AUSTRALIA

PATENTS ACT 1990

IN THE MATTER OF
Australian Patent Application
Number 2012220990 in the name
of:

Nalco Company

and

IN THE MATTER OF
Section 104(4) opposition thereto
by:

Cytec Industries, Inc.

WRITTEN SUBMISSION ON BEHALF OF THE APPLICANT, NALCO COMPANY

Background

1. Australian Patent Application No 2012220990 (AU '990; the opposed application) in the name of Nalco Company (the Applicant) was filed on 7 February 2012 as the Australian national phase application corresponding to PCT/US2012/024099, published as WO 2012/115769 (WO '769; the specification as filed; the complete specification).

2. A request for examination was filed on 21 August 2013. As such, the opposed application is subject to the substantive amendments of the Act brought about by the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012 (Cth).*

3. The opposed application was accepted by IP Australia on 1 May 2015 and acceptance was advertised on 21 May 2015. Cytec Industries, Inc (the Opponent) filed a notice of opposition to the grant of a patent on the opposed application under s.59 of the *Patents Act 1990 (Cth)* (the Act) on 21 August 2015 (the main opposition).

4. The Applicant filed an amendment in respect of the opposed application on 25 May 2016 (the amendment; the opposed amendment) to replace claims 1-22 as initially accepted (the accepted claims) with amended claims 1-19 (the amended claims); the amendment was filed on the same day as the Applicant's evidence in answer in respect of the main opposition.

5. An examination report on voluntary amendments issued from IP Australia on 17 June 2016. The examiner assigned was Makiko Umehara. A single objection was raised under ss.102(2)(a) – namely, that the amended claims 1, 3, 4 and 13-19 were not allowable because such amended claims defined matter which did not in substance fall within the scope of the accepted claims (i.e., the same objection as that now pursued by the Opponent under Ground 2, discussed below). Examiner Umehara's objection related to compounds (LXVI) and (LXVII) only. No other objections were raised.

6. The Applicant filed a response to the examination report on 22 June 2016. No further amendments were proposed, with the Examiner's ss.102(2)(a) objection addressed and overcome by argument alone.

7. The amendment was then advertised on 14 July 2016. The same Opponent filed a notice of opposition to the amendment under ss.104(4) of the Act on 14 September 2016 (the amendment opposition). The Opponent's Statement of Grounds and Particulars (SoGP) was filed on 14 October 2016.

8. The Opponent's evidence in support was filed on 19 December 2016; this comprised a declaration by Professor Christopher John Easton accompanied by Exhibits CJE-A1 to CJE-A9 (Easton-1).

9. The Applicant's evidence in answer was filed on 17 March 2017; this comprised a declaration by Dr John David Kildea accompanied by Exhibits JDK-1a and JDK-2a (Kildea-1).

10. The Opponent's evidence in reply was filed on 20 April 2017; this comprised a further declaration by Professor Easton accompanied by Exhibit CJE-A10 (Easton-2) and a

declaration by Dr Roderick Glyn Ryles accompanied by Exhibits RGR-A1 to RGR-A7 (Ryles).

11. On 21 June 2017, the Applicant requested that the Commissioner consider a further declaration by Dr Kildea dated 22 May 2017 (Kildea-2) under Regulation 5.23 of the *Patents Regulations 1991 (Cth)*. The Kildea-2 declaration was made for the purposes of contesting the Ryles declaration (given that Dr Ryles was introduced for the first time during evidence in reply and that his opinion would otherwise go unchallenged in evidence).

12. As per precedent[1], the Commissioner would have granted the sought request if "the information is likely, if not certain, to change the outcome of the opposition in a significant way". On 4 July 2017, the Commissioner refused the sought leave, from which it follows that nothing in the Ryles or indeed the Kildea-2 declarations was likely to be determinative of the present opposition.

13. The hearing scheduled for 12 October 2017 is to decide the amendment opposition.

The opposed amendment

14. The opposed amendment seeks to replace the accepted claims 1-22 with the amended claims 1-19. The accepted claim 1 defined Markush groupings for the R_1, R_2 and R_3 moieties of the claimed small molecule of type $NR_1R_2R_3$; this allowed for literally thousands of combinations and permutations as to what the small molecule could be. The opposed amendment replaced the Markush groupings with 64 small molecules drawn out by way of their respective structural formulae.

15. Accordingly, claim 1 of the opposed amendment, recites: "A method for the reduction of aluminosilicate containing scale in a Bayer process comprising the steps of: adding to the Bayer process stream an aluminosilicate scale inhibiting amount of a composition comprising at least one small molecule, wherein the small molecule is selected from the group consisting of compounds (I) through (XIII), (XV) through (XXX), (XXXII)

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[1] *Merial Limited v Bayer Intellectual Property GmbH* [2015] APO 16 at [24]

through (LVIII) and (LX) through (LXVII): [the structural formulae of these 64 compounds are then listed].”

16. As noted by Dr Kildea,[2] “the 64 compounds now claimed can be rationalised as follows. In the opposed application, 65 compounds were directly drawn out by way of their chemical structures; these were denoted compounds (I) to (LXV). Compounds (LXVI) and (LXVII), respectively, are the third and fourth compounds exemplified in Table II of the opposed application; the first, second and fifth compounds fall within the originally-depicted structures (I) to (LXV) (i.e., they are structures (XXXV), (XLV) and (LV), respectively). Accordingly, there were 67 compounds directly and unambiguously disclosed in the opposed application; all 67 were foreshadowed in identical terms in the PCT application and in the priority application. However, it was noted that the 67 compounds contained three instances of duplication. Specifically, compound (IV) was duplicated in compound (XXXI); compound (XIV) was the same as (XXVI); and compound (LIX) was the same as compound (XXXVII). Accordingly, compounds (XIV), (XXXI) and (LIX) were omitted from the opposed amendment to claim 1, bringing the total number of compounds within the ambit of claim 1 to 64”.

17. Professor Easton’s observations[3] are consistent with those noted by Dr Kildea:

    (a) The general compound formula ($NR_1R_2R_3$) has been deleted from independent claim 1 as initially accepted and replaced with 64 individual compound structures numbered (I)-(XIII), (XV)-(XXX), (XXXII)-(LVIII) and (LX)-(LXVII).

    (b) Structures (I)-(XIII), (XV)-(XXX), (XXXII)-(LVIII) and (LX)-(LXV) previously appeared in accepted claims 4-13.

    (c) New structures (LXVI) and (LXVII) have been added to amended claim 1 (and also appear or are referenced in new amended claims 3, 4 and 14).

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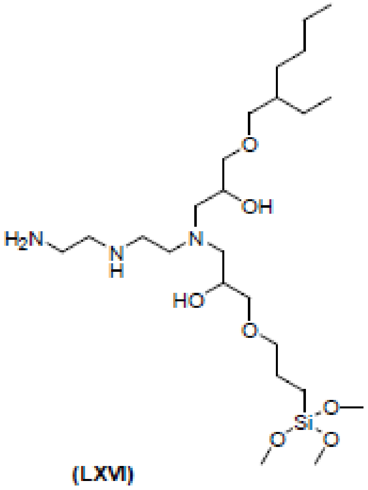
[2] Kildea-1 at [29]-[31]

[3] Easton-1 at [7]

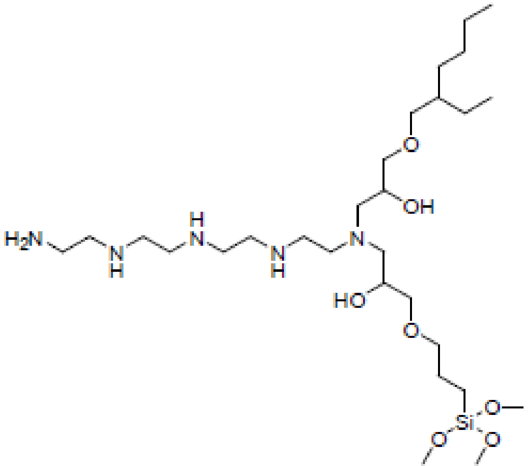
(d) New claims 2-14 have been added and refer, respectively, to various combinations of the compound structures listed in amended claim 1.

(e) Claims 2, 3 and 19-22 as initially accepted have been deleted.

18. As per the Opponent’s SoGP, only compounds (LXVI) and (LXVII) are at issue by way of the present amendment opposition. The structures of the contested compounds (LXVI) and (LXVII) are provided below:



(LXVI)



(LXVII)

19. Both compounds (LXVI) and (LXVII) are small molecules of the general formula $NR_1R_2R_3$, as described in the specification as filed originally. In respect of compound (LXVI), NR_1 is derived from diethylene triamine (DETA); R_2 is derived from 3-glycidoxypropyltrimethoxysilane; and R_3 is derived from 2-ethylhexyl glycidyl ether. Compound (LXVI) is the reaction product of these three molecules, following the synthetic method as taught in the opposed specification.

20. Similarly, in respect of compound (LXVII), NR_1 is derived from tetraethylene pentamine (TEPA); R_2 is derived from 3-glycidoxypropyltrimethoxysilane; and R_3 is derived from 2-ethylhexyl glycidyl ether. Compound (LXVII) is the reaction product of these three molecules, following the synthetic method as taught in the opposed specification.

Grounds of opposition

21. The grounds of opposition relied upon by the Opponent, as set out in its SoGP are as follows:

    (a) Ground 1: As a result of the amendment, the specification would claim or disclose matter that extends beyond that disclosed in the complete specification as filed, namely, new compounds (LXVI) and (LXVII) – ss.102(1).

    (b) Ground 2: As a result of the amendment, claims 1, 3, 4 and 14-19 would not in substance fall within the scope of the claims of the specification before amendment – ss.102(2)(a).

    (c) Ground 3: As a result of the amendment, the specification does not disclose the invention in a manner which is clear enough and complete enough for the invention defined by claims 1, 3, 4 and 14-19 to be performed by a skilled person – ss.102(2)(b) and ss.40(2)(a).

    (d) Ground 4: As a result of the amendment, the specification does not disclose the best method of performing the invention – ss.102(2)(b) and ss.40(2)(aa).

    (e) Ground 5: As a result of the amendment, amended claims 1, 3, 4 and 14-19 are not supported by matter disclosed in the specification – ss.102(2)(b) and ss.40(3).

22. The Applicant submits that the onus lies with the Opponent to satisfy the Commissioner, to the requisite degree, that the opposed amendment does not meet the requirements of section 102 of the Act[4].

23. The Applicant denies all grounds of opposition advanced by the Opponent and asserts that: (a) the opposed amendment is fully compliant with the requirements of section 102 of the Act; and (b) the Opponent has failed to discharge its burden of proof in relation to any such ground of opposition.

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[4] *CSR Building Products Limited v United States Gypsum Company* [2016] APO 41 at [18]

The person skilled in the art (PSA)

24. For the avoidance of doubt, the terms "skilled addressee", "notional skilled addressee", "uninventive skilled worker in the particular field", "non-inventive worker in the field", "person skilled in the art", "non-inventive hypothetical skilled addressee", etc., as they appear in the Act and/or in the various authorities are all used synonymously. Justice Middleton has confirmed this impression to be correct.[5]

25. A prelude to any reasonable analysis of the opposed amendment is an appropriate definition of the person skilled in the art (PSA) – the intended addressee of the specification. The authorities converge around the general proposition[6] that the PSA "..is the person to whom the patent is addressed and who must construe it."

26. Generally speaking, the PSA is the person who works in the relevant field of art or science with which the invention in a given case is connected.[7] They are of ordinary skill,[8] and are equipped with common general knowledge in the art. They are a construct, a hypothetical person.[9]

27. Accordingly, one of the more artificial aspects of an Australian patent opposition is the appropriation of PSA status by the expert/s assisting the respective sides. Whilst no expert/s could ever rightly claim to be "the PSA", they can nonetheless provide probative insight as to what qualities, expertise and experience such a hypothetical person may possess.

28. The PSA is to be identified in light of the problem[10] that the claimed invention is directed to solving and not in light of the claimed solution. This requirement is significant insofar as the opposed application[11] relates to the Bayer process, which is a highly significant industrial process for the preparation of alumina from Bauxite ore. However, as taught in

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[5] "The skilled addressee", The Honourable Justice John Middleton, 9 September 2012, for the 26th Annual IPSANZ Conference, p.2

[6] *Root Quality Pty Ltd v Root Control Technologies Pty Ltd* [2000] FCA 980 at [70]

[7] *Root Quality Pty Ltd v Root Control Technologies Pty Ltd* [2000] FCA 980 at [71]

[8] *Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd (No 3)* (2011) 196 FCR 1 at 52

[9] *Ajinomoto Co Inc v Nutrasweet Australia Pty Ltd* (2008) 247 ALR 552 at 572

[10] Patent Manual of Practice & Procedure, section 2.5.2.4A

[11] Kildea-1 at [16]

the specification as filed originally, it is beset by certain process inefficiencies or limitations. The specification[12] explains why DSP scale formation is such a known industrial problem when spent Bayer process liquor is recycled back into the process circuit:

> *As liquor flows repeatedly through the circuit of the Bayer process, the concentration of silica in the liquor further increases, eventually to a point where it reacts with aluminium and soda to form insoluble aluminosilicate particles. Aluminosilicate solid is observed in at least two forms, sodalite and cancrinite. These and other forms of aluminosilicate are commonly referred to, and for the purposes of this application define, the terms "desilication product" or "DSP".*
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> *DSP can have a formula of* $3(Na_2O.Al_2O_3.2SiO_2.0\text{-}2H_2O).2NaX$ *where X represents* OH^-, Cl^-, CO_3^{2-}, SO_4^{2-}. *Because DSP has an inverse solubility (precipitation increases at higher temperatures) and it can precipitate as fine scales of hard insoluble crystalline solids, its accumulation in Bayer process equipment is problematic. As DSP accumulates in Bayer process pipes, vessels, heat transfer equipment, and other process equipment, it forms flow bottlenecks and obstructions and can adversely affect liquor throughput. In addition because of its thermal conductivity properties, DSP scale on heat exchanger surfaces reduce the efficiency of heat exchangers.*
>
> *These adverse effects are typically managed through a descaling regime, which involves process equipment being taken off line and the scale being physically or chemically treated and removed. A consequence of this type of regime is significant and regular periods of down-time for critical equipment. Additionally as part of the descaling process the use of hazardous concentrated acids such as sulfuric acid are often employed and this constitutes an undesirable safety hazard.*

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[12] Specification as filed, from p.2, l.3

> *Another way Bayer process operators manage the buildup of silica concentration in the liquor is to deliberately precipitate DSP as free crystals rather than as scale. Typically a "desilication" step in the Bayer process is used to reduce the concentration of silica in solution by precipitation of silica as DSP, as a free precipitate. While such desilication reduces the overall silica concentration within the liquor, total elimination of all silica from solution is impractical and changing process conditions within various parts of the circuit (for example within heat exchangers) can lead to changes in the solubility of DSP, resulting in consequent precipitation as scale.*

29. As noted by Dr Kildea,[13] DSP scale formation is one of the more significant hurdles that those practising the Bayer process as at the priority date of the opposed application (25 February 2011) would have encountered. This is not disputed in evidence by either Professor Easton or Dr Ryles. Accordingly, "the invention", *per se,* relates to a method of increasing the efficiency of the Bayer process circuit by adding to it one or more compounds that function as DSP scale inhibitors. Dr Ryles[14] in fact agrees with Dr Kildea's characterisation of the Bayer process and the inventive problem.

30. We submit as a matter of necessity that the PSA in respect of the opposed application (i.e., the person to whom the opposed specification is addressed) should have significant (not merely some, and certainly not none at all) experience in actually having worked the Bayer process on an industrial scale. The commercial embodiment of the method of claim 1 (both pre- and post-amendment) is performed on an industrial scale – not on a laboratory scale.

31. There is a marked difference in the experts assisting the respective sides in this opposition. The primary expert assisting the Opponent, Professor Easton, is a University Professor of considerable academic renown. However, we submit, critically within the context of the inventive problem identified above, he admits to never having actually worked the Bayer process.[15] Professor Easton merely claims to have taught the Bayer

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[13] Kildea-1 at [17]

[14] Ryles at [23]

[15] Declaration of Professor Christopher John Easton, dated 23 February 2016, filed in respect of the main opposition at

process as part of lectures to undergraduate students.[16] Indeed, paragraphs [24] through [29], spanning around half a page of his declaration filed in respect of the main opposition, do not suggest anything more than a “textbook” appreciation of the Bayer process.

32. In *Catnic*,[17] Lord Diplock confirmed that the skilled addressee is “likely to have a *practical* interest in the subject matter of the invention”[18] [*emphasis added by Applicant*].

33. The Opponent notes[19] that in *Generic Health Pty Ltd v Bayer Pharma Aktiengesellschaft*[20] the evidence of a particular expert was challenged on the basis that he ‘had not himself formulated an enteric coating’. The Full Court rejected the submission that that expert’s evidence should therefore be discounted in some way because the evidence established that the expert was sufficiently familiar with enteric coating to express the opinions he did.” We respectfully disagree with the Opponent’s contention that the same could be said of Professor Easton’s evidence. As explained above (paragraphs 29 and 30) and as agreed by Dr Ryles, the invention of the opposed application takes place on an *industrial* scale under *industrial* conditions. Professor Easton’s opinions do not (and cannot) take account of this.

34. In significant contrast to Professor Easton, the expert assisting the Applicant, Dr Kildea, has “..more than 20 years’ experience in research roles directly related to Bayer process plant applications and operations, including direct, hands-on experience in all aspects of the Bayer process across a range of countries, operators and plants. [He has] more than eight years experience working on-site within operating Bayer process plants”.[21]

35. We submit that within the context of an invention directed to an industrial-scale chemical process there is a world of difference between practical and textbook knowledge. Dr

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[25]

[16] Declaration of Professor Christopher John Easton, dated 23 February 2016, filed in respect of the main opposition at [25]

[17] *Components Ltd v Hill and Smith Ltd* [1982] RPC 183

[18] *Ibid* at 235; *Root Quality P/L v Root Control Technologies P/L* (2000) 177 ALR 231 at 247

[19] Opponent’s written submission at [20]

[20] *Generic Health Pty Ltd v Bayer Pharma Aktiengesellschaft* [2014] FCAFC 73 at [74]

[21] Kildea-1 at [18]-[25]

Kildea notes[22] that this is especially true of the Bayer process: "Respectfully, based upon my experience of Bayer process chemistry, there are significant and crucial differences between what is taught in a textbook and what is experienced in day-to-day life. I will touch upon some of the practical difficulties in scaling up a laboratory process to an industrial scale later on in this document". In this respect, it is noteworthy that Dr Kildea also has a PhD in chemistry and a further 22 research publications and 9 conference papers *directly related to the Bayer process*. Thus, like Professor Easton, there is significant and sound academic basis for his opinions – the difference, we submit, is by way of his *practical* experience in actually working the technology.

36. The perceptibly different skill sets of Dr Kildea and Professor Easton predictably give rise to the very different approaches they have adopted to the task at hand – namely, to assist in the assessment of whether the opposed amendment satisfies the requirements of section 102 of the Act. In broad summary, Dr Kildea has adopted a <u>purposive</u>[23] approach – armed with his common general knowledge in the art (gleaned from both academic and practical bases), he has approached the task from the standpoint of looking for solutions, not problems; interpreting the invention described with a view to what the patentee actually intended, as opposed to looking to achieve an incongruous result[24]; and the recognition that in industrial processes, it is commonplace for the chemistry to be defined in somewhat less precise, yet unambiguous, terms than it is in the classroom or in a chemical journal.[25]

37. In complete contrast, Professor Easton has approached his task from a <u>literal</u> ("is means is") standpoint. He appears to have looked for problems, not solutions, interpreted various terms so as to arrive at illogical results that upon any reasonable reading of the specification were never intended by the Applicant, and generally marked the opposed application as he might a university-level chemistry exam. The Applicant's respectful submission is that this approach is contrary to that which the PSA would, or should, properly adopt.

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[22] Declaration of Dr John David Kildea, dated 25 May 2016, filed in respect of the main opposition at [51]-[53] and [110]

[23] Patent Manual of Practice & Procedure, section 2.11.2.2.4

[24] Patent Manual of Practice & Procedure, section 2.11.2.2.6

[25] Kildea-1 at [83]-[84]

38. The late introduction of Dr Ryles as an expert assisting the Opponent at the evidence in reply stage does not remedy the deficiencies of Professor Easton's approach. Indeed, it amounts to little more on the part of the Opponent than a tacit admission that the diametrically-opposed approaches of Kildea and Easton may have exposed certain deficiencies in the Opponent's approach. As such, they opted to bring in an expert having a more closely-matching skill set to that of Dr Kildea. However, as noted above, Dr Ryles' evidence has been deemed unlikely determinative of the opposition matter – and to the extent that any such evidence is considered of probative value, the Applicant has not been afforded the opportunity to contest such evidence.

39. As an example of the dangers of uncontested evidence, Dr Ryles states[26] that it is common in industry to consult with academics in the course of a research project or when faced with a particular technological problem encountered in an industrial context. The Applicant has not been afforded the opportunity to challenge this opinion in evidence. Moreover, when the PSA is asserted to be a "team" of skilled people, the *3M* decision[27] requires that evidence should be led about how the team members would interact to solve the various problems; vague statements in the Ryles declaration and silence in the Easton-2 declaration do not address this requirement.

40. Were Dr Ryles' "teamwork" opinions presented at the time of filing evidence in support, the Applicant could have advanced a counter argument that had an industrial worker consulted Professor Easton with a view to addressing the problem of DSP scale accumulation in the Bayer process, they may well have been told that the small molecules of the invention would not work because they had not been purified, characterised, stoichiometrically-applied, etc. Nothing in the Ryles evidence reconciles the essential disconnect between the identified approaches of the academic and the worker in the field – how then could a "team" of such people be successful? The Opponent's evidence falls perceptibly short in this regard.

41. Significantly also, the Easton evidence[28] is wholly silent as to times when he has been consulted or otherwise professionally engaged with respect to working the Bayer process.

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[26] Ryles at [14], [23]-[26]

[27] *Minnesota Mining & Manufacturing Co v Tyco Electronics P/L* (2002) 56 IPR 248 at 257

[28] Both Easton declarations, Easton-1 and Easton-2

As none of his disclosed publications relates to Bayer process chemistry, and his experiences clearly point in a different direction altogether, it is in fact unsurprising that he has not been engaged in such a manner.

Common general knowledge (CGK)

42. In *3M,*[29]*Justice* Aickin stated that: “The notion of common general knowledge itself involves the use of that which is known or used by those in the relevant trade. It forms the background knowledge and experience which is available to all in the trade in considering the making of new products, or the making of improvements in old, and it must be treated as being used by an individual as a general body of knowledge.”

43. Compliance with the requirements of section 40 of the Act is assessed through the eyes of the addressee of the specification.[30] A patent specification is addressed to a person skilled in the relevant art of the specification. The qualities of the appropriate addressee have been discussed above. This person brings their understanding of the terminology and workings of the art to the construction of the specification. Lord Shaw[31] has stated that: “a specification must take its rank among all ordinary documents which are submitted to a reader for his guidance or instruction, and a reader ordinarily intelligent and versed in the subject matter. Such a reader must be supposed to bring his stock of intelligence and knowledge to bear upon the document, *not unduly to struggle with it, but anyhow to make the best of it*” [*emphasis added by Applicant*]. In other words, the addressee should exercise commonsense with a view to any ambiguities or errors s/he encounters; the finding of any such error does not of itself invalidate the entire document. This requirement again highlights the perceptibly different approaches that Dr Kildea and Professor Easton have taken in assessing the opposed amendment.

44. Thus, the specification is to be construed in the light of the common general knowledge in the relevant art, as at the priority date of the application. “If it is impossible to ascertain what the invention is from a fair reading of the specification as a whole, that, of course, is an end of the matter. But this objection is not established by reading the

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[29] *Minnesota Mining & Manufacturing Co v Beiersdorf (Australia) Limited* (1980) 144 CLR 253 at 292
[30] Patent Manual of Practice & Procedure, section 2.11.2.1
[31] *B.T.H. v Corona Lamps* 39 RPC 49

specification in the abstract. It must be construed in the light of the common general knowledge in the art before the priority date."[32]

45. A further prescription of the interplay between the skilled addressee and the common general knowledge was provided in *Valensi*[33]: "We think that the effect of these cases as a whole is to show that the hypothetical addressee is not a person of exceptional skill and knowledge, that he is not expected to exercise any invention nor any prolonged research inquiry or experiment. *He must, however, be prepared to display a reasonable degree of skill and common knowledge of the art in working trials and to correct obvious errors in the specification if a means of correcting them can readily be found*" [*emphasis added by Applicant*]. Thus, this authority is consistent with the Applicant's proposition that the addressee of the specification should rightly be looking for solutions, not problems.

Claim construction

46. Patent claims and specifications are to be construed in light of the skilled addressee's common general knowledge and the body of the specification.[34]

47. Australian patent law has long observed the principles of purposive claim construction[35]. Relevant to the present opposition, the specification must be read as a whole, a purposive construction should be employed rather than a purely literal one, and if an expression in a claim is not clear or is ambiguous, it is permissible to resort to the body of the specification to define or clarify the meaning of the words used in the claim. By corollary, a literal approach is dangerous insofar as a simple error in claim drafting could result in invalidity despite the fact that it may be easily reconciled with reference to the body of the specification – that is, what the patentee really intended. Accordingly, one of the functions of the PSA in respect of claim construction is to bridge the gap, should one exist, between what is written (literally) and what is meant (purposively). In essence, they achieve this through applying their common general knowledge.

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[32] *Welch Perrin v Worrel* (1961-62) 106 CLR 588 at 610

[33] *Valensi & Another v British Radio Corporation* (1973) RPC 337 at 377

[34] *Britax Childcare Pty Ltd v Infa-Secure Pty Ltd* (2012) 96 IPR 1 at [236], citing *H Lundbeck A/S v Alphapharm Pty Ltd* (2009) 177 FCR 151 at [52]-[53]

[35] *Décor Corporation Pty Ltd v Dart Industries Inc*, [1988] FCA 399, (1988) 13 IPR 385 at 400 [14]

48. Justice Bennett[36] has discussed the approach to the construction of claims as follows: "..the words in a claim should be read through the eyes of the skilled addressee in the context in which they appear. ..While the claims define the monopoly claimed in the words of the patentee's choosing, the specification should be read as a whole. ..It is not permissible to read into a claim an additional integer or limitation to vary or qualify the claim by reference to the body of the specification. ..However, terms in the claim which are unclear may be defined or clarified by reference to the body of the specification."

49. Justice Middleton[37] went even further: "It is well settled that the Court should, from the outset, approach the task of patent construction with a generous measure of common sense. The Court must place itself in the position of a person skilled in the relevant art, being the subject matter of the patent. From this perspective, the patent is to be read as a whole, in the context of the specification and in light of the prevailing common general knowledge and state of the relevant art at the priority date." The required "generous manner of common sense" is notably absent in any literal interpretation of the claim language.

<u>Ground 1</u>: The Opponent has failed to show that as a result of the amendment, the specification would claim or disclose matter that extends beyond that disclosed in the complete specification as filed, namely, new compounds (LXVI) and (LXVII) – ss.102(1).

50. The Applicant denies this ground of opposition and submits that the Opponent has failed to make its case to the requisite degree.

51. The relevant legal principle is that an amendment should not extend beyond matter which, after reading the specification as filed originally, would not be at the disposal of the skilled person.[38] The correct approach to applying this principle, as noted in the Manual of Examination Practice and Procedure,[39] "is to ask whether the person skilled in the art would, on looking at the specification as proposed to be amended, learn anything

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[36] *H Lundbeck A/S v Alphapharm Pty Ltd*, [2009] FCAFC 70 at [118]-[120]
[37] *Eli Lilly and Company Ltd v Apotex Pty Ltd*, [2013] FCA 214 at [139]
[38] *Generics (UK) Limited and others v H Lundbeck A/S* [2009] UKHL 12 at [36]
[39] Patent Manual of Practice & Procedure, section 2.23.8.2A

about the invention which they could not learn from the complete specification as filed."[40] Thus, to a large extent, whether an amendment falls within the scope of ss.102(1) depends upon what the skilled person understands as having been disclosed, which in turn depends on the disposition and skill set of that person.

52. In the specification as filed, the "Summary of the Invention" states that at least one embodiment of the invention is directed towards a method for reducing siliceous scale in a Bayer process comprising adding to a Bayer liquor an aluminosilicate scale inhibiting amount of a *reaction product* between an "amine-containing" molecule and an "amine-reactive" molecule containing a silane group, and optionally a non-polymeric amine-reactive hydrophobic hydrocarbon [*emphasis added by Applicant*].[41] The Summary section further describes embodiments directed to small molecules that are the reaction products of such amine-containing and an amine-reactive molecules.[42] From these disclosures, and the examples in the description, it is clear that the specification broadly relates to reaction products of amine-containing and amine-reactive molecules. This is consistent with Dr Kildea's evidence[43] and is not disputed in the Opponent's evidence.

53. Against this backdrop, Dr Kildea notes that the Examples section describes a synthesis reaction between three constituents: A, G and E, and describes the ring-opening of an epoxide (i.e., "amine-reactive") group by an "amine-containing" molecule.[44] Table II lists relative scale inhibiting performance for what are referred to as "various A:G:E synthesized reaction mixtures".

54. Prior to addressing what the skilled person would learn about the invention from the Examples in the specification as filed, we first address the Opponent's submissions regarding component "G" in Table II. In relation to component "G", Professor Easton notes that above Table II, "G" is defined as "glycidoxypropyltrimethoxysilane" and not "<u>3</u>-glycidoxypropyltrimethoxysilane".[45] Professor Easton further opines "there is no basis to assume that "G" also refers specifically to 3-glycidoxypropyltrimethoxysilanse as

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[40] *Richardson-Vicks Inc's Patent* [1995] RPC 568 at 576
[41] Specification as filed at p.3, l.21 to p.4, l.7
[42] Specification as filed at p.7, ll.1-9
[43] Kildea-1 at [58]-[59]
[44] Kildea-1 at [59]-[60]
[45] Easton-1 at [19]

opposed to some other structural isomer".

55. The Applicant submits that contrary to Professor Easton's assertions, the "G" component being 3-glycidoxypropyltrimethoxysilane is *plainly evident* from description in the specification as filed,[46] in "Example I",[47] and in the structures of compounds (I) to (XIII), (XV) to (XXX), (XXXII) to (LVIII), and (LX) to (LXV).

56. In its broadest sense, "G" is only ever contemplated to be one of a selected group of 3-substituted propyl silanes; no other substitutions are described in the specification.[48] Professor Easton's comments relating to the disclosure of the specification all note that "G" describes "3-substituted-propyl" compounds,[49] and at no other point in his evidence does he describe the disclosure of any other isomers or point to any suggestion that other isomers are contemplated. Accordingly, his assertion that there is "no basis" to assume "G" in Table II is the 3-substituted isomer[50] is itself without basis.

57. The Applicant submits that the evidence of Dr Kildea that the "G" component in Table II would be interpreted as 3-glycidoxypropyltrimethoxysilane is to be preferred.[51]

58. Having established that "G" in Table II is clearly 3-glycidoxypropyltrimethoxysilane, we now turn to the issue of the disclosure of compounds (LXVI) and (LXVII). The Opponent's position is that compounds (LXVI) and (LXVII) are not explicitly or implicitly disclosed in the specification as filed, and they rely on two lines of argument to support this contention: firstly, that compounds (LXVI) and (LXVII) are not produced from the reaction of materials in Table II as "discrete" or "unique" compounds,[52] and secondly, that compounds (LXVI) and (LXVII) are not encompassed or implicitly disclosed by the general formula $NR_1R_2R_3$.[53]

59. In response to the first line of argument, we submit that the claims and the teaching of the

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[46] Specification as filed at p.8, ll.3-8
[47] Specification as filed at p.34, ll.8-9; p.35, ll.7-8
[48] Specification as filed at p.8, ll.3-8
[49] Declaration of Professor Christopher John Easton, dated 23 February 2016, filed in respect of the main opposition at [71]-[72], [95]
[50] Easton-1 at [19]
[51] Easton-1 at [47]-[50]
[52] Opponent's written submission at [35]-[39], citing Easton-1 at [12]-[13], [16], [18], [20]-[21]
[53] Opponent's written submission at [40]-[42]

specification do not require compounds (LXVI) and (LXVII) to be made as discrete entities. Indeed, the Opponent's written submissions attempt to cast doubt over the quality of Dr Kildea's evidence that compounds (LXVI) and (LXVII) are disclosed on the basis that he "admits that the information in Table II would result in mixtures of compounds".[54] Much of the Opponent's evidence on the point of 'discrete entities' suggests that if a mixture of products is produced by the reaction of compounds listed in Table II, that the product mixture, *ipso facto*, does not amount to disclosure of any compounds. This suggestion should be rejected.

60. The Applicant notes in this regard that nowhere in their respective declarations do Professor Easton or Dr Ryles assert that compounds (LXVI) and (LXVII), as drawn, were *not* formed. Indeed, Professor Easton fails to provide any evidence demonstrating that the described reaction *prevents* the formation of the specified compounds within the reaction.

61. The Applicant submits that the teachings provided in the description are more than adequate to allow the skilled addressee to repeat the reactions in Table II and obtain compounds (LXVI) and (LXVII), and whether or not conducting these reactions ultimately leads to the production of other reaction products (such as those described previously by Professor Easton)[55] is inconsequential: the question at issue is whether the person skilled in the art would, on looking at the specification as proposed to be amended, learn anything about the invention which they could not learn from the complete specification as filed. If the skilled person learns to synthesise a mixture of compounds comprising the A, G and E components listed in Table II by following the teachings in the specification as filed, and these compounds include amongst them compounds (LXVI) and (LXVII), then the Applicant's onus of disclosure is discharged. The mere existence of other compounds in the reaction products fails to show that compounds (LXVI) and (LXVII) were not formed by the synthesis reaction scheme disclosed in the specification and hence fails to demonstrate that compounds (LXVI) and (LXVII) were not disclosed.

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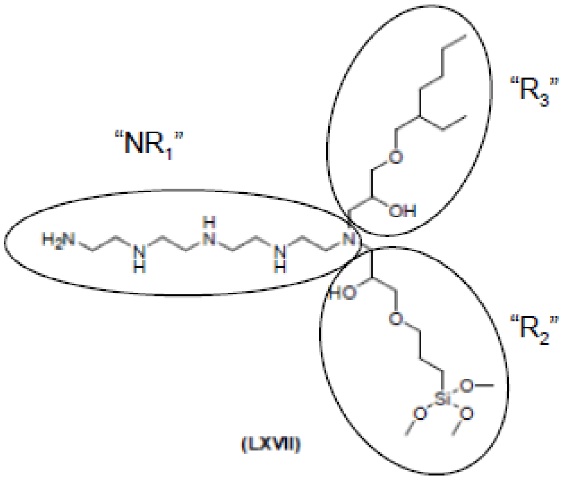
[54] Opponent's written submission at [36]

[55] Declaration of Professor Christopher John Easton, dated 23 February 2016, filed in respect of the main opposition at [142]

62. Accordingly, contrary to Professor Easton's assertions, the Applicant submits that compounds (LXVI) and (LXVII) do not extend beyond the disclosure of the originally-filed specification.

63. The Opponent's second argument is that compounds (LXVI) and (LXVII) are not encompassed or implicitly disclosed by the general formula $NR_1R_2R_3$.[56] However, as per the evidence of Dr Kildea,[57] "both compounds [(LXVI) and (LXVII)] clearly fall within the definition of the original definition of "small molecule" of the general formula $NR_1R_2R_3$". In respect of compound (LXVI), NR_1 is derived from diethylene triamine; R_2 is derived from 3-glycidoxypropyltrimethoxysilane; and R_3 is derived from 2-ethylhexyl glycidyl ether, and in respect of compound (LXVII), NR_1 is derived from tetraethylene pentamine; R_2 is derived from a 3-glycidoxypropyltrimethoxysilane; and R_3 is derived from 2-ethylhexyl glycidyl ether.

64. For example, with respect to compound (LXVII), the "NR_1" moiety is derived from tetraethylene pentamine; the "R_2" moiety is derived from 3-glycidoxypropyltrimethoxysilane; and the "R_3" moiety is derived from 2-ethylhexyl glycidyl ether:



(LXVII)

65. The Opponent's written submission[58] claims that the Applicant has attempted "to shoehorn compounds (LXVI) and (LXVII) into the formula $NR_1R_2R_3$". In fact, this could

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[56] Opponent's written submission at [40]-[42]

[57] Kildea-1 at [33]-[50]

[58] Opponent's written submission at [41]

not be further from the truth. Rather, having regard to the teaching of the specification as a whole, with the addressee looking for solutions, not problems, we submit that compounds (LXVI) and (LXVII) are clearly evident from the information provided.

66. As a peripheral issue, Dr Ryles[59] noted an error in Dr Kildea's depiction of the NR_1 moiety, above. In particular, what was identified[60] as R_1 is in fact $\underline{N}R_1$. This impression remains fully consistent with other aspects of the Kildea-1 declaration in which it is clear and consistent that:
    a) The small molecules of the invention have the general formula $NR_1R_2R_3$[61]
    b) The A:G:E and $NR_1R_2R_3$ nomenclatures are synonymous[62]
    c) A ("amine") equates to NR_1[63]
    d) The opposed specification teaches that the compounds are the *synthesis products* of an amine (NR_1 in the resultant compounds)[64]

67. Thus, the typographical error noted by Dr Ryles and any attempt to place uncertainty or ambiguity around it are readily reconciled on the above bases. The skilled person, armed with the common general knowledge and reading the opposed specification as a whole would clearly arrive at the same conclusion.

68. On the above bases, the Applicant respectfully submits that Ground 1 has not been made out by the Opponent; we request that it is dismissed.

<u>Ground 2</u>: The Opponent has failed to show that as a result of the amendment, claims 1, 3, 4 and 14-19 would not in substance fall within the scope of the claims of the specification before amendment – ss.102(2)(a)

69. The Applicant denies this ground of opposition and submits that the Opponent has failed to make its case to the requisite degree.

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[59] Ryles at [30]
[60] Kildea-1 at [48]
[61] Kildea-1 at [35]
[62] Kildea-1 at [40]
[63] Kildea-1 at [44]
[64] Kildea-1 at [58]

70. Firstly, as noted above, an examination report on voluntary amendments issued from IP Australia on 17 June 2016. The Opponent had filed comments in relation to the amendment two days prior; the comments largely mirrored the arguments put forth in this ground of opposition. A single objection was raised under ss.102(2)(a) – namely, that the amended claims 1, 3, 4 and 13-19 were not allowable because such amended claims defined matter which did not in substance fall within the scope of the accepted claims (i.e., the same objection as that now pursued by the Opponent under Ground 2). The Examiner's objection related to compounds (LXVI) and (LXVII) only.

71. The Applicant filed a response to the examination report on 22 June 2016. No further amendments were proposed, with the Examiner's ss.102(2)(a) objection addressed and overcome by argument alone.

72. The Applicant's firm position remains that compounds (LXVI) and (LXVII) fall within the scope of claim 1, as accepted, because they fall within the definition of the original definition of "small molecule" of the general formula $NR_1R_2R_3$.

73. In respect of the NR_1 component; both diethylene triamine (LXVI) and tetraethylene pentaamine (LXVII) fall within the definition of "amine" provided in claim 1 as accepted.

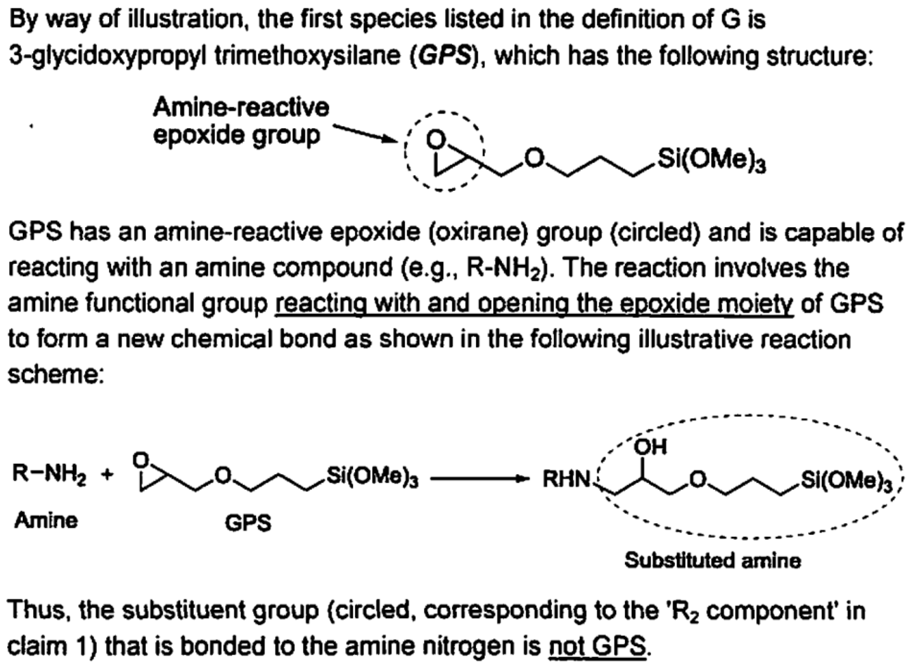
74. The R_2 moieties are the same in compounds (LXVI) and (LXVII); R_2 is derived from 3-glycidoxypropyltrimethoxysilane ("GPS"). The relevant text of the accepted claim 1 recites:

> *..each R_2 is G..*
>
> *..each G is one item independently selected from the group consisting of: 3-glycidoxypropyltrimethoxysilane,..*

75. Thus, R_2 is G; and G is the first of the substituents defined in the relevant listing.

76. Taking the purely literal approach to claim construction, the R_2 moieties, as defined in the accepted claims have an epoxide functionality. The skilled person would readily understand that the epoxide does not bind to the terminal nitrogen of the NR_1 group

without first ring-opening, meaning that in the chemical sense R_2 cannot be G; it must be derived from G. Helpfully, as noted above in respect of Ground 1, Professor Easton[65] has explained the nomenclature in an appropriate manner:



> By way of illustration, the first species listed in the definition of G is 3-glycidoxypropyl trimethoxysilane (***GPS***), which has the following structure:

> GPS has an amine-reactive epoxide (oxirane) group (circled) and is capable of reacting with an amine compound (e.g., $R\text{-}NH_2$). The reaction involves the amine functional group <u>reacting with and opening the epoxide moiety</u> of GPS to form a new chemical bond as shown in the following illustrative reaction scheme:

> Thus, the substituent group (circled, corresponding to the 'R_2 component' in claim 1) that is bonded to the amine nitrogen is <u>not GPS</u>.

77. Thus, the meaning of R_2 is clearly apparent as demonstrated by Professor Easton. Furthermore, the opposed specification, especially at p.34, "Example of a synthesis reaction of A, E and G", very clearly teaches that the small molecules are the synthesis products of an amine (NR_1 in the resultant small molecule), a "G" moiety (3-glycidoxypropyltrimethoxysilane is given as an example) and an "E" component (ethylhexyl glycidyl ether is given as an example).

78. The Applicant submits that the common R_2 component of compounds (LXVI) and (LXVII) is thereby defined in claim 1, as accepted. On the basis of Professor Easton's own evidence, a skilled person clearly recognises what is intended by the nomenclature used in the original claim.

79. An analogous argument applies in respect of the common R_3 moiety of compounds (LXVI) and (LXVII); R_3 is derived from 2-ethylhexyl glycidyl ether. The relevant text of

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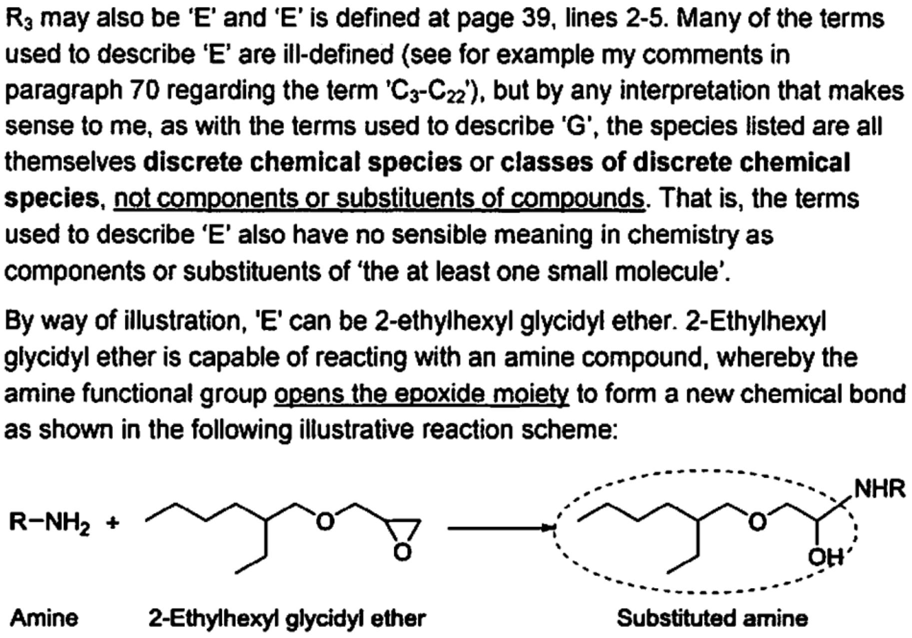
[65] Declaration of Professor Christopher John Easton, dated 23 February 2016, filed in respect of the main opposition at [Schedule 1; page ii]

the accepted claim 1 recites:

> *..each R_3 is independently selected from the group consisting of..*
>
> *..E..*
>
> *..each E is independently selected from the group consisting of 2-ethylhexyl glycidyl ether..*

80. Thus, R_3 is E; and E is the first of the substituents defined in the relevant listing.

81. As with R_2 discussed above, the common R_3 moieties, as defined in the accepted claims have an epoxide functionality. However, Professor Easton[66] has again explained the nomenclature in an appropriate manner:



R_3 may also be 'E' and 'E' is defined at page 39, lines 2-5. Many of the terms used to describe 'E' are ill-defined (see for example my comments in paragraph 70 regarding the term 'C_3-C_{22}'), but by any interpretation that makes sense to me, as with the terms used to describe 'G', the species listed are all themselves **discrete chemical species or classes of discrete chemical species**, not components or substituents of compounds. That is, the terms used to describe 'E' also have no sensible meaning in chemistry as components or substituents of 'the at least one small molecule'.

By way of illustration, 'E' can be 2-ethylhexyl glycidyl ether. 2-Ethylhexyl glycidyl ether is capable of reacting with an amine compound, whereby the amine functional group opens the epoxide moiety to form a new chemical bond as shown in the following illustrative reaction scheme:

82. Thus, the meaning of R_3 is clearly apparent as demonstrated by Professor Easton. Furthermore, the opposed specification, especially at p.34, "Example of a synthesis reaction of A, E and G", very clearly teaches that the small molecules are the synthesis products of an amine (NR_1 in the resultant small molecule), a "G" moiety (3-glycidoxypropyltrimethoxysilane is given as an example) and an "E" component (ethylhexyl glycidyl ether is given as an example).

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[66] Declaration of Professor Christopher John Easton, dated 23 February 2016, filed in respect of the main opposition at [Schedule 1; page iii]

83. The Applicant submits that the common R_3 component of compounds (LXVI) and (LXVII) is thereby defined in claim 1, as accepted. On the basis of Professor Easton's own evidence, a skilled person clearly recognises what is intended by the nomenclature used in the original claim.

84. The Opponent's position, as stated by Professor Easton, is that "is means is" – the literal approach. The Applicant's position assumes a purposive approach – in other words, what does the patentee actually intend? The opposed specification clearly teaches that the compounds of the invention are formed from (i.e., the synthesis product of), amongst other components, a "G" moiety (e.g., 3-glycidoxypropyltrimethoxysilane). As noted by Dr Kildea,[67] "anybody nominally skilled in chemistry knows that the nature of a reactant is that it "reacts" (i.e., changes) to form a product. In this case, 3-glycidoxypropyltrimethoxysilane reacts (ring-opens) to form the "N-R_2" moiety of the compounds being synthesised, which is consistent with the synthesis scheme disclosed in the specification".

85. Further, page 34, lines 20-24 of the specification as filed teaches that in the reaction of the epoxide ("G"; R_2; GPS) with a reactive amine ("A"), the epoxide ring is opened: "It is common to those skilled in the art to conduct the ring opening of an epoxide with a reactive amine in a batch mode..". Indeed, Professor Easton summarises the ring-opening of the epoxide as reproduced above (see, paragraph 66). Thus, and in total consistency with Professor Easton's own evidence, the epoxides ring-open upon reaction with the reactive amine to give rise to a synthesis product. In its appropriate context, "is" correctly means "is derived from".

86. A useful test[68] for the allowability of amendments under section 102(2)(a) is: "would the amendment make anything an infringement which would not have been an infringement before the amendment?"[69] On the basis on the above discussion, compounds (LXVI) and (LXVII) were both clearly within the definition of the original Markush grouping of claim 1, as accepted. Accordingly, the use of such compounds to reduce DSP scale

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[67] Kildea-1 at [59]

[68] Patent Manual of Practice & Procedure, section 2.23.9.3

[69] *The Distillers Co. Ltd.'s Application* (1953) 70 RPC 221 at 223

formation in a Bayer process stream would have infringed the accepted claim 1, just as it would the amended claim 1; the amendment thereby satisfies the Distillers test and is allowable under subsection 102(2)(a).

87. On the above bases, the Applicant respectfully submits that Ground 2 has not been made out by the Opponent; we request that it is dismissed.

<u>Ground 3</u>: The Opponent has failed to show that as a result of the amendment, the specification does not disclose the invention in a manner which is clear enough and complete enough for the invention defined by claims 1, 3, 4 and 14-19 to be performed by a skilled person – ss.102(2)(b) and ss.40(2)(a).

88. The Applicant denies this ground of opposition and submits that the Opponent has failed to make its case to the requisite degree.

89. Subsection 40(2)(a) of the Act provides that a complete specification "must disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the relevant art". Accordingly, there is a requirement to provide an enabling disclosure across the full scope of the claims.[70]

90. Relevantly, in *CSR Building Products Limited v United States Gypsum Company* [2015] APO 72,[71] the Delegate reproduced the following passage from *Eli Lilly & Co v Human Genome Sciences, Inc* [2008] RPC 29 at [241]:

> *"The sub-section, by using the words, clearly enough and completely enough, contemplates that patent specifications need not set out every detail necessary for performance, but can leave the skilled man to use his skill to perform the invention. In so doing he must seek success. He should not be required to carry out any prolonged research, enquiry or experiment. He may need to carry out the ordinary methods of trial and error, which involve no inventive step and generally are*

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[70] *CSR Building Products Limited v United States Gypsum Company* [2015] APO 72 at [89]
[71] *CSR Building Products Limited v United States Gypsum Company* [2015] APO 72 at [93]

> *necessary in applying the particular discovery to produce a practical result. In each case, it is a question of fact, depending on the nature of the invention, as to whether the steps needed to perform the invention are ordinary steps of trial and error which a skilled man would realise would be necessary and normal to produce a practical result."*

91. The Applicant's respectful position is an appropriate enabling disclosure of compounds (LXVI) and (LXVII) has been provided in the specification as filed, when considered by one of appropriate skill in the art in view of the common general knowledge that person might possess.

92. As noted above – and for the reasons noted above, compounds (LXVI) and (LXVII), as well as a general synthetic method for their preparation and their use in a method for the reduction of aluminosilicate containing scale in a Bayer process stream, are disclosed with reference to Table II of the specification as filed originally. Moreover, compounds (LXVI) and (LXVII) are supported by the description of what R_1, R_2 and R_3 may be, bridging pages 7 and 8 of the specification.

93. As noted by Dr Kildea,[72] the specification further provides a general method for the synthesis of the claimed compounds and provides data, in Table II, that support the efficacy of the claimed compounds – in particular, compounds (LXVI) and (LXVII), as DSP scale inhibitors in a Bayer process stream. As described in the paragraph immediately preceding Table I, [73] a number of different methods can be used to prepare a composition comprising the compounds of the invention. A batch process results in the formation of compounds as described in the opposed specification. However, as stated, in performing the reaction in this way, a number of undesirable side reactions may occur. The occurrence of such "internal coupling" reactions is readily diagnosable by an observable increased viscosity and the presence of methanol. This effect is very clearly demonstrated in the data provided in Table I of the specification, reproduced below:

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[72] Kildea-1 at [66]-[78]

[73] Specification as filed p.35, ll.7-16

Batch #	Method	Reaction Temp F	Viscosity of Reaction Intermediate, cps	MeOH isolated, lbs
1	Batch	240-265	550	9.8
2	Batch on Batch	225-235	240	1.6
3	Semi-Batch	180-200	65	0.7

94. Similarly, a “batch on batch” procedure may also be employed to produce the desired compounds. However, a range of undesirable side reactions may occur. While these side reactions are less common in the batch on batch process compared to the single batch process (as indicated by the lower viscosity and lower mass of methanol produced) the optimal process in terms of minimising these side reactions was found to be a semi-batch method as described in the specification.[74]

95. In practice, any of the three methods described in the specification can be used to manufacture the compounds of the invention. However, the details as shown in Table I and described in the preceding paragraphs demonstrate how the outcome may be optimised. Indeed, the description of the semi-batch process as “continuous or separate or slow sequential or individual or combined feed of the E and G epoxides” deliberately describes a variety of process operations that may be achieved across a variety of reaction vessel types.[75]

96. The description of the reaction in the terms used in the opposed application clearly outlines how to optimally produce the desired compounds while minimising any undesirable side reaction products that may hinder both performance and materials handling or manufacturing logistics. What is provided is an appropriately-detailed prescription of how to make the claimed compounds, which provides adequate information as to allow a skilled reader to practise the invention.

97. In terms of optimum performance, it should be noted that while total inhibition of DSP scale formation in Bayer process operations was possible as at the priority date of the opposed application, it is rarely practised using commercially-available inhibitors. Indeed, preferred industrial practice was typically a reduction in DSP scale formation <u>rate</u> rather than a comprehensive elimination of scale formation. Scale is still formed in the

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[74] Specification as filed at p.35, ll.12-16
[75] Specification as filed at p.35, ll.12-14

heat exchangers but was controlled to deposit more slowly. This practice was based on both an economic argument (it would be very expensive to add the dose of inhibitor required to stop all scale formation) and a process control argument (regular maintenance of heat exchangers for reasons other than scale removal is typically required, so there is little benefit in terms of reduced down time in eliminating all scale formed).[76]

98. As a consequence, Dr Kildea notes[77] that any reduction in scale formation (even small) would be considered "effective" and could render downstream benefits to the efficiency of the Bayer process operation. While there may be a spectrum of inhibitory performance across the concentration range, any reduction in scale formation may be considered to be "effective" and as such, a broad concentration range of the described compounds is specified (e.g., opposed amendment claim 15: "about 0.01 to about 100 wt%").

99. Dr Kildea further notes[78] that in the application of scale inhibitors – not just for DSP scale in the Bayer process but also in control of various scales in mineral processing more generally, the dose range is typically in the range of about 1 to about 100 ppm, and more often about 5 to about 50 ppm. As a consequence, for a skilled worker familiar with the application of scale inhibitors and specifically considering the inhibition of DSP scale in Bayer process applications, a dose in the range of about 5 to about 10 ppm would be considered "low" and a dose in the range of about 50 to about 100 ppm would be considered "high".

100. In effect, Table II of the opposed application demonstrates the dose response typical of scale inhibitors in the "usable" dose range (below 100%) and shows the expected dose response of a higher dose delivering less scale. The data provided in Table II are fully consistent with these teachings.

101. Accordingly, using the disputed compound (LXVI) as an example, a high dose provided a greater reduction in scale formation than a low dose (i.e., 61.5 cf. 31.5% inhibition, respectively). In practice, the skilled worker would need to determine on a cost versus efficiency basis, whether the 50% inhibition increase upon moving from a low (i.e., about

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[76] Kildea-1 at [71]
[77] Kildea-1 at [72]
[78] Kildea-1 at [73]

5 to 10 ppm) to a high (i.e., about 50-100 ppm) dosage justified the additional expense. In practice, a decision to use a high dose, a low dose or something in between is necessarily a matter of economic and practical considerations by the skilled worker.

102. Similarly, using the disputed compound (LXVII) as another example, a high dose again provided a greater reduction in scale formation than a low dose (i.e., 31.7 cf. 8.5% inhibition, respectively). Similar to compound (LXVI) the skilled worker in practice would need to determine on a cost versus efficiency basis, whether the nearly four-fold inhibition increase upon moving from a low (i.e., about 5 to 10 ppm) to a high (i.e., about 50-100 ppm) dosage justified the expense. The opposed specification does not teach every conclusion for every eventuality. However, the disclosed performance parameters, including dosage, inhibition, and efficiency, provide sufficient guidance and teachings such that the skilled worker can reasonably arrive at a useful dosing level for reducing scale formation in a Bayer process without undue experimentation.

103. Professor Easton[79] attempts to rationalise other compounds that may be formed from the described reaction. However, none of these arguments convey, suggest or indicate that compounds (LXVI) and (LXVII) are prevented or prohibited from expressly forming within the reaction mixture. The Applicant submits on the contrary, that the reaction, under the specified conditions with which the skilled person would be well-familiar, of diethylene triamine (DETA), 3-glycidoxypropyltrimethoxysilane and 2-ethylhexyl glycidyl ether gives rise to compound (LXVI); and that the reaction of tetraethylene pentamine (TEPA), 3-glycidoxypropyltrimethoxysilane and 2-ethylhexyl glycidyl ether gives rise to compound (LXVII).

104. Professor Easton[80] is of the opinion that "..no method of making any such compound [(LXVI) or (LXVII)] is provided..". However, as explained by Dr Kildea,[81] standard industry practice within the Bayer process does not utilise specific isolated compounds, but rather employs a range of additives, many of which are known and identified as specific compounds. This practice is extensive, despite the fact that in essence such "compounds" exist and are provided and used as a mixture of components.

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[79] Easton-1 at [55]
[80] Easton-1 at [56]
[81] Kildea-1 at [77]

105. As noted by Dr Kildea,[82] an abiding theme of the Opponent’s evidence is that a unique compound cannot be defined in an impure state (for example, as part of a mixture) and that the definition of a structure somehow requires the compounds recited in the claims to be provided in a discrete, isolated form. This opinion belies standard industrial practices – especially in respect of the Bayer process. The use of chemical structures to denote specific components of industrial grade materials or mixtures is both common and well understood. For example, Bayer process liquor is often referred to as a “sodium aluminate solution” (and is labelled as such for shipping purposes). However, those familiar with the process would be well aware that the liquor is indeed a *mixture* of components and not a pure solution uniquely and exclusively containing sodium aluminate.

106. Similarly, those familiar with operating the Bayer process do not expect, and do not require the use of chemical additives to the process to be 100% pure, unique compounds in order to effect a desired outcome. The use of chemicals in industrial processes typically employs industrial-grade products that may, and often do, contain mixtures of specific products. Rarely are these industrial grade products provided as pure single compounds. However, despite this lack of a single component, these products are often identified and known by a single chemical name and/or a single chemical structure. Purity and isolation is simply not a requirement.

107. Professor Easton[83] suggests that the specification fails to adequately disclose compounds (LXVI) and (LXVII) because the compounds are not disclosed in an isolated form. In particular, Professor Easton asserts (lines 8-9) that the specification provides “..no information that would enable me to separate compound (LXVI) and (LXVII) from the inevitable complex mixture..”. However, as explained by Dr Kildea,[84] isolation and separation of the individual compounds is not a requirement or indeed feature of standard industry practice in respect of the Bayer process; mixtures are used routinely. Second, the specification describes the synthesis scheme and structure of the compounds, which would allow a skilled worker to use conventional analytical equipment and methods to

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[82] Kildea-1 at [81]

[83] Easton-1 at [57]

[84] Kildea-1 at [78]

identify the compounds within a mixture without undue experimentation.

108. On the above bases, the Applicant respectfully submits that Ground 3 has not been made out by the Opponent; we request that it is dismissed.

Ground 4: The Opponent has failed to show that as a result of the amendment, the specification does not disclose the best method of performing the invention – ss.102(2)(b) and ss.40(2)(aa).

109. The Applicant denies this ground of opposition and submits that the Opponent has failed to make its case to the requisite degree.

110. Subsection 40(2)(aa) of the Act requires that a complete specification discloses the best method known to the Applicant of performing the invention.

111. In its written submission,[85] the Opponent cites two recent decisions of the Full Court, namely, *Servier*[86] and *Sandvik*,[87] which have established that the requirement to disclose the best method will not be satisfied where it can be established that the Applicant was aware of, but failed to disclose a better method of performing the invention at the filing date of the complete specification.

112. The Applicant's immediate observation is that "where it can be established" presents a very high bar – especially in the context of proceedings before the Australian Patent Office. We submit that the Full Court was able to "establish" the absence of a best method only following the lengthy and arduous discovery process that characterised matters before this authority. This provides an immediate distinction to the present opposition, as no discovery process has been undertaken and the Opponent is simply unable to "establish" what the inventors did or did not know by way of disclosing their best method. For example, in *Expo-Net Danmark A/S v Buono-Net Australia Pty Ltd (No*

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[85] Opponent's written submission at [98]
[86] *Les Laboratoires Servier v Apotex Pty Ltd* [2016] FCAFC 27
[87] *Sandvik Intellectual Property AB v Quarry Mining & Construction Equipment Pty Ltd* [2017] FCAFC 138

2),[88] Justice Bennett endorsed the following analysis in respect of what an applicant for revocation on the ground of failure to disclose the best method must show:

> *(1) The method which the patentee failed to disclose is a method of performing the invention.*
>
> *(2) The method is in fact a better method of performing the invention than the method disclosed in the specification.*
>
> *(3) The method was known to the patentee at the time when the application for the Patent was lodged at the Patent Office.*
>
> *(4) The method is not disclosed in the specification.*
>
> *(5) The patentee knew that the method was better than the method(s) described in the specification.*

113. In the present case, the Opponent has not presented any such information. To this end, the comments of the Delegate in *Kineta*[89] seem apt: "The ground of best method of performance does not often arise as the subject of a hearing".

114. Indeed, the present application is further distinguished from *Kineta* insofar as the Delegate's conclusory remarks stated: "The applicant was required to provide a best method of performing the invention in relation to the preparation of the novel compounds. The specification does not set out any method of preparing the compounds, and no method is apparent when the specification is read in the light of the common general knowledge…".[90] On the contrary, the present specification a) makes no promise that the small molecules of the invention are novel; and b) provides a method for their synthesis that when considered in light of the common general knowledge adequately enables their preparation.

115. Moreover,[91] in cases where the disputed compounds are not the invention, per se, (the present invention residing in the use of such compounds in reducing scale formation in the Bayer process), it may not be necessary to disclose how starting materials for a process are to be obtained. Accordingly, even in the event where no process was

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[88] *Expo-Net Danmark A/S v Buono-Net Australia Pty Ltd (No 2)* [2011] FCA 710 at [16]

[89] *Kineta, Inc.* [2017] APO 45 at [19]

[90] *Kineta, Inc.* [2017] APO 45 at [46]

[91] Blanco-White, *Patents for Inventions,* 4th ed, 1974, para 4-516

described from which compounds (LXVI) and (LXVII) could be prepared, the opposed amendment still may not fall foul of ss.40(2)(aa).

116. The opposed specification provides not only a method for the synthesis of the disputed small molecules (LXVI) and (LXVII),[92] and teaches that a semi-batch process is preferred, it also teaches the skilled addressee how to evaluate the scale inhibiting performance of a given small molecule, and includes the results of putting a selection of such molecules to their claimed use in inhibiting DSP scale build-up in the Bayer process.[93] In respect of the disputed compounds (LXVI) and (LXVII), the opposed specification gives quantitative efficacy data at both high and low dosages as readily explained by Dr Kildea.[94] His ability to reconcile such variables is a function of his common general knowledge in the art, as opposed to his status as an inventor as put forward by the Opponent.[95]

117. On the above bases, the Applicant respectfully submits that Ground 4 has not been made out by the Opponent; we request that it is dismissed.

<u>Ground 5</u>: The Opponent has failed to show that as a result of the amendment, the amended claims 1, 3, 4 and 14-19 are not supported by matter disclosed in the specification – ss.102(2)(b) and ss.40(3).

118. The Applicant denies this ground of opposition and submits that the Opponent has failed to make its case to the requisite degree.

119. As noted by the Opponent,[96] the concepts of support and disclosure are similar and necessarily overlap to some extent. The Applicant thereby reiterates the comments made above in respect of Ground 1.

120. Subsection 40(3) of the Act requires that the claims must be supported by matter disclosed

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[92] Specification as filed, pp.34-35

[93] Specification as filed, pp.35-36

[94] Kildea-1 at [73]-[75]

[95] Opponent’s written submission at [107]

[96] Opponent’s written submission at [115]

in the specification. The requirement for support is intended to ensure that the scope of claims corresponds to the Applicant's contribution to the art,[97] which in effect means that the claims should not extend to subject matter which, upon reading the description, would still not be at the disposal of the person skilled in the art.[98]

121. As noted by the Opponent,[99] in the case of a compound, where the Applicant can show a principle of general application by which each member of the class to which that compound belongs exhibits a particular beneficial effect, the Applicant is entitled to claim that class, even though not all members of the class have been shown to exhibit that beneficial effect.[100] Notwithstanding, in the case of the opposed amendment, both disputed compounds (LXVI) and (LXVII) have been shown to elicit the beneficial technical effect of reducing DSP scale formation in a Bayer process stream (31.5% (low dose) and 61.5% (high dose) inhibition for (LXVI); and 8.5% (low dose) and 31.7% (high dose) inhibition for (LXVII)).[101] Accordingly, the *Biogen* precedent strongly favours the allowability of the opposed amendment.

122. Professor Easton[102] is of the opinion that the disputed compounds are not supported because "..compounds (LXVI) and (LXVII) are not disclosed as discrete compounds in Table II or otherwise in the AU '990 specification." Dr Kildea[103] has reconciled Easton's mistaken impression that purity/isolation of the claimed compounds is a requirement of the invention. In particular, Professor Easton's apparent requirement that the opposed specification should provide for the specific isolation and characterisation of the compounds recited in the claims does not reflect common industrial practices – especially in respect of the Bayer process.

123. The Opponent concludes[104] that Dr Kildea may be able to work the invention because he "has insights and know-how not at the disposal of the objective skilled person". The Applicant's position is to the contrary – of the three experts who have provided evidence

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[97] *Fuel Oils/EXXON* (T409/91) [1994] OJ EPO 653 at 659
[98] *Fuel Oils/EXXON* (T409/91) [1994] OJ EPO 653 at 659-660
[99] Opponent's written submission at [118]
[100] *Biogen Inc v Medeva plc* [1996] UKHL 18; [1997] RPC 1 at 48
[101] Specification as filed, pp.35-36
[102] Easton-1 at [59]-[60]
[103] Kildea-1 at [81]-[85]
[104] Opponent's written submission at [129]

in this matter, Dr Kildea is the only one who has sought answers, not problems. He is the only one who has applied his CGK to the teaching of the specification in order to ascertain precisely what was intended by the Applicant and how that can be reconciled within the bounds of the teaching provided. For all their credentials, Professor Easton and Dr Ryles have not even tried to understand.

124. Applying the appropriate level of common general knowledge, the PSA could readily identify compounds (LXVI) and (LXVII) from Table II, could prepare them from the general prescription of Example I, and could apply each such compound to a Bayer process stream in an amount effective to inhibit DSP scale formation. Compounds (LXVI) and (LXVII) are thereby appropriately supported by the specification as filed.

125. On the above bases, the Applicant respectfully submits that Ground 5 has not been made out by the Opponent; we request that it is dismissed.

Concluding remarks

126. The Opponent has categorically failed in its onus of showing that the introduction of new compounds (LXVI) and (LXVII) falls foul of subsection 104(5) of the Act. In particular:

    (a) No new subject matter has been added to the specification. Compounds (LXVI) and (LXVII) were adequately disclosed in the specification as filed originally.

    (b) The scope of the accepted claims has not been broadened. Compounds (LXVI) and (LXVII) fall within the Markush groupings defined in the accepted claim 1, when considered purposively by one of appropriate skill in the art.

    (c) The specification provides a clear enough and complete enough disclosure that would enable the skilled person to perform the invention across its entire scope, which includes the use of compounds (LXVI) and (LXVII). Synthesis and scale inhibition methods are provided in the Examples, each of which is readily reproducible by the skilled person.

(d) The Applicant has not withheld information that was available before the filing date pertaining to the best method for preparing and using compounds (LXVI) and (LXVII). Precedent law from the Full Court (following discovery) and Australian Patent Office (where no synthetic method was provided) are readily distinguished from the present facts.

(e) The amended claims, which encompass the use of compounds (LXVI) and (LXVII), are fully supported by the description. The skilled addressee, considering the teaching in light of his/her common general knowledge is taught how to prepare and apply compounds (LXVI) and (LXVII).

127. We respectfully submit that the opposed amendment is indeed allowable and should be incorporated into the specification pursuant to subsection 104(5).

Relief sought

128. The Applicant seeks the following relief:
    (i) Dismissal of the section 104(4) opposition;
    (ii) Incorporation of the amendments into the official copy of the specification
    (iii) Failing that, leave to amend the claims in order to address any grounds of opposition the decision maker considers to have been made out; and
    (iv) The costs of these proceedings.

Dated this 5th day of October 2017
by Gareth Dixon and Jessica Chadbourne
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Attorneys for: The Applicant, Nalco Company