An Analysis of Obviousness in *Aktiebolaget Hässle v Alphapharm*: Implications for the Pharmaceutical Industry

MICHAEL J PAPHÁZY*

Losec™ is the world's largest selling pharmaceutical drug and the second largest beneficiary of the pharmaceutical benefits scheme in Australia.[1] *This article concerns a judgment given by a single judge of the Federal Court and its impact on patent law in Australia. In particular, the finding on obviousness by Lehane J in* Aktiebolaget Hässle v Alphapharm[2] *has potentially serious implications for the pharmaceutical industry in Australia.*

OMEPRAZOLE PATENT

The issue of obviousness, or lack of inventive step, arose in proceedings involving a cross-claim for revocation of an Aktiebolaget Hässle patent by Alphapharm. Aktiebolaget Hässle is part of the AstraZeneca (Astra) pharmaceutical group, and Astra is the exclusive licensee of the patent for Losec™ in Australia. Losec™ is the trade name for an omeprazole formulation designed to inhibit the secretion of gastric juice in the stomach. Losec™ is made up of three components: an active core of omeprazole, an inert subcoat and an outer coat made of enteric acid. The effectiveness of Losec™ is that its active core, omeprazole, is released in a controlled way in the intestinal tract, rather than in the stomach. Omeprazole degrades in acidic environments, like the stomach, and would not be an effective proton-pump inhibitor if it broke down in the stomach.[3] A further problem is that omeprazole reacts with its outer enteric coat unless an inert subcoat shields it. The essential inventiveness of the omeprazole patent is that the use of the subcoat enables the drug to pass safely through the stomach and be absorbed in the gastrointestinal tract, where it is highly bioavailable. The resultant efficacy of Losec™ in preventing gastric acid release in the stomach is several times that of other pharmaceutical drugs on the market.[4]

* BSc (Hons), Law Student of Monash University. The author wishes to thank Moira Paterson for her advice and encouragement.

1 [http://www.astrazeneca-us.com/news/article.asp?file=1997092901.htm (Accessed 6 May, 2000.)]. *See also Aktiebolaget Hässle v Alphapharm* (1999) 44 IPR 593,595.

2 *Aktiebolaget Hässle v Alphapharm* (1999) 44 IPR 593.

3 A proton-pump inhibitor is the name given to pharmaceutical drugs which act to inhibit the action of an enzyme (H+/K+-ATPase — the proton pump) responsible for the release of gastric acid in the stomach.

4 Oliver James and Karen Parry-Billings, 'Comparison of omeprazole and histamine H2-receptor antagonists in the treatment of elderly and young patients with reflux oesophagitis' (1994) 23(2) *Age & Ageing* 121 [http://gateway.ovid.com/ server1/ovidweb.cgi?T=fullText&RS=Results.bib%7c4%7cArticle+Review&D=mesz&S=IDNJHKEKOFFNAM (Accessed 6 May, 2000.)]. Cimetadine and ranitidine are H2-receptor antagonists that inhibit gastric acid secretion. See Humphrey Rang, Maureen Dale and James Ritter, *Pharmacology* (3rd ed, 1996) 389–90.

AN ALTERED TEST FOR OBVIOUSNESS?

An essential requirement for the grant of a patent is that the invention claimed involves an inventive step where there is 'some barrier crossed.'[5] The obviousness requirement in s 100(1)(e) of the *Patents Act* 1952 (Cth),[6] which was at issue in *Aktiebolaget Hässle*, and which bears similarities to the current requirement for an inventive step[7] under s 18(1)(b)(ii) of the *Patents Act* 1990 (Cth),[8] was enunciated by Aickin J in *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd.*[9] Aickin J's test for obviousness possesses two limbs, namely whether it is obvious to the non-inventive skilled worker:

(a) 'to select from a possibly very large range of publications the particular combination subsequently chosen by the opponent in the glare of hindsight'; and
(b) to select the particular combination of integers from the selected publications.[10]

Crucially, Aickin J also emphasised the following in relation to whether mosaicing was permitted, stating that the true question is, 'is the invention itself obvious, not whether a diligent searcher might find pieces from which there might have been selected the elements which make up the patent.'[11]

In *Aktiebolaget Hässle* Lehane J appears superficially to endorse the *3M Case*,[12] but a closer inspection reveals that his methodology varies from that of Aickin J.[13] *Aktiebolaget Hässle* hinged on what Lehane J deemed to be common general knowledge, and while he rejected the submission that it includes 'literature searches resulting in the discovery of documents containing information of which the formulator was previously unaware,' he accepted that 'it may not necessarily follow that ... documents which would have been found on search, but do not form part of the common general knowledge are simply irrelevant.'[14] Lehane J placed considerable emphasis on

5 *R D Werner & Co Inc v Bailey Aluminium Products Pty Ltd* (1989) 13 IPR 513, 523 (Lockhart J).
6 1952 Act
7 The 1952 Act use of the phrase 'what was known or used in Australia on or before the priority date' in s 100(1)(e) equates with the 1990 Act's use of the phrase 'in the light of common general knowledge' in assessing the prior art base for inventive step. The difference between the 1952 Act and the 1990 Act is that the new Act also allows for an assessment of how much the hypothetical 'person skilled in the relevant art' would be imputed to know not only in 'the light of common general knowledge' but also with respect to the additional 'kinds of information' referred to in s 7(3). Such 'kinds of information' in s 7(3) can be assessed either separately or together with the 'common general knowledge' referred to in s 7(2), and are information which a 'person skilled in the relevant art ... could ... reasonably be expected to have ascertained, understood and regarded as relevant to work in the relevant art'.
8 1990 Act.
9 *Minnesota Mining & Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253.('3M' case).
10 Ibid 293.
11 Ibid.
12 *Aktiebolaget Hässle v Alphapharm* (1999) 44 IPR 593, 603–4.
13 Ibid 624–26.
14 Ibid 606.

whether a hypothetical formulator, 'equipped with common general knowledge, would have been likely to arrive at the combination by taking routine steps which such a formulator would take for the purpose of formulating a drug'.[15]

It is submitted that Lehane J, to the extent he accepted both manufacturers' literature and the evidence given by an Alphapharm witness, Dr Story, that 'one reads [such material] for more general ideas' in the course of the drug formulation process, has expanded the notion of what can constitute common general knowledge.[16] From here, Lehane J accepts that such routine steps in the drug formulation craft would lead obviously to the use of a water soluble subcoat, in combination with the other elements, to produce the desired result.[17] While the use of routine steps is accepted as being sufficient to defeat a claim for patentability,[18] the question as to what are routine steps is vexed. At issue is how far should the prior art base be expanded to accommodate material which can be found by a competent but non-inventive drug formulator as a matter of routine such that the invariable stumbling blocks involved in drug formulation are overcome by a routine process of trial and error. In *The Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd*,[19] Aickin J, in an unanimous decision of the High Court of Australia, warned of the limitations of attacking a patent simply by means of a 'routine steps' argument, and queried whether 'resort by those attacking a patent to the research and experiments of the inventor can often be helpful on the issue of obviousness.'[20] The evidence gleaned from Astra's expert witnesses seems to cast doubt over whether use of the particular subcoat was obvious[21] when compared to the fact there were no other drugs which had the 'characteristics of omeprazole.'[22] Again, Aickin J stated in Wellcome Foundation that once the inventive step is taken 'the perception of the true nature of the problem', can result in 'straightforward experiments ... providing the solution'.[23] It appears as though Lehane J places more emphasis on the 'obviousness' of the latter experiments than on the preceding inventive step.

Lehane J, in determining whether the omeprazole formulation patent was valid, placed considerable weight on the evidence of an Alphapharm witness, Dr Marshall, who fell within the class of skilled formulators at the time the patent was granted.[24] Dr Marshall had not seen the patent and was given several scenarios in which to come up with a solution. In one of his six reports, Dr Marshall came somewhat close to predicting the patent.[25] Lehane J took an

15 *Aktiebolaget Hässle v Alphapharm* (1999) 44 IPR 593, 626 applying *The Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262, 286.
16 *Aktiebolaget Hässle v Alphapharm* (1999) 44 IPR 593, 628–9.
17 Ibid 629.
18 *Sartas No 1 Pty Ltd v Koukourou & Partners Pty Ltd* (1994) 30 IPR 479, 512 (Gummow J).
19 (1981) 148 CLR 262, 286.('Welcome Foundation' case).
20 Ibid.
21 *Aktiebolaget Hässle v Alphapharm* (1999) 44 IPR 593 at 618–624.
22 Ibid 619.
23 (1981) 148 CLR 262, 281.
24 *Aktiebolaget Hässle v Alphapharm* (1999) 44 IPR 593, 629–30.
25 Ibid 616–17. See also Wayne Condon, 'Controlled Release Pharmaceutical Found to be Obvious' (1999) 12(8) *IP Asia* 15, 16.

expanded view of what constitutes common general knowledge compared with the *3M Case* and found the combination of integers to be obvious.[26] In doing so, he has arguably changed the meaning of the phrase 'what was known or used in Australia' in the context of assessing the inventiveness of the patent.[27]

In contrast to Dr Marshall, one of Astra's witnesses, Professor Brown, suggested that the interaction between the core and the enteric coat was not common knowledge.[28] Professor Brown suggested it was more likely that the degradation of omeprazole would have been thought to occur because of the 'presence of free water, rather than by a reaction between a dry core and an enteric coat.'[29] Notwithstanding the doubts cast by Professor Brown, Lehane J preferred the evidence given by the industrial formulators to that of the academics.[30] However, in doing so, Lehane J adopted a position contrary to Aickin J's warning about the impermissibility of mosaicing[31] with respect to the issue of obviousness by taking into consideration a patchwork of previous patents to do with enteric coats and alkaline cores.[32] The *Aktiebolaget Hässle* approach to 'what was known or used' in the context of assessing the inventiveness of the patent, seemingly allows for an illicit mosaicing of the kind described by Aickin J as 'the picking out of individual items of information ... so as to give them an appearance of unity and then alleging that such mosaic reveals the very thing claimed.'[34] Stringing together a series of unrelated documents in order to defeat a patent is the very danger which Aickin J sought to avoid, and which Lehane J has partially accepted. By allowing documents in existence to be used to form a 'background or matrix' which the non-inventive formulator may have taken into account,[35] Lehane J has opened the previously locked door of mosaicing. This type of judicial reasoning fails to take into account the difficulties and inherent uncertainties associated with scientific research and the formulation of drugs, and places too great an emphasis on the imaginative spark concept.[36] *Aktiebolaget Hässle* sets an unfortunate precedent by permitting the mosaicing of prior art documents which do not expressly or impliedly refer to each other.[37]

26 Ibid, 625–29. The integers are the constituents which make up the omeprazole formulation.

27 See *Minnesota Mining & Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253, 292 which interprets the phrase found in s 100(1)(e) of the *Patents Act* 1952 (Cth).

28 *Aktiebolaget Hässle v Alphapharm* (1999) 44 IPR 593, 624.

29 Ibid.

30 Ibid 625.

31 *Minnesota Mining & Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253, 292–3.

32 *Aktiebolaget Hässle v Alphapharm* (1999) 44 IPR 593, 626–30.

33 s 100(1)(e) *Patents Act* 1952 (Cth).

34 *Minnesota Mining & Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253, 292.

35 Wayne Condon, 'Controlled Release Pharmaceutical Found to be Obvious', (1999) 12(8) *IP Asia* 15, 16.

36 In *Sunbeam Corporation v Morphy-Richards (Aust.) Pty Ltd* (1967) 37 ALJR 212, 219, the High Court stressed the need for 'the exercise of (both) imagination and ingenuity' over mere mechanical ingenuity. Also in *ICI Chemicals & Polymers Ltd v Lubrizol Corporation Inc* (1999) 45 IPR 577, 601, where Emmett J states that an 'inventive step...does not necessarily have to involve a flash of inspiration'.

37 *Aktiebolaget Hässle v Alphapharm* (1999) 44 IPR 593, 625–9.

FOLLOWING THE ENGLISH APPROACH?

The concept of an inventive step is found in s 1(1)(b) of the *Patents Act* 1977 (UK) (1977 Act). Section 3 of the 1977 Act, in combination with s 2(2), states that 'an invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to...all matters ... which ... (have) been made available to the public...by written or oral description, by use or in any other way'. *Mölnlycke AB v Procter & Gamble Ltd*,[38] is a leading English Court of Appeal decision interpreting the question of obviousness. Mölnlycke discounted earlier authorities which referred to 'a scintilla of invention' deserved of the grant of a patent, stressing instead that the statute had 'laid down ... a qualitative not a quantitative test.'[39] Furthermore, the Court of Appeal stated that the 'inventive step involves having an insight ... rather than a mere development and application of existing ideas.'[40] Such an approach seems to have been mirrored in *Aktiebolaget Hässle*, where the methodology of Astra's research team was deemed insufficient to overcome the obviousness threshold.[41]

OBVIOUSNESS IN EUROPE AND THE UNITED STATES

The European Patent Office (EPO) uses an inventive step test which is similar to that employed in Australia. The EPO test for obviousness resembles s 7(3)(b) of the 1990 Act as it allows for 'documents to be combined ... only if it would have been obvious for the skilled person to do so at the time of filing.'[42] The European approach to the granting of patents lies somewhere between the relatively more relaxed English and Australian position, and that of the United States of America (USA), where it is more difficult to obtain a patent[43]. Section 103(a) of the *Patent Act* 1952 (USA) also deals with the question of obviousness, and states that 'patentability shall not be negatived by the manner in which the invention is made'. In the USA, it is immaterial whether the patentable invention 'resulted from long toil and experimentation or from a flash of genius.'[44] The US approach is one in which it is possible 'to mosaic together any number of prior art documents,'[45] and this makes the hurdle for proving an inventive step, or non-obviousness, higher than in Europe or Australia.[46]

38 [1994] RPC 49.
39 Ibid 112.
40 Ibid 131.
41 *Aktiebolaget Hässle v Alphapharm* (1999) 44 IPR 593, 624. See also Wayne Condon, 'Controlled Release Pharmaceutical Found to be Obvious' (1999) 12(8) *IP Asia* 15, 16.
42 Phillip Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy* (1999) 64.
43 Ibid 91.
44 [http://law2.house.gov/uscodecgi/fastweb.exe?(Accessed 6 May, 2000.)].
45 Grubb, above n 42, 64.
46 Ibid 91.

OBVIOUSNESS IN AUSTRALIA POST-*AKTIEBOLAGET HÄSSLE*

It seems doubtful to say that the selection of documents from the prior art base was obvious in *Aktiebolaget Hässle*, let alone that the solution, necessary to overcome the omeprazole stability problem, involved the taking of mere routine steps. If the development of Losec™ was obvious, why was its efficacy several times that of its nearest competitors? Normally, the issue of commercial success is merely an aid to determine the question of inventiveness,[47] but it was more significant in this instance. The absence of a formulation akin to omeprazole on the market during the mid to late 1980s is strong and compelling evidence that the subject matter of the patent involved something new and inventive. A recent Federal Court case has suggested that 'while the matter [of commercial success] is not decisive, it may be regarded as supporting a conclusion that an inventive step was involved'.[48] Losec™ was a clear improvement when compared with other like products in the market, and the 'disclosure of information which is of value to the public'[49] of such a proton-pump inhibiting drug has progressed undeniably the 'store of knowledge'[50] in this particular pharmacological area.

Ultimately, it seems as if the economic philosophy of the courts will determine what approach they take to the issue of obviousness.[51] Advocates of a 'fairness approach' to the question of obviousness, exemplified by Aickin J,[52] when assessing the prior art base for inventive step, will agree with the proposition that the question of obviousness should be 'whether the inventor has made a contribution to the public good which would not have occurred to less inventive people to make.'[53]

COMMON GENERAL KNOWLEDGE UNDER THE 1990 ACT

It is, however, important to note that in assessing the impact of *Aktiebolaget Hässle*, it was based on the 1952 Act. The 1952 Act did not include a reference to 'kinds of information' referred to in s 7(3) of the 1990 Act.[54] Section 7(3) thus allows consideration of documents not considered part of common general knowledge. What role s 7(3) is to play in the light of *Aktiebolaget Hässle*

47 *Meyers Taylor Pty Ltd v Vicarr Industries Ltd* (1977) 137 CLR 228, 239 (Aickin J).

48 *ICI Chemicals & Polymers Ltd v Lubrizol Corporation Inc* (1999) 45 IPR 577, 607 (Emmett J).

49 Ibid 601.

50 Ibid.

51 Donald Speagle and Michael Dowling, 'The 1990 Patents Act: Unfinished Reform' (1993) 4 *Australian Intellectual Property Journal* 166, 175.

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

53 Speagle, above n 51, p 175.

54 Section 7(2) of the *Patents Act* 1990 (Cth) states that 'an invention is to be taken to involve an inventive step when compared with the prior art base unless the invention would have been obvious to a person skilled in the relevant art in the light of common general knowledge as it existed in the patent area before the priority date of the relevant claim, whether the knowledge is considered separately or together with either of the kinds of information mentioned in subsection (3), each of which must be considered separately.

is unclear, but as courts read statutes so as to give them effect rather than to let them be redundant, the effect of the new approach may be to raise the inventive step threshold higher than the legislature intended. If the approach to common general knowledge in Aktiebolaget becomes the norm, then the s 7(2) requirement to view the invention 'in the light of common general knowledge' becomes more onerous than case law suggested at the time the 1990 Act was drafted. In combination with s 7(3),[55] the effect of a more encompassing view of 'common general knowledge' is to raise the standard of inventiveness even higher than was thought necessary at the time the 1990 Act was passed. On the other hand, as a counterpoint to this raised standard of inventiveness, it is likely that inventors will argue for a narrow interpretation of what constitutes 'the relevant art' in s 7(3) in the 1990 Act.[56]

IMPLICATIONS FOR THE PHARMACEUTICAL INDUSTRY

Claims that the awarding of patents to foreign firms runs counter to Australia's national interest fail to acknowledge the net social benefits of a strong patent system.[57] While more than 90% of patents are held by non-Australian firms, it is also true that countries which have low levels of intellectual property protection and weak patent systems are ones where there is a low level of innovation by industry.[58] Australia has an excellent patent regime which should not be diminished, especially in the light of its 'interaction with the international patent system.'[59] The courts' approach to obviousness is a critical factor in the award or revocation of a patent. Judicial reasoning of the kind exhibited in *Aktiebolaget Hässle* can significantly weaken the ability of potential patentees to obtain patents. More importantly, such an approach does not reward innovation by indigenous industries, and promotes conservatism in industry over the higher risk and higher reward pathway of research and development.

Patents offer industry a great incentive to research and develop novel and valuable pharmaceuticals. The development of the groundbreaking anti-flu drug Relenza™ by local manufacturer Biota is a case in point. Without strong protection of novel products it is too easy for generic drug manufacturers to reap reward where others have sown. Such a result may result in an increased exodus of talented scientists overseas and in pharmaceutical companies opting to conduct their research and development offshore, rather than in Australia.

55 Refer to footnote n 7.

56 Speagle, aboven 51, 175.

57 Paul David, 'Intellectual Property Institutions and the Panda's Thumb: Patents, Copyright and Trade Secrets in Economic Theory and History' in Mitchel Wallerstein, Mary Mogee and Roberta Schoen (eds) *Global Dimensions of Intellectual Property Rights in Science and Technology* (1993) 24.

58 Australia, Bureau of Industry Economics, *The Economics of Patents*, Occasional Paper 18, (AGPS, Canberra, 1994), 34–6, cited by Sam Ricketson and Megan Richardson, *Intellectual Property: Cases, Materials and Commentary* (2nd ed, 1998), 572.

59 Australia, Industrial Property Advisory Committee, Patents, *Innovation and Competition in Australia* (1984), 17.

Especially, in relation to the pharmaceutical industry the easier it is to defeat a patent via obviousness, the more free-riders will benefit at the expense of those companies which seek innovative solutions to tomorrow's problems.

The cost to develop and market a drug is estimated to be up to $500 million.[60] Only 10% of drugs make it through clinical trials and of these, only three out of ten generate revenues higher than the average cost of the development of a drug.[61] Hence, the importance of patents for research-based pharmaceutical companies' profitability is that it provides the funds necessary for the next generation of drugs.[62] Generic pharmaceutical manufacturers benefit from a weak patent system as they merely reproduce known drugs without having to bear the risks of developing drugs. Viewed in this light, the decision of Lehane J poses a real concern for pharmaceutical companies.

Addendum: The Full Federal Court dismissed an appeal against the decision of Lehane J:

Aktiebolaget Hässle v Alphapharm Pty Limited [2000] FCA 1303. The primary issue at appeal was whether Lehane J had erred in accepting certain documents as part of the stock of common general knowledge. Emmett, Merkel and Wilcox JJ endorsed Lehane J's reasoning but queried the extent to which his Honour relied on those documents to defeat the patent on the ground of obviousness. However, the Full Court overcame this difficulty by viewing the documents in question as merely corroborating, not establishing, the assertions of Alphapharm's expert witnesses.

60 Lisa Bellavance, 67(2) (2000) Chemistry in Australia 14. GlaxoWellcome, a research based pharmaceutical company, spent £1.26 billion in 1999 on R&D. [http://www.glaxowellcome.co.uk/about/fr_about.html (Accessed 6 May, 2000.)].

61 Ibid 15.

62 Brenadan Nugent, 67(2) (2000) *Chemistry in Australia* 21. One commentator believes that such research is directly linked to patent protection. See Otto Stamm, 'Intellectual Property Rights and Competitive Strategy' in MB Wallerstein, ME Mogee and RA Schoen (eds) *Global Dimensions of Intellectual Property Rights in Science and Technology* (1993), 223.