus, for instance, I accept the general descriptions given by Dr Story and Dr Rowe of the way in which they would go about the formulation of a new drug. Nor do I see any reason to doubt the evidence of Dr Story, Dr Rowe and Dr Thiel about the importance of the role played by manufacturers' literature or the evidence of Dr Story and Dr Rowe about the significance, to formulators in Australia, of patent searches. That was evidence of factual matters within the knowledge and experience of the witnesses and which no one, with experience of the practice of formulators in Australia, was called to contradict."

189

It seems to me, with respect, that his Honour placed too much emphasis upon the question whether the relevant steps could be regarded as "routine" or not. I do not think the use of that word in the circumstances particularly helpful, because, as I have pointed out, although the taking and retracing of steps almost certainly would be done as a matter of routine, the selection of each of the steps to be retraced and taken, and the identification of error, are by no means necessarily dictated by any particular routine. Aickin J, although he used the word "routine"²⁵⁷ in his judgment in *Wellcome Foundation* was not in my opinion intending to substitute an exclusive test of routineness for the test posed by the statutory language. It is important to keep in mind that the attention of the Court there was focused upon an issue of discovery only, and that his Honour's remarks naturally took into account the types of activities in which researchers and manufacturers would ordinarily be concerned.

²⁵⁶ *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262 at 286.

²⁵⁷ *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262 at 281.

It is only to be expected that an expression (now found in the definitions section of the Act²⁵⁸) "manner of new manufacture"²⁵⁹ which predated the *Statute of Monopolies* in 1623²⁶⁰ and has repeatedly been construed by courts throughout the common law world, would not have escaped the application of layers of gloss. "Obviousness" has also, naturally, received much judicial attention, for example: something which "would at once occur to anyone acquainted with the subject"²⁶¹; "the obvious or natural suggestion of what was previously known"²⁶²; "whether the hypothetical addressee faced with the same problem would have taken as a matter of routine whatever steps might have led from the prior art to the invention, whether they be the steps of the inventor or not"²⁶³; and, simply "very plain"²⁶⁴. It is difficult to see why, with respect, any court would have gone beyond the last of the suggested meanings. Authority in the United Kingdom has however entrenched a judicial approach to par (e) of s 100(1) of the Act and its near analogues and analogues elsewhere that questions whether "the alleged inventive step [would be] obvious to a normally skilled addressee in the art"²⁶⁵. The variety of forms in which the questions have been asked on other occasions is further illustrated by some examples collected in the *Manual of Practice and Procedure*²⁶⁶:

"The test is whether the hypothetical addressee faced with the same problem would have taken as a matter of routine whatever steps might have led from the prior art to the invention, whether they be the steps of the inventor or not.'

258 See definition of "invention": *Patents Act* 1952 (Cth), s 6; *Patents Act* 1990 (Cth), Sched 1.

259 *Wellcome Foundation Ltd v Commissioner of Patents* (1980) 145 CLR 520 at 524-528.

260 21 Jac I c 3. The Statute was declaratory of the pre-existing common law.

261 cf *Vickers, Sons & Co v Siddell* (1890) 15 App Cas 496 at 501-502 per Lord Herschell.

262 *Savage v D B Harris and Sons* (1896) 13 RPC 364 at 370 per Lopes LJ.

263 *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262 at 286 per Aickin J.

264 *General Tire & Rubber Company v Firestone Tyre and Rubber Company Ltd* [1972] RPC 457 at 497 per Sachs LJ.

265 *General Tire & Rubber Company v Firestone Tyre and Rubber Company Ltd* [1972] RPC 457 at 497.

266 Australian Patent Office, *Manual of Practice and Procedure*, vol 2, Pt 4 at [4.1.5.1].

Aickin J in *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262 at page 286

'was so obvious that it would at once occur to anyone acquainted with the subject, and desirous of accomplishing the end'.

Allsop Inc & Another v Bintag Ltd & Ors (1989) AIPC 90-615 at page 39,332 [per Bowen CJ, Beaumont and Burchett JJ]

'Would the notional research group at the relevant date in all the circumstances ... directly be led as a matter of course to try [the invention claimed] in the expectation that it might well produce [a useful desired result].'

Olin Mathieson v Biorex [1970] RPC 157 at page 187 [per Graham J]

'In the case of a combination patent the invention will lie in the selection of integers, a process which will necessarily involve rejection of other possible integers. The prior existence of publications revealing those integers, as separate items, and other possible integers does not of itself make an alleged invention obvious. It is the selection of the integers out of, perhaps many possibilities, which must be shown to be obvious.'

Minnesota Mining & Manufacturing Co v Beiersdorf (Australia) Ltd (1979-80) 144 CLR 253 at page 293 [per Aickin J]

'so easy that any fool could do it'

Edison Bell v Smith (1894) 11 RPC 389 at page 398 [per Lord Esher MR]".

I would myself have thought, as I have indicated, that all that the language of the statute requires is three questions: was the manner of manufacture new; was the manner of manufacture obvious; and, did it involve any inventive step. Such questions might very frequently, but by no means always overlap, and elicit overlapping answers. The question, whether the "inventive step" "was obvious" could equally, in ordinary English have been asked in one of these ways: was the step obvious, or, was the step inventive, or was the step not inventive, or was the step not obvious? The questions conventionally asked transfer the adjective "obvious" from its position as a qualifier of the (alleged) manner of manufacture, the invention, to a new position, as a qualifier of the step alleged to be inventive.

191

In *General Tire & Rubber Company* Sachs LJ²⁶⁷ traced some of the history of the current forms of questions, and the use in patent law of the word "obvious",

²⁶⁷ *General Tire & Rubber Company v Firestone Tyre and Rubber Company Ltd* [1972] RPC 457 at 497.

to the speech of Lord Herschell in the *American Braided Wire* case²⁶⁸. What his Lordship was referring to however when he used the word "obvious" in that latter case was the manner of manufacture in total, the "mode" of use, application and fixation of the various components, and not, each, or any, particular step, whether inventive or not, in the achievement of the total invention.

192 It is easy to see how the tension created by the competing considerations of policy, between reward and incentive for ingenuity, and the desirability of the general availability to humankind of the products of that ingenuity, has contributed to different approaches to the questions and their answers. The problems are compounded by the difficulties of assessing, after the event, what the relevant and reasonably accessible learning or art was at the material time, the complexities for lawyers of the scientific and technical matters in issue, and the fact that almost everything, particularly to people knowledgeable in the field, can have an appearance of obviousness after the event. Also almost always present in these cases is the fact that those who seek the revocation of a patent are commercial competitors with like resources and goals to those of the patentee but who have not themselves been able to, or have not had the inspiration to invent the invention. Here, a skilled practitioner, Dr Marshall, armed with suggestions from the respondent, and with the desired result identified for him, was unable to replicate the appellants' pill.

193 I have formed the view that on any of the stated tests, having regard to Dr Marshall's uncontradicted evidence, its source, from the respondent's side, and the trial judge's apparent and necessary acceptance of it, the answer must still be in the negative. The respondent's submission in this Court that Dr Marshall may have, indeed, even probably would have arrived at the solution had he had more time for experimentation demands no different an answer. The fact alone that he was still weighing up possible alternative methods that may or may not have worked, is a clear indication of an absence of obviousness.

194 The particular question that authority in this country requires me to ask is the one posed by this Court in *Minnesota Mining*²⁶⁹: whether the pill (as a combination patent) would have been obvious to a *non-inventive* skilled worker in the field able to select from a possibly large range of publications, and whether it would have been obvious to that worker to select the particular combination of integers from those selected publications²⁷⁰. It is important to keep in mind what

268 *Thomson v The American Braided Wire Company* (1889) 6 RPC 518 at 528.

269 *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253.

270 *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253 at 293 per Aickin J.

the question is not, that is, "whether a diligent searcher might find pieces from which there might have been selected the elements which make up the patent."²⁷¹

195 It may be that in Australia a less rigorous test is adopted than the one currently used in England²⁷² as was suggested by the Full Court of the Federal Court in *ICI Chemicals & Polymers Ltd v The Lubrizol Corporation Inc*²⁷³. United States authority does not assist very much because the statutory provision there contains manifestly different language – 35 USC §103(a) provides as follows:

"A patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made."

It is important also to remember that in Australia, a "scintilla of inventiveness"²⁷⁴ will suffice: "no smallness or simplicity will prevent a patent being good"²⁷⁵. The answer to the correct question as posed and required by *Minnesota Mining* therefore remains no.

196 There are, it may be accepted, problems unique to combination patents in assessing obviousness and novelty. A combination patent combines known information and is therefore susceptible to allegations of obviousness and lack of novelty. A particular danger, "that a court will assume, in retrospect, that anyone would have understood the desirability of combining the individual

271 *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253 at 293 per Aickin J.

272 See for example that put forth by Mustill LJ in *Genentech Inc v Wellcome Foundation Ltd* (1988) 15 IPR 423; [1989] RPC 147.

273 (2000) 106 FCR 214 at 240.

274 *Meyers Taylor Pty Ltd v Vicarr Industries Ltd* (1977) 137 CLR 228 at 249 per Aickin J:

"It is trite law that a 'scintilla of inventiveness' is sufficient and that 'no smallness or simplicity will prevent a patent being good' (*Riekman v Thierry* (1896) 14 RPC 105 at 115; and see *Vickers, Sons & Co v Siddell* (1890) 15 App Cas 496 at 502). I am satisfied that there was here an inventive step in the devising of a new combination of features to obtain an improved result."

275 *Meyers Taylor Pty Ltd v Vicarr Industries Ltd* (1977) 137 CLR 228 at 249.

components"²⁷⁶ was acknowledged by Fletcher-Moulton LJ in *British United Shoe Machinery Company Ltd v A Fussell & Sons Ltd*²⁷⁷:

"When you come to a machine of this type, you have to alter very seriously the canons which influence you in deciding such questions as novelty^[278]. In the case of operations which have to be done under normal circumstances, in the absence of any special difficulties arising from speed, small and trivial alterations in the apparatus are viewed with suspicion, as possibly being idle variants; but when you come to machines which with this demand upon them still give uniform success, I think any tribunal will be very careful before it applies its ordinary ideas of what are mere idle and trivial changes to those alterations which have resulted in a success so triumphant. So that I approach the consideration of novelty in this case, ie, of the importance of apparently slight variations in the combination, in a very humble spirit, willing to be taught by those who know the practical performance of the machine, and are able to judge of the means which render that practical performance so successful. I remember very well a machine for printing newspapers, and turning them out in a folded form, in which the whole difference between hopeless failure and most valuable commercial success *depended on a trivial change in the arrangement ... a matter which, if you read it on paper seemed to be perfectly trivial, but which, I have no doubt, required very long continued experiment in order to arrive at the proper arrangement and demonstrate its importance, but which, once arrived at, actually turned failure into success.*" (emphasis added)

197 In my opinion the primary judge erred in focusing upon, and, with respect, not only attaching too much importance to routineness, but also in failing to distinguish between an established routine, no doubt followed by experiments, of research, of trying out ideas, identifying and correcting errors, of retracing old and taking new steps on the one hand, and, on the other, of the ingenuity involved, in carrying out the routine, of finding and eliminating error and choosing which out of a multiplicity of choices, was the right one. The Full Court of the Federal Court should therefore have upheld the appeal to it.

198 The Full Court (Wilcox, Merkel and Emmett JJ) chose a different test from either the one that *Minnesota Mining* requires or the one of "routineness" that the

276 Lahore, *Patents, Trade Marks & Related Rights*, vol 1 at 13,081 [12,905].

277 (1908) 25 RPC 631 at 646. In that case the invention was a minor addition to a known machine, but one which determined the success or failure of the machine.

278 Lahore submits that in the context of today his Lordship's references to "novelty" would be more appropriate when considering "obviousness" rather than novelty, see Lahore, *Patents, Trade Marks & Related Rights*, vol 1 at 13,082 [12,905].

primary judge sought to apply. The Full Court adopted the question posed by Buckley LJ in *Beecham Group*²⁷⁹, whether "it is shown that it would appear to anyone skilled in the art but lacking in inventive capacity that to try the step or process would be *worthwhile*" (emphasis added). And, the Full Court did not, in any event, in applying that test, give effect to the important qualification contained in it, that the notional skilled worker be lacking in inventive capacity.

199 It is interesting that the Full Court dealt over some fifty or so paragraphs in great detail with the evidence of all of the experts called, with one critical exception, Dr Marshall. Of his evidence the Full Court only observed, erroneously, that his "practical reactions"²⁸⁰ supported the theoretical evidence of two of the respondent's experts. The primary judge's finding in relation to those two experts was no more than that their "general descriptions ... of the way in which they would go about the formulation of a new drug" should be accepted²⁸¹.

200 I cannot leave the discussion of the evidence without some observations of my own. It is clear that at the trial, each of the parties, particularly the appellants took lengthy objections to much of the evidence, especially to parts of the affidavits of the respondent's experts upon which the primary judge did not rule. As almost always, and at this trial, that course was bound to create difficulties for the appellants in cross-examination. What was in evidence, and what was not? What could be taken to have been sufficiently challenged by the tendering of the appellants' own experts' affidavits? The difficulties stemming from his Honour's abstention from ruling were increased by the absence of clear findings as to what he relied upon and accepted.

201 In those circumstances the Full Court's reliance on a claimed failure of the appellants' counsel to put various matters to the respondent's experts was, with respect, misplaced. These matters strengthen my opinion that the appeal should be upheld. Trial judges should insist upon proper proof of controversial material, and limit the reception of evidence, including evidence in writing, to what is relevant and admissible, by timely rulings on it.

202 I do not overlook that the issue for decision under par (e) of s 100(1) of the Act has long been said to be in the nature of a jury question. Even so, for the reasons I have given, the appeal must be allowed. Not only was the right test not posed by both the primary judge and the Full Court, but also it was not posed in relation to the compelling uncontradicted evidence of the respondent's own expert, Dr Marshall, whose evidence bore much more directly on the issue than any of the other evidence in the case. And, because this is so, I would not remit the case to the Full Court for further consideration of the application of par (e) of s 100(1) of

279 [1980] RPC 261 at 290-291.

280 (2000) 51 IPR 375 at 407 [143].

281 (1999) 44 IPR 593 at 626-627 [110].

the Act. There are however other issues outstanding, and the case will need to be remitted for the resolution of these.

203

I would allow the appeal with costs and order that the respondent pay the appellants' costs of the trial so far, and the appeal to the Full Court. I would remit the case to the Full Court for further disposal.